SCIENTIFIC PAPERS OF THE

INDIA FERTILITY RESEARCH PROGRAMME

THE INDIA FERTILITY RESEARCH PROGRAMME

1980

PREFACE

This volume contains scientific papers reporting results of recent research studies of the India Fertility Research Programme (India FRP). Since its inception in 1971, the India FRP has regularly organized Annual Contributors' Conferences to provide a forum for the scientific exchange of ideas and to afford an opportunity for its national network of contributors to present their research results which are subsequently published in Conference Transactions. This year, although a conference was not organized by the India FRP, the Programme has, through this publication, continued its tradition of disseminating its research findings.

The India FRP provides its contributors with standardized study protocols, data collection instruments and computerized feedback of study results for several study areas including pregnancy termination and menstrual regulation procedures, male and female sterilisation methods, intrauterine devices, systemic and conventional contraceptives, maternity care monitoring and primary health care delivery systems. Thus far, data on about 100,000 cases have been reported for over 200 research studies. The Programme has pioneered, through multicentric clinical field trials, very important innovations which have considerably enhanced the evolution of fertility control technology especially in the areas of menstrual regulation, pregnancy termination and female sterilisation. This technology now forms an integral part of the national programme and has found widespread acceptance in both urban and rural areas. The present work plan of the India FRP focuses on improving health care in rural areas by: (a) evaluating promising innovations in fertility regulation especially nonsurgical female sterilisation methods, which are expected to have an important impact on programmes in the 1980s, (b) establishing systems for monitoring maternity care at various service levels and (c) implementing and evaluating service delivery systems which have the potential for widespread, rapid adoption in remote rural areas.

My thanks are due to the contributors of the India FRP who have conducted the research studies and have carefully documented their research results. The Programme, undoubtedly, owes its success to their continuing enthusiasm and interest. The inspiring leadership of the Chairman, Dr. C.L. Jhaveri and the support of members of the Executive Committee of the India FRP is acknowledged. I gratefully acknowledge the guidance, encouragement and support provided by Dr. Elton Kessel, Executive Secretary of the International Federation for Family Health, for bringing out this publication and for his untiring efforts to assist the Programme. I also thank all the staff of the India FRP for their help and cooperation.

Saroj Pachauri

Hyderabad, India
May 1980

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TABLE II

COMPLAINTS REPORTED FOR WOMEN UNDERGOING STERILISATION IN BARODA, 1973 TO 1979

Complaints	Follow-up Visits (Months) 6 N = 770 No.	%	12 N = 805 No.	%	18 N = 829 No.	%	24 N = 1798 No.	%
Pelvic pain								
Mild	53	6.9	35	4.3	27	3.3	55	3.1
Moderate	9	1.2	6	0.7	7	0.8	8	0.4
Severe	0	0.0	0	0.0	0	0.0	1	0.1
Abdominal pain	5	0.6	3	0.4	4	0.5	7	0.4
Total	67	8.7	44	5.5	38	4.6	71	3.9
Incision related								
Mild wound pain	17	2.2	9	1.1	1	0.1	2	0.1
Moderate wound pain	10	1.3	1	0.1	0	0.0	2	0.1
Total	27	3.5	10	1.2	1	0.1	4	0.2
Others								
Leucorrhoea	1	0.1	6	0.7	0	0.0	0	0.0
Weakness/dizziness	3	0.4	4	0.5	1	0.1	4	0.2
Frequent/burning micturition	0	0.0	0	0.0	1	0.1	1	0.1
Weight gain	0	0.0	0	0.0	1	0.1	0	0.0
Psychoneurosis	0	0.0	0	0.0	0	0.0	5	0.3
Total	4	0.5	10	1.2	3	0.4	10	0.6
Women with one or more Complaints	98	12.7	64	7.9	42	5.1	85	4.7

Menstrual Pattern Changes

The vast majority (90.0%) of the women reported no change in menstrual cycle regularity. The percentage of women who reported that their menstrual cycles had changed from regular to irregular (an unfavourable change), was 2.8, 1.6, 3.1 and 3.1 at the 6, 12, 18 and 24 months follow-up visits respectively. A change from irregular to regular menstrual cycles was reported by 1.6, 2.9, 3.1 and 1.7 percent women respectively (Fig 3). Until the 18 months follow-up visit, the rates of women reporting an unfavourable change in menstrual cycle regularity were not significantly different when compared to rates of women reporting a favourable change and no consistent pattern of changes in this parameter was observed at different time periods. However, at 24 months, the unfavourable change was significantly more frequent than the favourable change in menstrual cycle regularity (Fig 3).

Most (84.7% to 88.8%) of the women reported no change in the duration of menstrual flow. While an increase in the duration of menstrual flow (the unfavourable change in this parameter), was reported by 7.0, 7.0, 5.2 and 7.8 percent women at the 6, 12, 18 and 24 months follow-up visits respectively, a decrease in the duration of menstrual flow

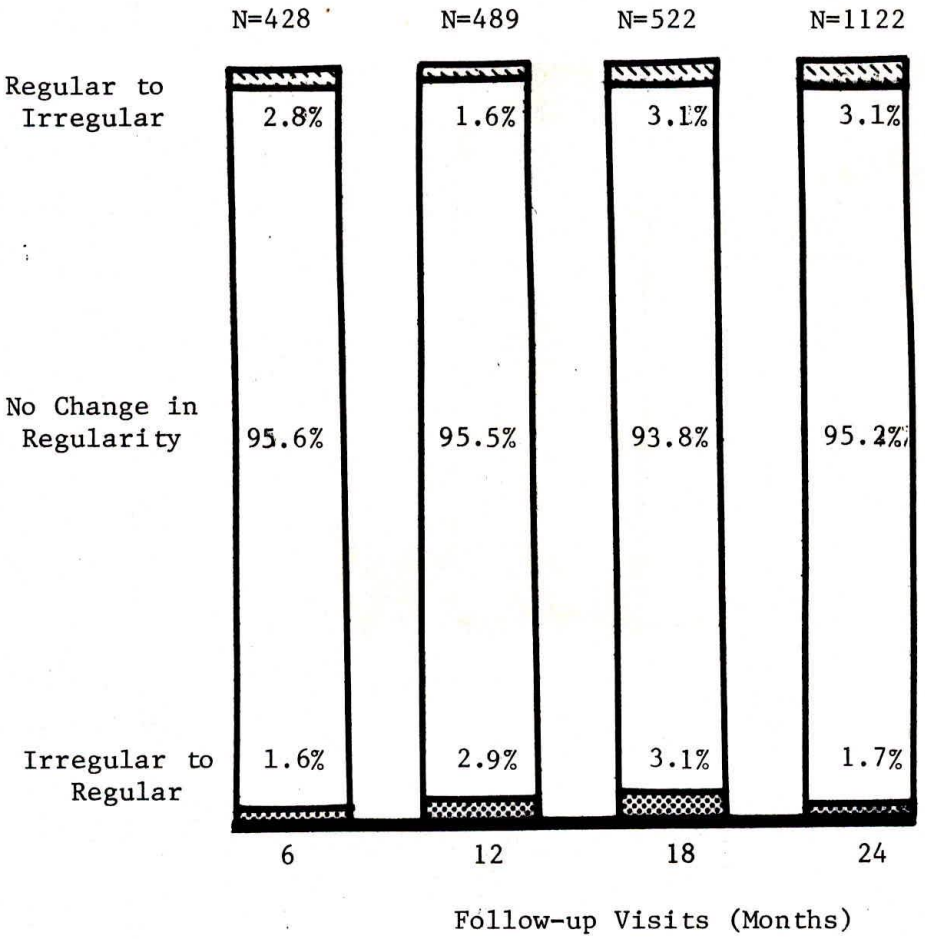

Fig 3

CHANGES IN MENSTRUAL CYCLE REGULARITY FOR WOMEN UNDERGOING STERILISATION IN BARODA, 1973 TO 1979

was reported by 4.2, 5.7, 6.9 and 7.5 percent women respectively (Fig 4). At all time periods except at 18 months, more women reported an unfavourable change than a favourable change in this parameter. Until the 18 months follow-up visit, there was no significant difference in the proportion of women reporting an increase in the duration of menstrual flow. At 24 months, however, significantly more women reported such increase. Differences in the rates of women reporting a decrease in the duration of menstrual flow at different time periods were not statistically significant. At the 6 months follow-up visit, significantly more women reported an increase as compared to those who reported a decrease in the duration of menstrual flow (Fig 4).

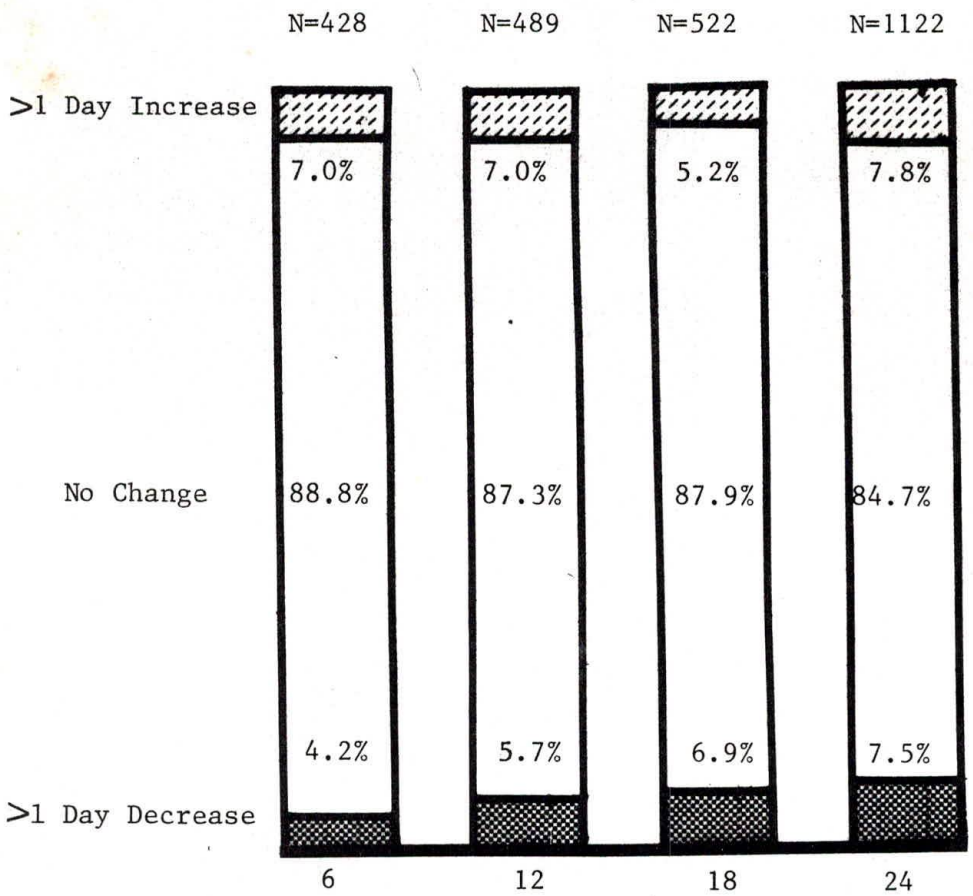

Fig 4

CHANGES IN DURATION OF MENSTRUAL FLOW FOR WOMEN UNDERGOING STERILISATION IN BARODA, 1973 TO 1979

Most (66.8% to 88.9%) of the women reported no change in the amount of menstrual flow. At the 6, 12, 18 and 24 months follow-up visits, an increase in the amount of menstrual flow (an unfavourable change), was reported by 4.9, 3.5, 6.9 and 5.4 percent women and a decrease by 0.2, 1.2, 3.2 and 4.7 percent women (Fig 5). Between the 18 and 24 months follow-up visits, a significantly lower proportion of women reported an increase in the amount of menstrual flow. Between the 6, 12 and 18 months follow-up visits the differences in this parameter were not statistically significant. At all, except at the 24 months follow-up visit, a significantly higher proportion of women reported an increase in comparison to those who reported a decrease in the amount of menstrual flow (Fig 5).

There was a significant decline in the incidence of amenorrhoea at the various follow-up visits. While 28.2 and 18.2 percent of the women reported amenorrhoea at the 6 and 12 months follow-up visits respectively; the percentage of amenorrhoea cases decreased to 7.9 and 1.1 percent respectively at the 18 and 24 months follow-up visits (Fig 5). The high incidence of amenorrhoea in the first six months was, probably, due to lactational amenorrhoea among the postpartum cases.

While the majority (82.4% to 87.6%) of the women reported no change in dysmenorrhoea following sterilisation, an increase in dysmenorrhoea was reported by 5.8, 7.0, 6.1 and 4.4 percent and a decrease by 6.5, 9.2, 11.5 and 9.8 percent women respectively

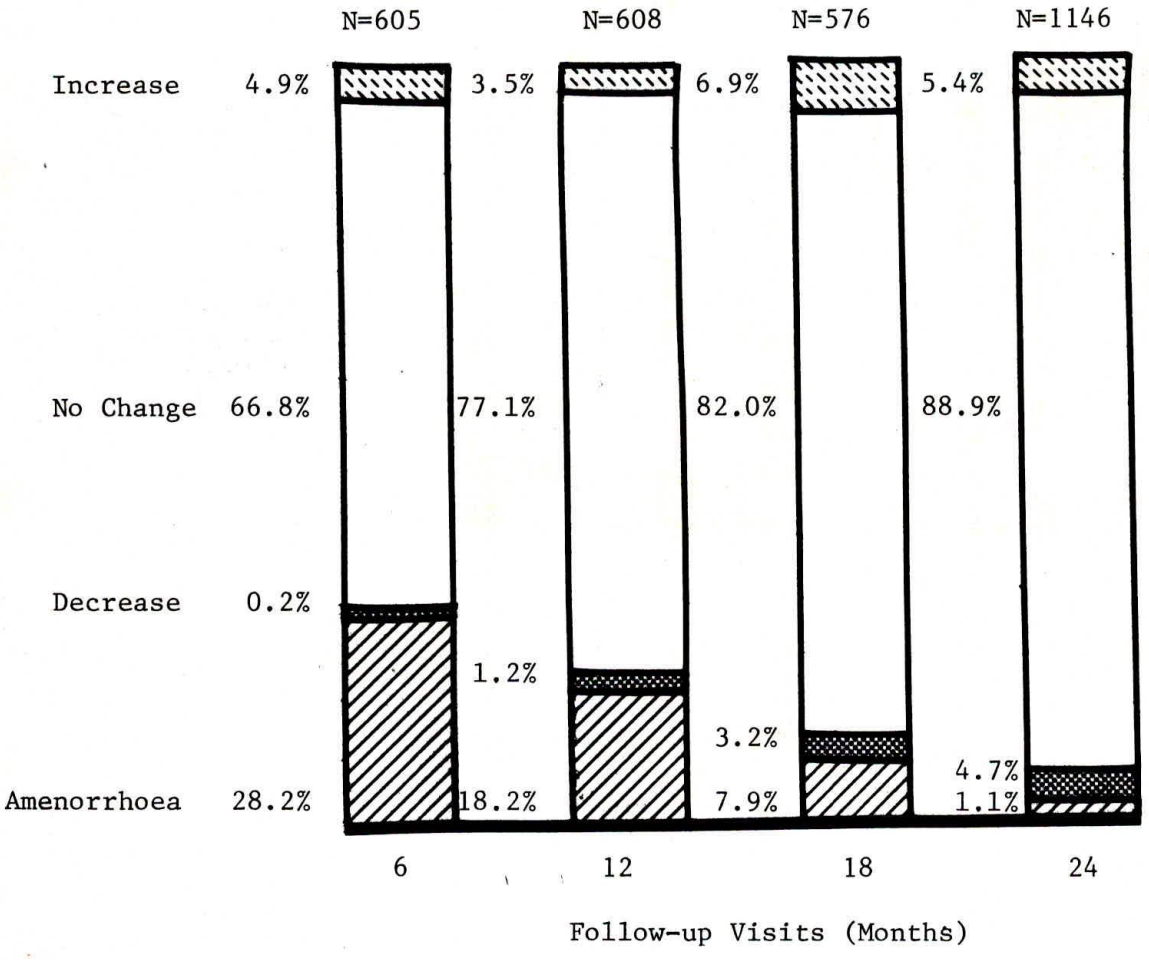

Fig 5

CHANGE IN AMOUNT OF MENSTRUAL FLOW FOR WOMEN UNDERGOING STERILISATION IN BARODA, 1973 TO 1979

at the 6, 12, 18 and 24 months follow-up visits. It is interesting to note that at each time period, more women reported a decrease as compared to those who reported an increase in dysmenorrhoea (Fig 6). However, the differences were statistically significant only at the 18 and 24 months follow-up visits.

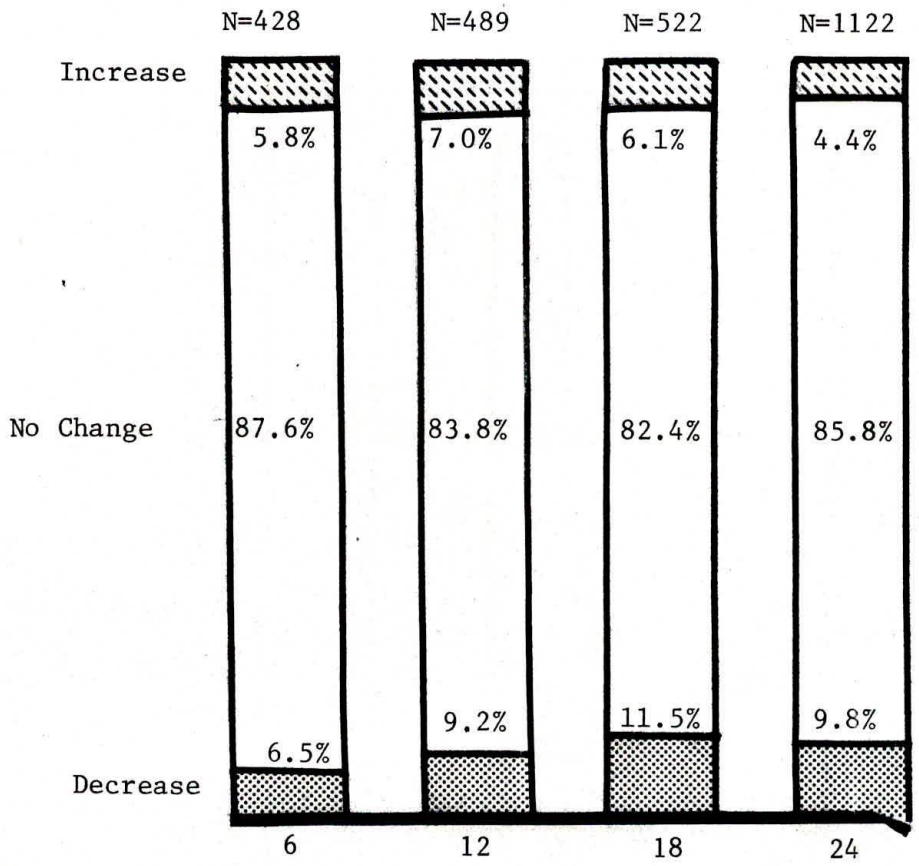

Fig 6

CHANGES IN SEVERITY OF DYSMENORRHOEA FOR WOMEN UNDERGOING STERILISATION IN BARODA, 1973 TO 1979

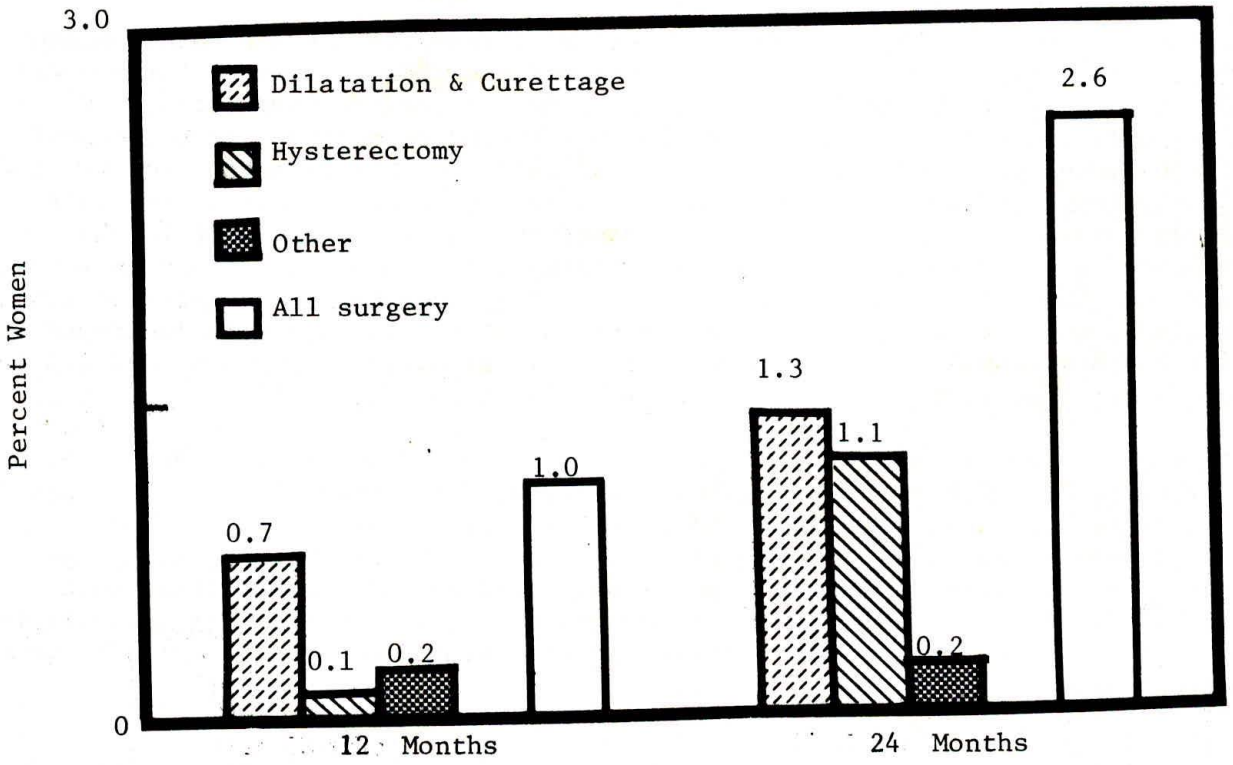

Fig 7

CUMULATIVE RATES OF GYNAECOLOGICAL SURGERY REPORTED FOR WOMEN UNDERGOING STERILISATION IN BARODA, 1973 TO 1979

TABLE III

GYNAECOLOGICAL SURGERY PERFORMED SUBSEQUENT TO STERILISATION IN BARODA, 1973 TO 1979

Gynaecological Surgery	Months Following Sterilisation							
	6 N=770		12 N=805		18 N=829		24 N=1798	
	No.	%	No.	%	No.	%	No.	%
Dilatation and curettage	1	0.1	5	0.6	13	1.6	5	0.3
Hysterectomy	0	0.0	1	0.1	2	0.2	16	0.9
Repair of prolapse	0	0.0	0	0.0	1	0.1	0	0.0
Repair of incisional hernia	0	0.0	1	0.1	0	0.0	1	0.1
Tubal reanastamosis	0	0.0	1	0.1	0	0.0	1	0.1
TOTAL	1	0.1	8	1.0	16	1.9	23	1.3

A COMPARISON OF THE TUBAL RING APPLIED VIA LAPAROSCOPY, MINILAPAROTOMY AND COLPOTOMY IN POSTABORTION CASES

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Elizabeth John, MSc[2]

ABSTRACT

This is an analysis of 692 laparoscopy, 149 minilaparotomy and 264 colpotomy postabortion sterilisation procedures performed with the tubal ring technique. The data are drawn from comparative, randomized studies conducted by the India Fertility Research Programme (India FRP) to evaluate the safety and effectiveness of these procedures.

Surgical and operating room time were significantly lower for laparoscopy than for minilaparotomy and colpotomy. All the women undergoing colpotomy were hospitalised; 55.3 and 30.9 percent of those undergoing laparoscopy and minilaparotomy respectively were sterilised on an outpatient basis. Although the planned procedure was successfully completed in all cases, alternative techniques for tubal occlusion were employed for two laparoscopy and four colpotomy procedures. Technical failure rates were not significantly different for the three sterilisation methods. The incidence of surgical difficulties was, however, higher for minilaparotomy.

The incidence of operative complications was similar for all three procedures. Immediate and early postoperative complication rates were significantly higher for minilaparotomy because of the high incidence of mostly minor, incision-related complications. The incidence of complaints (predominantly pelvic pain), was significantly higher for minilaparotomy in the immediate but not in the early postoperative period. Although the incidence of gynaecological abnormalities six months after sterilisation was significantly higher for colpotomy, it was not significantly different for laparoscopy and minilaparotomy at later follow-up. Only one pregnancy following laparoscopy was reported in this series. The relative merits and demerits of the three sterilisation procedures for large-scale programmes in India are discussed.

INTRODUCTION

In recent years there has been an increasing demand for female sterilisation in India. A woman who has completed her desired family size is generally faced with the choice between twenty or more years of fertility regulation by contraception and fertility termination by sterilisation and she often opts for permanent sterilisation.

A wide range of female sterilisation approaches and techniques have been used depending upon a variety of factors such as availability and cost of equipment as well as safety, effectiveness and acceptability of methods. Sterilisation has been extensively

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performed via minilaparotomy, colpototmy and laparoscopy. Minilaparotomy is often preferred to laparoscopy because it can be performed with simple and inexpensive instruments and is, therefore, considered more suitable for developing countries. The colpotomy approach has been extensively used in India as the absence of an abdominal scar makes this method highly acceptable to the Indian woman (1,2). While laparoscopy is a highly acceptable method of female sterilisation, the expensive sophisticated equipment and potentially serious hazards associated with electrocoagulati have limited its application. Mechanical occlusive techniques have been developed to eliminate these hazards. A variety of clips were tried and abandoned because of the unacceptable failure rates associated with them (3-8). The tubal ring technique is gaining popularity and has been used via laparoscopy (9-13), minilaparotomy (12-15) and colpotomy (16,17).

Well controlled, random, comparative studies are needed to scientifically evaluate and compare the safety and effectiveness of different approaches to the Fallopian tubes and different techniques for occluding them. This report evaluates the short and long-term safety and effectiveness of the tubal ring technique applied via laparoscopy, minilaparotomy and colpotomy in postabortion cases. The evaluation is based on comparative studies conducted by the India FRP.

MATERIALS AND METHODS

Data on 692 laparoscopy, 149 minilaparotomy and 264 colpotomy procedures are reported. The standard protocol of the India FRP was used for all studies. Clinical events within 21 days were reported for all study cases. Long-term follow-up data were reported for 540 cases at six months, for 288 cases at twelve months, for 187 cases at eighteen months and 97 cases at 24 months poststerilisation. For colpotomy cases, follow-up data were reported for the six months visit only.

Study Methodology

Data from five comparative studies of the India FRP are reported in this paper. In all study cases, the tubal ring was used to occlude the Fallopian tubes and sterilisation was performed immediately after first trimester pregnancy termination by vacuum aspiration. The female sterilisation approach was randomly allocated in all studies. To eliminate inter-operator variability, in each study a single operator performed all the surgical procedures and recorded data related to procedures and events which occurred while the patient was in the operating room. To evaluate evaluator bias, a second physician (the evaluator) was responsible for the care of the patient after her discharge from the operating room, The evaluator also provided follow-up care and recorded data on all postoperative events from the time of discharge from the operating room to the time of the early and long-term follow-up visits.

Premedication and Anaesthesia

The study subject received 0.6 mg of atropine intramuscularly about half an hour before surgery. When local anaesthetics were used, premedication, generally in the form of diazepam with pethidine, was administered intravenously about 15 minutes before

surgery. Most of the laparoscopic sterilisations were performed with local anaesthesia (67.9%); 15 to 20 ml of 1 percent lidocaine was infilterated at the operation site. General anaesthesia was administered to 20.5 percent and regional anaesthesia to 11.6 percent women undergoing laparoscopy. While all the minilaparotomy procedures were performed with local anaesthesia, only 6.8 percent of the colpotomy procedures were performed with local anaesthesia. General anaesthesia was used for 56.8 percent and regional anaesthesia for 36.4 percent of the colpotomy procedures.

Surgical Technique

For laparoscopic sterilisation, atmospheric air or carbon dioxide was used to create pneumoperitoneum. Sterilisation was performed using the standard surgical technique. The tubal ring was applied to the tube at a distance of 3 to 4 cm from its cornual end. The tubes were occluded through a second incision in 21.8 percent cases. The skin incision was closed using either a single catgut stitch or a tincture-benzoin seal.

For minilaparotomy, the patient was placed in the Trendlenburg position and the Vitton's manipulator was introduced into the uterus. A 4 cm incision was made two fingers above the symphasis pubis. After opening the peritoneum, the uterus was manipulated to bring the Fallopian tube into view. The tube was gently caught with the Babcock's forceps and the tubal ring applied 4 cm from its cornual end. This procedure was repeated on the other side. The peritoneum was closed by continuous catgut sutures and the skin by subcuticular catgut.

Colpotomy was performed through an incision in the posterior fornix. The tubal ring was applied using the tubal ring applicator. The vaginal wall and peritoneum were closed together with chromic catgut sutures.

Subject Selection, Definitions and Criteria

Only women who underwent sterilisation for family size limitation were included in the study.

Surgical time was defined as the time from the commencement of dilatation to final closure. Operating room time was the time from entering to leaving the operating room and included surgical time.

Complications and complaints due to the sterilisation procedure were categorised as operative, immediate, early and delayed postoperative. Operative complications and complaints were those occurring during surgery. Immediate postoperative complications and complaints were those occurring after surgery but prior to the patient's discharge from the hospital. Early postoperative complications and complaints were those reported between discharge and the first follow-up visit 7 to 21 days after sterilisation. (For patients who were hospitalised for 7 or more nights, this category of complications were reported during hospitalisation). Delayed postoperative complications and complaints were those reported at the follow-up visits at six, twelve, eighteen and twenty four months and included all gynaecological abnormalities detected and complaints reported at these visits.

All statistical tests were performed using a significance level (p value) of 0.05.

RESULTS

Sociodemographic Characteristics

Sociodemographic characteristics including age, parity and education were similar for women undergoing laparoscopy, minilaparotomy and colpotomy (Table I).

TABLE I

SOCIODEMOGRAPHIC CHARACTERISTICS OF 1,105 WOMEN UNDERGOING LAPAROSCOPY, MINILAPAROTOMY AND COLPOTOMY IN INDIA, 1975 TO 1979

Sociodemographic Characteristics	Laparoscopy N=692		Minilaparotomy N=149		Colpotomy N=264	
	No.	%	No.	%	No.	%
Age (Years)						
20 - 24	40	5.8	13	8.7	12	4.5
25 - 29	224	32.4	54	36.2	69	26.1
30 - 34	247	35.7	69	46.3	94	35.6
35 - 39	144	20.8	13	8.7	68	25.8
40 +	37	5.3	0	0.0	21	7.9
Mean	31.4		29.8		32.3	
Parity						
0	1	0.1	0	0.0	1	0.4
1 - 2	149	21.5	22	14.8	40	15.1
3 - 4	402	58.1	87	58.4	162	61.4
5 - 6	121	17.5	40	26.8	49	18.6
7 +	19	2.7	0	0.0	12	4.5
Mean	3.5		3.7		3.7	
Education (School years)						
0	202	29.2	42	28.2	106	40.1
1 - 3	39	5.6	6	4.0	22	8.3
4 - 6	156	22.5	36	24.2	52	19.7
7 - 9	131	18.9	26	17.4	47	17.8
10 - 12	137	19.8	33	22.1	32	12.1
13 +	27	3.9	6	4.0	5	1.9
Mean	5.6		5.8		4.4	

Surgical Time and Hospitalisation

Mean surgical time was significantly lower when sterilisation was performed via laparoscopy (10.4 minutes) than when it was performed via minilaparotomy (18.7 minutes) and colpotomy (15.2 minutes) (Table II and Fig 1). While 95.6 percent of the laparosco procedures were completed within 20 minutes, 67.1 percent and 87.2 percent of the minilaparotomy and colpotomy procedures respectively were completed within this time.

TABLE II

SURGICAL AND OPERATING ROOM TIME FOR 1,105 WOMEN UNDERGOING LAPAROSCOPY, MINILAPAROTOMY AND COLPOTOMY IN INDIA, 1975 TO 1979

Time (Minutes)	Laparoscopy N=692		Minilaparotomy N=149		Colpotomy N=264	
	No.	%	No.	%	No.	%
Surgical Time						
≤ 5	93	13.4	0	0.0	2	0.8
6 - 10	306	44.2	3	2.0	60	22.7
11 - 15	194	28.0	38	25.5	72	27.3
16 - 20	69	10.0	59	39.6	96	36.4
21 - 25	23	3.3	32	21.5	19	7.2
26 +	7	1.0	17	11.4	15	5.7
Mean	10.4		18.7		15.2	
Operating Room Time						
Mean	28.8		46.2		31.8	

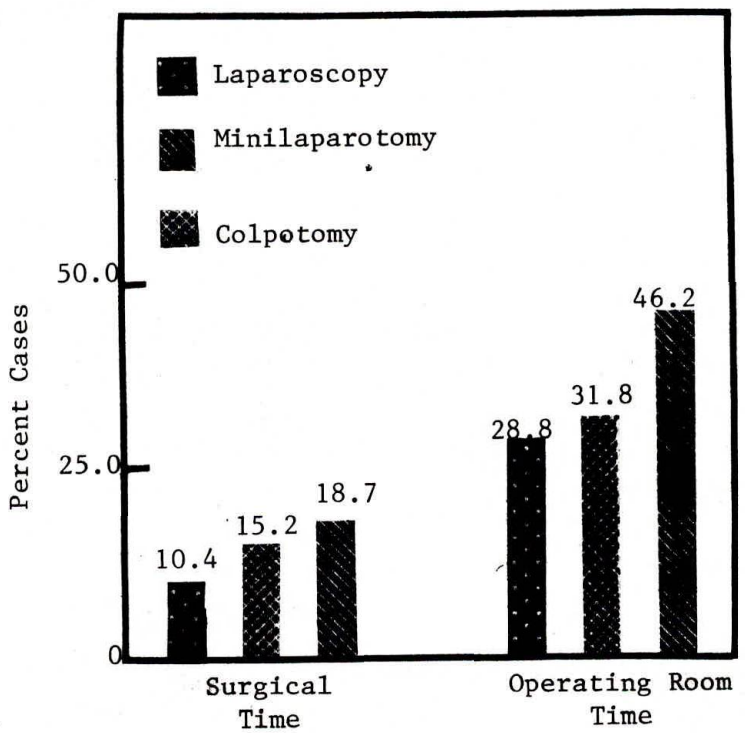

Fig 1

SURGICAL AND OPERATING ROOM TIME FOR 1,105 WOMEN UNDERGOING LAPAROSCOPY, MINILAPAROTOMY AND COLPOTOMY

The average time spent in the operating room was also lower for women who underwent laparoscopy (28.8 minutes) than for those who underwent minilaparotomy (46.2 minutes) and colpotomy (31.8 minutes) (Table II and Fig 1). While all the women who underwent colpotomy were hospitalised, 55.3 and 30.9 percent of those who underwent laparoscopy and minilaparotomy respectively were sterilised on an outpatient basis.

Technical Failures

There were two (0.3%) technical failures among the laparoscopy cases. The tubal ring could not be applied on the right side in one patient as carbon dioxide had leaked out through the spoilt rubber gasket and the operator had difficulty reaching the Fallopian tube. The right tube was, therefore, occluded by electrocoagulation, and the left tube with the tubal ring. In the second case, the tubal ring could not be applied because the Fallopian tubes were thick and so could not be pulled into the ring applicator. The right tube got cut while applying the ring and so a clip was applied on either side of the knuckle to go across the tube and onto the mesosalpinx. The tubal ring technique was not attempted on the left side as the left tube was thickened at the cornual end; two clips were applied to occlude it.

No technical failures were reported among the minilaparotomy cases. Four (1.5%) technical failures were reported among the colpotomy procedures. In all four cases sterilisation was successfully performed via colpotomy. However, the technique used for tubal occlusion was different from the planned tubal ring technique. In one case, the tubal ring was applied successfully to the right tube but the left tube was ligated by the Madleiner's technique because the mesosalpinx and the tubal wall were torn by the grasping forceps. In another case, the right tube was successfully occluded with the tubal ring but as the left tube was adherent and could not be visualised, it was ligated by the Pomeroy technique and a part of it was sectioned. In two cases, the tubal ring technique was used successfully to occlude one tube. However, the other tube could not be brought into the operation field owing to the presence of adhesions and so it was sectioned and tied.

Technical and Surgical Difficulties

The incidence of technical difficulties was higher for laparoscopy (1.9%) than for colpotomy (0.8%). No technical difficulties were reported for minilaparotomy (Table III and Fig 2). The differences in the rates of technical difficulties were not statistically significant.

The incidence of surgical difficulties was highest for minilaparotomy (6.0%) and lowest for colpotomy (1.9%); this difference was statistically significant. The rate of surgical difficulties was 3.8 percent for laparoscopy (Table III and Fig 2). Adhesions were a cause of surgical difficulty with all three approaches. While omentum interference was the most common cause of surgical difficulty for laparoscopy (1.0%) difficulty in exteriorizing the tubes was the most frequent problem for minilaparotomy (4.0%) and colpotomy (0.8%) (Table III).

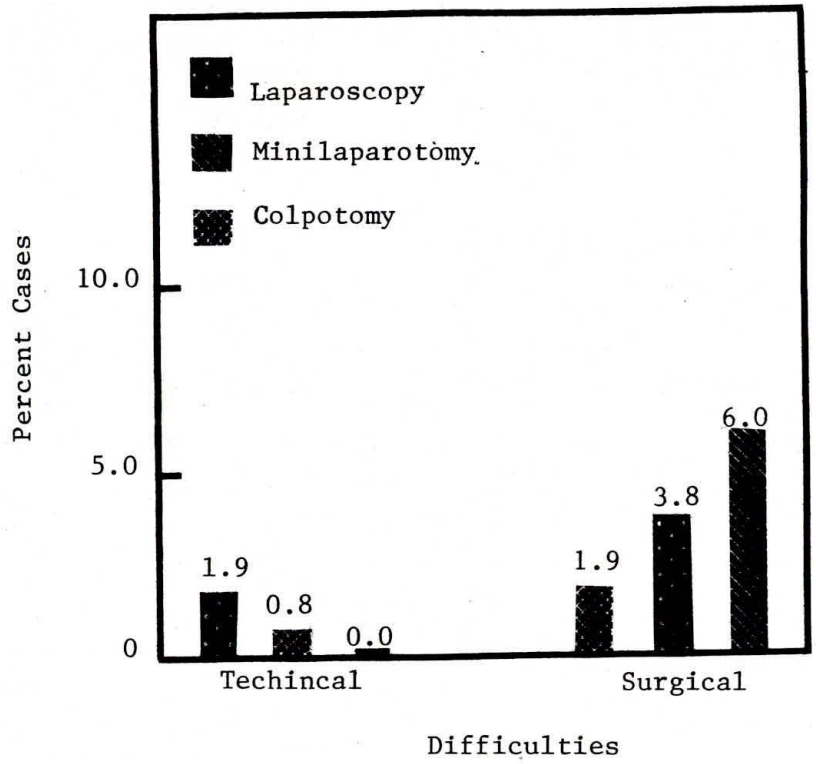

Fig 2

TECHNICAL AND SURGICAL DIFFICULTIES REPORTED FOR 1,105 WOMEN UNDERGOING LAPAROSCOPY, MINILAPAROTOMY AND COLPOTOMY IN INDIA, 1975 TO 1979

TABLE III

TECHNICAL AND SURGICAL DIFFICULTIES REPORTED FOR 1,105 WOMEN UNDERGOING LAPAROSCOPY, MINILAPAROTOMY AND COLPOTOMY IN INDIA, 1975 TO 1979

Difficulties	Laparoscopy N-692		Minilaparotomy N=149		Colpotomy N=264	
	No.	%	No.	%	No.	%
Technical:						
Gas leakage through rubber gasket	6	0.9	0	0.0	0	0.0
Improper ring application	6	0.9	0	0.0	0	0.0
Applicator problems	2	0.3	0	0.0	1	0.4
Needle broke	1	0.1	0	0.0	0	0.0
Ring broke	1	0.1	0	0.0	0	0.0
Poor light source	0	0.0	0	0.0	1	0.4
Total	13	1.9	0	0.0	2	0.8
Surgical:						
Omentum interference	7	1.0	0	0.0	0	0.0
Difficulty in exteriorizing tubes	0	0.0	6	4.0	2	0.8
Thick/tortous tubes	6	0.9	0	0.0	1	0.4
Adhesions	6	0.9	3	2.0	2	0.8
Difficulty in creating pnuemoperitoneum	2	0.3	0	0.0	0	0.0
Difficulty in inserting needle/trocar	2	0.3	0	0.0	0	0.0
Cystic ovary	2	0.3	0	0.0	0	0.0
Enlarged uterus	1	0.1	0	0.0	0	0.0
Total	26	3.8	9	6.0	5	1.9

Complications

The incidence of operative complications was not significantly different for women undergoing laparoscopy (0.7%), minilaparotomy (1.3%) and colpotomy (1.1%) (Table IV and Fig 3). Bladder injury occurred during one minilaparotomy procedure; no other serious operative complications attributable to the sterilisation procedure were reported (Table IV).

The immediate postoperative complication rate was significantly lower for laparoscopy (0.7%) than for colpotomy (2.3%) and minilaparotomy (6.7%) (Table IV and Fig 3). The most common complications for minilaparotomy (5.2%) were incision-related. Fever (1.9%) was the most frequently reported complication for women sterilised via colpotomy. One woman undergoing laparoscopy had excessive bleeding requiring transfusion (Table IV).

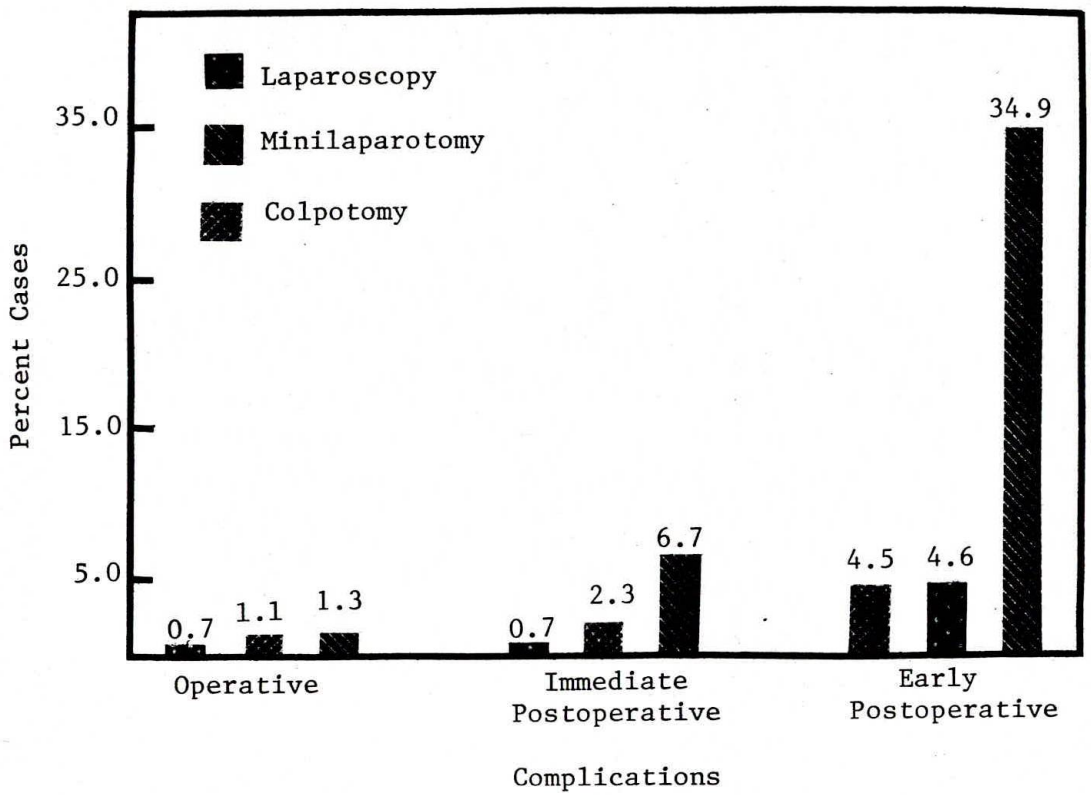

Fig 3

COMPLICATIONS REPORTED FOR 1,105 WOMEN UNDERGOING LAPAROSCOPY, MINILAPAROTOMY AND COLPOTOMY IN INDIA, 1975 TO 1979

TABLE IV

COMPLICATIONS REPORTED FOR 1,105 WOMEN UNDERGOING LAPAROSCOPY, MINILAPAROTOMY AND COLPOTOMY IN INDIA, 1975 TO 1979

Complications	Laparoscopy N=692		Minilaparotomy N=149		Colpotomy N=264	
	No.	%	No.	%	No.	%
Operative:						
Bladder injury	0	0.0	1	0.7	0	0.0
Avulsion of tube	1	0.1	0	0.0	1	0.4
Partial tear of tube	1	0.1	0	0.0	0	0.0
Knuckle of tube divided	1	0.1	0	0.0	0	0.0
Tear of mesosalpynx	1	0.1	1	0.7	1	0.4
Brochospasm due to anaesthesia	1	0.1	0	0.0	1	0.4
Total	5	0.7	2	1.3	3	1.1
Immediate postoperative:						
Blood loss requiring transfusion	1	0.1	0	0.0	0	0.0
Haematoma	2	0.3	0	0.0	0	0.0
Vasovagal attack	2	0.3	0	0.0	0	0.0
Fever	0	0.0	2	1.3	5	1.9
Bleeding per vagina	0	0.0	0	0.0	1	0.4
Incision related:						
Infection	0	0.0	2	1.3	0	0.0
Gaping wound	0	0.0	2	1.3	0	0.0
Serous discharge	0	0.0	2	1.3	0	0.0
Induration	0	0.0	2	1.3	0	0.0
Total	5	0.7	10	6.7	6	2.3
Early postoperative:						
Pelvic infection	1	0.1	2	1.3	0	0.0
Mild salpingitis	1	0.1	0	0.0	0	0.0
Fever	2	0.3	0	0.0	11	4.2
Bleeding	1	0.1	0	0.0	1	0.4
Vaginitis	2	0.3	1	0.7	0	0.0
Incision related:						
Mild infection	6	0.9	9	6.0	0	0.0
Sepsis	2	0.3	0	0.0	0	0.0
Gaping wound	2	0.3	8	5.4	0	0.0
Omental herniation from wound	1	0.1	0	0.0	0	0.0
Serous discharge	9	1.3	16	10.7	0	0.0
Induration	5	0.7	15	10.1	0	0.0
Haematoma	0	0.0	1	0.7	0	0.0
Total	32	4.6	52	34.9	12	4.5

In the early postoperative period, the rate of complications for minilaparotomy (34.9%) was six times higher than that for laparoscopy (4.6%) and colpotomy (4.5%) (Table IV and Fig 3). The vast majority of the early postoperative complications reported for women undergoing minilaparotomy were, however, incision-related (32.9%) and most of these were minor complications including serous discharge (10.7%) and induration (10.1%). Mild infection and gaping wound were reported for 6.0 and 5.4 percent of these cases respectively. Among the colpotomy cases, fever (4.2%) was the most commonly reported early postoperative complication. The incidence of incision-related complications for laparoscopy was 3.6 percent (Table IV).

Complaints

The incidence of complaints in the immediate postoperative period was significantly higher for minilaparotomy (24.2%) than for laparoscopy (9.7%) and colpotomy (3.4%) (Table V and Fig 4). The most frequently reported complaint was pelvic pain. The frequency of pelvic pain was significantly higher for women undergoing minilaparotomy (18.1%) and was considerably lower for those undergoing laparoscopy (6.8%) and colpotomy (2.3%) (Table V).

TABLE V

COMPLAINTS REPORTED BY 1,105 WOMEN UNDERGOING LAPAROSCOPY, MINILAPAROTOMY AND COLPOTOMY IN INDIA, 1975 TO 1979

Complaints	Laparoscopy N=692		Minilaparotomy N=149		Colpotomy N=264	
	No.	%	No.	%	No.	%
Immediate postoperative:						
Pelvic pain	47	6.8	27	18.1	6	2.3
Giddiness/weakness	7	1.0	3	2.0	1	0.4
Vomiting	7	1.0	1	0.7	1	0.4
Abdominal distention	3	0.4	0	0.0	0	0.0
Chest pain	2	0.3	0	0.0	1	0.4
Frequent/burning micturition	1	0.1	0	0.0	1	0.4
Depression	0	0.0	1	0.7	0	0.0
Incision pain	0	0.0	3	2.0	0	0.0
Iodine burns	0	0.0	1	0.7	0	0.0
Total	67	9.7	36	24.2	9	3.4
Early postoperative:						
Pelvic pain	35	5.1	13	8.7	5	1.9
Spotting per vagina	9	1.3	0	0.0	4	1.5
Bleeding per vagina	0	0.0	0	0.0	5	1.9
Abdominal distention	5	0.7	0	0.0	0	0.0
Nausea/vomiting	5	0.7	0	0.0	0	0.0
Giddiness/weakness	2	0.3	0	0.0	1	0.4
Depression	0	0.0	1	0.7	0	0.0
Frequency of micturition	0	0.0	1	0.7	0	0.0
Incision related:						
Induration	3	0.4	0	0.0	0	0.0
Pain	2	0.3	0	0.0	0	0.0
Itching	1	0.1	1	0.7	0	0.0
Total	62	9.0	16	10.7	15	5.7

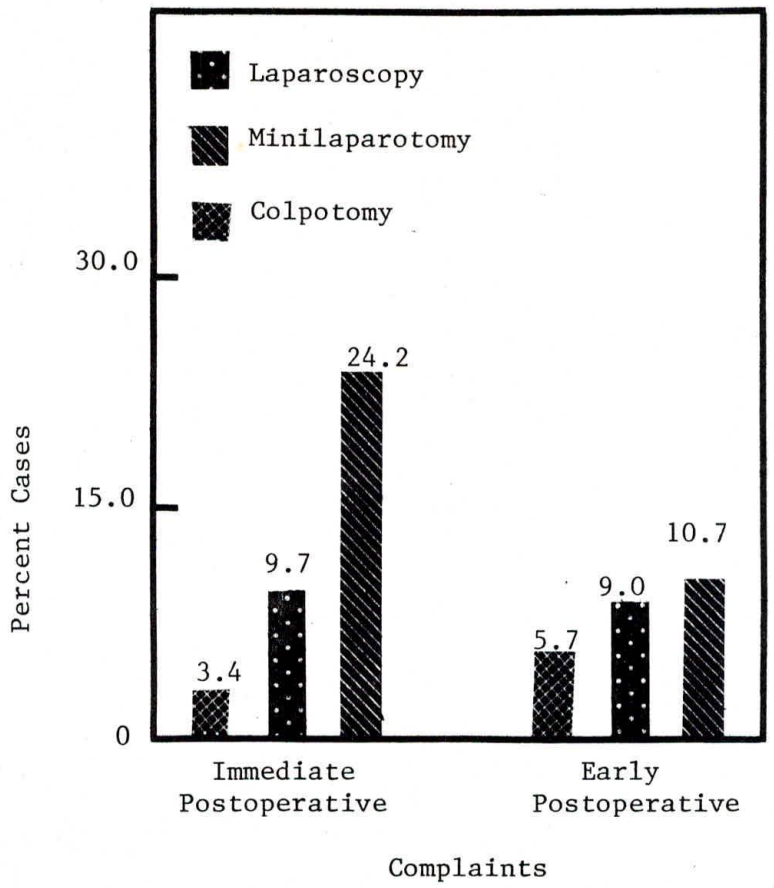

Fig 4

COMPLAINTS REPORTED FOR 1,105 WOMEN UNDERGOING LAPAROSCOPY, MINILAPAROTOMY AND COLPOTOMY IN INDIA, 1975 TO 1979

In the early postoperative period, complaints were reported with similar frequency by women undergoing laparoscopy (9.0%) and minilaparotomy (10.7%). The incidence of early postoperative complaints was lower for women undergoing colpotomy (5.7%) (Table V and Fig 4). While pelvic pain (5.1%) and spotting per vagina (1.3%) were the most common complaints after laparoscopy, pelvic pain was, by far, the most frequently reported complaint after minilaparotomy (8.7%) and pelvic pain (1.9%), spotting (1.5%) and bleeding per vagina (1.9%) were the most frequently reported complaints after colpotomy (Table V).

Delayed complications and Complaints

While these conditions are reported for all three groups of cases 6 months after sterilisation, they are reported only for the laparoscopy and minilaparotomy cases at 12, 18 and 24 months after sterilisation.

The incidence of gynaecological abnormalities 6 months after sterilisation was significantly higher for women who underwent colpotomy (42.2%). Gynaecological abnormalities were reported more frequently for women who underwent minilaparotomy (20.7%) than for those who underwent laparoscopy (15.5%) but the difference was not statistically significant (Table VI and Fig 5). Cervical erosion was the most frequently reported gynaecological abnormality for all three groups of cases. Conditions that accounted for the higher rate among colpotomy cases were mainly cervical erosion, pelvic infection and tubo-ovarian masses (Table VI).

TABLE VI

GYNAECOLOGICAL ABNORMALITIES REPORTED AT 6 MONTHS FOR 540 WOMEN UNDERGOING LAPAROSCOPY, MINILAPAROTOMY AND COLPOTOMY IN INDIA, 1975 TO 1979

Gynaecological Abnormalities	Laparoscopy N=310		Minilaparotomy N=121		Colpotomy N=109	
	No.	%	No.	%	No.	%
Cervical erosion	20	6.4	7	5.8	19	17.4
Endocervicitis	3	1.0	2	1.6	3	2.7
Thickened/tender adnexae	8	2.6	2	1.6	5	4.6
Pelvic infection	2	0.6	3	2.5	9	8.3
Salpingitis	1	0.3	0	0.0	0	0.0
Parametritis	0	0.0	1	0.8	0	0.0
Tubo-ovarian masses	0	0.0	1	0.8	4	3.7
Vaginitis	3	1.0	1	0.8	0	0.0
Vaginal cyst	1	0.3	0	0.0	0	0.0
Vulval furuncles	0	0.0	0	0.0	1	0.9
Urinary tract infection	2	0.6	1	0.8	0	0.0
Carcinoma in situ	0	0.0	0	0.0	1	0.9
Leuplakic patch	1	0.3	0	0.0	0	0.0
Dysplasia	1	0.3	0	0.0	0	0.0
Cystocoele	4	1.3	1	0.8	2	1.8
Rectocoele	1	0.3	0	0.0	2	1.8
Uterine prolapse	1	0.3	1	0.8	0	0.0
Wound sepsis	0	0.0	1	0.8	0	0.0
Keloid	0	0.0	4	3.3	0	0.0
TOTAL	48	15.5	25	20.7	46	42.2

Twelve months after sterilisation, gynaecological abnormalities were reported more frequently for women who underwent laparoscopy (12.6%) than for those who underwent minilaparotomy (11.2%) but the difference was not statistically significant (Table VII and Fig 5). While the incidence of cervical erosion and thickened/tender adnexae was higher for women who underwent laparoscopy, the incidence of pelvic infection was higher for those who underwent minilaparotomy (Table VII).

TABLE VII

GYNAECOLOGICAL ABNORMALITIES REPORTED AT 12, 18 AND 24 MONTHS FOR WOMEN UNDERGOING LAPAROSCOPY AND MINILAPAROTOMY IN INDIA, 1975 TO 1979

Gynaecological Abnormalities	Laparoscopy		Minilaparotomy	
	No.	%	No.	%
Twelve Months:	N=199		N=89	
Thickened/tender adnexae	8	4.0	1	1.1
Mass in fornix	1	0.5	1	1.1
Pelvic infection	2	1.0	3	3.4
Cervical erosion	10	5.0	2	2.2
Vaginitis	2	1.0	1	1.1
Urinary tract infection	1	0.5	1	1.1
Keloid	1	0.5	1	1.1
Total	25	12.6	10	11.2
Eighteen Months:	N=92		N=95	
Pelvic infection	0	0.0	2	2.1
Thickened/tender adnexae	0	0.0	3	3.2
Cervical erosion	5	5.4	2	2.1
Endocervicitis	1	1.1	1	1.0
Vaginal infection	1	1.1	0	0.0
Uterine prolapse	0	0.0	2	2.1
Cystocoele	1	1.1	0	0.0
Incisional hernia	0	0.0	1	1.0
Total	8	8.7	11	11.6
Twenty-four Months:	N=52		N=45	
Pelvic infection	0	0.0	1	2.2
Cervical erosion	0	0.0	1	2.2
Irregular cervix	1	1.9	0	0.0
Tender fornix	1	1.9	0	0.0
Uterine prolapse	1	1.9	1	2.2
Cystocoele	1	1.9	1	2.2
Total	4	7.7	4	8.9

At 18 months, a higher incidence of gynaecological abnormalities was reported for the minilaparotomy (11.6%) than for the laparoscopy (8.7%) cases but the difference was not statistically significant (Table VII and Fig 5). The incidence of pelvic infection (2.1%), uterine prolapse (2.1%) and thickened/tender adnexae (3.2%) accounted for the higher rate among the minilaparotomy cases (Table VII).

At 24 months also the incidence of gynaecological abnormalities was higher for women who underwent minilaparotomy (8.9%) than for those who underwent laparoscopy (7.7%) but the difference was not statistically significant (Table VII and Fig 5). The higher rate for minilaparotomy was due to the higher incidence of pelvic infection (2.2%) and cervical erosion (2.2%) among these cases (Table VII).

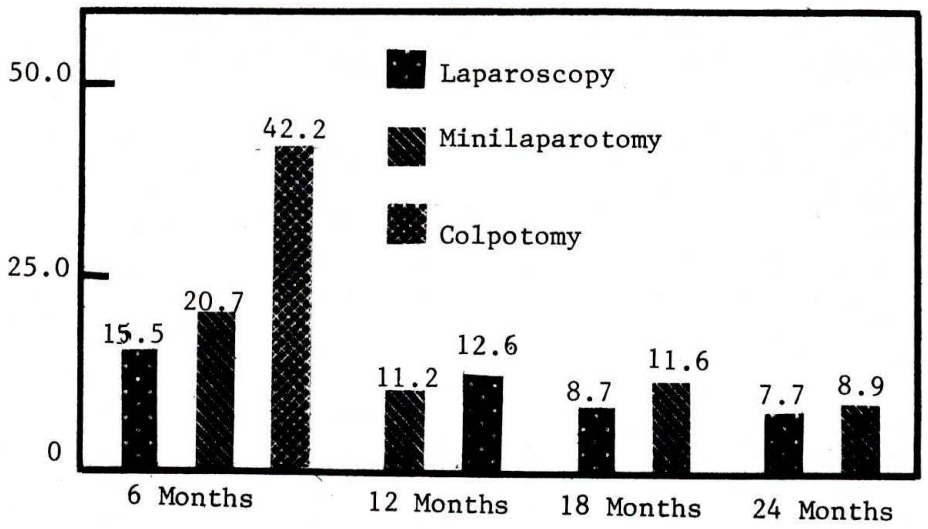

Fig 5

GYNAECOLOGICAL ABNORMALITIES REPORTED AT LONG TERM FOLLOW-UP FOR WOMEN UNDERGOING LAPAROSCOPY, MINILAPAROTOMY AND COLPOTOMY IN INDIA, 1975 TO 1979

Complaints

At 6 months, the incidence of complaints was significantly lower for women who underwent laparoscopy (7.4%); the frequency of complaints was similar for those who underwent minilaparotomy (22.3%) and colpotomy (22.0%). Pelvic pain was reported more frequently by women who underwent colpotomy (22.0%) than for those who underwent minilaparotomy (13.2%) and for those who underwent laparoscopy (5.8%). These differences were statistically significant (Table VIII and Fig 6). Wound pain was reported more frequently by women who underwent minilaparotomy (9.1%) than for those who underwent laparoscopy (1.6%).

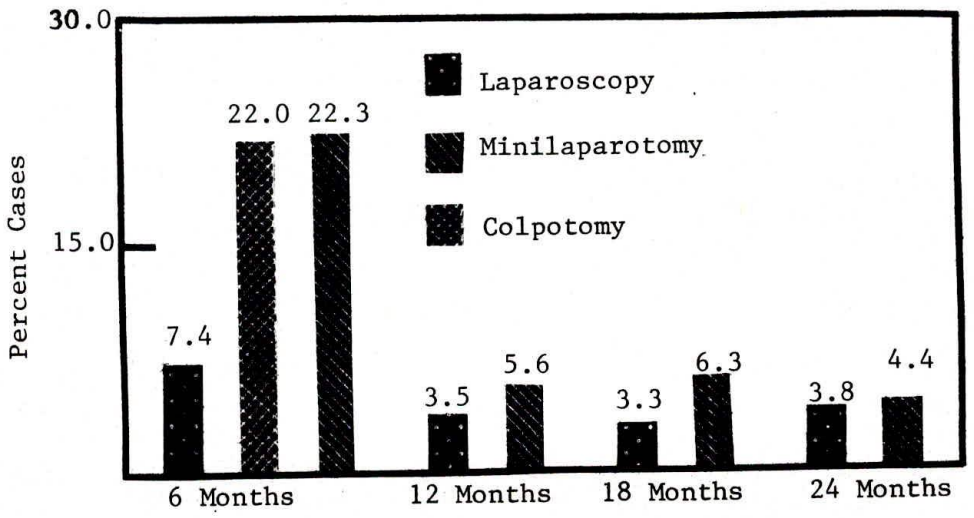

Fig 6

COMPLAINTS REPORTED AT LONG-TERM FOLLOW-UP BY WOMEN UNDERGOING LAPAROSCOPY, MINILAPAROTOMY AND

TABLE VIII

COMPLAINTS REPORTED AT LONG-TERM FOLLOW-UP BY WOMEN UNDERGOING LAPAROSCOPY, MINILAPAROTOMY AND COLPOTOMY IN INDIA, 1975 TO 1979

Complaints	Laparoscopy No.	Laparoscopy %	Minilaparotomy No.	Minilaparotomy %	Colpotomy No.	Colpotomy %
Six Months:	N=310		N=121		N=109	
Pelvic pain	18	5.8	16	13.2	24	22.0
Wound pain	5	1.6	11	9.1	0	0.0
Total	23	7.4	27	22.3	24	22.0
Twelve Months:	N=199		N=89			
Pelvic pain	5	2.5	3	3.4	-	-
Wound pain	1	0.5	2	2.2	-	-
General weakness	1	0.5	0	0.0	-	-
Total	7	3.5	5	5.6	-	-
Eighteen Months:	N=92		N=95			
Pelvic pain	2	2.2	5	5.3	-	-
Wound pain	0	0.0	1	1.0	-	-
Weight gain	1	1.1	0	0.0	-	-
Total	3	3.3	6	6.3	-	-
Twenty four Months:	N=52		N=45			
Pelvic pain	2	3.8	2	4.4	-	-
Total	2	3.8	2	4.4	-	-

Note: Follow-up data after 6 months was not available for women who underwent colpotomy.

The incidence of complaints decreased markedly after 6 months for **women** who underwent minilaparotomy. At 12 months, the incidence of pelvic pain and wound pain was significant higher for the minilaparotomy than for the laparoscopy cases (Table VIII and Fig 6). At 18 and 24 months also complaints were reported more frequently by women who underwent minilaparotomy than those who underwent laparoscopy (Table VIII and Fig 6). However, these differences were not statistically significant.

Gynaecological Surgery

After laparoscopic sterilisation, dilatation and curettage (D&C) was performed in three (0.6%) cases; one woman underwent D&C at six months and two women underwent this procedure at 18 months. After minilaparotomy, D&C was performed in one (1.0%) case 18 months after sterilisation and hysterectomy in 3 (6.7%) cases 24 months after sterilisation.

Pregnancies

Only one pregnancy was reported in this series. This pregnancy was reported six months after laparoscopy at another institution and so the patient could not be investigated.

DISCUSSION

With the increasing demand for female sterilisation in recent years there have been concomitant technological advancements in an effort to provide safe, effective and acceptable methods of female sterilisation. For implementing large-scale programmes in developing countries, methods that are adaptable to varied clinical settings and are acceptable both to the clinician and patient are needed. Laparoscopy and minilaparotomy have been extensively used under varied conditions in a number of countries including India, and appear to be the most promising of the currently available methods. While the colpotomy approach has been widely accepted and used in India, in recent years it has lost some of its popularity owing to the high incidence of complications reported by some workers. To assist in the search for methods which will best meet large-scale needs, the India Fertility Research Programme is conducting well controlled, comparative studies which are designed to scientifically evaluate and compare the safety, effectiveness and acceptability of a wide range of sterilisation approaches and techniques in different patient categories.

The present analysis is based on pooled data from studies conducted at different centres and so all inter-centre variables are not controlled for in this series. However, by using standard protocols, it has been possible to draw certain conclusions. This analysis shows that sterilisation can be performed safely and effectively via laparoscopy, minilaparotomy and colpotomy in postabortion cases. Operative complication rates were similar for all three approaches and were comparable to rates reported in a pooled analysis of 2,904 laparoscopy and 532 minilaparotomy procedures (3). However, there was a significantly higher incidence of immediate and early postoperative complications and complaints for women undergoing minilaparootmy in this series. The main reason for the differential in the morbidity rates was the high incidence of, mostly minor, incision-related complications with minilaparotomy. Hence, if these problems could be minimized, the complication rates for minilaparotomy could be substantially decreased and would then compare favourably with the low morbidity rates reported for laparoscopy in this and other studies (3,12,13). Training in the procedure is an important factor for minimizing morbidity with all three sterilisation approaches as knowledge of details of the procedure prevents potential complications. For laparoscopy, possibly a higher level of skill, qualifications and training are needed.

The tubal ring technique offers a distinct advantage for laparoscopy as it obviates the dangers of burns associated with electrocoagulation. For minilaparotomy and colpotomy, standard ligation techniques may be favoured because of the interrelated problems of tubal transection due to tubal ring application and problems of providing special applicators for this technique. Reported failure rates with the tubal ring were low in this and other studies (6,9,11,18). With the availability of locally manufactured tubal rings this technique is gaining popularity in India. The better chances of future tubal reanastomosis, another possible advantage of this technique, has not been validated so far.

For the successful implementation of service programme, the cost factor is obviously an important criterion. This includes the initial cost of equipment, maintenance costs, time of the surgeon and other staff and hospital costs. While the initial investment and maintenance costs are higher for laparoscopic equipment, this and other studies (3,12,13) show that surgical and operating room time as well as hospital stay are considerably lower for this method. In the present study, the incidence of technical difficulties was not significantly different for the three sterilisation approaches. Technical failures reported for laparoscopy and colpotomy involved only

a change to an alternative sterilisation technique and the planned approach was successfully employed to complete the procedure. A pooled analysis of data from several centres showed significantly higher failed procedures for laparoscopy than for minilaparotomy (3). For large-scale sterilisation programmes, the initial outlay and the logistical considerations of costs and continued maintenance of laparoscopic equipment should be weighed against the lower programme costs related to staff time and hospitalisation. Laparoscopic equipment is being modified to minimize its costs and to make it more durable, practical and adaptable to field conditions in developing countries. Early reports with the laparocator, which has been designed to fulfill these requirements, are encouraging (19,20). Outpatient sterilisation with minilaparotomy is certainly cost-effective and hospitalisation for colpotomy is a disadvantage.

The question of late sequelae and menstrual disturbances subsequent to sterilisation is still unanswered. While some workers believe that there is considerable late morbidity following sterilisation, results in literature are quite conflicting (21,22) probably due to the lack of adequate control groups in most studies and the absence of comparable data from the general female population. It is postulated that the interruption of the terminal branch of the uterine artery to the ovary results in ovarian dysfunction (23). The incidence of late morbidity has been related to the sterilisation procedure and one study showed significantly higher morbidity rates for laparoscopy than for tubal ligation; this was attributed to increased tissue destruction and disruption of blood supply by diathermy (21). In the present series, the incidence of gynaecological abnormalities was significantly higher for colpotomy than for laparoscopy and minilaparotomy six months after sterilisation. Follow-up rates were dissimilar for the three groups of cases and later follow-up data are reported only for laparoscopy and minilaparotomy. While the incidence of gynaecological abnormalities and complaints and gynaecological surgery was higher for minilaparotomy than for laparoscopy, the differences were not statistically significant. Since the tubal ring techniques damages only a limited segment of the tube, unlike electrocoagulation, and as the technique for tubal occlusion in this study was the same for all three approaches, these differentials may be attributed to the surgical procedures employed to approach the Fallopian tubes. To scientifically evaluate long-term sequelae following sterilisation, random, controlled long-term follow-up studies are recommended.

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COMPLICATIONS AND SEQUELAE FOR 17,492 STERILISATION CASES - A FIVE YEAR STUDY

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ABSTRACT

Complications/sequelae following sterilisation are reported for 645 cases in whom sterilisation was performed concurrently with caesarian section and/or other gynaecological surgery and for 2,937 postpartum, 4,225 postabortion and 1,427 interval sterilisation cases. The incidence of psychological complaints was high for all patient categories. The incidence of wound infection was highest among postpartum cases. Menstrual problems were most frequently reported for postpartum and post-abortion cases. The mortality rate for the series was 0.02 percent. The pregnancy rate was 0.3 percent.

INTRODUCTION

Sterilisation of the female has been of interest to the medical profession since Hippocrates first proposed it as a means of avoiding perpetuation of insanity through heredity. Later, this concept was extended to include the prevention of other heriditary diseases and conditions which could endanger the life of the mother. With the population explosion a dynamic change has occurred in the concept of sterilisation which has been extended from the need of the individual to the need of the nation. Since sterilisation is now a national need it becomes imperative to study complications and sequelae of the present day methods of sterilisation in order to offer the safest available methods to the population.

MATERIALS AND METHODS

In this study, 17,492 women undergoing sterilisation from 1974-1978 at the Madurai Medical College Hospital, Madurai were included. Sterilisation was performed in all cases as an inpatient procedure with atleast 8 days hospitalisation. The modified Pomeroy technique was used in all study cases.

Patient Category:

Women undergoing sterilisation were categorised as follows:

Group I included 1,711 women in whom the sterilisation procedure was performed via the abdominal route, concurrently with caesarian section and/or other major gynaecological surgery.

Group II included 4,926 women in whom sterilisation was performed via the abdominal route, as a postpartum procedure within 48 hours of delivery.

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Group III included 7,479 women in whom sterilisation was performed via the abdominal or the vaginal routes, concurrently with pregnancy termination.

Group IV included 3,376 women in whom sterilisation was performed via the abdominal or vaginal routes, as an interval procedure 1½ to 2 years after the last child birth.

Follow-Up

The woman was advised to return for follow-up after 15 days. Thereafter, she was advised to visit whenever she experienced any problem or difficulty. At each review, a routine pelvic examination was performed. Other relevant examinations were performed according to the specific complaints. In this series, 52.8 percent of the women were followed up. Table I shows the follow-up rates for various patient categories. Complication/sequelae are reported only for women who were followed-up.

TABLE I

FOLLOW-UP RATES BY PATIENT CATEGORY FOR 17,492 WOMEN UNDERGOING STERILISATION AT THE MADURAI MEDICAL COLLEGE HOSPITAL, MADURAI, 1974 TO 1978

Type	With Follow-up		Without Follow-up		Total	
	No.	%	No.	%	No.	%
Group I						
Caesarian section and/or gynaecological surgery	645	37.7	1066	62.3	1711	100.0
Group II						
Postpartum	2937	59.6	1989	40.4	4926	100.0
Group III						
Postabortion	4225	56.5	3254	43.5	7479	100.0
Dilatation and curettage	1984	52.1	1821	47.9	3805	50.9
Vacuum aspiration	1512	64.3	839	35.7	2351	31.4
Hysterotomy	252	57.5	186	42.5	438	5.9
Extraamniotic saline	38	58.5	27	41.5	65	0.9
Intraamniotic saline	412	52.0	381	48.0	793	10.6
Prostaglandin	27	100.0	0	0.0	27	0.4
Group IV						
Interval	1427	42.3	1949	57.7	3376	100.0
TOTAL	9234	52.8	8258	47.2	17492	100.0

Definitions and Criteria

Complications/sequelae reported within 3 months of sterilisation were categorized as early. Complications/sequelae reported after 3 months were categorized as late.

RESULTS

Complications/Sequelae

For women who underwent sterilisation concurrently with caesarian section or other gynaecological surgery, the most frequently reported early complications were general debility (7.0%) and wound infection (6.7%) and the most frequently reported late complications were leucorrhoea (4.0%), menorrhagia (3.9%) and incisional hernia (3.3%) (Table II).

TABLE II

REPORTED COMPLICATIONS/SEQUELAE BY TIME OF ONSET FOR 645 WOMEN UNDERGOING STERILISATION CONCURRENTLY WITH CAESARIAN SECTION AND/OR OTHER GYNAECOLOGICAL SURGERY AT THE MADURAI MEDICAL COLLEGE HOSPITAL, MADURAI, 1974 TO 1978

Complications/Sequelae	Time of Onset			
	Early		Late	
	No.	%	No.	%
Infection				
Wound infection	43	6.7	0	0.0
Urinary tract infection	7	1.1	16	2.5
Thrombophlebitis	3	0.5	0	0.0
Total	53	8.2	16	2.5
Menstrual disorders				
Amenorrhoea	17	2.6	19	3.0
Menorrhagia	13	2.0	25	3.9
Intermenstrual spotting	3	0.5	20	3.1
Oligomenorrhoea	1	0.2	9	1.4
Total	34	5.3	73	11.3
Psychological				
Nonspecific aches	134	20.8	274	42.5
General debility	45	7.0	102	15.8
Dyspepsia	8	1.2	18	2.8
Dysparunia	0	0.0	1	0.2
Total	187	29.0	395	61.3
Miscellaneous				
Leucorrhoea	25	3.9	26	4.0
Incisional hernia	8	1.2	21	3.3
Other	26	4.0	47	7.3
Total	59	9.1	94	14.6

Note: For this table and for Table III, IV and V, complications/sequelae were categorized as early if reported within 3 months and late if reported after 3 months of sterilisation.

Among the postpartum cases, wound infection (16.7%) was the most frequently reported early complication. The incidence of leucorrhoea, amenorrhoea and menorrhagia was 5.5, 3.9 and 2.4 percent within 3 months. After 3 months, the incidence of leucorrhoea was 15.6 percent and amenorrhoea was reported in 8.6 percent cases. The incidence of incisional hernia (0.5%) was low for this series (Table III).

TABLE III

REPORTED COMPLICATIONS/SEQUELAE BY TIME OF ONSET FOR 2,937 WOMEN UNDERGOING POSTPARTUM STERILISATION AT THE MADURAI MEDICAL COLLEGE HOSPITAL, MADURAI, 1974 TO 1978

Complications/Sequelae	Time of Onset			
	Early		Late	
	No.	%	No.	%
Infection				
Wound infection	490	16.7	0	0.0
Urinatry tract infection	33	1.1	86	2.9
Thrombophlebitis	27	0.9	0	0.0
Total	550	18.7	86	2.9
Menstrual Disorders				
Amenorrhoea	115	3.9	252	8.6
Menorrhagia	71	2.4	179	6.1
Intermenstrual spotting	15	0.5	70	2.4
Oligomenorrhoea	6	0.2	49	1.7
Dysmenorrhoea	1	0.0	41	1.4
Total	208	7.1	591	20.1
Psychological				
Nonspecific aches	873	29.7	1600	54.5
General debility	327	11.1	735	25.0
Dyspepsia	49	1.7	125	4.3
Dysperunia	0	0.0	11	0.4
Total	1249	42.5	2471	84.1
Miscellaneous				
Leucorrhoea	162	5.5	459	15.6
Incisional hernia	2	0.1	15	0.5
Other	211	7.2	326	11.1
Total	375	12.8	800	27.2

When sterilisation was performed concurrently with pregnancy termination, menorrhagia, leucorrhoea and wound infection were reported in 10.0, 8.9 and 6.9 percent cases respectively, within 3 months of sterilisation. The most frequently reported late complications in this series were leucorrhoea (13.9%) and menorrhagia (7.4%) (Table IV).

TABLE IV

REPORTED COMPLICATIONS/SEQUELAE BY TIME OF ONSET FOR 4,225 WOMEN UNDERGOING STERILISATION CONCURRENTLY WITH PREGNANCY TERMINATION AT THE MADURAI MEDICAL COLLEGE HOSPITAL, MADURAI, 1974 TO 1978

Complications/Sequelae	Time of Onset			
	Early		Late	
	No.	%	No.	%
Infection				
Wound infection	290	6.9	0	0.0
Urinary tract infection	71	1.7	151	3.6
Thrombophlebitis	57	1.4	0	0.0
Pelvic infection	35	0.8	29	0.7
Total	453	10.7	180	4.3
Menstrual Disorders				
Menorrhagia	422	10.0	312	7.4
Amenorrhoea	111	2.6	159	3.8
Intermenstrual spotting	49	1.2	142	3.4
Oligomenorrhoea	17	0.4	118	2.8
Dysmenorrhoea	11	0.3	28	0.7
Total	610	14.4	759	18.0
Gynaecological Problems				
Prolapse uterus	0	0.0	4	0.1
Psychological				
Nonspecific aches	1678	39.7	2530	59.9
General debility	478	11.3	1058	25.0
Dyspepsia	72	1.7	213	5.0
Dysparunia	0	0.0	14	0.3
Total	2228	52.7	3815	90.3
Miscellaneous				
Leucorrhoea	375	8.9	587	13.9
Incisional hernia	1	0.0	7	0.2
Scar endometriosis	0	0.0	18	0.4
Other	363	8.6	608	14.4
Total	739	17.5	1220	28.9

Among the interval sterilisation cases, wound infection (7.8%) and leucorrhoea (5.0%) were the most common early complications and leucorrhoea (13.3%) and menorrhagia (4.2%) were the most frequently reported late complications (Table V).

The incidence of wound infection was highest among postpartum (16.7%) cases and it was 6 to 8 percent among the other patient categories. For all patient categories, the reported incidence of leucorrhoea ranged between 3.9 to 8.9 percent within 3 months and 4.1 to 15.6 percent after 3 months of sterilisation.

The incidence of psychological complaints was high for all categories; it was highest for the postpartum (84.1%) and postabortion (90.3%) cases (Tables III and IV).

TABLE V

REPORTED COMPLICATIONS/SEQUELAE BY TIME OF ONSET FOR 1,427 WOMEN UNDERGOING INTERVAL STERILISATION AT THE MADURAI MEDICAL COLLEGE HOSPITAL, MADURAI, 1974 TO 1978

Complications/Sequelae	Time of Onset			
	Early		Late	
	No.	%	No.	%
Infection				
Wound infection	111	7.8	0	0.0
Urinary tract infection	20	1.4	31	2.2
Pelvic infection	10	0.7	4	0.3
Thrombophlebitis	5	0.4	0	0.0
Total	146	10.2	35	2.5
Menstrual Disorders				
Amenorrhoea	29	2.0	35	2.5
Menorrhagia	26	1.8	60	4.2
Intermenstrual spotting	10	0.7	38	2.7
Oligomenorrhoea	4	0.3	16	1.2
Dysmenorrhoea	2	0.0	15	1.1
Total	71	5.0	164	11.5
Gynaecological Problems				
Prolapse	0	0.0	3	0.2
Uterine myoma	0	0.0	1	0.1
Ovarian tumour	0	0.0	1	0.1
Cancer cervix	0	0.0	1	0.1
Total	0	0.0	6	0.4
Psychological				
Nonspecific aches	312	21.9	637	44.6
General debility	113	8.0	289	20.3
Dyspepsia	25	1.8	42	2.9
Dysparunia	2	0.0	15	1.1
Total	450	31.5	976	68.4
Miscellaneous				
Leucorrhoea	71	5.0	190	13.3
Other	110	7.7	182	12.8
Total	181	12.7	372	26.1

The incidence of menstrual complaints within three months of sterilisation was highest among postabortion(14.8%) cases. Menorrhagia (10.3%) was the most frequently reported menstrual problem in this group of cases. The incidence of menorrhagia was 2.9 to 3.8 percent in the other patient categories. The incidence of amenorrhoea ranged between 2.7 to 5.0 percent for various patient categories (Fig 1).

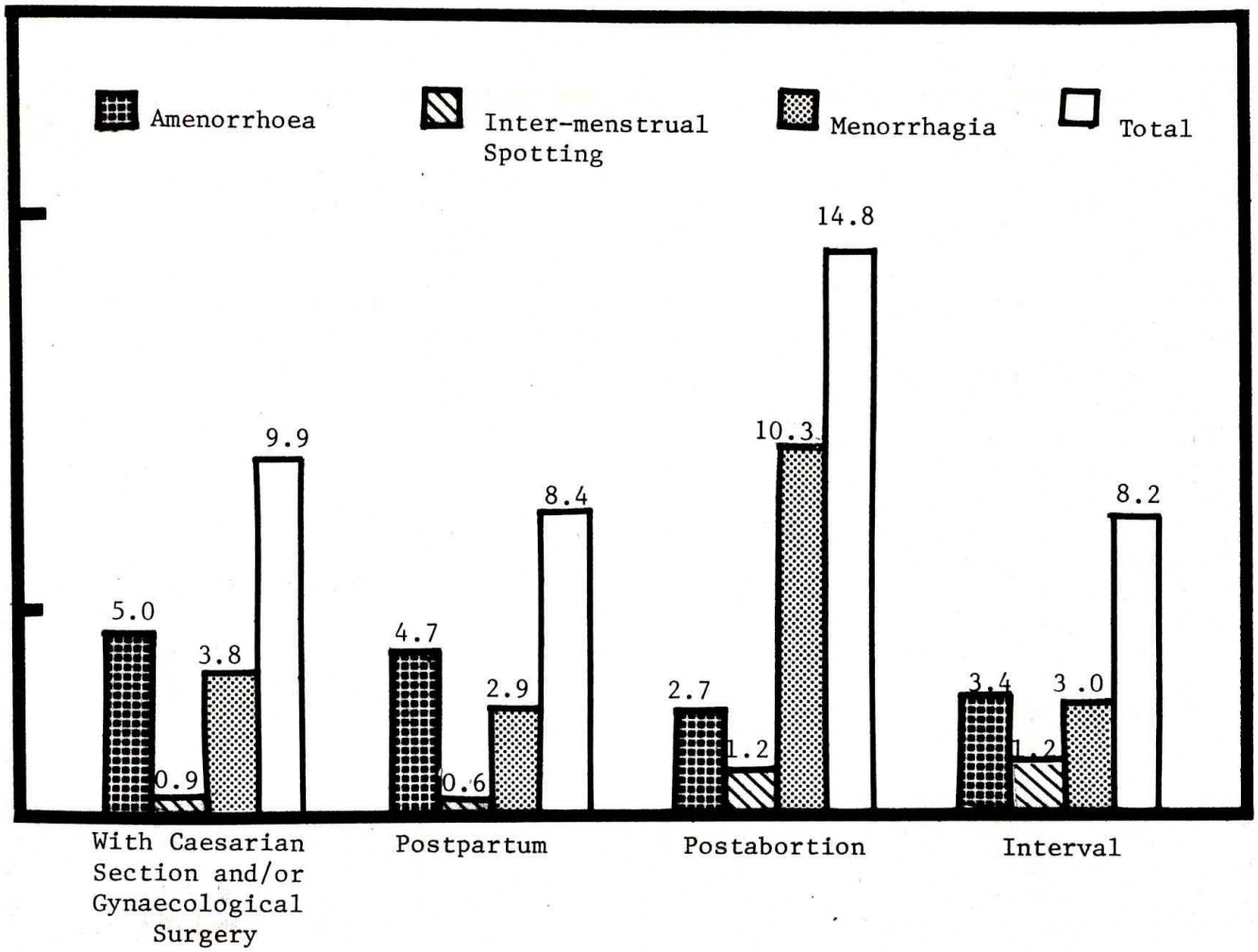

Fig 1

MENSTRUAL DISORDERS WITHIN THREE MONTHS OF STERILISATION AT THE MADURAI MEDICAL COLLEGE HOSPITAL, MADURAI, 1974 TO 1978

After 3 months of sterilisation, the highest incidence of menstrual problems was reported for the postpartum (14.2%) cases; it was 12.7 percent for the postabortion cases and also for those in whom sterilisation was performed concurrently with caesarian section or other gynaecological surgery, and was 10.5 percent for the interval sterilisation cases. The incidence of amenorrhoea was 2.3 to 6.1 percent and that of menorrhagia was 3.9 to 5.2 percent for the various patient categories (Fig 2).

Mortality

There were 3 deaths in the series. Thus the mortality rate was 0.02 percent. While one death was reported for a woman undergoing postpartum sterilisation, two were reported among women in whom sterilisation was performed concurrently with caesarian section or other gynaecological surgery.

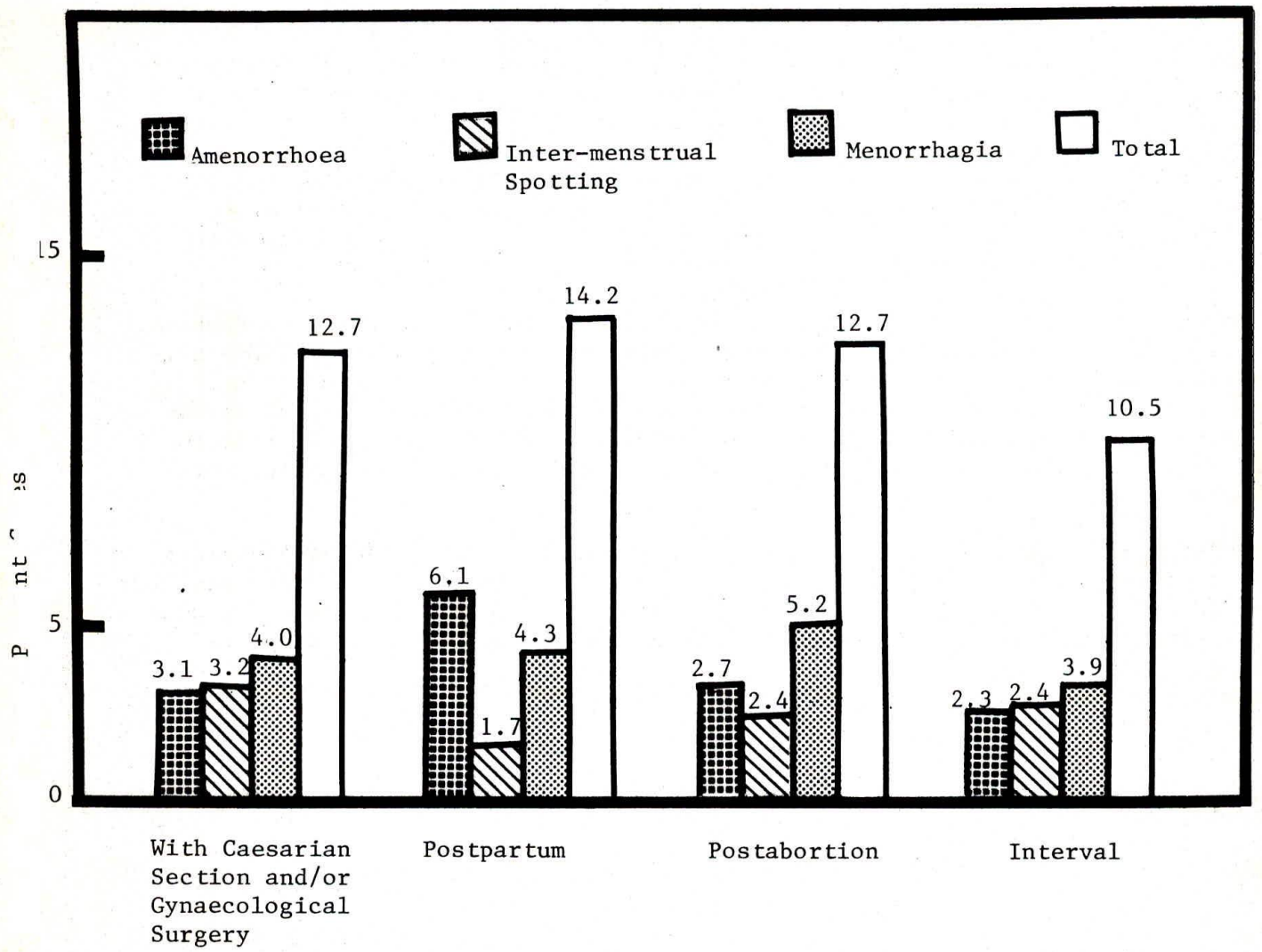

Fig 2

MENSTRUAL DISORDERS AFTER THREE MONTHS OF STERILISATION AT THE MADURAI MEDICAL COLLEGE HOSPITAL, MADURAI, 1974 TO 1978

Pregnancies

There were 49 pregnancies in the series; the pregnancy rate for the total series was 0.3 percent. The pregnancy rate was 0.5 percent for cases in whom concurrent caesarian section or pelvic surgery was performed, 0.2 percent for postpartum cases, 0.3 percent for postabortion cases and 0.3 percent for interval cases. One ectopic pregnancy was reported.

COMMENT

A high percentage of women undergoing sterilisation reported psychological complaints such as general debility and non-specific aches and pains. These complaints were successfully treated with symptomatic or even placebo therapy.

The incidence of leucorrhoea within 3 months of sterilisation ranged between 3.9 to 8.9 percent for the various patient categories; it was 4.0 to 15.6 percent after three months. This complaint was attributed to prior local pelvic pathology which was, probably, not recognized before sterilisation.

The author believes that tubal ligation per se does not cause menstrual disturbances. Khanna et al (1) and Nandekar (2) showed that ovarian activity was not reduced after the tubectomy procedure. In this study, patients with menstrual problems did not require any major medical or surgical treatment. The authors recommend that in the case of high parity women menstrual history should be carefully evaluated prior to sterilisation and hysterectomy should be be considered in cases with a history of menorrhagia.

As female sterilisation is used extensively on a nation-wide basis, it is important to consider its risks and benefits. In this analysis, the complications and sequelae of sterilisation are evaluated to highlight the risks associated with presently used methods. Further prospective long-term follow-up studies are recommended for further evaluation.

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EXPERIENCE WITH LOW WATTAGE BIPOLAR CAUTERIZATION OF THE TUBES FOR FEMALE STERILISATION - A FOLLOW-UP STUDY

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ABSTRACT

Prehysterectomy studies on 10 cases and clinical trial of 53 women undergoing sterilisation with the low wattage bipolar cauterization technique are reported. The technique is described. The results of these studies indicate that this technique is safe and effective and offers a better potential for recanlization since tubal damage is minimized. The advantages of this method over the unipolar cauterization and tubal ring techniques are discussed.

INTRODUCTION

It is universally acknowledged that the electrosurgical cauterization of the tubes via laparoscopy is an easy and effective method of female sterilisation (1,2). Unfortunately, the electrical system has not lived upto its former expectations because of the rare but serious complication of bowel burns with the high frequency unipolar instrument (3,4,5) and fear of a failure, however, rare with the bipolar instrument. This method, therefore, no longer enjoys universal acceptability. The gynaecological world is consequently losing interest in electrosurgical techniques. However, bipolar electrosurgery has several advantages (6,7). This study was undertaken to evaluate the low wattage bipolar cauterization technique of female sterilisation.

MATERIALS AND METHODS

Basic Principles of Electrosurgery

With the unipolar system of electrosurgery, a high frequency current is delivered through a small active electrode (Fig 1). The density of the current at the point of contact causes wide destruction of the tissues by dissolution of its molecular structure. As the current returns to the ground plate and finally to the generator a large area of the tube is invariably destroyed. The neighbouring mesosalpinx may also be destroyed, thereby, endangering the tubal blood supply and frequently resulting in excessive necrosis of the tube which may render a future tubal anastomosis almost impossible. The onward journey of the current from the tube to the ground plate is unpredictable as it seeks the path of least resistance and in doing so may cause damage to the person of the operator and also cause burns to the bowel or whatever tissue is in its way.

The bipolar principle eliminates the faults inherent in the unipolar technique. In this case, the electrodes are placed within the instrument itself so that the current passes selectively from one prong of the forceps to the other and so destroys

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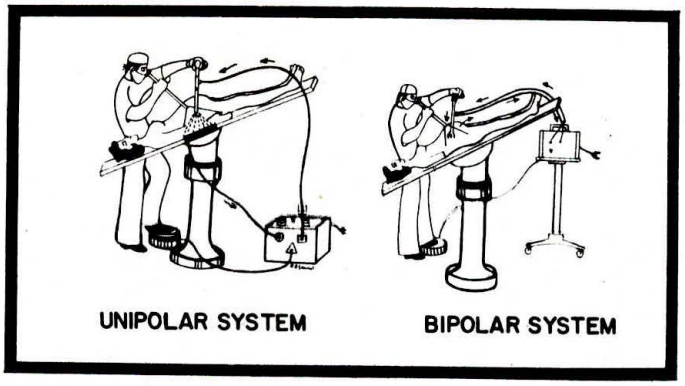

Fig 1

PATH OF CURRENT WITH THE UNIPOLAR AND BIPOLAR SYSTEMS

only that tissue which is interposed between the prongs (Fig 1). In this system, the ground plate is eliminated along with its danger of intraabdominal sparking and injury to intraabdominal viscera. As in this case the current has to traverse only a short distance between the two prongs of the forceps and has to destroy only a small portion of the tissue that is held between the prongs, a very low voltage of current is needed and the final low wattage of current required for the purpose is safe for intraabdominal use. Furthermore, the low temperature obtained at low wattage eliminates over-heating of the forceps and the associated inadvertent accidental damage which can occur on contact with tissues while withdrawing the forceps. Thus, the destruction of tubal tissue is limited to a small area and does not extend to the mesosalpinx. This factor is most critical as it has important implications for future surgical reversal.

Prehysterectomy Study

The procedure was performed 6 to 12 weeks prior to hysterectomy in ten women who were scheduled for hysterectomy and who consented to participate in the study. The Fallopian tubes were cauterized with the Storz bipolar coagulator and bipolar grasping forceps, using the Storz single puncture laparoscope. Coagulation for 80 to 180 seconds (depending upon the thickness of the tubes), at a setting of 50 on the Storz bipolar coagulator, was found to produce optimum results. Histopathologically, the effects of cauterization were similar to those obtained with the classical unipolar method.

Studies of the hysterectomy specimens included: (a) macroscopic examination of the tubes, (b) cryosectioning, (c) histopathological examination and (d) hysterosalpingogram of the complete specimen.

Clinical Study

From January 1977 to June 1979, 53 women underwent sterilisation with the low wattage bipolar cauterization technique. All procedures were performed by the author. In the majority of the cases intravenous analgesia and local anaesthesia were used. The following are some of the important details of this technique:

(1) By correct placement of the atraumatic forceps, the full thickness of the tube should be grasped so that when the jaws of the forceps are closed they completely encircle the tube. Care should be taken to ensure that the mesosalpinx is avoided. (2) The tube should be coagulated at a single site about 3 cm from the uterine cornu. Division or severance of the tube should be avoided. (3) Depending on the thickness of the tube, a current should be passed for a minimum of 80 and maximum of 180 seconds at a setting 50. Almost simultaneously, the fluid in the tissue starts boiling (as evidenced by the appearance of bubbles) and steam is liberated. The effected portion of the tube gets dessicated and flattens out within the jaws of the forceps. On withdrawal of the forceps, approximately 5 mm of the tube are completely coagulated and a 2 to 3 mm area on either side of the tube shows lower degrees of coagulation. Thus, not more than about one centimetre of the tube is cauterized and a reasonable length of the tube is conserved for possible future reversibility. The study subjects were scheduled for follow-up at 7 days, 3 months and yearly thereafter.

RESULTS

Prehysterectomy Study

The following results were reported in cases in whom hysterectomy was performed six weeks after tubal cauterization:

On macroscopic examination, the coagulated area of the tube was found to be dull grey in colour and slightly shrunken. The neighbouring areas showed hypermia but no adhesions were seen. On histopathological examination, the coagulated area revealed avascular necrosis of all the coats of the tube; the tubal mucosa was totally destroyed (Fig 2). The area immediately adjacent to the coagulated portion revealed a lesser degree of necrosis and damage (Fig 3). A section through an area 5 mm away from the coagulated site revealed no changes in any of the coats of the tube and the mucosa was intact.

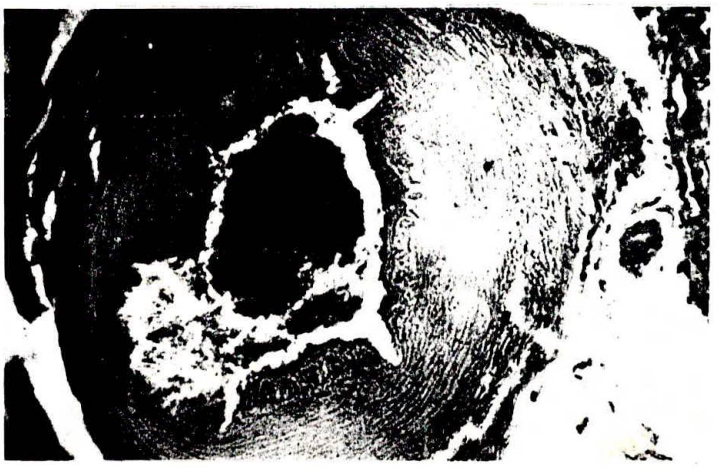

Fig 2: FALLOPIAN TUBE SIX WEEKS AFTER CAUTERIZATION, SHOWS AVASCULAR NECROSIS OF ALL THE COATS AND TOTAL DESTRUCTION OF THE TUBAL MUCOSA

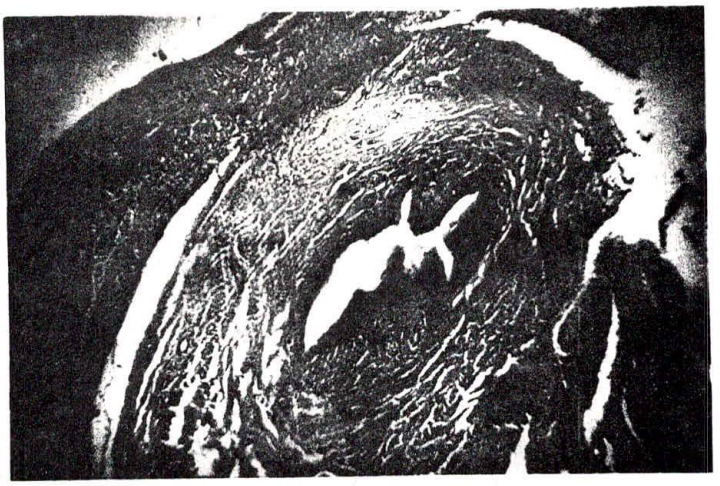

Fig 3: SECTION OF FALLOPIAN TUBE 5 MM AWAY FROM COAGULATED SITE SIX WEEKS AFTER CAUTERIZATION SHOWS NO CHANGE AND INTACT MUCOSA

The following results were reported when hysterectomy was performed twelve weeks after tubal cauterization:

On macroscopic examination, the coagulated area appeared whitish and was shrivelled to a thin cord. Histologically, intense fibrosis was evident in all the coats of the tube as shown with Masson's trichrome stain. The tubal lumen was lost in the scar tissue (Fig 4). Adhesions in the surroundings were conspicuous by their absence. The hysterosalpingogram confirmed that the occlusion of the lumen was total.

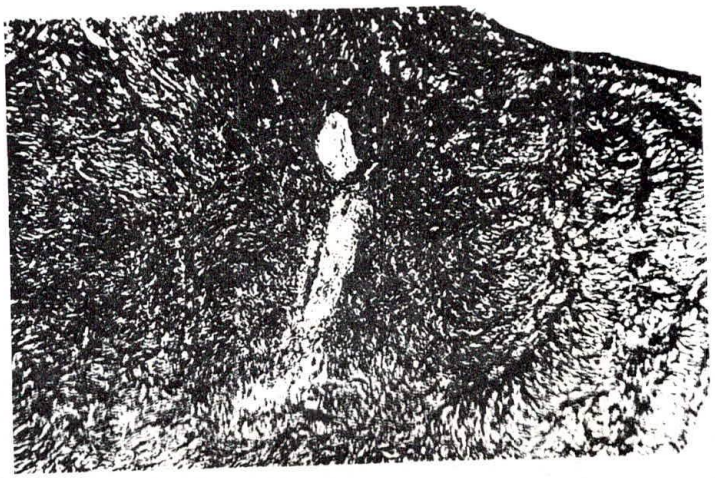

Fig 4: FALLOPIAN TUBE TWELVE WEEKS AFTER CAUTERIZATION SHOWS LOSS OF TUBAL LUMEN IN SCAR TISSUE. NO ADHESIONS IN SURROUNDING TISSUES

Clinical Study

The mean age of the women in the study group was 30.9 years; their mean parity was 2.5. More than half of the women in the series had completed high school (Table I).

While 9 women were followed up within 8-11 months, 26 were followed up within 12-24 months and 18 within 25-36 months.

TABLE I

SOCIODEMOGRAPHIC CHARACTERISTICS OF 53 WOMEN UNDERGOING STERILISATION WITH THE LOW WATTAGE BIPOLAR CAUTERIZATION TECHNIQUE, BOMBAY, 1977 TO 1979

Sociodemographic Characteristics	Number	Percent
Age (Years)		
21 - 25	4	7.5
26 - 30	23	43.4
31 - 35	17	32.1
36 - 40	9	17.0
Mean	30.9	
Parity		
1	2	3.8
2	23	43.4
3	28	52.8
Mean	2.5	
Patient's Education (School years)		
≤ 10	23	43.4
10 +	30	56.6

There were no technical failures or surgical difficulties. The procedure was successfully completed in all cases. No immediate or delayed complications were reported within the two year follow-up period. No menstrual irregularity was reported. No pregnancies have been reported so far. Three of the study subjects underwent hysterosalpingography six to twelve months after sterilisation. In all three cases complete occlusion in the juxtauterine part of the tube was noted (Fig 5).

Fig 5: HYSTEROSALPINGOGRAM SHOWS COMPLETE OCCLUSION IN THE JUXTAUTERINE PART OF BOTH TUBES

DISCUSSION

The results of the prehysterectomy and clinical studies indicate that the low wattage bipolar technique is safe and effective. This technique appears to offer a better potential for future surgical recanlisation since with this method only about one centimetre of the isthmic portion of the tube is sacrificed (8). The mesosalpinx with its blood supply is effectively spared from the ravages of electrocoagulation.

In sharp contrast to this, tubal cauterization with the unipolar high frequency current results in the destruction of a larger area of the tube and often includes the mesosalpinx. Over half the length of the tube is usually destroyed leaving a chance of just 17 percent for successful reversal later (9). While sterilisation should be regarded as a final end to child-bearing, in view of the ever increasing number of sterilisations that are performed and the gradually increasing requests for reversals, especially from younger women who might experience child loss subsequent to sterilisation, the potential for reversal is an important criterion in selecting the sterilisation technique. Winston emphasized that the success of surgical recanalisation is directly proportional to the total available length of the oviduct (9). At attempted recanalisation in rabbits, Boeckx reported that with the Falope ring a 1.5 to 2 cm segment of the rabbit's oviduct was destroyed (10). In human beings, the segment-wise destruction could be larger because of the shape of the loop occluded. The tubal segment lost between the prongs of an atraumatic forceps with low voltage bipolar coagulation is not more than about one centimetre. Although there has been no occasion for reversal in this small series of cases, the author feels that with this technique the chances of a successful outcome are favourable. Furthermore, as the tubal blood supply is not effected with this method it does not result in menstrual disturbances. This sterilisation method reduces the danger of intraabdominal sparking and thereby, enhances the safety factor. The author recommends that the safety, effectiveness and reversability with this method of female sterilisation should be scientifically investigated through clinical trials.

CONCLUSIONS

The present study permits the following conclusions:

- Low wattage bipolar cauterization results in successful occlusion of the tubes. However, long-term follow-up is needed to document the effectiveness of this technique.
- A low wattage current at a setting 50 for 100 seconds produces optimum results.
- The risk of serious complications which is inherent with the high frequency unipolar current is considerably minimized with this technique.
- Tubal cauterization is limited to only about one centimetre of the tissue between the prongs of the forceps which is an improvement over other methods of laparoscopic sterilisation.
- The mesosalpinx with the tubal blood supply is free from damage enabling future reversal and minimizing resulting menstrual disorders.

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FEMALE STERILISATION SERVICES IN RURAL INDIA - PROBLEMS AND SOLUTIONS

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ABSTRACT

This is a report of 4,948 women undergoing sterilisation at periodic camps in Baroda District. Their mean age was 28.7 years and mean parity was 4.0. More than half the women and a fourth of the husbands had received no formal education. Only 1.4 percent of the couples had used a contraceptive. The vast majority of the sterilisation procedures were performed with regional anaesthesia, via laparotomy and with modified Pomeroy technique.

Mean surgical time was 16.3 minutes and mean hospital stay was 8.9 nights. Eight (0.2%) technical failures were reported. The incidence of surgical difficulties was 0.4 percent. Two deaths were reported. Operative and early postoperative complication rates were 0.2 and 3.4 percent respectively. The incidence of early postoperative complaints was 17.0 percent. The incidence of gynaecological abnormalities was 2.7, 5.4, 5.3 and 2.9 percent at the 6, 12, 18 and 24 months follow-up visits respectively; 3.1, 7.9, 7.4 and 5.0 percent of the women respectively reported complaints. Gynaecological surgery was performed in 3.4 percent cases. The pregnancy failure rate was 0.06 percent.

INTRODUCTION

In recent years, the camp approach has been widely used in India for providing sterilisation services to rural areas. While rural communities have the greatest need for such services, the infrastructure needed for organising these services is inadequate in rural areas and even the available facilities are generally inaccessable to most rural populations. In India, mobile camps are extensively used as a service delivery mechanism for providing sterilisation services in rural areas. Generally large-scale camps are organized on a one-time basis to meet the demand for sterilisation. This mass approach has been criticised as it is associated with several disadvantages. The limited staff available at the camp site after the visiting team leaves is unable to provide adequate postoperative care to the large number of women who have been sterilised and this results in high complication rates which in turn affects patient acceptability.

This paper reports our experience in rural areas with periodic, small camps. The objective of this approach is to provide high quality services through camps and also strengthen the existing infrastructure in rural areas by training the local physicians in surgical procedures. This approach was developed to ensure continuing service delivery even after the camps are discontinued.

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MATERIALS AND METHODS

The experience of 4,948 women undergoing sterilisation between 1972 and 1978 at bi-weekly camps organized in the Baroda District of Gujarat by visiting teams from the Department of Obstetrics and Gynaecology at the Baroda Medical College Hospital is reported.

All data for this study were recorded on standard forms of the India Fertility Research Programme. Data are reported on sociodemographic and fertility characteristics of women sterilised at the camps, surgical time and hospital stay, technical failures, surgical difficulties, complications and failure rates. The number of cases followed up at 6, 12, 18 and 24 months was 224, 203, 243 and 617 respectively.

Sterilisation camps were organized at six Primary Health Centres (PHCs). The PHC facilities that were used for camps usually had five maternity beds, a labour room, and areas where prenatal and child health clinics were held. Since these health centres have no regular operating theatres, artificial lighting, equipment for sterilising instruments, and a source of running water had to be improvised. Natural lighting was most often relied upon, but a battery-operated light was used when necessary. Instruments were sterilised in boiling water on a kerosene stove, and a brass tank was filled to provide running water.

The local PHC staff were responsible for: (i) visiting the area to motivate women for sterilisation, (ii) making local arrangements for camps, (iii) assisting the visiting team during the camp and (iv) providing follow-up care after the visiting team left the PHC. The resident medical officers at these PHCs have since been trained to provide surgical sterilisation at these facilities. The team has moved to provide services and train the local physicians at other PHCs.

Definitions and Criteria

Technical failure was defined as a case in which the designated procedure could not be completed. Technical difficulty was defined as any difficulty associated with the equipment. Surgical difficulty was defined as any difficulty encountered during the procedure which was not due to equipment-related problems. Surgical time was defined as the time from the initial incision to final closure.

Complications and complaints were categorized as operative and early postoperative. Opererative complications were those occurring during surgery. Early postoperative complications and complaints were those reported within the first three weeks after surgery.

All statistical tests were performed using a significance level (p value) of 0.05.

RESULTS

Sociodemographic Characteristics

The mean age of women undergoing sterilisation in camps was 28.7 years; 45.4 percent were 30 years or older. Their mean parity was 4.0; 41.8 percent had less than four live births and 30.1 percent had five or more live births. The mean number of living children for this group of women was 3.7; 22.0 percent had five or more living children (Table I).

TABLE I

SOCIODEMOGRAPHIC CHARACTERISTICS OF 4,948 WOMEN UNDERGOING STERILISATION IN SMALL CAMPS IN BARODA DISTRICT, NOVEMBER 1972 TO AUGUST 1978

Sociodemographic Characteristics	Number	Percent
Age (Years)		
< 20	3	0.1
20 - 24	588	11.9
25 - 29	2108	42.6
30 - 34	1664	33.6
35 - 39	495	10.0
40 +	90	1.8
Mean	28.7	
Parity		
2	560	11.3
3	1509	30.5
4	1391	28.1
5	771	15.6
6	415	8.4
7 +	302	6.1
Mean	4.0	
Number of Living Children		
≤ 2	679	13.7
3 - 4	3177	64.2
5 - 6	956	19.3
7 +	136	2.7
Mean	3.7	
Patient's Education (School years)		
0	2802	56.6
1 - 3	413	8.3
4 - 6	839	17.0
7 - 9	615	12.4
10 +	279	5.6
Mean	2.5	
Husband's Education (School years)		
0	1323	26.8
1 - 3	499	10.1
4 - 6	1269	25.7
7 - 9	870	17.6
10 +	979	19.8
Mean	5.0	

*For those women who are currently married.

TABLE I (CONTD)

Sociodemographic Characteristics	Number	Percent
Marital Status		
Currently married	4940	99.8
Formerly married	8	0.2
Religion		
Hindu	4445	89.8
Muslim	481	9.7
Other	22	0.4
Gainfully employed		
No	4871	98.4
Yes	76	1.5
Unknown	1	0.0
Residence		
Rural	1652	33.4
Urban	3294	66.6
Unknown	2	0.0
Previous Contraceptive Practice		
None	4877	98.6
IUD	27	0.5
Condom	26	0.5
Orals	6	0.1
Tubectomy	5	0 .1
Vasectomy	4	0.1
Rhythm/withdrawal	3	0.1

More than half the women and a fourth of the husbands had received no formal education; their mean educational achievement was 2.5 and 5.0 years of formal schooling respectively The vast majority of the women were unemployed (98.4%), Hindu (89.8%) and one third were from rural areas (Table I).

Prior Contraceptive Experience

Only 1.4 percent of the couples had used a contraceptive method prior to sterilisation. It is of interest to note that five women and four men had previously undergone a sterilisation operation (Table I).

Pregnancy Wastage and Child Loss

The reported incidence of induced and spontaneous abortions was 1.4 and 25.4 per 1000 pregnancies respectively and that for stillbirths was 5.4 per 1000 pregnancies. The child loss rate reported for this series was 83.6 per 1000 live births (Table II).

TABLE II

PRIOR PREGNANCY WASTAGE AND CHILD LOSS FOR 4,948 WOMEN UNDERGOING STERILISATION IN SMALL CAMPS IN BARODA DISTRICT, NOVEMBER 1972 TO AUGUST 1978

Pregnancy Wastage/Child Loss	Number	Rate/1000
Induced abortion*	26	1.4
Spontaneous abortion*	479	25.4
Stillbirth*	102	5.4
Child loss**	1527	83.6

*Rates based on the total number of pregnancies.
**Rate based on the number of live births.

Prior Surgery and Preexisting Medical Conditions

Previous pelvic surgery was reported for 27 (0.5%) and prior abdominal surgery for 21 (0.4%) women respectively. About a third of the women undergoing sterilisation had less than 10 grams haemoglobin, 12 (0.5%) were overweight, 50 (1.0%) had systemic disease and 10 (0.2%) had pelvic infection (Table III).

TABLE III

PREEXISTING MEDICAL CONDITIONS AND PRIOR SURGERY FOR 4,948 WOMEN UNDERGOING STERILISATION IN SMALL CAMPS IN BARODA DISTRICT, NOVEMBER 1972 TO AUGUST 1978

Condition	Number	Percent
Haemoglobin (< 10 gms)	1592	32.2
Systemic disease	50	1.0
Overweight*	12	0.5
Pelvic infection	10	0.2
Pelvic surgery	27	0.5
Abdominal surgery	21	0.4

*Weight was reported for interval cases.

Concurrent Surgery

In this series 29 (0.6%) women underwent other surgical procedures concurrently with sterilisation. In 19 cases dilatation and curettage was performed. Cysts were removed in five and lysis of adhesions was performed in two cases. Three women underwent other procedures.

Sterilisation Approach, Method and Technique

While half of the sterilisations were interval procedures, 39.6 percent were postpartum and 9.1 percent were postabortion procedures. The vast majority of the sterilisation procedures were performed via laparotomy (98.6%), 1.3 percent were performed via colpotomy; the modified Pomeroy technique was used in all except ten cases. Sterilisation was performed via laparoscopy in 105 (2.1%) cases. In these cases, the tubes were occluded by the electrocoagulation technique in 86.7 percent, by the tubal ring technique in 12.4 percent and by the modified Pomeroy technique in 1.0 percent cases.

Anaesthesia

The vast majority of the sterilisation procedures were performed using regional anaesthetics (92.4%). Local anaesthestics were used in 6.8 percent cases and in 0.6 percent cases general anaesthetics were employed.

Surgical Time and Hospital Stay

Mean surgial time for performing sterilisation was 16.3 minutes. Most (80.0%) of the procedures were performed within 10 to 19 minutes (Table IV).

The majority (87.5%) of the women were hospitalised for seven or more nights. Mean hospital stay for the series was 8.9 nights (Table V). Mean postoperative hospital stay was 7.3 nights.

TABLE IV

SURGICAL TIME REPORTED FOR 4,948 WOMEN UNDERGOING STERILISATION IN SMALL CAMPS IN BARODA DISTRICT, NOVEMBER 1972 TO AUGUST 1978

Surgical Time (Minutes)	Number	Percent
< 10	40	0.8
10 - 19	3950	80.0
20 - 29	829	16.8
30 - 39	52	1.1
40 +	66	1.3
Mean	16.3	

TABLE V

HOSPITAL STAY FOR 4,948 WOMEN UNDERGOING STERILISATION IN SMALL CAMPS IN BARODA DISTRICT, NOVEMBER 1972 TO AUGUST 1978

Hospital Stay (Nights)	Number	Percent
0 - 1	61	1.2
2 - 4	71	1.4
5 - 6	465	9.4
7 +	4331	87.5
Unknown	20	0.4
Mean	8.9	

Technical Failures

In 8 (0.2%) cases the planned technique could not be successfully performed on one or both sides and alternative techniques were used for occluding the Fallopian tubes. The most common cause of technical failures was the presence of adhesions.

Surgical Difficulties

Surgical difficulties were encountered during 18 (0.4%) procedures. In 11 (0.2%) cases surgical difficulty was due to the presence of adhesions. In 4 (0.1%) cases there was some difficulty in visualizing or exteriorizing the tubes (Table VI).

TABLE VI

SURGICAL DIFFICULTIES REPORTED FOR 4,948 WOMEN UNDERGOING STERILISATION IN SMALL CAMPS IN BARODA DISTRICT, NOVEMBER 1972 TO AUGUST 1978

Surgical Difficulty	Number	Percent
Adhesions	11	0.2
Difficulty in visualizing/exteriorizing the tubes	4	0.1
Difficulty in opening peritoneum	1	0.0
Ovarian cyst	1	0.0
Other	1	0.0
TOTAL	18	0.4

Complications

The operative complications reported for the series were bowel or bladder injury in 6 (0.1%) and spinal shock in 5 (0.1%) cases. Early postoperative complications were reported for 3.4 percent cases. Fever was the most frequently reported complication. Of the 82 (1.6%) cases with fever, 35 (0.7%) required antibiotics. Two patients developed peritonitis (Table VII).

TABLE VII

OPERATIVE AND EARLY POSTOPERATIVE COMPLICATIONS REPORTED FOR 4,948 WOMEN UNDERGOING STERILISATION IN SMALL CAMPS IN BARODA DISTRICT, NOVEMBER 1972 TO AUGUST 1978

Complications	Number	Percent
Operative:		
Bowel/bladder injury	6	0.1
Spinal shock	5	0.1
Total	11	0.2
Early postoperative:		
Fever not requiring antibiotics	47	0.9
Fever requiring antibiotics	35	0.7
Pelvic peritonitis	2	0.0
Incision complications		
Infection	50	1.0
Dehiscence	27	0.5
Haematoma	1	0.0
Other	6	0.1
Total	168	3.4

Complaints

The incidence of early postoperative complaints was 17.0 percent. The most common of these complaints were related to the use of spinal anaesthetics (7.7%). While pelvic pain and backache were reported by 4.3 and 1.6 percent cases respectively, the incidence of incision-related complaints was 1.7 percent (Table VIII).

Mortality

Two deaths occurred in this series. One patient died as a result of spinal shock after she received spinal anaesthesia. The second woman developed tetanus on the eighth day after sterilisation and died on the ninth postoperative day. She had had an incompleted abortion at home 15 days before sterilisation and presumably acquired the tetanus infection at that time; ten women were sterilised on the same day and none developed tetanus. The mortality rate for this series was 0.04 percent.

TABLE VIII

EARLY POSTOPERATIVE COMPLAINTS REPORTED FOR 4,948 WOMEN UNDERGOING STERILISATION IN SMALL CAMPS IN BARODA DISTRICT, NOVEMBER 1972 TO AUGUST 1978

Complaints	Number	Percent
Anaesthesia related		
Headache	325	6.6
Vomiting	52	1.1
Pelvic pain	212	4.3
Backache	79	1.6
General pain	6	0.1
Headache	14	0.3
Incision related		
Spotting/bleeding/serous discharge	42	0.8
Keloid formation/induration	27	0.5
Pain/tenderness/itching	21	0.4
Dizziness	19	0.4
Vomiting/nausea	11	0.2
Vaginal discharge/leucorrhoea	9	0.2
Frequent micturition	2	0.0
Other	22	0.4
TOTAL	841	17.0

Because rural women in this area live in close proximity to their cattle in small huts with walls that are covered with cow dung, tetanus toxoid is now being administered routinely as a preventive health measure prior to camp surgery. In addition, women who have had a home delivery or an abortion in the prior three weeks are no longer accepted for camp sterilisation due to the high likelihood of infection. There has been no mortality since these measures were implemented.

Gynaecological Abnormalities and Complaints

The incidence of gynaecological abnormalities was 2.7 percent at 6 months, 5.4 percent at 12 months, 5.3 percent at 18 months and 2.9 percent at 24 months. The most frequently reported condition was cervical erosion (1.6 percent at 24 months). Other conditions reported were incisional hernia, keloid, cervicitis and vaginitis (Table IX).

The percentage of women reporting complaints at 6, 12, 18 and 24 months was 3.1, 7.9 7.4 and 5.0 reepectively. Pelvic pain was the most frequently reported complaint (1.8 to 6.5%). However, it was mild in most cases. Wound pain was reported by 0.3 to 1.5 percent of the women at long-term follow-up. The other complaints were abdominal pain, weakness and depression (Table IX).

TABLE IX

GYNAECOLOGICAL ABNORMALITIES AND COMPLAINTS REPORTED FOR WOMEN UNDERGOING STERILISATION IN SMALL CAMPS IN BARODA DISTRICT, NOVEMBER 1972 TO AUGUST 1978

Gynaecological Abnormalities/ Complaints	Follow-up Visit (Months) 6 N = 224		12 N = 203		18 N = 243		24 N = 617	
	No.	%	No.	%	No.	%	No.	%
Gynaecological Abnormalities:								
Incisional hernia	2	0.9	1	0.5	0	0.0	2	0.3
Keloid	1	0.4	1	0.5	1	0.4	1	0.2
Acute pelvic infection	0	0.0	0	0.0	1	0.4	0	0.0
Cervicitis	0	0.0	1	0.5	2	0.8	1	0.2
Tender/thickened adenexae	1	0.4	0	0.0	2	0.8	2	0.3
Cervical erosion	2	0.9	7	3.4	4	1.6	10	1.6
Cervical polyp	0	0.0	0	0.0	1	0.4	0	0.0
Vaginitis	0	0.0	0	0.0	2	0.8	2	0.3
Leucorrhoea	0	0.0	1	0.5	0	0.0	0	0.0
Total	6	2.7	11	5.4	13	5.3	18	2.9
Complaints:								
Wound pain								
Mild	1	0.4	3	1.5	1	0.4	2	0.3
Moderate	1	0.4	0	0.0	0	0.0	2	0.3
Pelvic pain								
Mild	4	1.8	9	4.4	12	4.9	16	2.6
Moderate	0	0.0	2	1.0	4	1.6	5	0.8
Others	1	0.4	2	1.0	1	0.4	6	1.0
Total	7	3.1	16	7.9	18	7.4	31	5.0
TOTAL	13	5.8	27	13.3	31	12.8	49	7.9

Gynaecological Surgery

In this series, 21 (3.4%) women underwent gynaecological surgery within two years of of the sterilisation procedure. Dilatation and curettage (D&C) was performed in seven (1.1%) cases. Five women underwent D&C for treatment of menorrhagia and two for dysfunctional uterine bleeding. Hysterectomy was performed in 7 (1.1%) cases, uterine prolapse was the indication for hysterectomy in three and chronic cervicitis in two cases Two women who had sterilisation failure underwent suction evacuation for pregnancy termination. One woman underwent tubal reanastomosis because she lost both her sons. (Table X).

TABLE X

POST-STERILISATION SURGERY REPORTED FOR 617 WOMEN UNDERGOING STERILISATION IN SMALL CAMPS IN BARODA, NOVEMBER 1972 TO AUGUST 1978

Surgery After Sterilisation	Number	Percent
Dilatation and Curettage		
For menorrhagia	5	0.8
For dysfunctional uterine bleeding	2	0.3
Unknown	3	0.5
Total	10	1.6
Hysterectomy		
For uterine prolapse	3	0.5
For chronic cervicitis	2	0.3
For pelvic inflammatory disease	1	0.2
Unknown	1	0.2
Total	7	1.1
Suction evacuation for pregnancy termination	2	0.3
Polypectomy	1	0.2
Tubal reanastamosis	1	0.2
TOTAL	21	3.4

Failure Rates

Three pregnancies were reported in this series. Thus the failure rate was 0.06 percent. In all three cases sterilisation was performed via the abdominal route and the modified Pomeroy technique was used. In one case a 19 weeks pregnancy was found 18 months after sterilisation. The woman decided to continue the pregnancy; the husband agreed to undergo a vasectomy. Another woman who reported a 14 weeks pregnancy 18 months after sterilisation underwent pregnancy termination. In the third case an eight weeks pregnancy was reported two years after sterilisation. This woman also underwent pregnancy termination.

DISCUSSION

In rural India today, the camp approach is being extensively used as a service delivery mechanism because the existing medical infrastructure is inadequate for provinding services to the extensive eligible population. Female sterilisation receives a well deserved emphasis in the national programme since it is not only the most effective method of fertility control for women who have completed their desired family size but also offers significant programmatic advantages over other methods since potential acceptors need to be motivated and medical staff and facilities mobilised on a one-time basis only. To avoid the negative features of the mass camp approach, the present trend is to provide female sterilisation services by organizing periodic, small camps. This study was conducted to document the feasibility, safety, effectiveness and acceptability of this service delivery approach utilizing available facilities and personnel in existing rural health centres.

Sterilisation can have a major impact on fertility. Each voluntary sterilisation operation is estimated to avert 1.5 to 2.5 births--a higher number than with the continued use of any other method of fertility control (1,2). It is estimated that if voluntary sterilisation were fully available in developing countries, it would reduce the fertility of women over 30 years by about 25 percent, to approximately the Japanese and Taiwanese level (3). The demographic impact of sterilisation programmes depends upon the number of acceptors as well as their age and parity. As younger couples with fewer children adopt sterilisation, the number of births averted obviously increases.

Worldwide, the average woman obtaining sterilisation is in her early 30s (4). The average number of living children for women adopting sterilisation varies widely in different countries--from 2.6 in England to 8.7 in the Sudan (5,6). In Asian countries, an average of five living children was reported (5,6,7). The mean age was 29.7 years and the mean number of living children was 4.2 for 7,598 women undergoing sterilisation in seven hospitals and three camp sites in India (10). In the present series, the average woman undergoing sterilisation was younger (28.7 years) and had fewer living children (3,6). Corresponding figures for age and parity were higher in earlier reports from these camps (9,10). These findings indicate that younger women with fewer children are now opting for sterilisation.

In the present series, more than half the women undergoing sterilisation, and more than a fourth of their husbands were illiterate, Similar findings were reported in another camp series in India (8). High illiteracy rates among female sterilisation acceptors ranging from 47 to 86 percent have been reported from other developing countries such as Bangladesh (11), Lebanon (13) and Iran (12). These data examplify that education is not a determining factor for sterilisation acceptance among these populations.

Studies from several developing countries reveal that a surprisingly large number of women accepting sterilisation have never used contaaception before (4). In the present study, also the vast majority of the women had not used any method prior to sterilisation indicating that female sterilisation programmes are reaching population who have no access to family planning services and also that these women are more concerned with limiting their family size than with spacing their births.

Mortality and morbidity rates following sterilisation are, understandably, of considerable concern in rural camp programmes. Complication rates following Pomeroy sterilisations in various Indian reports range between 10.5 and 50.0 per 100 cases (14). The complication rate was significantly lower for the present series and the vast majority of the

complications were not of a serious nature. The morbidity rates in this study were lower than rates reported in other camps in India (15,16). Complication rates at these camps have declined in recent years as evidenced by the comparatively higher figures reported earlier (9,10). Since the last report (10) no further deaths have occurred at these camps. This lowering of morbidity and mortality is attributed to the experience of the doctors with camp surgery and to the successful implementation of prophylactic measures for combatting possible infection at camp settings. It is interesting to note that lower morbidity rates were reported for women sterilised in camps than for those sterilised at the Medical College Hospital in Baroda in this (17) and pervious reports (9,10). This is probably due to the better preselection of cases and, possibly a better response to prophylactic antibiotics at the camps as hospitals generally harbour resistant strains of bacteria.

The reported failure rate among 23,603 sterilisation cases in ten countries was 0.1 percent (18). Failure rates ranged between 0.1 to 0.4 percent for Indian studies where the Pomeroy technique was used for tubal ligation (19,20,21). The failure rate for the present series was lower. Although the follow-up rate in this study is low, it is expected that if a woman suspects pregnancy following the sterilisation operation she will report to the health centre. Intensive follow-up efforts are presently underway as the authors propose to report the longterm sequelae, menstrual pattern changes and failure rates for women sterilised at these camps.

Duration of hospital stay greatly contributes to the overall cost of services. Hospital stay for the present series was considerable. To minimize this problem, outpatient laparoscopic procedures have been initiated at these camp sites. Laparoscopic camp programmes are gaining rapid momentum in the state of Gujarat. As many as one hundred laparoscopic sterilisations have been performed by the author (RB) in a single day. Experience shows that patient acceptance is higher and morbidity significantly lower when sterilisation is performed via laparoscopy than when it is performed via minilaparotomy (22). For implementing large-scale programmes, the logistics of providing laparoscopic equipment and training to local doctors in rural areas require careful consideration.

The results of this study indicate that the small, periodic camp approach has been effective in providing female sterilisation services in rural areas. Experience shows that rural women accept these services readily. The visiting team is able to provide training to the local doctors-- several have been trained and are now able to provide sterilisation services at their health centres. Since the number of women sterilised at a single camp is limited, the usual activities of the health centre are not disrupted and postoperative care can be effectively provided by the local staff. It is expected that with continued efforts, a permanent infrastructure will gradually be developed for the delivery of sterilisation services in rural areas.

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QUINACRINE FOR FEMALE STERILISATION

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ABSTRACT

This is a report of a ten case study conducted to evaluate the safety and efficacy of quinacrine hydrochloride solution for female sterilisation. The side effects of the method are reported. Laparoscopy performed in five cases following sterilisation showed successful tubal occlusion. The advantages and disadvantages of this method of chemical sterilisation are discussed. The need to perfect this method for delivering the chemical at the uterotubal junction is stressed and present methods of chemical sterilisation are discussed.

INTRODUCTION

Although a wide range of new surgical methods for female sterilisation has been developed in recent years, most available methods require a good operating theatre and well trained medical personnel. Efforts are, therefore, being made to search for a method which could be a quick, outdoor procedure requiring minimal equipment and training of personnel. Chemical sterilisation has the potential for fulfilling these criteria. As this method is not reversible, it is more suitable for women who have three or more living children. It could, therefore, be a valuable addition to the presently available methods in India where there are large numbers of such women. This paper reports the results of a study conducted to evaluate the safety and efficacy of the intrauterine instillation of quinacrine hydrochloride solution for female sterilisation

MATERIALS AND METHODS

Ten women who were 25 to 40 years of age and had three or more healthy, living children were included in this study which was conducted at the KEM Hospital in Bombay. The procedure was performed in the early part of the proliferative phase of the menstrual cycle by the intrauterine instillation of 1.5 gms of quinacrine hydrochloride suspended in 7 ml of distilled water. The chemical was instilled through a Foley's catheter which prevented the reflux of the chemical. The study protocol required that the procedure be repeated for three successive cycles. However, in this series three women returned for the second instillation and only two returned for the third instillation. To prevent conception between instillations, 50 mgm of Depoprovera was administered intramuscularly once in three months for a period of six months.

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RESULTS

Side Effects

In this series, mild abdominal discomfort, nausea, vomiting, giddiness and bleeding were reported in 4 (40.0%) cases after the first instillation of quinacrine hydrochloride. One woman collapsed after the first instillation but recovered following immediate resuscitation and was in good condition when she was discharged after three days of hospitalisation. Another woman developed an allergic rash all over the body three days after the second instillation.

Laparoscopic Findings

Laparoscopy was performed in five cases following chemical sterilisation. Three of these women had undergone three instillations and two had undergone only two instillations of quinacrine hydrochloride. In all five cases the uterus was found to be normal. The tubes were blocked and appeared somewhat thinner and whitish in colour along their entire length. No intraperitoneal or peritubal adhesions were seen

DISCUSSION

Various chemical agents have been tried for occluding the Fallopian tubes. Gelatin-resorcinol formaldehyde (GRF) tried by Falb et al is an adhesive which is instilled by a balloon-tipped cannula (1). As this chemical provokes tissue growth, it is essential to deliver it at the cornual ends of the tubes. GRF has a two-part formulation; the gelatin resorcinol is not mixed with formaldehyde until immediately before administration because the material undergoes rapid solidification. The procedure requires an inbuilt mixing apparatus to ensure that the chemical is delivered at the uterotubal junction and is, therefore, a complicated one.

Methyl cyano-acrylate (MCA), another agent used for tubal occlusion polymerizes on contact with moist biologic tissues. Although it flows easily into the Fallopian tube it does not spill into the peritoneal cavity as polymerization stops its flow. Stevenson reported tubal occlusion in 70.0 percent cases after a single instillation of MCA through a balloon catheter and no recanalisations were reported during three years follow-up (2). In using MCA it is necessary to prevent its contact with any tissue in the genital tract except the Fallopian tubes. As proliferating endometrium acts as a valve and closes the tubal ostia against the rise in intrauterine pressure, the instillation of MCA is confined to the time when the endometrium is thin as after menstruation or prolonged oral contraceptive therapy.

Caustic solutions such as zinc chloride, phenol and sodium morrhuate can also produce occlusion of the tubes but they are not used in practice as peritoneal spillage of these agents causes chemical peritonitis.

Quinacrine hydrochloride was first tried by Zipper who used quinacrine suspension with xylocaine. The chemical was instilled through a Kahn's cannula and an occlusion rate of 80.0 percent was reported after three instillations (3). Davidson reported a success rate of 60.0 percent three to four months after a single instillation through a plastic cannula. He felt the prevention of cervical reflux during the procedure allowed the chemical to enter both the uterotubal junctions and better results were achieved (4).

While a hysteroscope is required for the delivery of both GRF and MCA at the cornual ends of the tubes, quinacrine has an advantage in that it can be instilled into the uterus through a catheter. However, it also has certain drawbacks. As more than one instillation is required to produce tubal occlusion, the failure rate is high because women may not return for the second and third instillations. In such cases, partial occlusion of the tubes is an additional sequel. Failure to use contraceptives between instillations can result in intrauterine or ectopic pregnancy. Intravasation, postinstillation shock and excitation of the central nervous system are other undesirable side effects.

To minimize these problems, sterilisation by quinacrine pellets is being tried--pellets enable a slow release of the chemical and thereby bring it into prolonged contact with the tubal area. Zipper showed encouraging results after six months follow-up of his series of 139 cases (3).

Another method of delivering quinacrine at the tubal ostea is by inserting a Copper T IUD with quinacrine applied at the two tips of its transverse limb. A pilot study of the quinacrine IUD is presently underway at our institution. The Copper T IUD acts as a carrier for the chemical and also as a contraceptive. Histopathological examinations will be conducted to evaluate tubal occlusion following hysterectomy.

Chemical sterilisation with quinacrine hydrochloride has considerable scope for developing countries. However, a practical method needs to be developed for the effective delivery of this chemical at the uterotubal junction to enable widespread use of this technique. Research is presently underway to perfect this technique.

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FACTORS INFLUENCING A WOMAN'S DECISION TO UNDERGO STERILISATION - A CAMP STUDY

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ABSTRACT

This paper analyses the sociodemographic characteristics, fertility patterns, previous contraceptive experience and reasons for adopting sterilisation as a method of fertility control by 4,948 women who underwent sterilisation at camps in Baroda District. In this series, the average woman seeking sterilisation was 28.7 years of age,had 2.5 years of formal education and had not used contraception prior to undergoing sterilisation. Most (64.2%) of the women had 3 to 4 living children; 22.0 percent had 5 or more living children. There was a marked preference for male offsprings. The child loss rate was 83.6 per 1000 live births. In a fourth of the cases the husband was the main person who influenced the woman to undergo sterilisation and was also the referral source. Unreliability (45.0%), side-effects (36.1%) and inconvenience (18.9%) of other methods were reasons given for preferring sterilisation to other methods of fertility control.

INTRODUCTION

In India, sterilisation camps in rural areas have gained considerable momentum during the past few years. These camps are sporadic and offer limited follow-up care. Despite this, female sterilisation is highly acceptable to rural women mainly because of non-availability of other effective fertility control methods. Voluntary sterilisation offers considerable programmatic advantages as it is a cost-effective, one-time method which does not require continued supervision. It does, however, necessitate contacting the potential acceptor when her motivation is at its maximal threshold. To accomplish this effectively, it is important to understand the factors which effect the woman's decision to adopt sterilisation. This paper analyses the sociodemographic and fertility characteristics and previous contraceptive experience of women undergoing sterilisation in camps and evaluates reasons for adopting sterilisation as a method of fertility control.

MATERIALS AND METHODS

Data on 4,948 women undergoing sterilisation from November 1972 to August 1978 at bi-weekly, small camps in the Baroda District of Gujarat are reported. These camps were organized by visiting teams from the Department of Obstetrics and Gynaecology of the Baroda Medical College Hospital.

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Definitions and Criteria

Data were recorded on standard forms of the India Fertility Research Programme using standard definitions and criteria. Only women undergoing sterilisation for family size limitation were included in the study. Prior abortion, stillbirth and live birth rates are expressed per 1000 pregnancies. Rates for living children and child loss are expressed per 1000 live births. Child loss includes neonatal, infant and child mortality. Child loss-parity ratio is calculated per 1000 live births and sex ratio is the number of males per 100 females.

RESULTS

Age and Parity

In this series, women seeking sterilisation were in their late 20s; their mean age was 28.7 years. The majority of the women (76.2%) were between 25 to 34 years of age. Mean parity (live births) was 4.0. While 58.6 percent of the women had 3 to 4 live births, 14.3 percent had more than 5 live births (Table I). Figure 1 shows an increase in parity from 2.0 at $\leq$ 19 years of age to 6.0 at 45+ years of age.

Employment and Education

The vast majority (98.4%) of the women in this study were not gainfully employed (Table I). More than half of the sterilisation adopters (56.6%) had no formal education. While 12.4 percent had attended school for 7-9 years, only 56 percent had completed school or had been to college. Their husbands had attained higher educational status. While 25.7 percent of the husbands had completed 4 to 6 years of school education; 19.8 percent had completed high school or had attended college. Only 26.8 percent of the husbands were illiterate (Table I).

Marital Status, Religion and Residence

Only eight (0.2%) women in this series were not currently married. The majority (89.8%) were Hindu, 9.7 percent were Muslim and 0.4 percent were Christian. Most (66.6%) of the women were from rural areas (Table I).

Previous Pregnancy Outcome

The women in this series experienced a total of 18,878 pregnancies prior to sterilisation. The live birth rate for the series was 967.8 per 1000 pregnancies. The spontaneous and induced abortion rates per 1000 pregnancies were 25.4 and 1.4 respectively. The stillbirth rate was 5.4 per 1000 pregnancies (Table II). The percentage of women reporting one or more spontaneous and induced abortion was 7.7 and 8.6 respectively.

TABLE I

SOCIODEMOGRAPHIC CHARACTERISTICS OF 4,948 WOMEN UNDERGOING CAMP STERILISATION IN BARODA DISTRICT, BARODA, NOVEMBER 1972 TO AUGUST 1978

Sociodemographic Characteristics	Number	Percent
Age(Years)		
≤ 24	591	12.0
25 - 29	2108	42.6
30 - 34	1664	33.6
35 - 39	495	10.0
40 +	90	1.8
Mean	28.7	
Live births		
≤2	560	11.3
3	1509	30.5
4	1391	28.1
5	771	15.6
6	415	8.4
7+	294	5.9
Unknown	8	0.2
Mean	4.0	
Patient's Education (School years)		
0	2802	56.6
1 - 3	413	8.3
4 - 6	839	17.0
7 - 9	615	12.4
10 - 12	263	5.3
13 +	16	0.3
Mean	2.5	
Husband's Education* (School years)		
0	1323	26.8
1 - 3	499	10.1
4 - 6	1269	25.7
7 - 9	870	17.6
10 - 12	844	17.1
13 +	135	2.7
Mean	5.0	
Gainfully Employed		
No	4871	98.4
Yes	76	1.5
Unknown	1	0.0
Religion		
Hindu	4445	89.8
Muslim	481	9.7
Christian	21	0.4
Other	1	0.0
Residence		
Rural	3294	66.6
Urban	1652	33.4
Unknown	2	0.0

*For currently married women only.

The induced abortion rates were 25.4 per 1000 pregnancies at < 25 years, 18.3 at 25-34 years and 31.6 at 34+ years of age. The spontaneous abortion rate increased with increasing age from 20.0 per 1000 pregnancies at < 25 years to 29.5 per 1000 pregnancies at 34+ years of age. There was an increase in the stillbirth rate from 4.3 at < 25 years to 5.6 at 25 - 34 years, and a slight decrease to 5.5 in older women per 1000 pregnancies (Fig 2).

Living Children and Child Loss

Most (64.2%) of the women had 3 to 4 living children; 22.0 percent had 5 or more living children. The age of the youngest child was between 1 and 2 years for 77.4 percent of the women. Only one woman had a child who was less than one year of age (Table III).

TABLE III

NUMBER OF LIVING CHILDREN AND AGE OF THE YOUNGEST CHILD REPORTED BY 4,948 WOMEN UNDERGOING CAMP STERILISATION IN BARODA DISTRICT, BARODA, NOVEMBER 1972 TO AUGUST 1978

Living Children and Age of the Youngest Child	Number	Percent
Living Children		
0	1	0.0
1 - 2	678	13.7
3 - 4	3177	64.2
5 - 6	956	19.3
7 +	136	2.7
Unknown	7	0.1
Mean	3.7	
Age of Youngest Child		
< 1	1	0.0
1 - 2	3829	77.4
2 - 3	382	7.7
3 - 4	363	7.3
4 - 7	275	5.6
7 +	91	1.8
Unknown	7	0.1
Mean	2.0	

The sex ratio for live births was 142.0 (Table IV). Women with 2 to 4 living children had more males than females. However, women with one living child had more females than males (Fig 3).

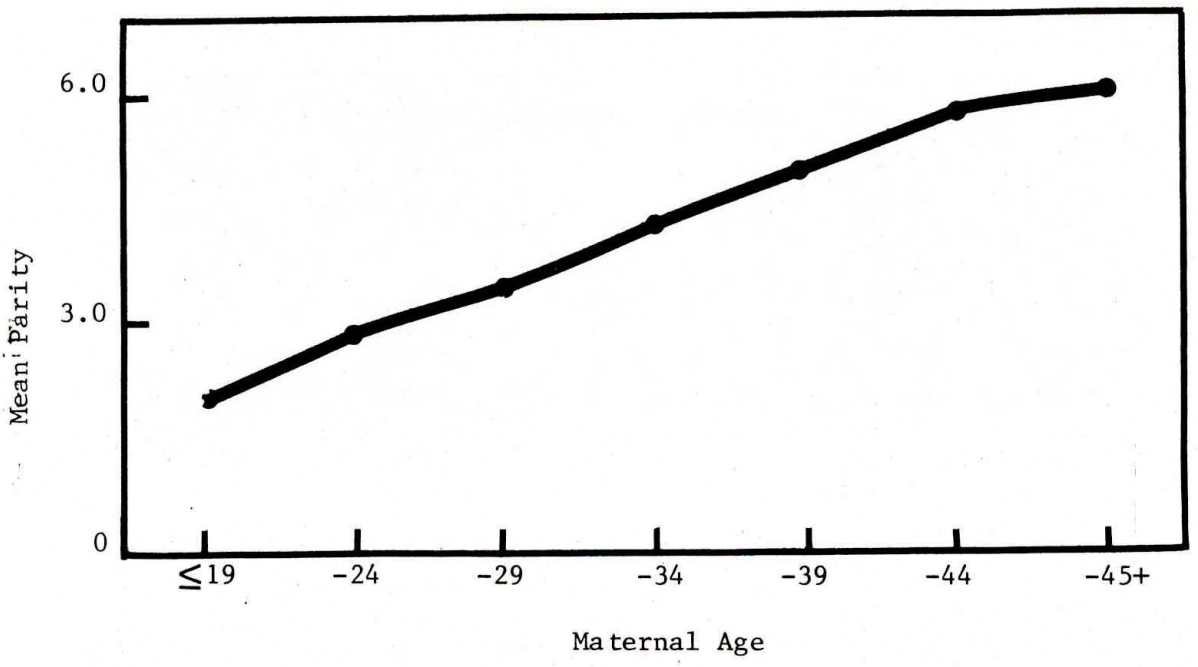

Fig 1

MATERNAL AGE BY PARITY FOR 4,948 WOMEN UNDERGOING CAMP STERILISATION IN BARODA DISTRICT, BARODA, NOVEMBER 1972 TO AUGUST 1978

TABLE II

PREVIOUS PREGNANCY OUTCOME FOR 4,948 WOMEN UNDERGOING CAMP STERILISATION IN BARODA DISTRICT, BARODA, NOVEMBER 1972 TO AUGUST 1978

Pregnancy Outcome	Number	Rate/1000
Live birth	18271	967.8
Spontaneous abortion	479	25.4
Induced abortion	26	1.4
Stillbirth	102	5.4
Total	18878	3815.3*

Note: The live birth, abortion and stillbirth rates are based on the number of pregnancies.

* This rate is based on the number of women.

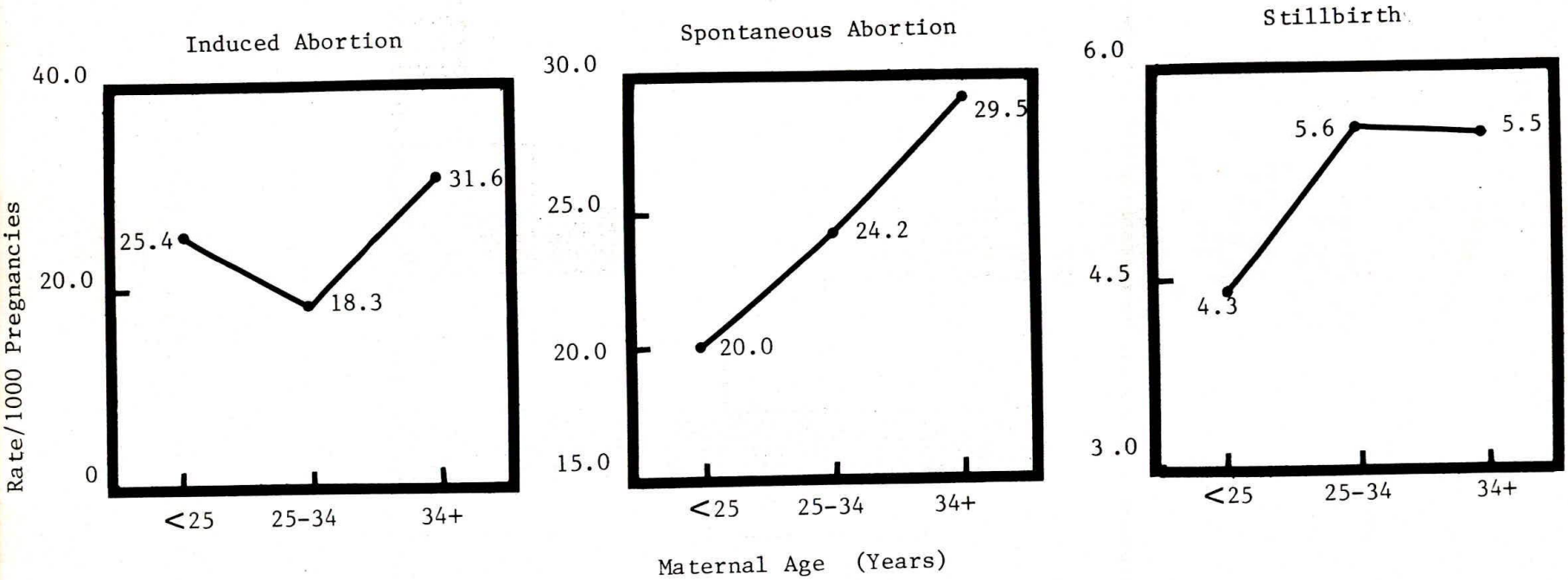

Fig 2

PREGNANCY WASTAGE BY MATERNAL AGE FOR 4,948 WOMEN UNDERGOING CAMP STERILISATION IN BARODA DISTRICT, BARODA, NOVEMBER 1972 TO AUGUST 1978

The child loss rate for the series was 83.6 per 1000 live births (Table IV) Child loss rates increased sharply with increasing maternal age (Fig 4). The child loss-parity ratio increased with increasing parity. The increase was very marked after parity 4--from 35.9 for parity 3 - 4 to 106.7 for parity 5 - 6 and 211.8 for parity 7+ (Fig 5).

Previous Contraceptive Practice

Prior to sterilisation, the majority (98.6%) of the women did not use any contraceptive method. The condom and IUD were each used by 0.5 percent of the women. Five women (0.1%) and four (0.1%) men had undergone sterilisation previously (Table V).

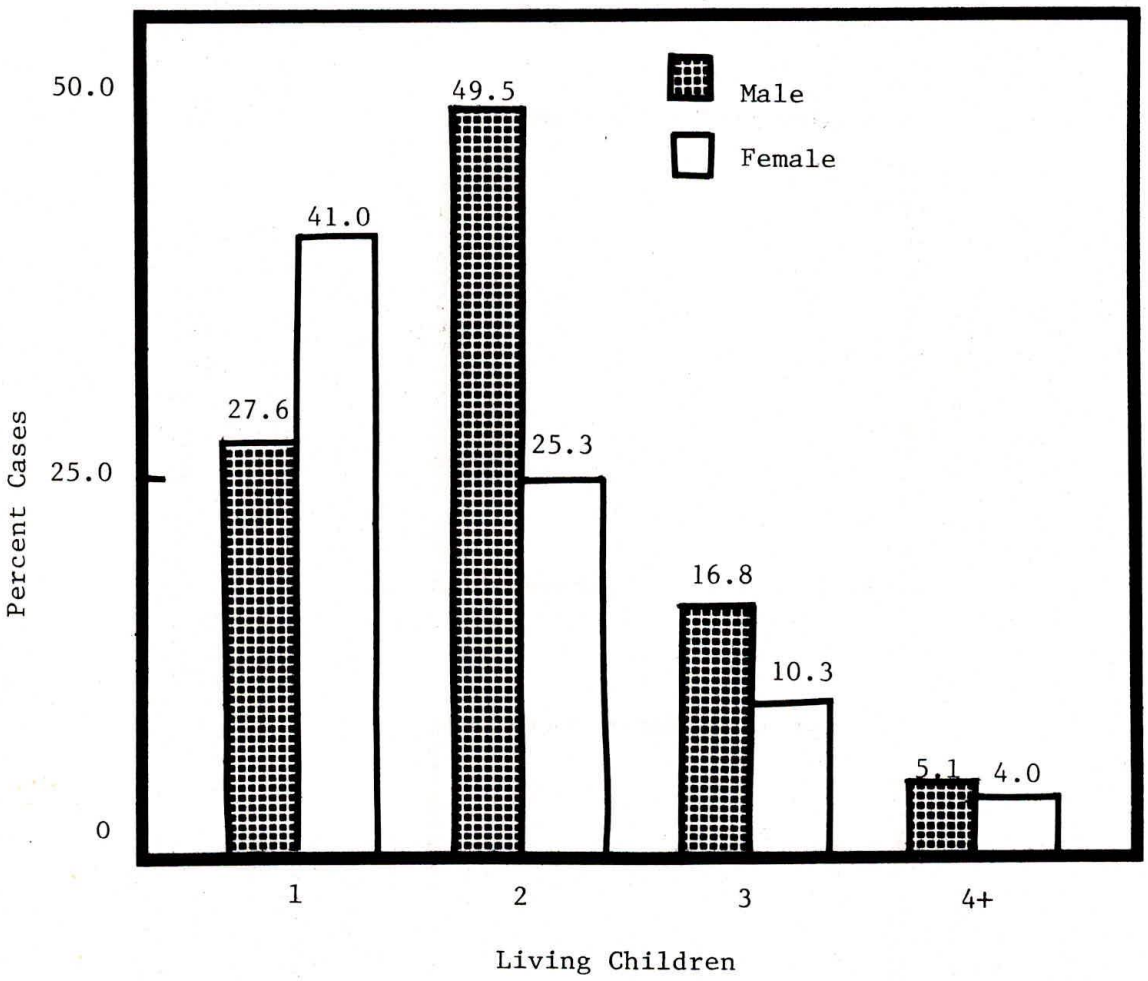

Fig 3

NUMBER OF LIVING CHILDREN BY SEX FOR 4,948 WOMEN UNDERGOING CAMP STERILISATION IN BARODA DISTRICT, BARODA, NOVEMBER 1972 TO AUGUST 1978

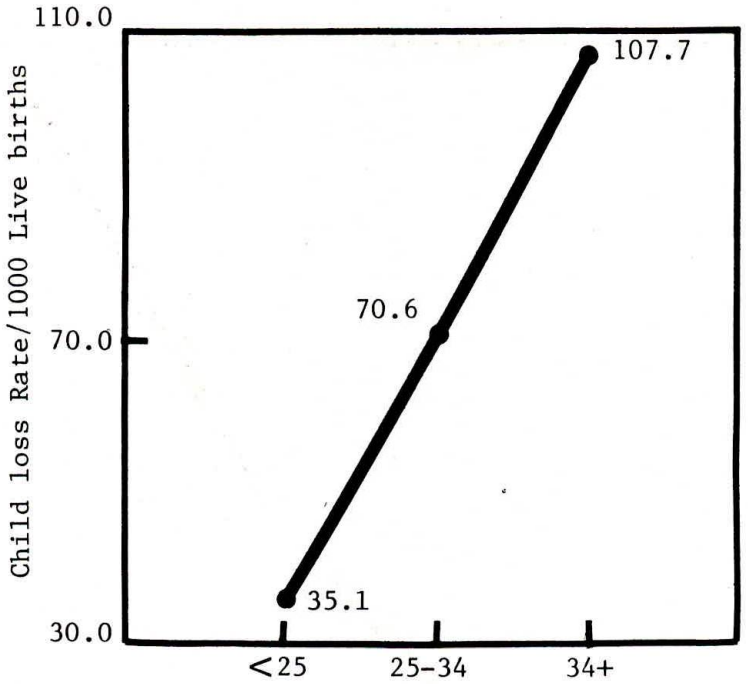

Fig 4
MATERNAL AGE BY CHILD LOSS REPORTED FOR 4,948 WOMEN UNDERGOING CAMP STERILISATION IN BARODA DISTRICT, BARODA, NOVEMBER 1972 TO AUGUST 1978

TABLE IV

OUTCOME OF LIVE BIRTHS REPORTED FOR 4,948 WOMEN UNDERGOING CAMP STERILISATION IN BARODA DISTRICT, BARODA, NOVEMBER 1972 TO AUGUST 1978

Outcome	Number	Rate/1000
Living children	16744	916.4
Male	9832	538.1
Female	6912	378.3
Sex ratio	142.0	
Child loss	1527	83.6
Total	18271	967.8*

Note: The rates for living children and child loss are based on the number of live births.
Sex ratio is the number of males per 100 females.

* This rate is based on the number of pregnancies.

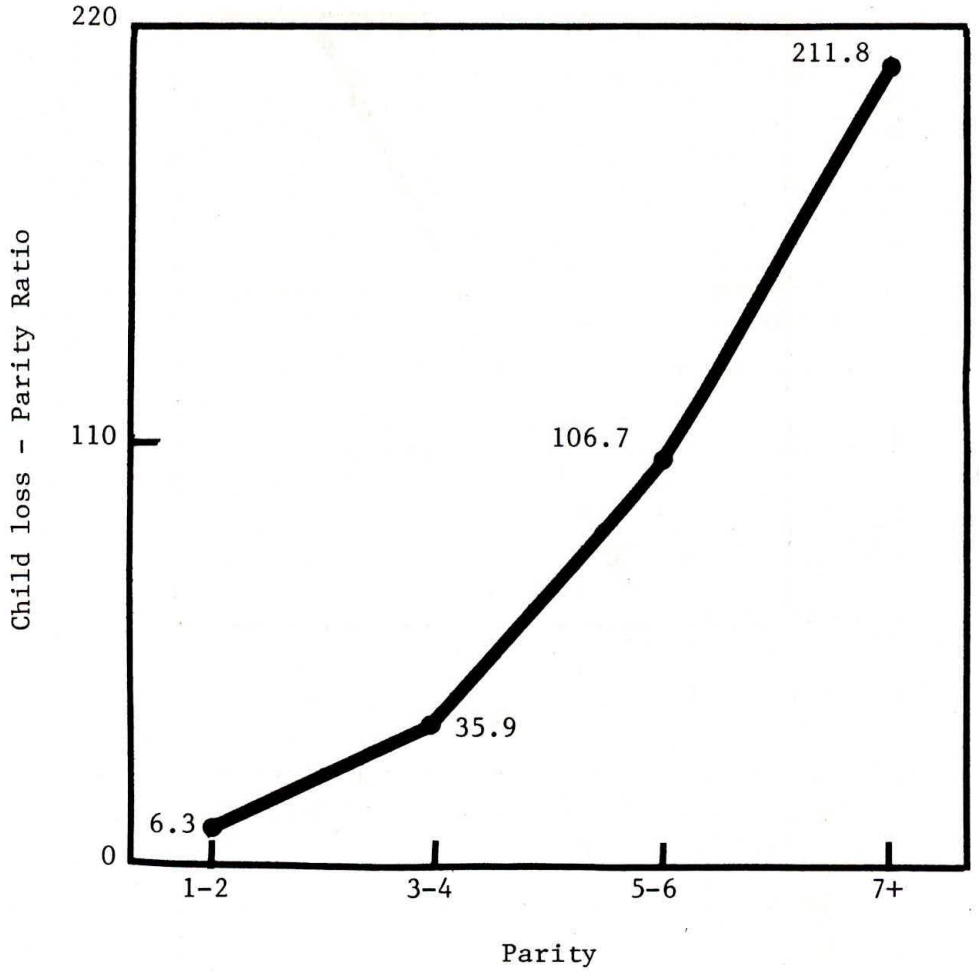

Fig 5

CHILD LOSS-PARITY RATIO BY PARITY FOR 4,948 WOMEN UNDERGOING CAMP STERILISATION IN BARODA DISTRICT, BARODA, NOVEMBER 1972 TO AUGUST 1978

TABLE V

PREVIOUS CONTRACEPTIVE METHOD USED BY 4,948 WOMEN UNDERGOING CAMP STERILISATION IN BARODA DISTRICT, BARODA, NOVEMBER 1972 TO AUGUST 1978

Contraceptive Method	Number	Percent
None	4877	98.6
IUD	27	0.5
Condom	26	0.5
Orals	6	0.1
Tubectomy	5	0.1
Vasectomy	4	0.1
Rhythm/withdrawl	3	0.1

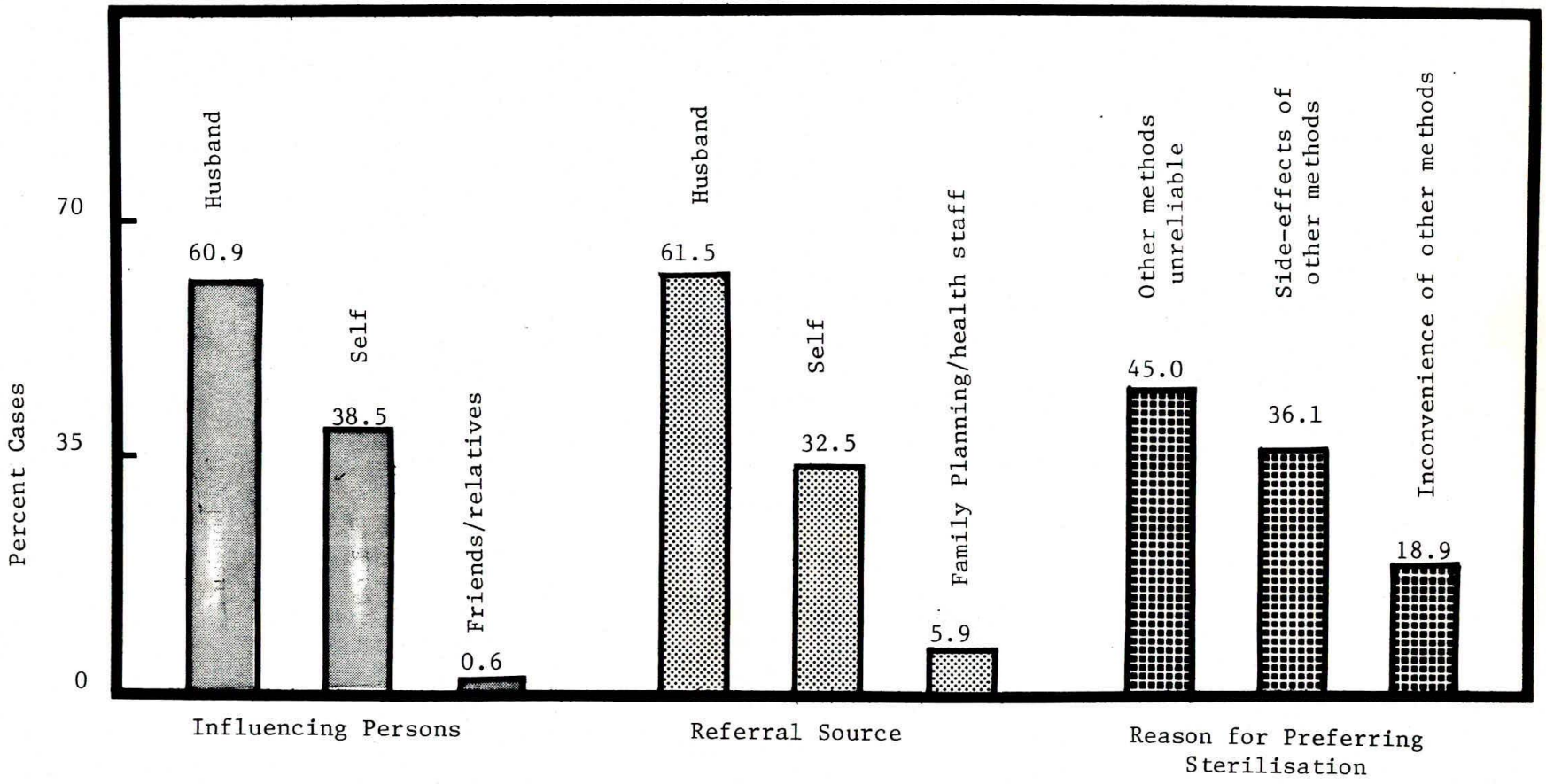

Fig 6

FACTORS INFLUENCING STERILISATION DECISION FOR 4,948 WOMEN UNDERGOING CAMP STERILISATION IN BARODA DISTRICT, BARODA, NOVEMBER 1972 TO AUGUST 1978

The Sterilisation Decision

In 60.9 percent of the cases, the husband was the main person who influenced the woman in her decision to undergo sterilisation; 38.5 percent of the women were themselves responsible for this decision. In 61.5 percent cases, the husband was the referral source. A third of the women went on their own for sterilisation. Only 5.9 percent were referred by family planning or health staff. Forty five percent of the women found other fertility control methods unreliable and so preferred to undergo sterilisation. Side-effects (36.1%) and inconvenience (18.9%) of other methods were other reasons given for preferring sterilisation (Fig 6).

DISCUSSION

Sterilisation in rural camps is becoming increasing popular in India. During 1977-78, when there was a general slump in sterilisation programmes, 52.4 percent of the sterilisations were performed in rural areas (1). By 1978 a total of 28.1 million sterilisations were performed, in India, of which about 30 percent were female sterilisations(1). However, for the sterilisation programme to have a demographic impact--to bring down the crude birth rate to 30 by 1983--an annual average of 3.5 to 4 million sterilisation procedures must be performed and another 4 million couples must be protected by other contraceptive methods (2).

Age, parity and sex of living children are some of the important variables that determine sterilisation acceptance. The older the woman and the more the number of children she has, the higher is the likelihood of her accepting sterilisation. In this analysis, 54.6 percent of the women were below 30 years of age. World-wide, the average woman seeking sterilisation is in her early 30s (3). In India, 43.4 percent of tubectomy acceptors in 1976-77 were below this age (1). This indicates that the Indian woman achieves her desired family size earlier than her counterpart in many other countries. Among female sterilisation acceptors in different countries, a wide range in the average number of living children is documented (4-9). In a pooled analysis of 2,802 female sterilisations in India, the average number of living children was 3.7 (10). In the present analysis also the mean number of living children was 3.7. The age of the youngest child was a crucial factor for female sterilisation adopters in El Salvador, England and the Philippines (11). The mean age of the youngest child ranged from 2.8 in the Philippines to 4.9 in England (11). In the present series, it was lower (2.0). Findings related to the number of living children and the age of the youngest child suggest that most of the women in this series were eager to limit their family size. These women had, in all probability, been potential acceptors for some time. Preferrence for male offsprings is most commonly the cause for an increase in family size. Several researchers have noted that most sterilisation adopters have at least one male child (12-15). This analysis also shows a marked preferrence for sons. This and other studies (9-12, 16,17) show that education is not a determining factor for sterilisation acceptance. In this study, religion also did not appear to be an important determinent.

The decision to undergo sterilisation is a very complex one. The interaction of several variables motivate the individual to decide to undergo sterilisation. This study indicates that about 61 percent of the women were influenced by their husbands. This finding is not surprising as a typical Indian woman plays a secondary role in the household. Ferguson and McCann (11) reported that more highly educated women consider themselves more responsible for undertaking the sterilisation decision. In this series, the majority of the women were uneducated and were, therefore, more likely to be influenced by their husbands. The results of this study focus on the need to concentrate efforts on motivating the husband whose attitude is critical in the decision- making processes. However, to achieve long-term gains, health education of the woman is of considerable importance. In Bangladesh, Chile, Mexico and the Philippines, seventy percent or more of the sterilisation adopters were referred by family planning or health staff (4, 12, 18, 19). In this series, most of the women were referred for sterilisation by their husbands. Efforts to promote sterilisation through family planning and health staff should be intensified.

In this series, unreliability and side effects of other contraceptive methods were reasons given by most of the women for preferring sterilisation. In the Philippines, El Salvador and England also there was an over-riding concern with side effects associated with other contraceptive methods; unreliability of other methods was another reason for preferring sterilisation (11). In a study of 2,802 cases in India, inconvenience of other methods was the primary reason given by more than half of the study group (10). A vast majority of the women in the present series had not used contraception before. This finding is common to several studies from developing countries (12,18,20). Female sterilisation appears to be a preferred method for limitation of family size in rural areas in India.

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LAPAROSCOPIC STERILISATION WITH ELECTROCOAGULATION PRIOR TO PREGNANCY TERMINATION

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ABSTRACT

This study was conducted to evaluate the safety and technical ease of performance of sterilisation by laparoscopic electrocoagulation when performed immediately prior to first trimester pregnancy termination. Three hundred procedures performed at the Kasturba Medical College Hospital, Manipal are reported. The results of this study showed that preabortion sterilisation by laparoscopic electrocoagulation did not increase the incidence of postoperative complications. However, this procedure was not technically easier than postabortion sterilisation as was originally hypothesized. For making scientific comparisons between preabortion and postabortion sterilisation procedures, controlled, random, comparative studies are needed.

INTRODUCTION

The high acceptance of fertility control methods after termination of pregnancy has been extensively documented (1-5). A woman who has completed her desired family size is readily motivated to undergo sterilisation when she requests termination of an unwanted pregnancy. Studies show that postabortion sterilisation is a safe and effective procedure (6-9). Sterilisation in the immediate postabortion period has, therefore, been performed extensively both in developed and developing countries. There are, however, numerous reported instances of women who agree to undergo sterilisation but change their mind after pregnancy is terminated. These women could be saved from the risk of yet another unwanted pregnancy if the sterilisation procedure is performed prior to the pregnany termination procedure. Such reversal may also make the sterilisation procedure technically easier since the Fallopian tubes are more readily identified when the uterus is enlarged. This study was undertaken to evaluate the safety and technical ease of performance of sterilisation by laparoscopic electrocoagulation when performed immediately prior to first trimester pregnancy termination.

MATIERIALS AND METHODS

From August 1975 to April 1979, 300 women underwent laparoscopic sterilisation by the electrocoagulation technique immediately prior to first trimester pregnancy termination at the Kasturba Medical College Hospital in Manipal.

Data Collection

Data on sociodemographic and reproductive characteristics of the study subjects and clinical aspects of the procedure were recorded on standard forms of the India Fertility Research Programme. All 300 study subjects returned for history and physical examination at the follow-up visits which was scheduled 7 to 21 days after surgery.

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Definitions and Criteria

Only women requesting sterilisation for family size limitation and concurrent termination of pregnancy of six to twelve weeks' gestation were included in the study. Surgical time was defined as the time from the initial incision to final closure. A technical failure was defined as a case in which the designated procedure could not be completed. Technical difficulty was defined as any difficulty associated with the equipment. Surgical difficulty was any difficulty encountered during the procedure which was not due to equipment-related problems.

Complications and complaints due to the sterilisation procedure was categorized as operative, immediate and early postoperative. Operative and immediate postoperative complications and complaints were those occurring during surgery and prior to discharge from the hospital. Early postoperative complications and complaints were those reported at the follow-up visit.

Surgical Procedure

An hour and a half before surgery, the patient received one 50 mg largactil tablet and one 25 mg phenergan tablet along with an intramuscular injection of 100 mgm of pethidine. Local anaesthesia was provided by infiltrating 15 to 20 ml of one percent xylocaine. The sterilisation procedure was performed using the standard laparoscopic electrocoagulation technique. Pregnancy termination by vacuum aspiration was performed while the patient was still under the effect of premedication. Prophylactic antibiotics were not administered routinely. However, analgesics were given for three days and ferrous sulphate and vitamin C were prescribed for one month.

RESULTS

Sociodemographic Characteristics

The mean age of the women in this study group was 32.4 years; 30.7 percent of the women were below 30 years of age. Their mean parity was 4.6; 11.7 percent had one to two live births and 16.6 percent had seven or more live births. The mean number of living children was 4.5; 73.3 percent of the women had three to six living children. The majority of the women were from rural areas (71.4%) and were not gainfully employed (82.3%). The mean level of education of these women was 4.8 and that of their husbands was 6.8 school years (Table I).

In this series, 21.0 percent of the women gave a history of one or more spontaneous abortions and 5.6 percent reported having had one or two induced abortions (Table I). While the majority (84.3%) of the couples in the study group had not used any method of contraception during the three months prior to the present conception, 6.0 percent had used IUDs, 5.7 percent were on oral contraceptives and 3.3 percent had used the condom (Table I).

Period of Gestation

About a third of the pregnancies were terminated at six to seven weeks' gestation, 62.3 percent were terminated at eight to ten weeks' gestation and only 5.7 percent were terminated at eleven to twelve weeks' gestation.

TABLE I

SELECTED SOCIODEMOGRAPHIC CHARACTERISTICS OF 300 WOMEN UNDERGOING LAPAROSCOPIC STERILISATION PRIOR TO PREGNANCY TERMINATION AT THE KASTURBA MEDICAL COLLEGE HOSPITAL, MANIPAL, AUGUST 1975 TO APRIL 1979

Sociodemographic Characteristics	Number	Percent
Age (Years)		
20 - 24	14	4.7
25 - 29	78	26.0
30 - 34	102	34.0
35 - 39	71	23.7
40 +	35	11.6
Mean	32.4	
Parity		
1 - 2	35	11.7
3 - 4	135	45.0
5 - 6	80	26.7
7 - 8	34	11.3
9 - 10	15	5.0
11 +	1	0.3
Mean	4.6	
Living Children		
1 - 2	35	11.7
3 - 4	140	46.7
5 - 6	80	26.6
7 - 8	31	10.3
9 - 10	14	4.7
Mean	4.5	
Residence		
Urban	86	28.6
Rural	214	71.4
Employed		
No	53	17.7
Yes	247	82.3
Patient's Education (School years)		
0	91	30.3
1 - 3	29	9.7
4 - 6	81	27.0
7 - 9	47	15.7
10 - 12	46	15.3
13+	6	2.0
Mean	4.8	

TABLE I (CONTD)

Sociodemographic Characteristics	Number	Percent
Husband's Education (School Years)		
0	60	20.0
1 - 3	16	5.3
4 - 6	63	21.0
7 - 9	58	19.3
10 - 12	76	25.3
13 +	27	9.0
Mean	6.8	
Spontaneous Abortion		
0	237	79.0
1	51	17.0
2	10	3.4
3+	2	0.6
Induced Abortion		
0	283	94.4
1	15	5.0
2	2	0.6
Previous Contraceptive Practice		
None	253	84.3
IUD	18	6.0
Orals	17	5.7
Condom	10	3.3
Rhythm/withdrawl	2	0.6

Technical Failures

Technical failure was reported for three cases. In one case, laparotomy was performed because the left tube was not connected to the uterus and was found to be lying in the left iliac fossa along with the ovary. In the second case, abdominal surgery was performed because pneumoperitoneum could not be achieved and in the third case laparoscopy was postponed as the patient developed hypotension after the laparoscope was introduced. The technical failure rate was 1.0 percent.

Surgical Time

The majority (93.0%) of the sterilisation procedures were performed within five to twelve minutes (Table II and Fig 1). Mean surgical time was 8.8 minutes (Table II).

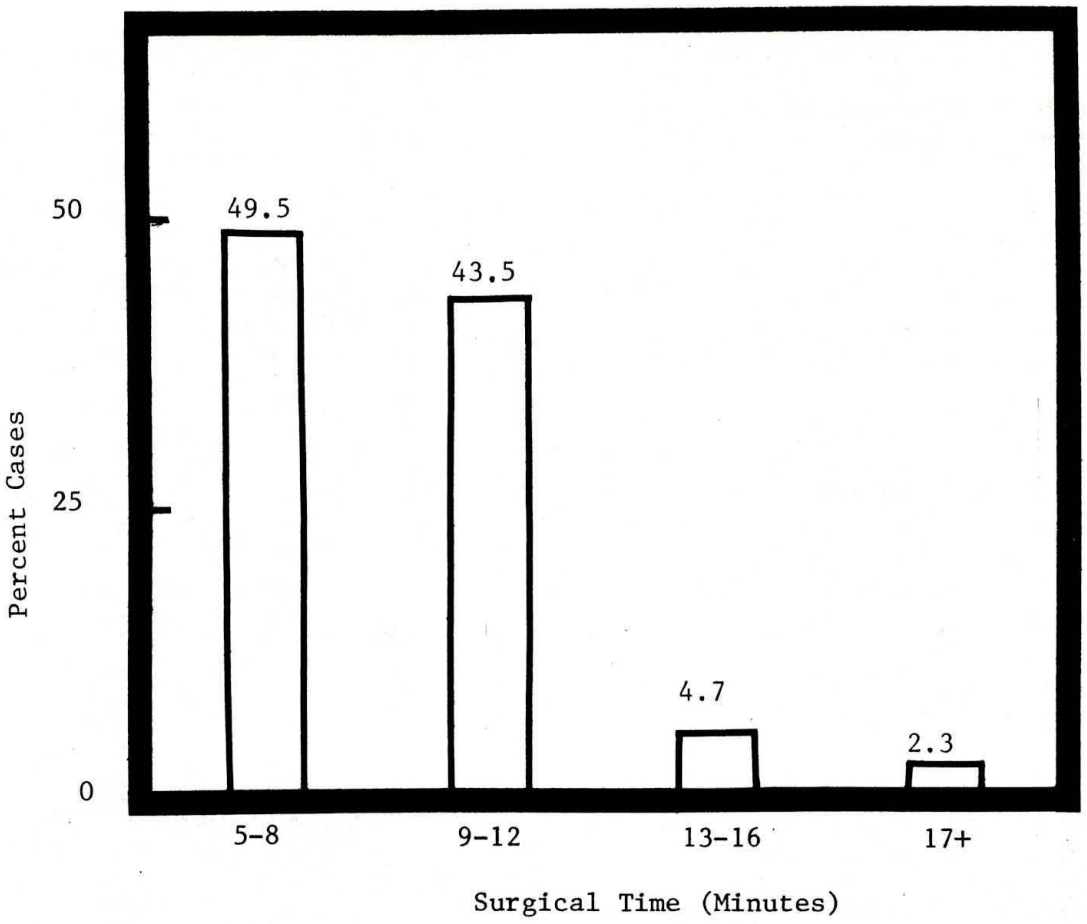

Fig 1

SURGICAL TIME FOR 296 LAPAROSCOPIC STERILISATION PROCEDURES PERFORMED PRIOR TO PREGNANCY TERMINATION AT THE KASTURBA MEDICAL COLLEGE HOSPITAL, MANIPAL, AUGUST 1975 TO APRIL 1979

TABLE II

SURGICAL TIME FOR 296 LAPAROSCOPIC STERILISATION PROCEDURES PERFORMED PRIOR TO PREGNANCY TERMINATION AT THE KASTURBA MEDICAL COLLEGE HOSPITAL, MANIPAL, AUGUST 1975 TO APRIL 1979

Surgical Time (Minutes)	Number	Percent
5 - 8	147	49.5
9 - 12	129	43.5
13 - 16	14	4.7
17 +	6	2.3
Mean	8.8	
TOTAL	296	100.0

Surgical Difficulties

Surgical difficulties were reported during 25 (8.3%) procedures. Difficulty in locating the tubes (2.7%) and need for vaginal manipulation (2.7%) were the most frequently reported causes of surgical difficulty. In this series, only one minor technical difficulty (light source fuse) was reported (Table III).

TABLE III

SURGICAL DIFFICULTIES EXPERIENCED DURING 296*LAPAROSCOPIC STERILISATION PROCEDURES PERFORMED PRIOR TO PREGNANCY TERMINATION AT THE KASTURBA MEDICAL COLLEGE HOSPITAL, MANIPAL, AUGUST 1975 TO APRIL 1979

Difficulties	Number	Percent
Difficulty in locating tubes	8	2.7
Vaginal manipulation required	8	2.7
Retroverted uterus	3	1.0
Difficulty in creating pneumoperitoneum	3	1.0
Thickened tubes	1	0.3
Distended omentum	1	0.3
Light source fused	1	0.3
Procedures with one or more Difficulties	25	8.3

*The three technical failures and one death are excluded from this table.

Mortality and Morbidity

There was one death in this series. The patient developed cardiac arrest soon after pneumoperitoneum was started when only 60 ml of air had been introduced. She could not be revived inspite of external and internal cardiac massage and defibrillation by a team of anesthetists and a cardothoracic surgeon. Death was not due to air embolism as indicated by the fact that no air was withdrawn from the right ventricle. The cause of death in this case was, probably, vasovagal shock due to heavy sedation. The sedation schedule has since been minimized.

In this series, 10 (3.4%) women reported one or more complications. Operative and immediate postoperative complications were reported for three (0.9%) cases. One patient (reported above) developed cardiac arrest, another hypotension and one patient had fever requiring antibiotics. The incidence of early postoperative complications was 2.4 percent. Infection was reported in all these cases (Table IV).

The incidence of complaints was 4.1 percent in the early postoperative period (Table IV).

TABLE IV

COMPLICATIONS AND COMPLAINTS FOR 297* WOMEN UNDERGOING LAPAROSCOPIC STERILISATION PRIOR TO PREGNANCY TERMINATION AT THE KASTURBA MEDICAL COLLEGE HOSPITAL, AUGUST 1975 TO APRIL 1979

Complications/Complaints	Number	Percent
Operative and Immediate Postoperative Complications:		
Cardiac arrest**	1	0.3
Hypotension	1	0.3
Fever requiring antibiotics	1	0.3
Total	3	0.9
Early Postoperative Complications:		
Fever requiring antibiotics	3	1.0
Wound infection	2	0.6
Pelvic infection	1	0.3
Urinary infection	1	0.3
Total	7	2.4
Women with one or more complications	10	3.4
Early Postoperative Complaints:		
Backache	4	1.4
Weakness	3	1.0
Abdominal pain	3	1.0
Pain over scar	2	0.6
Women with one or more complaints	12	4.1

* The three technical failures are excluded.
** Death occurred due to cardiac arrest.

DISCUSSION

When a woman requests sterilisation concurrently with abortion, the usual procedure is to perform sterilisation after terminating her pregnancy. In some cases, however, it may be desirable to perform sterilisation prior to pregnancy termination provided that this does not increase the surgical risk of the procedure.

The results of this study show that the complication rates in the immediate (0.9%) and early (2.4%) postoperative periods were lower than those reported in other postabortion series where sterilisation was performed via laparoscopy. Immediate and early postoperative complication rates in these series ranged between 1.3 and 1.4 and 4.6 and 11.3 percent respectively (6,7,10). In the present study, the incidence of surgical difficulties (8.4%) was higher than rates (5.6% to 8.0%) reported in other studies (6,7,10,11). The various surgical difficulties encountered in this

and other postabortion (7,10) and interval (12) laparoscopic series were of a similar nature. Difficulty in manipulating the heavy, pregnant retroverted uterus (2.7%) was, however, unique to the present series. The incidence of technical failures in this study was higher than that reported (0.0% - 0.7%) in other postabortion sterilisation series (6,7,10,11).

The results of this study suggest that preabortion sterilisation by laparoscopic electrocoagulation does not increase the incidence of postoperative complications. However, this procedure was not technically easier than postabortion sterilisation as was originally hypothesized. For making scientific comparisons between preabortion and postabortion sterilisation procedures, controlled, random, comparative studies are needed.

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A COMPARISON OF POSTABORTION STERILISATION BY LAPAROSCOPY AND COLPOTOMY

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ABSTRACT

This study was conducted to evaluate and compare the safety and efficacy of the tubal ring when applied via laparoscopy and colpotomy immediately after first trimester abortion by suction evacuation. The sterilisation method was randomly assigned to the study cases. A single operator performed all the surgical procedures and another physician evaluated postoperative events in all study cases. Mean surgical and operating room time were higher for colpotomy than for laparoscopy but the differences were not statistically significant. There were no technical failures among the laparoscopy cases. Although all sterilisation procedures were successfully performed via colpotomy, in four cases an alternative technique was employed to occlude the Fallopian tube. The incidence of technical and surgical difficulties was similar for the two study groups. Operative and postoperative complication and complaint rates were not significantly different when sterilisation was performed via laparoscopy and colpotomy. The incidence of gynaecological abnormalities reported six months poststerilisation were also similar for these two groups of cases. No pregnancies were reported.

INTRODUCTION

Laparoscopic sterilisation has found widespread acceptance in both developed and developing countries. As the electrocoagulation technique is associated with the potential hazards of bowel burns, efforts are being made to replace it with noncautery methods such as clips and rings. Most clips have been abandoned because of the high failure rates associated with them (1,2,3). Studies with the tubal ring show that it is a safe and effective technique of female sterilisation and that it can be used via laparoscopy, colpotomy and minilaparotomy (2, 4-7). The colpotomy approach has been extensively used in India as the absence of abdominal scar with this method makes it acceptable to the Indian woman. The present study was conducted to evaluate and compare the safety and efficacy of the tubal ring technique when applied via laparoscopy and colpotomy in postabortion cases. The two sterilisation methods were randomly assigned to the study subjects. All other variables such as type of anaesthesia, sterilisation of surgical instruments, and preoperative and postoperative procedures were held constant throughout the study.

MATERIALS AND METHODS

From April 1975 to January 1979, 292 women underwent sterilisation with the tubal ring at the KEM Hospital in Bombay. Sterilisation was performed immediately after suction abortion in all cases. Data were collected using the standardized protocol of the the India Fertility Research Programme. Six months follow-up data are reported for 95 cases.

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Study Design

The sterilisation method was randomly assigned to the patient immediately prior to surgery, by having the surgeon who performed the procedure (the operator) open a sealed envelope containing a card which specified the sterilisation method to be used for that particular patient. In order to minimize inter-operator variability, all study procedures were performed by a single operator.

In order to minimize evaluator bias, a second physician (the evaluator) was responsible for the care of the patient after she was discharged from the operating room. The evaluator was responsible for recording all complications, complaints, and other events during the patient's recovery period and at the time of the follow-up visits. Thus, the operator performed the procedure and recorded data related to the procedure and to events which occurred while the patient was in the operating room, The evaluator was responsible for providing postoperative care and for recording data on all subsequent visits.

Clinical Procedures

The uterus was evacuated by suction curettage in all cases. All the study procedures were performed with general anaesthesia. The patient was administered 0.6 mg of atropine sulphate untramuscularly half an hour before the sterilisation procedure.

When sterilisation was performed via laparoscopy, the modified Hulka's tenaculum was introduced into the uterine cavity with one arc grasping the anterior lip of the cervix. A small stab incision was made through the skin and subcutaneous fat just below the umbilicus and pneumoperitoneum was created. The incision was then enlarged transversely to accomodate the trocar and cannula and the operating laparoscope loaded with the tubal ring was introduced. The Fallopian tube was identified, picked up at a distance of about 4 cm from the uterine cornu by the grasping forceps and a loop of the tube was drawn into the sleeve of the instrument. The tubal ring was slipped on the tube which was then released from the grasping forceps. The procedure was repeated with the other Fallopian tube. The laparoscope was removed and the peritoneal cavity deflated. The skin incision was closed with a single stitch using No. 00 chromic catgut and a dry gauze dressing was applied.

For colpotomy, the vagina was thoroughly cleansed with one percent Cetavlon, for exactly 3 minutes by the clock. Cetavlon was wiped off with sterile gauze and the vagina was swabbed with tincture of iodine or methylated spirit. A transverse incision was made with scissors in the posterior fornix. The Fallopain tube picked up with a Babcock's forceps was held about 4 cm from the uterine cornu with the grasping forceps of the tubal ring applicator and a loop of the tube was drawn into the sleeve of the instrument. The tubal ring was slipped on to the tube which was then released from the grasping forceps. The procedure was repeated with the other tube. The vaginal wall and peritoneum were closed together with interrupted stitches using chromic catgut. The vagina was packed for six hours.

No prophylactic antibiotics were administered. Most of the study subjects were hospitalized for seven nights.

Subjects

Only women requesting sterilisation for reason of family limitation were included in the study. Pre-existing systemic and/or pelvic disease was not a contraindication. There was one case each of osteomalacia, treated tubercular meningitis, tuberculosis of the lung, kyphoscoliosis, bronchial asthma and chronic pelvic infection among the laparoscopy cases. There was one case each of chronic pelvic infection, removed goitre, pulmonary tuberculosis, tuberculosis of the spine and schizophrenia (under treatment) among the colpotomy cases. Previous pelvic surgery was reported for 3.5 and 6.7 percent of the laparoscopy and colpotomy patients respectively. This included dilatation and curettage, caesarian section, previous sterilisation by Madleiner's technique, abdominal surgery for lysis of burn adhesions, Meckel's diverticulum, ileal perforation, appendectomy, Fothergill's operation and perineal repair.

Definitions and Criteria

A technical failure was defined as a case in which the designated procedure could not be completed. Technical difficulty was defined as any difficulty associated with the equipment. Surgical difficulty was any difficulty encountered during the procedure which was not due to equipment-related problems.

Complications and complaints due to the sterilisation procedure were categorised as operative, immediate, early and delayed postoperative. Operative complications and complaints were those occurring during surgery. Immediate complications and complaints were those occurring after surgery but prior to the patient's leaving the operating room. Early postoperative complications and complaints were those reported before the patient's discharge from the hospital. Delayed postoperative complications and complaints were those reported at the six months follow-up visit.

Surgical time was defined as the time from the commencement of dilatation to final closure of the incision. Operating room time was the time from entering to leaving the operation room; it included surgical time.

All statistical tests were performed using a significance level (p value) of 0.05.

RESULTS

Sociodemographic Characteristics

Women undergoing sterilisation via laparoscopy and colpotomy were similar with respect to selected sociodemographic characteristics including age, parity, education, employment and religion (Table I). The average woman in the study group was an unemployed Hindu, in her early 30s with 3 to 4 live births and 4 to 5 years of formal school education.

TABLE I

SOCIODEMOGRAPHIC CHARACTERISTICS OF 292 WOMEN UNDERGOING POSTABORTION STERILISATION WITH THE TUBAL RING VIA LAPAROSCOPY AND COLPOTOMY AT THE KEM HOSPITAL, BOMBAY, APRIL 1975 TO JANUARY 1979

Sociodemographic Characteristics	Laparoscopy N = 142		Colpotomy N = 150	
	No.	%	No.	%
Age (Years)				
20 - 24	8	5.6	7	4.7
25 - 29	42	29.6	43	28.7
30 - 34	48	33.8	55	36.7
35 - 39	34	23.9	31	20.6
40 +	10	7.0	14	9.3
Mean	31.9		32.1	
Parity				
1 - 2	27	19.0	29	19.3
3 - 4	77	54.2	88	58.7
5 - 6	26	18.3	26	17.3
7 +	12	8.5	7	4.7
Mean	3.8		3.7	
Education (School years)				
0	56	39.4	65	43.3
1 - 3	8	5.6	7	4.7
4 - 6	33	23.2	23	15.3
7 - 9	27	19.0	29	19.3
10 - 12	14	9.9	21	14.0
13 +	4	2.8	5	3.3
Mean	4.5		4.6	
Employed				
No	118	83.1	124	82.7
Yes	24	16.9	26	17.3
Religion				
Hindu	117	82.4	124	82.7
Muslim	14	9.9	13	8.7
Christian	9	6.3	11	7.3
Other	2	1.4	2	1.3

Surgical and Operating Room Time

Mean surgical time was higher for colpotomy (14.7 minutes) than for laparoscopy (11.2 minutes) (Table II). However, the difference was not statistically significant. On an average, a woman undergoing laparoscopy spent 26.5 minutes and a woman undergoing colpotomy spent 30.5 minutes in the operating room (Table II). This difference was also not statistically significant.

TABLE II

SURGICAL AND OPERATING ROOM TIME FOR 292 WOMEN UNDERGOING POSTABORTION STERILISATION WITH THE TUBAL RING VIA LAPAROSCOPY AND COLPOTOMY AT THE KEM HOSPITAL, BOMBAY, APRIL 1975 TO JANUARY 1979

Time (Minutes)	Laparoscopy N = 142		Colpotomy N = 150	
	No.	%	No.	%
Surgical:				
≤ 5	13	9.2	1	0.7
6 - 10	65	45.8	32	21.3
11 - 15	35	24.6	61	40.7
16 - 20	20	14.1	34	22.7
21 - 25	6	4.2	14	9.3
26 +	3	2.1	8	5.3
Mean	11.2		14.7	
Operating Room:				
≤ 19	27	19.0	8	5.3
20 - 29	69	48.6	75	50.0
30 - 39	37	26.1	42	28.0
40 - 49	8	5.6	19	12.7
50 +	1	0.7	6	4.0
Mean	26.5		30.5	

Technical Failure

While there were no technical failures among the laparoscopy cases; four technical failures were reported among the colpotomy procedures. In all four cases, sterilisation was successfully performed via colpotomy. However, the technique used for tubal occlusion was different from the planned tubal ring technique. In one case, the tubal ring was applied successfully to the right tube but the left tube was ligated by the Madleiner's technique because the mesosalpinx and the tubal wall were torn by the grasping forceps. In another case the right tube was successfully occluded with the tubal ring but as the left tube was adherent and could not be visualised, it was consequently ligated by the Pomeroy technique and a part of it was sectioned. In two cases, the tubal ring was successfully applied to occlude one tube. However, the other tube could not be brought into the operation field owing to the presence of adhesions and so it was sectioned and tied.

Technical and Surgical Difficulties

Difficulties were reported with similar frequency when sterilisation was performed via laparoscopy (5.6%) and colpotomy (5.3%) (Table III). There was no significant difference in the incidence of technical difficulties encountered during the laparoscopy (2.1%) and colpotomy (1.3%) procedures (Table III). During one laparoscopic procedure the inner cylinder of the band applicator jammed with the outer cylinder. In another case, the tongs of the applicator were not properly aligned and in the third case the tubal ring broke during laparoscopic application. During one of the colpotomy procedures there was inadequate light effecting visibility, and in another case the applicator did not work well.

TABLE III

TECHNICAL/SURGICAL DIFFICULTIES REPORTED FOR 292 WOMEN UNDERGOING POSTABORTION STERILISATION WITH THE TUBAL RING VIA LAPAROSCOPY AND COLPOTOMY AT THE KEM HOSPITAL, BOMBAY, APRIL 1975 TO JANUARY 1979

Difficulty	Laparoscopy N=142		Colpotomy N=150	
	No.	%	No.	%
Technical:				
Applicator problems	2	1.4	1	0.7
Poor light source	0	0.0	1	0.7
Band broke	1	0.7	0	0.0
Total	3	2.1	2	1.3
Surgical:				
Omentum interference	2	1.4	0	0.0
Adhesions	2	1.4	2	1.3
Enlarged uterus	1	0.7	0	0.0
Difficulty in locating/exteriorising tubes	0	0.0	2	1.3
Oedamatous tubes	0	0.0	1	0.7
Cannula introduced into nonpregnant horn of bicornuate uterus	0	0.0	1	0.7
Total	5	3.5	6	4.0
Women with one or more difficulties	8	5.6	8	5.3

The incidence of surgical difficulties during laparoscopy (3.5%) and colpotomy (4.0%) was not significantly different. While the presence of adhesions and omental interference were the main causes of surgical difficulty during laparoscopy, difficulty in visualising and exteriorizing the tubes was the most common problem during colpotomy (Table III).

Complications

Abortion complications were encountered with similar frequency for laparoscopy (4.2%) and colpotomy (4.7%). Uterine perforation was reported for 3 (1.0%) cases and bleeding requiring transfusion for 2 (0.7%) cases (Table IV). In one case of uterine perforation the injury was not noticed during laparoscopy as the bleeding was extraperitoneal. Subsequently laparotomy was performed to remove the extravasated blood and to repair the rent.

The total incidence of sterilisation complications among women undergoing laparoscopy (4.9%) was not significantly different from those undergoing colpotomy (4.7%) (Table IV). The incidence of sterilisation and abortion complications were similar for the two groups of cases (Table IV).

TABLE IV

COMPLICATIONS REPORTED FOR 292 WOMEN UNDERGOING POSTABORTION STERILISATION WITH THE TUBAL RING VIA LAPAROSCOPY AND COLPOTOMY AT THE KEM HOSPITAL, BOMBAY, APRIL 1975 TO JANUARY 1979

Complications	Laparoscopy N=142		Colpotomy N=150	
	No.	%	No.	%
Abortion related:				
Blood loss > 100 ml				
With transfusion	1	0.7	1	0.7
Without transfusion	1	0.7	4	2.7
Cervical tear	2	1.4	1	0.7
Uterine perforation	2	1.4	1	0.7
Total	6	4.2	7	4.7
Sterilisation related:				
Operative:				
Partially torn tube	1	0.7	0	0.0
Tear in mesosalpinx	1	0.7	1	0.7
Knuckle of tube divided	1	0.7	0	0.0
Avulsion of tube	0	0.0	1	0.7
Bronchospasm due to anaesthesia	1	0.7	1	0.7
Total	4	2.8	3	2.1
Immediate Postoperative:				
Haematoma	2	1.4	0	0.0
Total	2	1.4	0	0.0
Early postoperative:				
Fever requiring antibiotics	0	0.0	2	1.3
Fever not requiring antibiotics	0	0.0	2	1.3
Serous discharge from wound	1	0.7	0	0.0
Total	1	0.7	4	2.6
Women with one or more sterilisation complications	7	4.9	7	4.7

The operative complication rates were 2.8 and 2.1 percent respectively for laparoscopy and colpotomy. The only immediate postoperative complication was the development of a haematoma in two patients who underwent laparoscopic sterilisation (Table IV). The incidence of early postoperative complications was higher for the colpotomy (2.6%) than for laparoscopy (0.7%) cases. However, this difference was not statistically significant (Table IV).

There was not significant difference in the incidence of gynaecological abnormalities 6 months after sterilisation for women who underwent laparoscopy (26.1%) and colpotomy (22.4%). Cervical erosion was reported for 8.7 and 10.2 percent cases respectively. One woman developed carcinoma in situ after colpotomy. A leukoplakic patch was reported for one and dysplasia for another case after laparoscopic sterilisation. Cystocoele was reported for 6.5 and 4.1 percent of the laparoscopy and colpotomy cases respectively and rectocoele for 2.2 and 4.1 percent cases respectively (Table V). In this series, there was only one woman who underwent pelvic surgery (dilatation and curettage) poststerilisation.

TABLE V

GYNAECOLOGICAL ABNORMALITIES REPORTED FOR 95 WOMEN SIX MONTHS AFTER STERILISATION VIA LAPAROSCOPY AND COLPOTOMY AT THE KEM HOSPITAL, BOMBAY, APRIL 1975 TO JANUARY 1979

Gynaecological Abnormalities	Laparoscopy N=46		Colpotomy N=49	
	No.	%	No.	%
Cervical erosion	4	8.7	5	10.2
Cystocoele	3	6.5	2	4.1
Leukoplakic patch	1	2.2	0	0.0
Carcinoma in situ	0	0.0	1	2.0
Rectocoele	1	2.2	2	4.1
Dysplasia	1	2.2	0	0.0
Vulval furuncles	0	0.0	1	2.0
Uterus descent	1	2.2	0	0.0
Vaginal cyst	1	2.2	0	0.0
Women with one or more abnormalities	12	26.1	11	22.4

Complaints

The incidence of immediate postoperative complaints was higher for women who underwent colpotomy (5.3%) than for those who underwent laparoscopy (2.8%). However, this difference was not statistically significant. Pelvic pain was reported by only 2.8 and 3.3 percent of these cases respectively (Table VI). The incidence of early postoperative complaints was similar for the laparoscopy (8.4%) and colpotomy (8.7%) cases. At six months follow-up visit, 15.2 and 14.3 percent of the women sterilised via laparoscopy and colpotomy reported pelvic pain (Table VI).

TABLE VI

COMPLAINTS REPORTED FOR 292 WOMEN UNDERGOING POSTABORTION STERILISATION WITH THE TUBAL RING VIA LAPAROSCOPY AND COLPOTOMY AT THE KEM HOSPITAL, BOMBAY, APRIL 1975 TO JANUARY 1979

Complaints	Laparoscopy N=142 No.	%	Colpotomy N=150 No.	%
Immediate Postoperative:				
Pelvic pain	4	2.8	5	3.3
Burning micturition	0	0.0	1	0.7
Chest pain	0	0.0	1	0.7
Weakness	0	0.0	1	0.7
Total	4	2.8	8	5.3
Early Postoperative:				
Pelvic pain	4	2.8	5	3.3
Spotting	8	5.6	3	2.0
Bleeding	0	0.0	4	2.7
Weakness	0	0.0	1	0.7
Total	12	8.4	13	8.7
	N=46		N=49	
Delayed postoperative: Pelvic pain	7	15.2	7	14.3

Failures

No pregnancies have been reported to date; 292 women in this study were followed up for 1,878 woman months.

COMMENT

The results of this carefully, controlled, random study indicate that the tubal ring technique can be safely applied via laparoscopy and colpotomy in postabortion cases. Both sterilisation approaches were associated with clinically acceptable complication rates. Infact, the abortion complications were of greater concern. The complication rate for colpotomy in this series was similar to that reported in other studies (5,8,9). The reported incidence of major complications for pooled analyses of 5,000 and 1,043 colpotomy cases was 3.5 and 5.6 percent respectively (10,11).

The rate of technical failure was 0.7 percent in a series of 5,000 pregnancies; the procedure could not be completed via the vaginal route and the reason for failure in most cases was the presence of adhesions (10). In a study of 1,164 colpotomy cases, the technical failure rate was 1.0 percent; laparotomy was performed to ligate one or both tubes (8). In the present study, the technique of tubal occlusion had to be changed in 0.7 percent colpotomy cases due to pelvic pathology. However, all procedures were completed through the colpotomy approach. The reported incidence of technical failures with laparoscopic application of the tubal ring range from 0.0 to

0.7 percent in various studies (1,4,10,12,13). No failures were reported for this series and the frequency of technical and surgical difficulties was similar for laparoscopy and colpotomy. It is hypothesized that the incidence of subsequent gynaecological pathology and consequent pelvic surgery is high among sterilised women. The reported incidence of gynaecological abnormalities on longterm follow-up of women undergoing sterilisation with the tubal ring was higher in this than in some other studies (2,13). However, this analysis included a smaller sample of cases. Longer follow-up of larger series is needed for this evaluation.

The six and twelve month failure rates in a pooled analysis of 797 tubal ring cases were 0.2 and 0.3 per 100 women respectively (1). In Singapore the corresponding rates were 1.4 and 2.7 for postabortion cases (4). No failures with the tubal ring were reported in studies conducted at Bombay (13) and Baroda (6). In this study, also no pregnancies were reported to date. Further follow-up is required to document failure rates, change in menstrual patterns and the incidence of future gynaecological abnormalities.

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MATERNITY CARE MONITORING: AN ILLUSTRATION FROM INDIA

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ABSTRACT

This paper presents a pooled analysis of data on 15,221 maternity cases at nine institutions in India. It documents the quality of feedback provided by the computerized system of Maternity Care Monitoring (MCM) and illustrates its utilization. MCM provides baselines on high risk groups and periodic examination of indices of maternal and perinatal health. It, thereby, serves as a tool for highlighting lacunae in service programmes and assists programme planners and service providers to delineate priorities and implement appropriate measures for improving the quality of care.

INTRODUCTION

Care of the mother and the infant before, during and after delivery is of the utmost concern to professionals engaged in the fields of obstetrics, gynaecology and perinatology. Efficient monitoring of maternity care programmes is, therefore, a priority for those engaged in these tasks. This involves the establishment of clinical baselines on the risk groups to be served, followed by periodic examination of indices of maternal and perinatal health to highlight lacunae and to implement appropriate health measures for reducing morbidity and mortality among populations served.

The International Federation for Family Health (IFFH) is assisting its member countries to incorporate within their service programmes, a standardized system for Maternity Care Monitoring (MCM) capable of providing periodic, computerized feedback for evaluating a broad range of factors governing high risk groups, management and outcome of delivery as well as intervention to improve future outcome. This system also enables epidemiological comparisons between biological and socio-environmental factors which operate interactively to influence pregnancy outcome (1-3). In India, more than 35 institutions have implemented this system (4-6). This paper presents a pooled analysis of maternity data from nine of these institutions; it documents the quality of feedback provided by this system and provides an illustration of its utilisation.

MATERIALS AND METHODS

Data on 15,221 women delivering 15,424 infants in India from January 1976 to December 1978 are reported. All institutions reporting data utilised the computerized and standardized system for MCM of the India Fertility Research Programme (India FRP).

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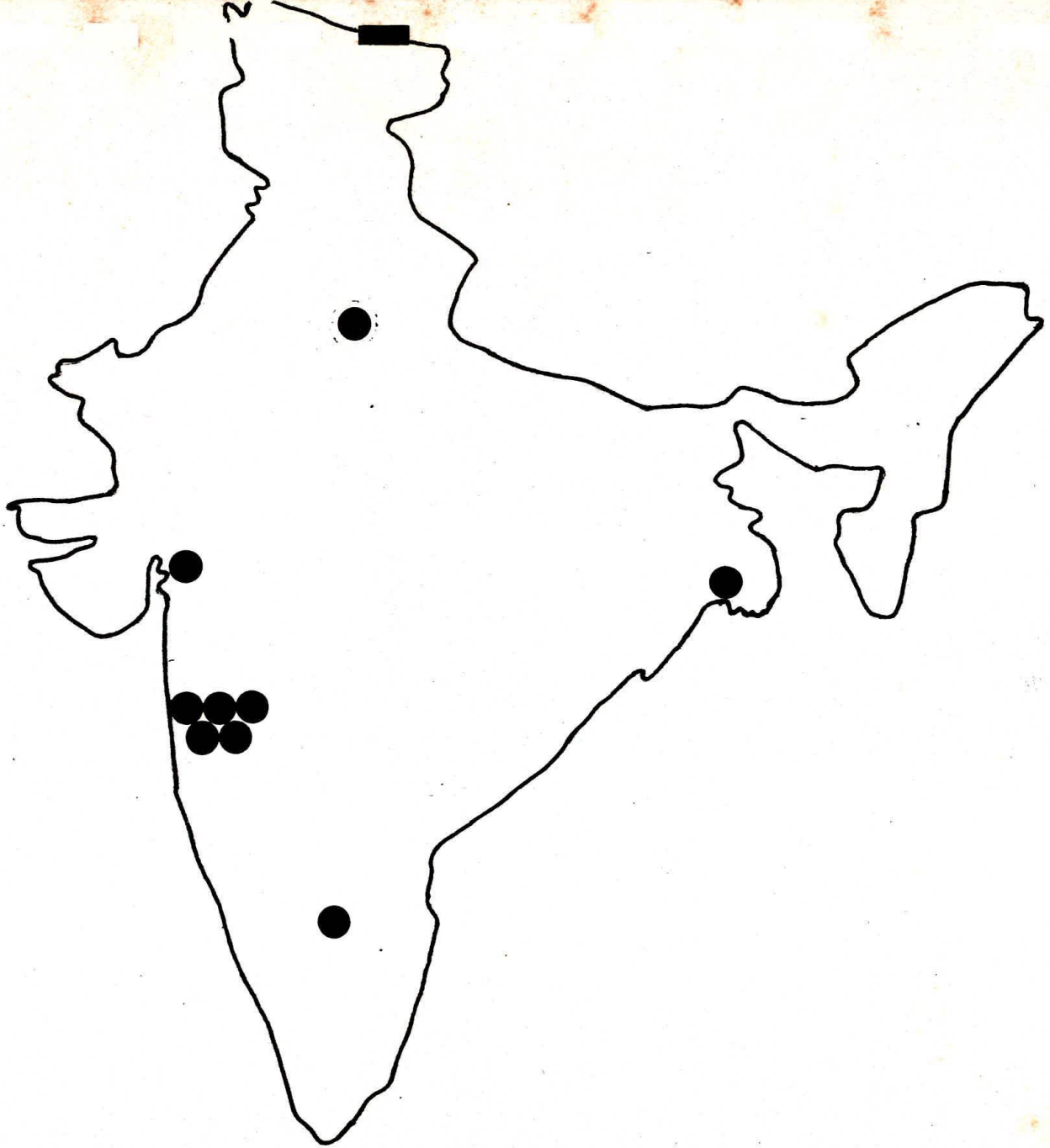

Fig 1

MAP OF INDIA SHOWING LOCATION OF CONTRIBUTING CENTRES

Figure 1 is a map of the country showing the location of institutions from which data for this paper are drawn. Table I lists these institutions by place and shows the number of deliveries by time for each participating institution. Data on sociodemographic characteristics, obstetric history, antenatal, intranatal and postnatal status of the mother, management and outcome of delivery and neonatal status were recorded on standard, one-page forms of the India FRP.

TABLE I

CONTRIBUTING INSTITUTIONS BY PLACE, TIME AND NUMBER OF DELIVERIES

State	Place	Institution	Contributor	Inclusive Delivery Dates	Number of Cases
Gujarat	Baroda	Baroda Medical College Hospital	R.V. Bhatt	January 1977 to July 1978	3686
Maharashtra	Bombay	Nowrosjee Wadia Maternity Hospital	Dina Patel	June 1977 to August 1978	3164
Maharashtra	Bombay	King Edward Memorial Hospital	V.N.Purandare	July 1977 to January 1978	1963
Maharashtra	Bombay	Balabhai Nanavati Hospital	C.L. Jhaveri	February 1977 to April 1978	1234
Maharashtra	Bombay	Cama & Albless Hospitals	S. Mehtaji	May 1977 to July 1978	729
Maharashtra	Bombay	Hospital for Women	A.C. Mehta	January 1977 to September 1978	907
Karnataka	Manipal	Kasturba Medical College & Hospital	Padma Rao	August 1977 to December 1978	2151
Delhi	New Delhi	Kasturba Hospital	M. Kochhar	August 1977 to December 1978	904
West Bengal	Calcutta	S.S.K.M. Hospital	S. Banerjee	June 1977 to December 1978	483

TABLE II

SOCIODEMOGRAPHIC CHARACTERISTICS OF 15,221 WOMEN DELIVERED IN SELECTED MATERNITY CENTRES IN INDIA, JANUARY 1976 TO DECEMBER 1978

Sociodemographic Characteristics	Number	Percent
Age (Years)		
≤ 19	984	6.5
20 - 24	5944	39.1
25 - 29	5107	33.6
30 - 34	2210	14.5
35 - 39	838	5.5
40 +	121	0.8
Unknown	17	0.1
Mean	25.9	
Number of Living Children		
0	5481	36.0
1	4015	26.4
2	2647	17.4
3 - 4	2073	13.6
5 - 6	452	3.0
7 +	113	0.7
Unknown	440	2.9
Mean	1.3	
Education (School years)		
0	1527	10.0
1 - 2	302	2.0
3 - 4	769	5.1
5 - 6	986	6.5
7 - 8	972	6.4
9 - 10	812	5.3
11 - 12	783	5.1
13 +	530	3.5
Unknown	8540	56.1
Mean	6.2	
Marital Status		
Currently married	14640	96.2
Formerly married	492	3.2
Never married	56	0.4
Other	6	0.0
Unknown	27	0.2
Residence		
Urban	9472	62.2
Rural	5161	33.9
Slum	560	3.7
Unknown	28	0.2

Definitions and Criteria

All deliveries regardless of outcome were included in the study. Women admitted for induced and spontaneous abortion (with a foetus weighing less than 500 grams and gestation upto 19 weeks), molar pregnancies and false labour were excluded.

The duration of pregnancy was estimated in completed weeks from the onset of the woman's last normal menstrual period to the day of delivery.

In cases with multiple complications, only the primary complication was reported. Women with haemoglobin less than 10 gm/100 ml were categorized as anaemic. For classifying antenatal conditions, the 9th edition of the WHO International Classification of Disease was used. For estimating perinatal mortality rates, stillborn infants weighing 1000 grams or more and early neonatal deaths were included. Neonatal death was defined as infant death prior to discharge from the hospital.

RESULTS

Sociodemographic Characteristics

The average woman in the study group was an urban resident (62.2%), 25.9 years of age with 1.3 living children and 6.2 years of formal education. The proportion of women below 19 (6.5%) and above 34 (6.3%) years of age was low. While 36.0 percent of the women had no living child, 26.4 percent had only one living child and only 3.7 percent had more than 4 living children (Table II). The desired family size of the study group was 3.4 children. For women below 20 years of age it was 2.9 children; for women at 20 to 29 and 30+ years it was 3.3 and 5.0 children respectively. The mean age of the youngest child was 3.2 years.

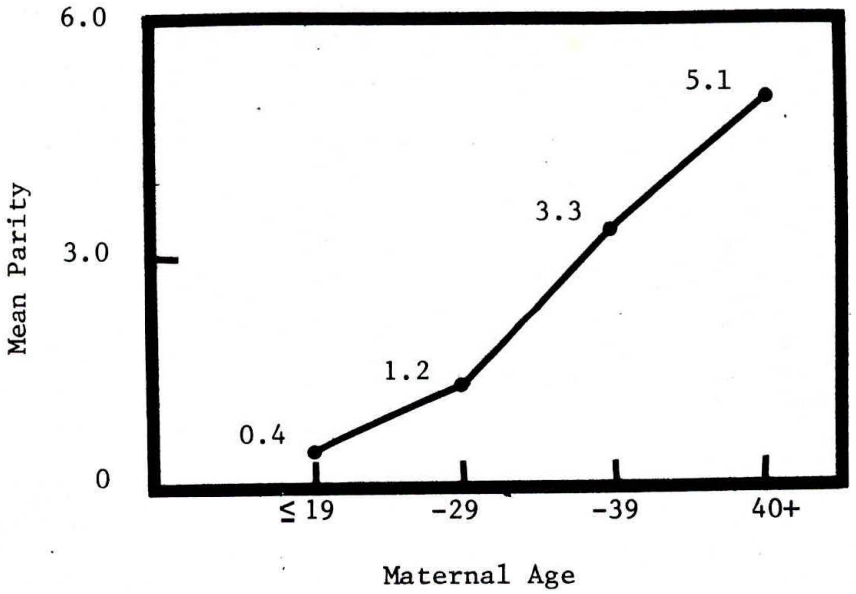

Fig 2

MATERNAL AGE BY PARITY FOR 15,221 WOMEN DELIVERED IN SELECTED MATERNITY CENTRES IN INDIA, JANUARY 1976 TO DECEMBER 1978

TABLE III

OBSTETRIC EVENTS REPORTED BY 15,221 WOMEN DELIVERED IN SELECTED MATERNITY CENTRES IN INDIA, JANUARY 1976 TO DECEMBER 1978

Obstetric Events	Number	Percent
Live births		
0	5215	34.3
1	4027	26.5
2	2768	18.2
3	1589	10.4
4	815	5.4
5 +	767	5.0
Unknown	40	0.3
Mean	1.5	
Infant Deaths		
0	13692	90.0
1	855	5.6
2	169	1.1
3 +	59	0.4
Unknown	446	2.9
Mean	0.1	
Stillbirths		
0	14646	96.2
1	452	3.0
2+	94	0.6
Unknown	29	0.2
Mean	0.04	
Spontaneous abortions		
0	13701	90.0
1	1153	7.6
2	261	1.7
3+	78	0.5
Unknown	28	0.2
Mean	0.1	
Induced abortions		
0	15008	98.6
1	164	1.1
2+	16	0.1
Unknown	33	0.2
Mean	0.01	

The percentage of illiterate women (10.0%) and those with < 5 years (7.1%) of formal education was low (Table II). The majority of the deliveries were booked (74.0%), non-private (84.5%) cases who were generally hospitalised for more than 3 nights (82.9%); only 0.8 percent were emergency admissions.

The women in this series had an average of 1.5 live births; 34.3 percent were nulliparous and 26.5 percent had had only one live birth (Table III). Mean parity gradually increased from 0.4 for women below 20 to 3.3 for women who were 30 to 39 years of age; there was a sharp increase to 5.1 for women who were 40+ years of age (Fig 2). Previous infant deaths, stillbirths, spontaneous and induced abortions were reported by 7.1, 3.6, 9.8 and 1.2 percent of the women respectively (Table III).

TABLE IV

DELIVERY DATA FOR WOMEN DELIVERED IN SELECTED MATERNITY CENTRES IN INDIA, JANUARY 1976 TO DECEMBER 1978

Delivery	Number	Percent
Type of Delivery	N = 14,656	
Spontaneous	11964	81.6
Spontaneous assisted	1220	8.3
Caesarian section	849	5.8
Outlet forceps	187	1.3
Vacuum extractor	114	0.8
Mid/high forceps	99	0.7
Breech	67	0.5
Destructive procedure	4	0.0
Other	152	1.0
Attendant at Delivery	N = 15,169	
Nurse	4842	31.9
Obstetric /gynaecologist physician	3818	25.2
General physician	2786	18.4
Student nurse/midwife	2217	14.6
Qualified midwife	1013	6.7
Paramedic	37	0.2
Medical student	156	1.0
Other	15	0.1
Type of Labour	N = 15,019	
Spontaneous	14094	93.8
Induced	408	2.7
No labour	357	2.4
Other	160	1.1

Note: Only cases with available data are included in this and subsequent tables.

The Delivery

Delivery was spontaneous in 81.6 percent cases. Caesarian section was performed in 5.8 and forceps were used in 2.8 percent cases. The incidence of breech deliveries was 0.5 percent (Table IV). Spontaneous deliveries were reported more frequently for multiparas (92.8%) and grand multiparas (94.9%) than for primiparas (83.6%). Caesarian section and forceps deliveries were more common among primiparas (8.4% and 6.3%) than among multiparas (4.8% and 1.0%) and grand multiparas (3.0% and 0.6%).

In 43.6 percent cases a doctor attended the delivery. A fourth of the deliveries were conducted by specialists in obstetrics and gynaecology. A third of the deliveries were conducted by nurses (Table IV).

Labour was spontaneous in 93.8 percent cases. In 2.7 percent cases labour was induced and 2.4 percent of the women did not go into labour (Table IV).

The mean birth weight of the infants in this series was 2668.4 grams. While 29.2 percent of the infants weighed less than 2500 grams, 7.6 percent weighed less than 2000 grams (Fig 3). Mean Apgar Score at one and five minutes was 7.4 and 7.5 respectively.

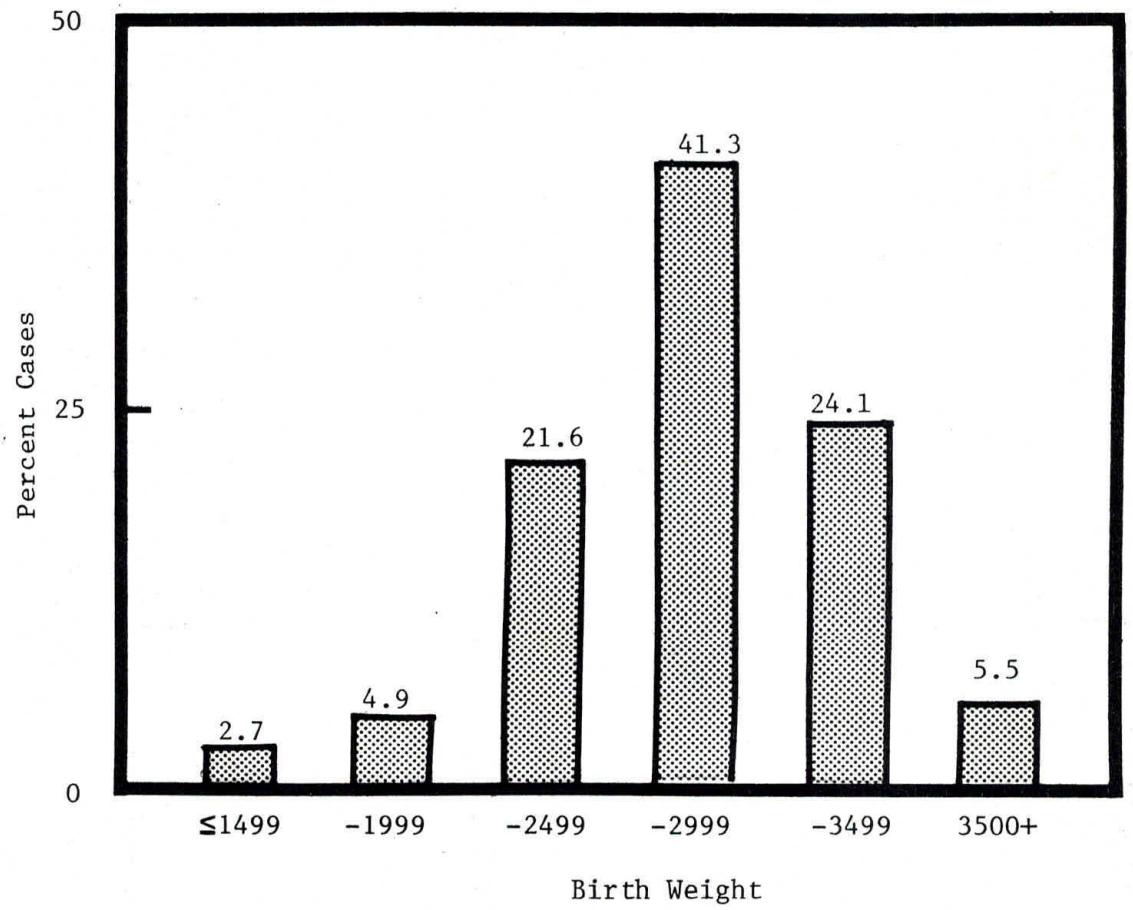

Fig 3

BIRTH WEIGHT OF 15,355 INFANTS DELIVERED IN SELECTED MATERNITY CENTRES IN INDIA, JANUARY 1976 TO DECEMBER 1978

TABLE V

ANTENATAL COMPLICATIONS FOR 13,162 WOMEN DELIVERED IN SELECTED MATERNITY CENTRES IN INDIA, JANUARY 1976 TO DECEMBER 1978

Antenatal Complications	Number	Percent
Blood Disorders		
Iron deficiency anaemia	1457	11.1
Sickle cell anaemia	28	0.2
Other anaemia	8	0.1
Isoimmunization due to Rh	21	0.2
Isoimmunization due to ABO	4	0.0
Other	1	0.0
Total	1519	11.5
Hypertensive Disorders		
Chronic hypertension	15	0.1
Chronic hypertensive/pre-ecclampsia	8	0.1
Hypertension of this pregnancy	24	0.2
Pre-ecclamptic toxemia	176	1.3
Ecclampsia	21	0.2
Other	3	0.0
Total	247	1.9
Bleeding Disorders		
Threatened abortion	25	0.2
Placenta previa	19	0.1
Placenta abruptio	20	0.2
Rupture of marginal sinus	1	0.0
Other bleeding per vagina	21	0.2
Total	86	0.7
Anamolies/Abnormalities		
Incompetent cervix	29	0.2
Vesicovaginal fistula	1	0.0
Rectovaginal fistula	1	0.0
Genital	8	0.1
Genito-urinary	1	0.0
Cardiac	10	0.1
Skeletal pelvic	41	0.3
Skeletal non-pelvic	3	0.0
Other	4	0.0
Total	98	0.7
Infections		
Chorio/amnionitis-other pelvic	18	0.1
Respiratory tract infections	16	0.1
Tuberculosis	9	0.1
Syphilis	7	0.1
Malaria	5	0.0
Other systemic infections	10	0.1
Total	65	0.5

TABLE V (CONTD)

Antenatal Complications	Number	Percent
Gastrointestinal Disorders		
Gastrointenstinal infections	24	0.2
Intestinal parasites	13	0.1
Ileitis/colitis	7	0.1
Cholecystitis/cholelithiasis	5	0.0
Appendicitis	2	0.0
Hemorrhoids	2	0.0
Other	8	0.1
Total	61	0.5
Cardiovascular Disorders		
Varicose veins	7	0.1
Thrombophlebitis	2	0.0
Other vascular disorders	8	0.1
Functional cardiac disorders	24	0.2
Total	41	0.3
Endocrinal Disorders		
Diabetes mellitus	16	0.1
Diabetes gestational	19	0.1
Hypothyroid	2	0.0
Hyperthyroid	1	0.0
Total	38	0.3
Urinary Tract Disorders		
Lower urinary tract infection	14	0.1
Acute nephritis/pyelonephritis	1	0.0
Chronic nephritis/pyelonephritis	4	0.0
Other	2	0.0
Total	21	0.2
Neurological Disorders		
Epilepsy	2	0.0
Encephalitis	1	0.0
Other	1	0.0
Total	4	0.0
Psychiatric Disorders		
Hyperemesis gravidarum	4	0.0
Psychosis	1	0.0
Total	5	0.0
Cancer		
Cervix	2	0.0
Leukemia	1	0.0
Total	3	0.0
Other Disorders	56	0.4

Maternal Morbidity

Iron deficiency anaemia (11.1%) was the most frequently reported primary antenatal complication. The incidence of other anaemias was 0.3 percent. After anaemia, the next most common antenatal complications were hypertensive disorders (1.9%) including hypertension, pre-ecclampsia and ecclampsia. Pre-ecclamptic toxemia with and without chronic hypertension was reported for 0.1 and 1.3 percent cases respectively. The incidence of ecclampsia was 0.2 percent for the series (Table V).

Bleeding disorders including threatened abortion (0.2%), placental haemorrhage (0.3%) and other vaginal bleeding (0.2%) were reported for 0.7 percent cases. The incidence of all anamolies and abnormalities was 0.7 percent; the most common of these were skeletal abnormalities of the pelvis (0.3%); incompetent cervix (0.2%) and cardiac (0.1%) and genital (0.1%) anamolies and abnormalities (Table V).

Infections including systemic and pelvic infections were reported for 0.5 percent cases. The incidence of intestinal disorders including infections, infestations, and inflammatory conditions was 0.5 percent. Cardiovascular and endocrinal disorders were each reported in 0.3 and urinary tract infection in 0.2 percent cases. The reported incidence of psychiatric and neurological disorders and cancers was less than 1.0 percent (Table V).

The incidence of intranatal complications was 8.9 percent. Prolonged/obstructed labour (4.6%) was the most common primary intranatal complication (Table VI).

TABLE VI

INTRANATAL COMPLICATIONS BY NEONATAL STATUS OF 14,703 CASES DELIVERED IN SELECTED MATERNITY CENTRES IN INDIA, JANUARY 1976 TO DECEMBER 1978

Intranatal Complications	Discharged Alive	Neonatal Death	Stillbirth	Total
Prolonged/obstructed labour	4.2	8.4	14.4	4.6
Placenta previa/abruptio	0.7	2.3	8.5	0.9
Hypotonic uterine contractions	0.6	0.3	0.2	0.6
Hypertonic uterine contractions	0.02	0.0	0.0	0.02
Other	2.3	7.7	14.0	2.8
TOTAL	7.8	18.7	37.1	8.9

Note: Only primary complications are reported.

Complications during the puerperium were reported for 3.5 percent cases. Postpartum haemorrhage (1.0%), fever requiring antibiotics (0.5%), urinary tract infection (0.1%), bleeding requiring treatment (0.1%)and dehiscence (0.1%) were frequently reported primary postnatal complications (Table VII). Blood transfusion was given to 1.5, 2.1 and 3.3 percent primiparas, multiparas and grand multiparas respectively.

TABLE VII

POSTNATAL COMPLICATIONS FOR 15,181 WOMEN DELIVERED IN SELECTED MATERNITY CENTRES IN INDIA, JANUARY 1976 TO DECEMBER 1978

Postnatal Complications	Number	Percent
Postpartum haemorrhage	149	1.0
Fever requiring treatment	78	0.5
Urinary tract infection	20	0.1
Dehiscence	15	0.1
Bleeding requiring treatment	13	0.1
Retained products	8	0.1
Mastitis	7	0.1
Phlebitis	3	0.0
Other	218	1.4
TOTAL	511	3.5

Note: Only primary complications are reported.

Foetal and Neonatal Mortality

In 92.0 percent cases the condition of the neonate was normal. Foetal distress during labour was reported for 3.5 percent cases and major and minor malformations for 0.6 and 0.1 percent cases respectively. Icterus was reported for 0.6 percent, respiratory distress syndrome for 0.2 percent and trauma for 0.2 percent of the newborn infants (Table VIII).

TABLE VIII

NEONATAL COMPLICATIONS BY STATUS OF THE NEWBORN FOR 14,659 INFANTS DELIVERED IN SELECTED MATERNITY CENTRES IN INDIA, JANUARY 1976 TO DECEMBER 1978

Neonatal Complications	Discharged Alive	Neonatal Deaths	Stillbirth	Total
Foetal Distress during labour	2.8	19.3	25.5	3.5
Minor malformation	0.1	0.5	0.6	0.1
Major malformation	0.3	8.9	9.2	0.6
Respiratory distress syndrome	0.1	10.9	0.0	0.2
Icterus	0.6	1.0	0.0	0.6
Neonatal sepsis	0.1	2.1	0.0	0.1
Trauma	0.2	2.1	0.6	0.2
Other	0.9	30.7	57.9	2.6
TOTAL	5.1	75.5	93.8	7.9

Note: Primary complications for only single deliveries are reported.

Maternal and Perinatal Mortality

Twenty maternal deaths were reported for this series. Thus, the maternal mortality rate was 1.3 per 1000. The perinatal mortality rate was 47.9 per 1000 and the stillbirth and neonatal mortality rates were 30.5 and 21.1 per 1000 respectively (Table IX). Of the perinatal deaths, death of the foetus occurred during the antenatal period in 29.1 percent cases. Death of the newborn occurred during the intranatal and postnatal periods in 30.0 and 37.8 percent cases respectively.

TABLE IX

MORTALITY RATES FOR 15,221 CASES DELIVERED IN SELECTED MATERNITY CENTRES IN INDIA, JANUARY 1976 TO DECEMBER 1978

Mortality	Number	Rate/1000 Deliveries
Maternal mortality	20	1.3
Stillbirths	470	30.5
Neonatal mortality*	315	21.1
Perinatal mortality**	739	47.9

*Deaths before discharge to infants born alive.
**Neonatal deaths plus stillbirths weighing at least 1000 grams.

Maternal Correlates

While the incidence of antenatal complications was highest for older women (40+ years), intranatal complications were reported more frequently for women below 20 and above 39 years of age (Fig 4). However, these age differentials were not statistically significant.* Maternal morbidity rates for all complications and also for the antenatal, intranatal, and postnatal categories of complications were significantly higher for primiparas than for multiparas and grand multiparas (Fig 4). The antenatal complication rate was significantly lower for grand multiparas (13.2%) than for multiparas (17.1%) and primiparas (18.2%) but the morbidity differential between primiparas (18.2%) and multiparas (17.1%) was not significant (Fig 4). The incidence of iron deficiency anaemia was significantly higher for multiparas (12.1%) than for primiparas (9.8%). It was also significantly higher for grand multiparas (9.9%) than for multiparas.

The intranatal complication rate was significantly higher for primiparas (15.9%) than for multiparas (6.9%) (Fig 4). The incidence of prolonged/obstructed labour and abnormal uterine contractions was significantly higher for primiparas. Placental complications and postpartum haemorrhage were reported more frequently for multiparas and grand multiparas than for primiparas but the differences were not statistically significant. Parity differentials for postnatal complications were not statistically significant (Fig 4).

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*For this and all subsequent significance tests, the probability is greater than 95 percent

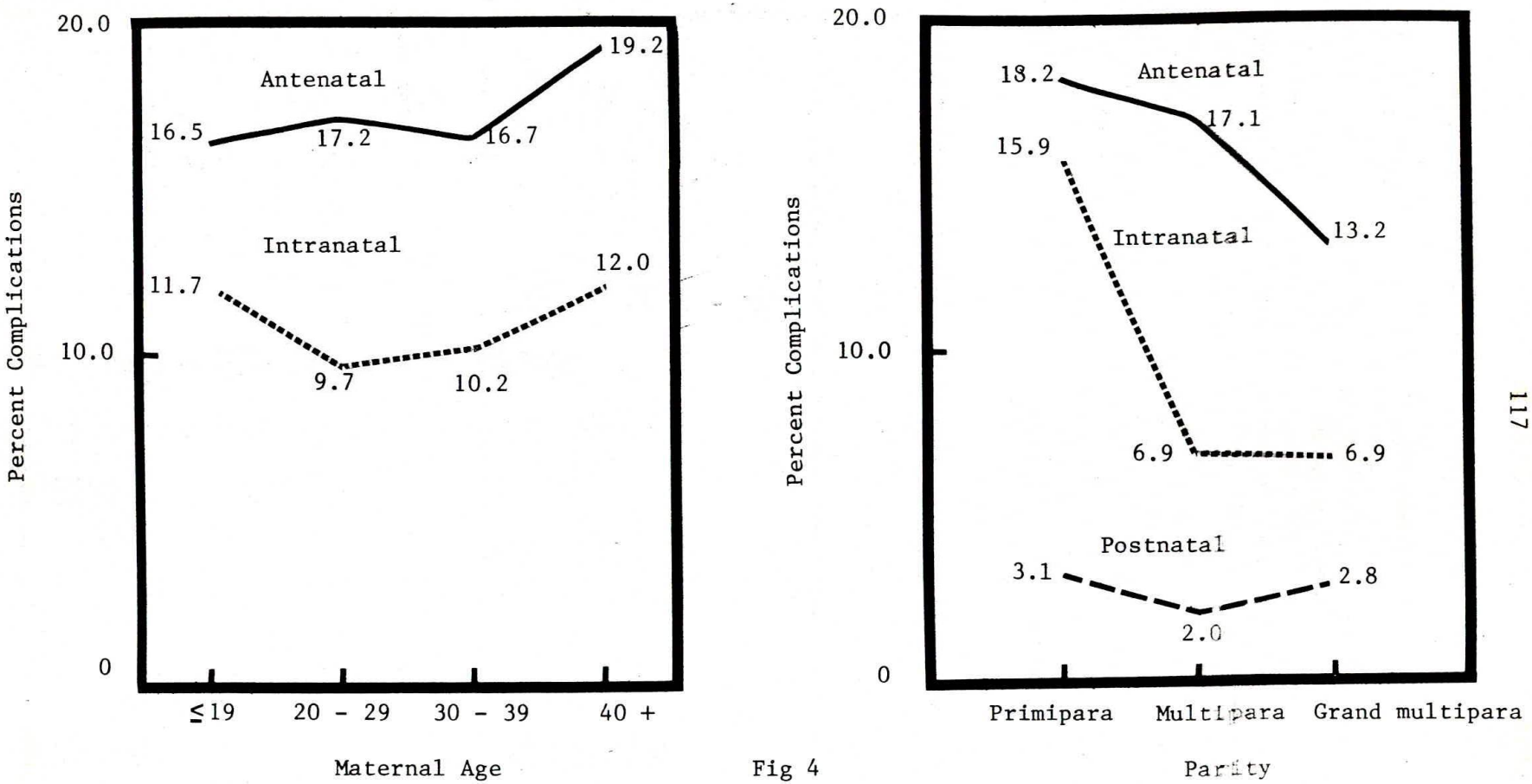

Fig 4

COMPLICATIONS BY AGE AND PARITY FOR 15,221 WOMEN DELIVERED IN SELECTED MATERNITY CENTRES IN INDIA, JANUARY 1976 TO DECEMBER 1978

Primiparas (2634.8 grams) delivered infants with lower mean birth weight than multiparas (2733.3 grams) and grand multiparas (2792.6 grams). Mean Apgar Scores were 7.4, 7.4 and 7.1 at one minute and 7.6, 7.5 and 7.2 at five minutes respectively for primiparas, multiparas and grand multiparas respectively. Parity differentials for birth weight and Apgar Score were not statistically significant. Mean birth weight was lower for anaemic (2601.8 grams) than for non-anaemic (2726.0 grams) women. This difference was also not statistically significant.

Neonatal Correlates

A significantly higher proportion of women who did not receive any antenatal care and stillbirths (60.9%) and neonatal deaths (45.1%) when compared to those whose infants were discharged alive (22.5%) (Fig 5).

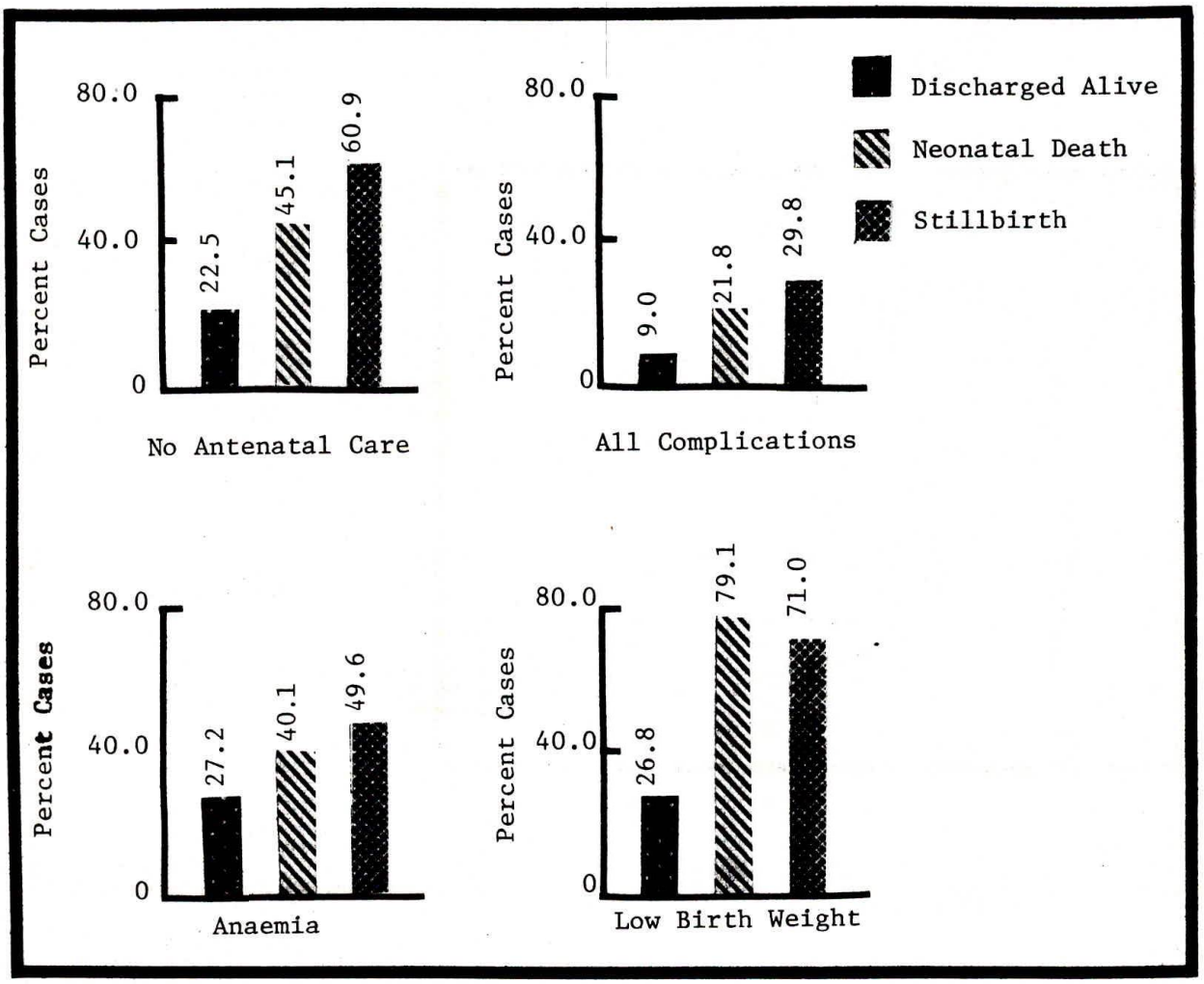

Fig 5

NEONATAL STATUS BY ANTENATAL CARE, COMPLICATIONS, ANAEMIA AND LOW BIRTH WEIGHT FOR 15,221 CASES DELIVERED IN SELECTED MATERNITY CENTRES IN INDIA, JANUARY 1976 TO DECEMBER 1978

The maternal morbidity rates for all complications as well as for the antenatal, intranatal and postnatal categories of complications were significantly higher for stillbirths and neonatal deaths than for infants who were discharged alive. These morbidity differentials were two to four fold (Fig 5). The incidence of anaemia was significantly higher for women with stillbirths (49.6%) and neonatal deaths (40.1%) than for those with infants who were discharged alive (27.2%) (Fig 5). The reported rates for prolonged/obstructed labour, placenta previa/abruptio, postpartum haemorrhage and retained products were also higher for women with stillbirths and neonatal deaths than for those with infants discharged alive. Anamolies and abnormalities were reported for the majority of the stillbirths (93.8%) and neonatal deaths (75.5%) but for only 5.1 percent of the infants discharged alive (Table VIII). The incidence of specific anamolies/abnormalities was higher for neonatal deaths and stillbirths than for infants discharged alive.

Mean gestational age was significantly higher for infants who were discharged alive (38.0 weeks) than for stillbirths (34.8 weeks) and neonatal deaths (32.4 weeks). Mean birth weight was also higher for infants discharged alive (2711.1 grams) than for neonatal deaths (1747.9 grams) and stillbirths (1969.3 grams) but the differences were not statistically significant. The incidence of low birth weight (< 2500 grams) was significantly higher for neonatal deaths (79.1%) and stillbirths (71.0%) than for infants discharged alive (26.8%) (Fig 5).

Fig 6

CONTRACEPTIVE ACCEPTANCE BEFORE AND AFTER DELIVERY FOR 15,158 WOMEN DELIVERED IN SELECTED CENTRES IN INDIA, JANUARY 1976 TO DECEMBER 1978

Acceptance of Fertility Control Methods

While 88.8 percent of the couples had not used any method of fertility control prior to the present delivery, only 34.8 percent did not agree to accept any fertility control method after delivery. There was an increase in the acceptance of all methods of fertility control except conventionals after delivery. Female sterilisation (17.3%), oral contraceptive (15.7%) and condoms (14.1%) were the most popular methods; IUDs were accepted by 10.2 percent cases (Fig 6).

DISCUSSION

The standard computer analysis from which this report is drawn , provides an insight into a wide range of factors related to obstetric care at the institutions utilising the Maternity Care Monitoring (MCM) System of the India FRP.

Generally, young, low parity women attended these institutions which drew their clientele from urban and rural areas in the ratio of 3:2. The results of this analysis showed that the key factors influencing pregnancy outcome were care during the antenatal period, morbidity experience during pregnancy and delivery, gestational age and birth weight. Women who did not receive any antenatal care experienced significantly higher foetal and neonatal mortality. Significantly higher complication rates were reported for women who had stillbirths and neonatal deaths than for those whose infants survived. Survival rates were significantly lower for infants with low birth weight and shorter gestational age . Nulliparous women were clearly a high risk group. Significant parity differentials for antenatal and intranatal complications were demonstrated. The incidence of anaemia, the most common cause of maternal morbidity, was significantly higher for multiparous women.

This analysis, not only describes the type of woman delivering at these institutions, her obstetrical background and her morbidity and mortality experience, but also substantiates the specific causes of maternal and neonatal morbidity in this population, demonstrates the multiple interactions between the various influencing variables and highlights the key factors such as parity, antenatal care, complication rates, birth weight and gestational age which effect morbidity and mortality. This feedback can be effectively utilised for defining priority problems for this population of women and instituting appropriate control measures.

MCM may also be used as a research tool to scientifically explore areas of special interest such as causes of maternal or perinatal morbidity and mortality in an area, epidemiology of low birth weight (7,8), related aspects of postpartum contraceptive acceptance (9,10) obstetrical problems (11) and a host of other unknowns in maternity care.

MCM permits evaluation of health indicators within institutions (6) or groups of institutions (4,5) and when such feedback is periodic, the effect of control measures on these health indices can be measured. Priorities may thus be effectively reassigned based on scientific study of institutional data. In addition to periodic evaluation within and between institutions, this system may be used for making comparisons between maternity care programmes operating in different parts of a country (10) and in different countries (2,12).

Thus, by incorporating the MCM system into service programmes, periodic, computerized feedback can be obtained for the review and scrutiny of administrators, health staff and policy makers to enable them to focus on priority tasks and effect appropriate measures for improving reproductive care and pregnancy outcome.

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MATERNITY CARE MONITORING PROGRAMME OF THE CHRISTIAN MEDICAL ASSOCIATION OF INDIA - EARLY EXPERIENCE OF ONE HOSPITAL

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ABSTRACT

Data on 1,226 women delivering 1,241 infants at the St. Catherine's Hospital,Kanpur, which is one of the institutions participating in the Maternity Care Monitoring (MCM) programme of the Christian Medical Association of India (CMAI) are reported. The standardized and computerized system of the India Fertility Research Programme was utilised. Data on sociodemographic characteristics, obstetric events, delivery, maternal and perinatal mortality and morbidity, birth weight and postpartum fertility control acceptance are described and discussed. MCM provides systematic feedback of reliable local data to enable epidemiologic surveillance and peer review. MCM is a useful tool for programme administrators as it assists in identifying priority problems and implementing cost-effective measures to maximally benefit high risk groups of populations served.

INTRODUCTION

Maternity Care Monitoring (MCM) is a fast growing effort to design,test and adapt data collection tools that can return information quickly to contributing centres and, in doing so, help professionals in maternity care in developing countries to better manage high risk mothers and infants before, during and after delivery (1). The Christian Medical Association of India (CMAI) has undertaken a programme funded by the Church World Service for implementing MCM in a sample of urban and rural institutions representing all the major geographical zones in India. The India Fertility Research Programme (India FRP) is monitoring and evaluating the project. This paper is a report from one of the institutions included in the programme.

MATERIALS AND METHODS

Data on 1,226 women delivering 1,241 infants at the St. Catherine's Hospital in Kanpur, Uttar Pradesh, from February 1978 to December 1978 are reported. Data on sociodemographic characteristics, obstetric history, management and outcome of delivery, antenatal complications, complications of labour, delivery and puerperium and foetal/neonatal status were recorded for consecutive deliveries using standard definitions and criteria on standard, single-page forms of the India FRP. For classifying antenatal conditions, the 9th edition of the WHO International Classification of Diseases was used.

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Definitions and Criteria

All deliveries, regardless of outcome were included in the study. Induced and spontaneous abortions with a foetus weighing less than 500 grams and gestation upto 19 weeks, molar pregnancies and false labours were excluded. The duration of pregnancy was estimated in completed weeks from the onset of the last normal menstrual period to the day of the delivery. In the case of multiple antenatal and puerperal complications, only the primary complications were reported. In the case of labour and delivery as well as foetal/neonatal conditions both primary and secondary complications were reported. Women with haemoglobin less than 10gm/100 ml were categorised as anaemic. For estimating perinatal mortality rates, stillborn infants weighing 1000 grams or more and early neonatal deaths were included. Neonatal death was defined as infant death prior to discharge from the hospital. Fertility control acceptance as discussed in this study, includes contraceptive methods planned and provided and, therefore, except in the case of women undergoing concurrent sterilisation or IUD insertion there is no evidence that the planned method was infact used. All statistical tests were performed using a significance level (p value) of 0.05.

RESULTS

Sociodemographic Characteristics

The majority of the women attending this centre for delivery were from urban (75.7%) and urban slum (23.8%) areas; only 0.6 percent of the women were from rural areas. The mean age of the women in this series was 25.4 years; 6.7 percent were below 20 and 4.3 percent were 35+ years of age. The mean number of living children was 1.2; 35.7 percent had no living child and only 16.2 percent had three or more living children. The mean educational achievement of these women was 9.6 school years; 39.9 percent had received college education. Mean age at marriage was 19.1 years and mean duration of marriage was 6.7 years. The vast majority (92.9%) were booked cases. None of the cases were admitted on an emergency basis (Table I).

Obstetric Events

The mean number of live births was 1.4. While 45.0 percent of the women had one to two live births, 32.9 percent had no live births and only 18.5 percent had three or more live births (Table II). The mean duration for which these women had breastfed their infants was 11.7 months; about a third had breastfed their infants for more than a year. In this series, 11.2 percent of the women reported infant losses. While 3.9 percent had experienced stillbirths, 15.3 and 2.5 percent respectively reported spontaneous and induced abortions (Table II).

Antenatal Care

Only 7.2 percent of the women did not receive any antenatal care; 48.4 percent had one to three antenatal visits and 38.4 percent had four to seven antenatal visits (Fig 1).

TABLE I

SOCIODEMOGRAPHIC CHARACTERISTICS OF 1,226 WOMEN DELIVERED AT THE ST CATHERINE'S HOSPITAL, KANPUR, FEBRUARY 1978 TO DECEMBER 1978

Sociodemographic Characteristics	Number	Percent
Age (Years)		
≤ 19	82	6.7
20 - 24	535	43.6
25 - 29	424	34.6
30 - 34	131	10.7
35 - 39	52	4.2
40 +	2	0.1
Mean	25.4	
Number of Living Children		
0	438	35.7
1	358	29.2
2	187	15.3
3	107	8.7
4	60	4.9
5+	32	2.6
Unknown	44	3.6
Mean	1.2	
Education (School years)		
0	153	12.5
1 - 2	5	0.4
3 - 4	20	1.6
5 - 6	137	11.2
7 - 8	173	14.1
9 - 10	248	20.2
11 - 12	180	14.7
13 +	309	25.2
Unknown	1	0.1
Mean	9.6	
Age at Marriage		
< 15	93	7.6
15 - 17	334	27.2
18 - 19	333	27.2
20 - 21	265	21.6
22 - 24	145	11.8
25 +	53	4.3
Unknown	3	0.2
Mean	19.1	
Registration Status		
Booked	1139	92.9
Not booked	85	6.9
Referred by physician	2	0.2

TABLE II

OBSTETRIC EVENTS OF 1,226 WOMEN DELIVERED AT THE ST. CATHERINE'S HOSPITAL, KANPUR, FEBRUARY 1978 TO DECEMBER 1978

Obstetric Events	Number	Percent
Live Births		
0	403	32.9
1	348	28.4
2	203	16.6
3	106	8.6
4	74	6.0
5 +	48	3.9
Unknown	44	3.6
Mean	1.4	
Infant Deaths		
0	1045	85.2
1	109	8.9
2	23	1.9
3+	5	0.4
Unknown	44	3.6
Mean	0.1	
Stillbirths		
0	1177	96.0
1	41	3.3
2 +	8	0.6
Mean	0.05	
Spontaneous Abortion		
0	1038	84.7
1	139	11.3
2 +	49	4.0
Mean	0.2	
Induced Abortion		
0	1195	97.5
1	24	2.0
2 +	7	0.5
Mean	0.03	

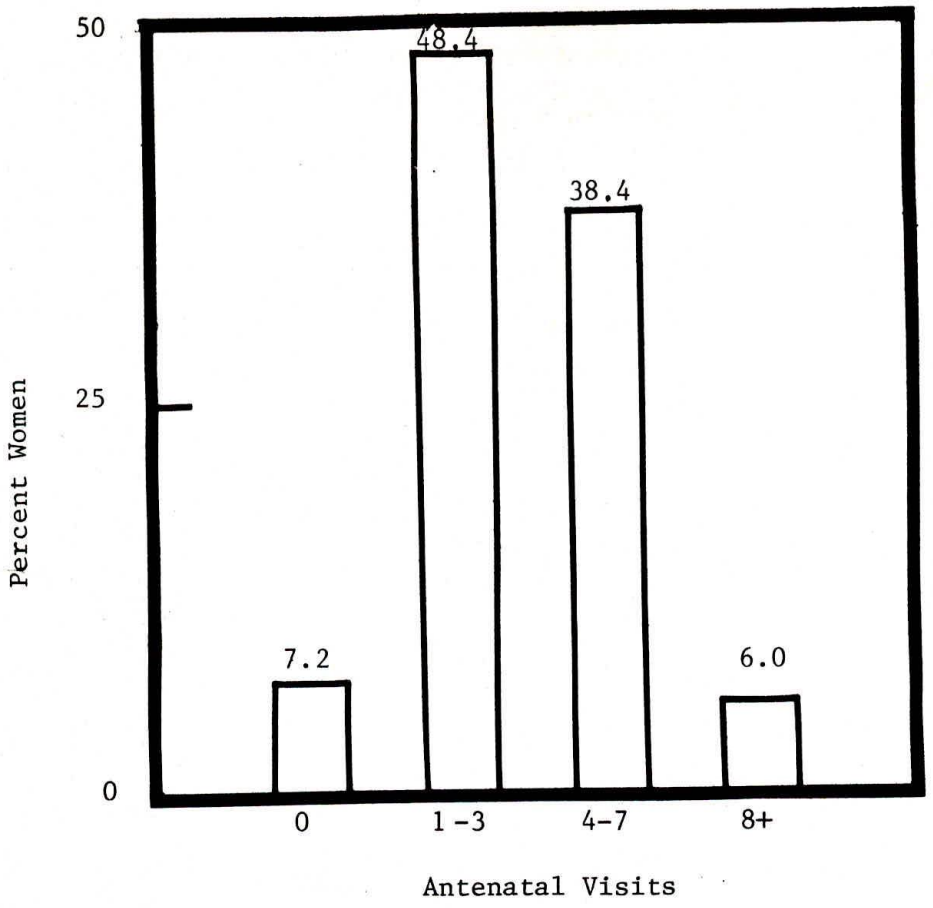

Fig 1

NUMBER OF ANTENATAL VISITS FOR 1,226 WOMEN DELIVERED AT THE ST. CATHERINE'S HOSPITAL, KANPUR, FEBRUARY 1978 TO DECEMBER 1978

The Delivery

Mean duration of pregnancy was 39.2 weeks. Labour was spontaneous in 94.9 percent cases. In 1.2 percent cases, labour was induced and 2.5 percent of the women did not go into labour. While the presentation was vertex occiput anterior in the vast majority (95.3%) of the cases, it was vertex occiput posterior in 1.2 and breech in 3.0 percent cases. Delivery was spontaneous in 91.6 percent cases. Caesarian section was performed in 3.9 percent cases and breech presentation and forceps were employed in 2.8 and 1.5 percent cases respectively (Table III).

Caesarian section was performed for all cases with cephalopelvic disproportion and placenta previa. However, it was performed only in 8.6 percent of the cases who had prolonged obstructed labour. Most (70.8%) of the cases who had a previous history of caesarian section underwent this procedure. Caesarian section was performed in 35.7 percent cases with foetal distress and 16.7 percent cases with toxemia. While all cases with breech presentation were delivered vaginally, 42.9 percent with other malpresentations underwent caesarian section. The majority (91.4%) of the cases with prolonged obstructed labour and all cases with hypertensive disorders, diabetes, cord prolapse and premature rupture of membranes were delivered vaginally (Table IV).

TABLE III

TYPE OF LABOUR, PRESENTATION AND DELIVERY OF 1,226 WOMEN DELIVERED AT THE ST. CATHERINE'S HOSPITAL, KANPUR, FEBRUARY 1978 TO DECEMBER 1978

Labour/Presentation/Delivery	Number	Percent
Type of Labour		
Spontaneous	1122	94.9
Induced	15	1.2
No labour	30	2.5
Other	15	1.3
Type of Presentation		
Vertex occiput anterior	1126	95.3
Vertex occiput posterior/transverse	14	1.2
Breech	35	3.0
Brow-face	1	0.1
Transverse lie	4	0.3
Other	2	0.2
Type of Delivery		
Spontaneous	1083	91.6
Caesarian section	46	3.9
Breech extraction	33	2.8
Forceps	18	1.5
Manual rotation	2	0.2

Note: Percentages are based on known cases only for this and all subsequent tables. Data were not reported for 44 cases.

TABLE IV

INCIDENCE OF CAESARIAN SECTION AND VAGINAL DELIVERY AMONG CASES WITH INDICATION FOR CAESARIAN SECTION FOR 1,226 WOMEN DELIVERED AT THE ST. CATHERINE'S HOSPITAL, KANPUR, FEBRUARY 1978 TO DECEMBER 1978

Indication	Caesarian Section		Vaginal Delivery	
	No.	%	No.	%
Previous caesarian section	17	70.8	7	29.2
Cephalopelvic disproportion	1	100.0	0	0.0
Placenta previa	1	100.0	0	0.0
Prolonged/obstructed labour	12	8.6	127	91.4
Breech presentation	0	0.0	34	100.0
Foetal distress	5	35.7	9	64.3
Malpresentation	3	42.9	4	57.1
Toxemia	2	16.7	10	83.3
Cord prolapse	0	0.0	1	100.0
Diabetes	0	0.0	1	100.0
Hypertensive disorders	0	0.0	4	100.0
Premature rupture of membranes	0	0.0	31	100.0
Other	1	16.7	5	83.3
No recorded conditions	4	0.4	947	99.6
TOTAL	46	3.7	1180	96.2

Maternal Morbidity

Antenatal complications were reported for 6.1 percent cases. Anaemia (2.8%) was the most commonly reported complication. Pre-eclampsia and eclampsia were reported for 1.1 and 1.0 percent cases respectively. Cephalopelvic disproportion and other hypertensive disorders were each reported for 0.1 percent cases (Table V).

TABLE V

ANTENATAL COMPLICATIONS FOR 1,226 WOMEN DELIVERED AT THE ST CATHERINE'S HOSPITAL, KANPUR, FEBRUARY 1978 TO DECEMBER 1978

Antenatal Complications	Number	Percent
Anaemia	32	2.8
Preeclampsia	12	1.1
Eclampsia	11	1.0
Cephalopelvic disproportion	1	0.1
Other hypertensive disorders	1	0.1
Diabetes	1	0.1
Other	12	1.1
TOTAL	70	6.1

Note: Data were not reported for 85 cases.

The incidence of complications reported during labour and delivery was 19.9 percent. Prolonged obstructed labour (12.0%) was, by far, the most frequently reported complication. Haemorrhage and retained products were reported for 2.2 and 0.8 percent cases and placental previa and cord prolapse were each reported for 0.2 percent cases (Table VI).

TABLE VI

COMPLICATIONS OF LABOUR/DELIVERY REPORTED FOR 1,226 WOMEN DELIVERED AT THE ST. CATHERINE'S HOSPITAL, KANPUR, FEBRUARY 1978 TO DECEMBER 1978

Complications	Number	Percent
Prolonged/obstructed labour	142	12.0
Haemorrhage	26	2.2
Retained products	10	0.8
Placenta previa	2	0.2
Cord prolapse	3	0.2
Hypertonic uterine contractions	1	0.1
Other	51	4.3
TOTAL	235	19.9

Note: Data are not reported for 44 cases.

Puerperal conditions were reported for 4.4 cases. The incidence of fever requiring antibiotics was 4.1 percent. Bleeding requiring treatment was reported for 2 (0.2%) cases and phelebitis for 1 (0.1%) case (Table VII).

TABLE VII

PUERPERAL CONDITIONS REPORTED FOR 1,226 WOMEN DELIVERED AT THE ST. CATHERINE'S HOSPITAL, KANPUR, FEBRUARY 1978 TO DECEMBER 1978

Puerperal Condition	Number	Percent
Fever requiring treatment	49	4.1
Bleeding requiring treatment	2	0.2
Phlebitis	1	0.1
TOTAL	52	4.4

Note: Data were not reported for 44 cases.

The incidence of antenatal complications was significantly higher for women of 35+ (21.3%) years of age than for those who were 18 to 34 (5.4%) years of age. Women below 18 years (12.5%) had a higher complication rate than those who were 18 to 34 years of age but the difference was not statistically significant. Complication rates during labour and delivery were higher for women under 18 years (22.2%) than for those who were 18 to 34 years (17.5%) and 35+ years of age (9.6%), but the difference was not statitically significant. No puerperal conditions were reported for women under 18 years of age, The incidence of puerperal conditions was similar for women in the 18 to 34 (4.5%) and 35+ years groups (3.8%) (Fig 2).

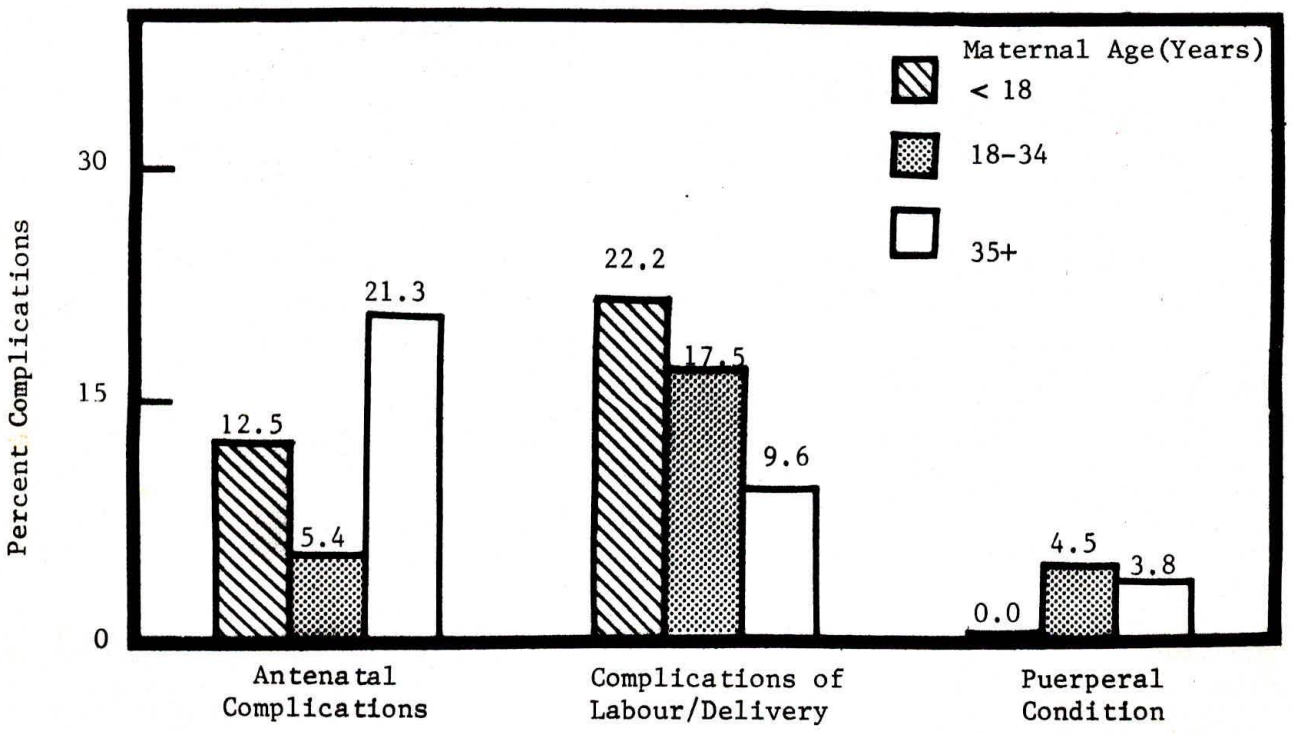

Fig 2

MATERNAL AGE BY COMPLICATIONS REPORTED FOR 1,226 WOMEN DELIVERED AT THE ST. CATHERINE'S HOSPITAL, KANPUR, FEBRUARY 1978 TO DECEMBER 1978

Antenatal complications rates were significantly higher among grandmultiparas (16.0%) and multiparas (5.4%). Primiparas (27.9%) had significantly more complications during labour and delivery than multiparas (12.0%). However, the difference in complication rates during labour and delivery between multiparas (12.0%) and grand multiparas (10.9%) were not statistically significant. The incidence of puerperal conditions was significantly higher for primiparas (6.6%) than for multiparas (3.3%). However, the difference in the incidence of puerperal conditions between grand multiparas (5.4%) and primiparas (6.6%) was not statistically significant (Fig 3).

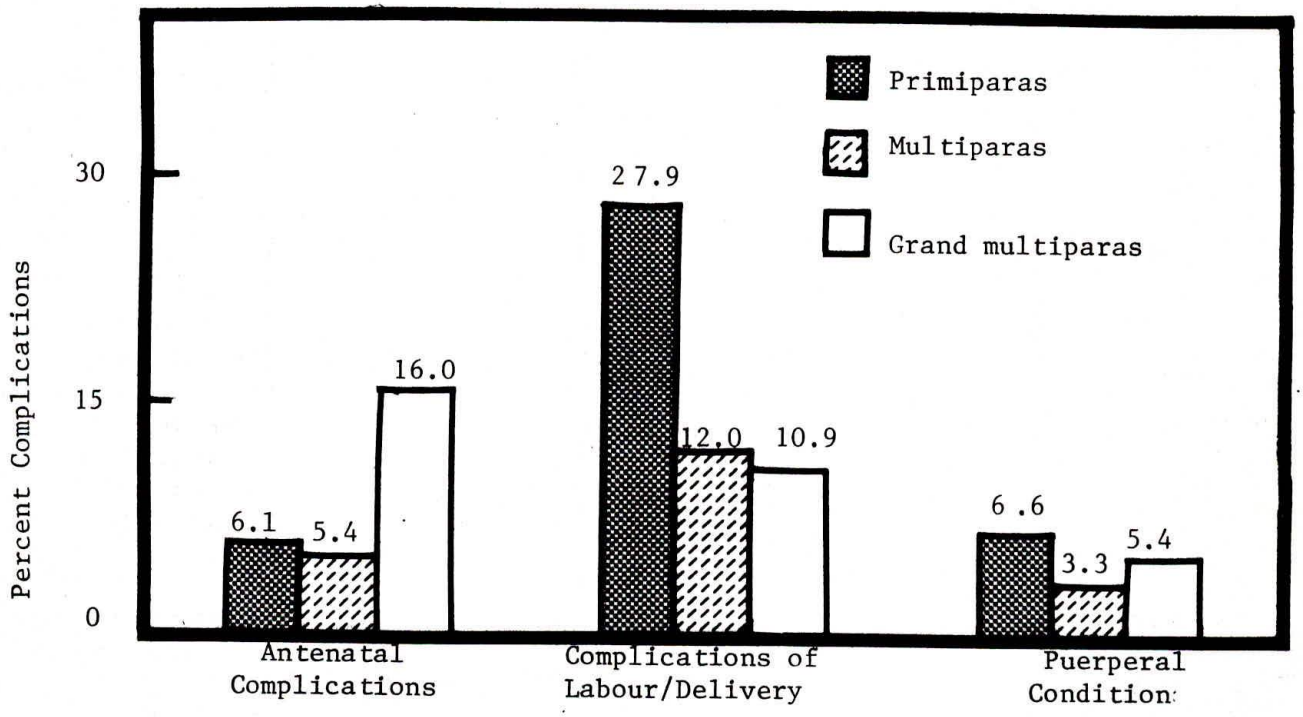

Fig 3

PARITY BY COMPLICATIONS REPORTED FOR 1,226 WOMEN DELIVERED AT THE ST. CATHERINE'S HOSPITAL, KANPUR, FEBRUARY 1978 TO DECEMBER 1978

Neonatal/Foetal Conditions

Foetal/neonatal conditions were reported for 6.0 percent cases. Foetal distress during labour and respiratory distress after delivery were reported for 3.0 and 0.5 percent cases. Major malformations were reported for 4 (0.3%) and minor malformations for 3 (0.2%) infants (Table VIII). Significantly higher rates for foetal/neonatal conditions

TABLE VIII

FOETAL/NEONATAL CONDITIONS FOR 1,226 WOMEN DELIVERED AT THE ST. CATHERINE'S HOSPITAL, KANPUR, FEBRUARY 1978 TO DECEMBER 1978

Condition	Number	Percent
Foetal distress during labour	36	3.0
Major malformations	4	0.3
Respiratory distress	6	0.5
Minor malformations	3	0.2
Trauma	1	0.1
Other	21	1.8
TOTAL	71	6.0

were reported for grandmultiparas (12.7%) and multiparas (3.4%). The incidence was higher for primiparas (8.4%) than for multiparas (3.4%) but the difference was not statistically significant. The incidence of foetal distress during labour (3.0%) was significantly higher for primiparas (5.6%) than for mulitparas (1.5%).

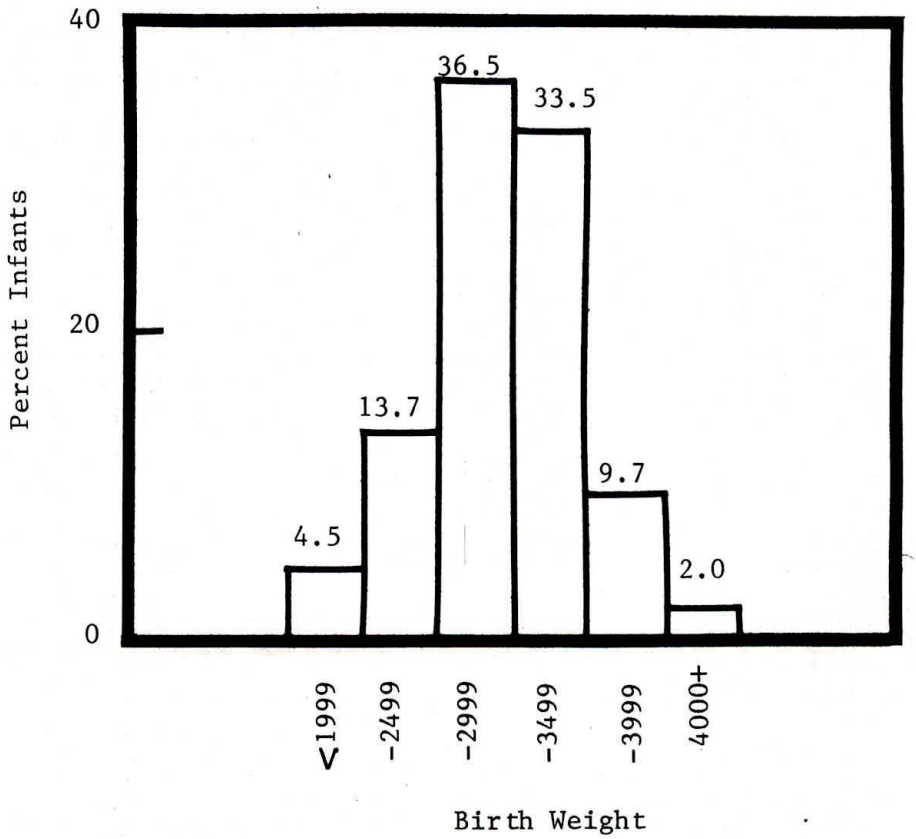

Fig 4

BIRTH WEIGHT OF 1,241 INFANTS DELIVERED AT THE ST. CATHERINE'S HOSPITAL, KANPUR, FEBRUARY 1978 TO DECEMBER 1978

Birth Weight

Mean birth weight for the study group was 2941.6 grams. In this series, 18.2 percent of the infants weighed less than 2500 grams and 4.5 percent weighed less than 2000 grams (Fig 4). Mean birth weight was significantly lower for women below 18 years of age (2458.9 grams) than for those who were 18 to 34 (2943.2 gms) and 35+ (2992.1 gms) years of age (Fig 5). Mean birth weight of infants born to primiparas (2721.6 gms) was significantly lower than of those born to multiparas (3001.9 gms) and grand multiparas (3071.8 gms) (Fig 5).

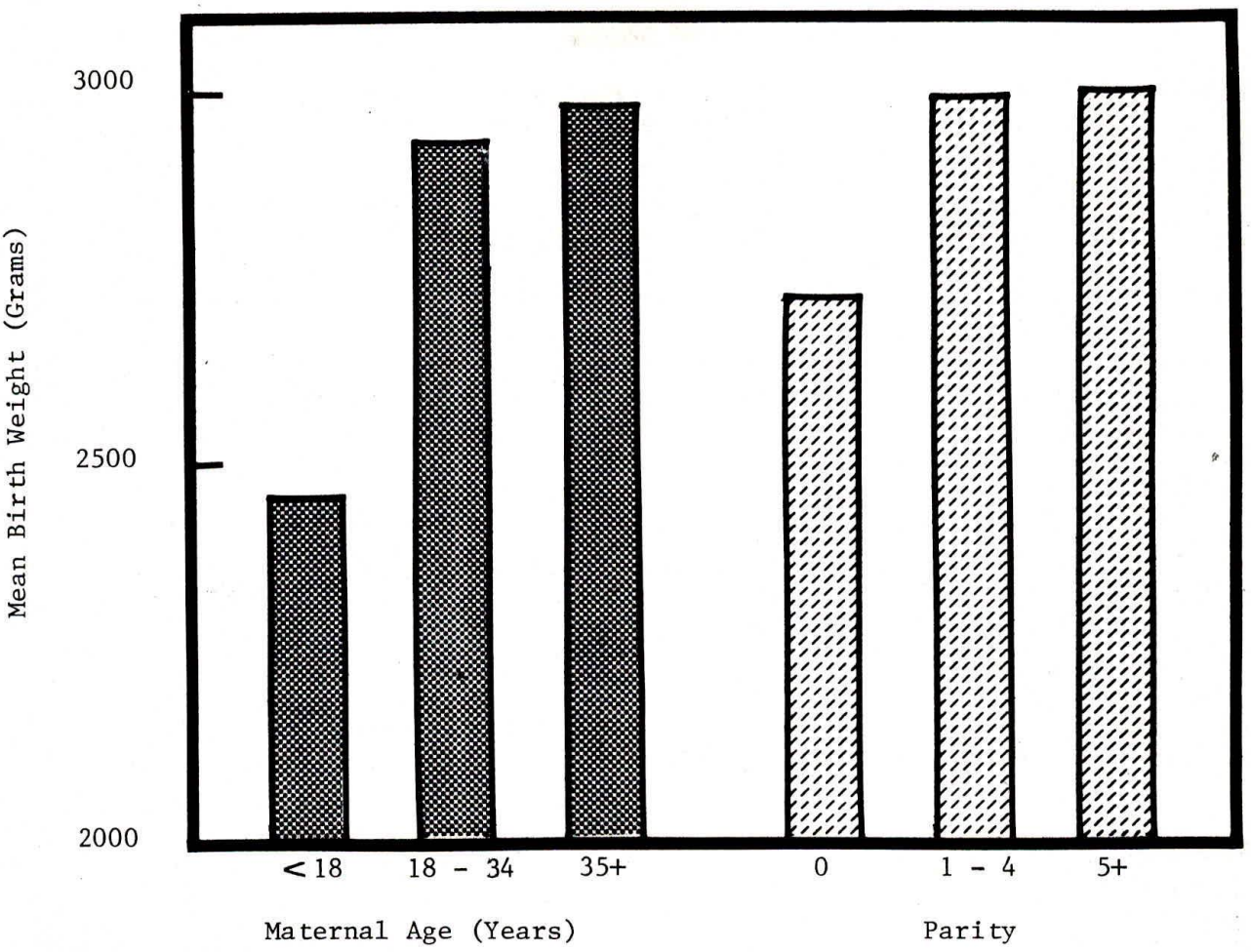

Fig 5

MEAN BIRTH WEIGHT BY MATERNAL AGE AND PARITY FOR 1,224 WOMEN DELIVERED AT THE ST. CATHERINE'S HOSPITAL, KANPUR, FEBRUARY 1978 TO DECEMBER 1978

Neonatal deaths were reported for 11.1 percent of the low birth weight infants with foetal distress in labour; only 1 (2.8%) weighing 2500+ grams died subsequent to foetal distress during labour. The incidence of low birth weight (< 2500 gms) was 75.0, 68.2 and 16.0 percent for stillbirths, neonatal deaths and infants discharged alive; the incidence of low birth weight (< 2000 gms) was 50.0, 45.4 and 2.9 percent respectively.

Mortality

There were two maternal deaths. The maternal mortality rate was 1.7 per 1000 live births. There were 17 reported stillbirths; of these 16 deaths occurred during the antepartum period and one during labour/delivery. The stillbirth and neonatal mortality rates were 13.7 per 1000 infants delivered and 18.0 per 1000 live births respectively. The perinatal mortality rate was 31.4 per 1000 infants delivered (Table IX).

TABLE IX

MORTALITY RATES REPORTED FOR 1,226 WOMEN DELIVERED AT THE ST. CATHERINE'S HOSPITAL, KANPUR, FEBRUARY 1978 TO DECEMBER 1978

Mortality	Number	Percent
Maternal mortality	2	1.7
Stillbirths	17	13.7
Neonatal mortality	22	18.0
Perinatal mortality	39	31.4

Note: 1. Maternal and neonatal mortality rates are expressed per 1000 live births and the stillbirth and perinatal mortality rates per 1000 infants delivered.

2. Neonatal mortality includes deaths before discharge to infants born alive and perinatal mortality included neonatal deaths plus stillbirths weighing at least 1000 grams.

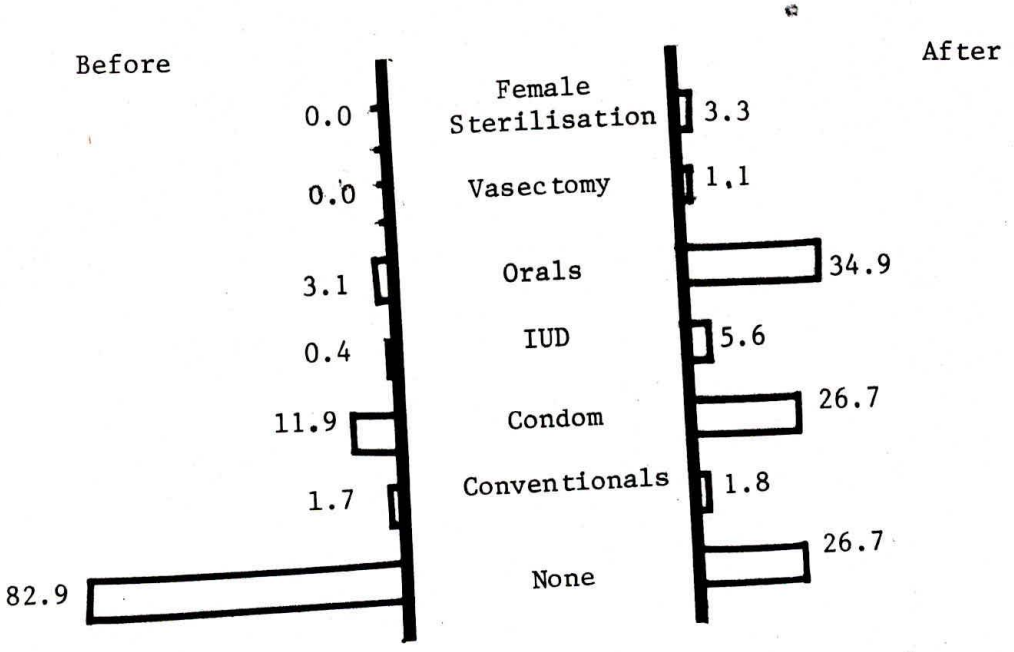

Fig 6

CONTRACEPTIVE PRACTICE OF 1,226 WOMEN BEFORE AND AFTER DELIVERY AT THE ST. CATHERINE'S HOSPITAL, KANPUR, FEBRUARY 1978 TO DECEMBER 1978

Postpartum Fertility Control

While 82.9 percent of the women had not used any method of fertility control before delivery, 73.3 percent accepted a method after delivery. Oral contraceptives (34.9%) and condoms (26.7%) were the most popular methods with this group; 3.3 percent of the women and 1.1 percent of the husbands underwent sterilisation (Fig 6). In this series, 53.3 percent of the women stated that they did not desire additional children. However, only 8 percent of the cases accepted a permanent method of fertility control; 59.7 percent accepted a temporary method. This focusses the need to concentrate efforts on motivating this group of cases.

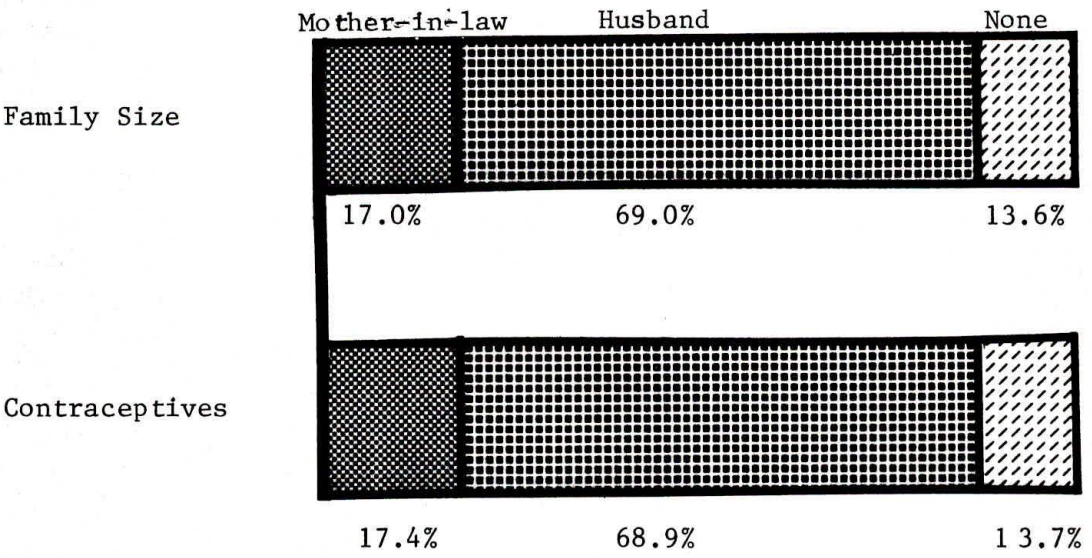

Fig 7

DISCUSSION OF FAMILY SIZE AND CONTRACEPTIVES BY 1,226 WOMEN DELIVERED AT THE ST. CATHERINE'S HOSPITAL, KANPUR, FEBRUARY 1978 TO DECEMBER 1978

While 69.0 percent of the women reported having discussed family size with their husbands 17.0 percent discussed this with their mothers-in-law and 13.6 percent reported that they did not discuss this with anyone. Methods of fertility control were discussed with the husbands and mothers-in-law by 68.9 and 17.4 percent women respectively; 13.7 percent did not discuss contraceptive methods with anyone (Fig 7).

COMMENT

This analysis provides sociodemographic and clinial baselines for maternity care provided at the hospital from which these data are drawn. The average woman who booked for delivery at this urban institution, was young and of low parity. She was fairly well educated and had received some antenatal care. Having married at the age of nineteen, she has been married for an average of six to seven years and although, in most cases, she had not used any method of fertility control before delivery, she generally accepted a temporary method of contraception after delivery. This analysis identifies the high risk groups of mothers and newborns, specifies the causes of maternal and perinatal morbidity and highlights the centre's policies for hospitalisation and for electing caesarian section and other methods for delivery. Similar baselines will be available for other CMAI institutions implementing MCM. With continued participation in the programme, periodic epidemiological analyses to evaluate performance of various participating institutions and to measure progress over time will become available.

MCM has the potential for reversing the 'top-down' planning process by stimulating the active involvement of those who are responsible for service delivery through peer review and discussion. It increases awareness, responsibility and accountability of service providers and links services in a referral system to the various levels of organized maternity care (2-3). By providing periodic, systematic feedback of such data, MCM permits evaluation of health indicators within institutions (4) and group of institutions (3,5,6) and when such feedback is periodic, the effect of control measures on these health indices can be measured. Priorities may thus be effectively assigned and reassigned based on scientific study of institutional data. This system may also be used for making comparisons between maternity care programmes operating in different parts of a country (3) and in different countries (1,2,7).

The authors propose to analyse data from several other CMAI institutions. Pooled analyses of these data will provide an overview of programme performance. By comparing results for similar institutions through this standardized system, differences in performance will be highlighted and the causes of such difference will be studied. Comparisons will also be made between urban and rural institutions as well as those in different geographical regions of the country. Continued epidemiologic surveillance by MCM will enable programme planners and service providers to formulate and implement measures for tackling priority problems to maximally benefit high risk groups served by these institutions.

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MATERNITY CARE MONITORING : A COMPARISON OF NINE CENTRES

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ABSTRACT

This paper describes the concept, scope and utilisation of the system for Maternity Care Monitoring (MCM) in service programmes. Data from nine centres are displayed on the abacus in a ranked manner, to show inter-centre differentials and to demonstrate associations between interrelated variables. Sociodemographic characteristics, mortality, morbidity, birth weight and postpartum fertility control acceptance are described. In the context of limited resources in developing countries, priorities must be clearly defined to ensure the appropriate allocation and optimal utilisation of available resources. This requires that an efficient monitoring system be built into service programmes so that present needs can be adequately assessed and future trends anticipated and planned for thorough continuous measurement and evaluation. The scope of MCM as a managerial and research tool for service providers and programme planners and as a means for providing referral linkages and staff supervision and training is discussed.

INTRODUCTION

In developing countries today, problems of high priority that need urgent attention are those related to the reduction of maternal and perinatal mortality and morbidity. To effectively combat these problems with limited available resources, it is imperative that programme priorities be clearly defined, evaluated and redefined, on a continual basis. An essential pre-requisite for this is an efficient system of monitoring which establishes sociodemographic and clinical baselines and provides periodic examination of indices of maternal and infant health. The standardized and computerized system for Maternity Care Monitoring (MCM) developed by the International Fertility Research Program (IFRP) in association with the International Federation of Gynecology and Obstetrics (FIGO) has been extensively pretested and is operational in several countries. Results to date indicated its potential internationally as a management tool (1-3).

The International Federation for Family Health (IFFH) is assisting its member countries to incorporate MCM within their service programmes. MCM enables the evaluation of maternity services and provides regular, systematic feedback of pertinent information to service providers and programme planners to enable them to implement appropriate and effective measures for improving maternity services on a continual basis. By providing sensitive indices which highlight important gaps in service delivery, MCM enables identification of priority areas for action at various service levels. This concept has the potential for stimulating peer review and discussion by service providers and, thereby, creating initiative for planning of service strategy by those responsible for providing services.

MCM is presently operational in more than thirty five institutions in India. In this paper data are reported from nine institutions with the objective of demonstrating the scope and utilisation of MCM within a country and documenting the methodology recommended by Bernard et al for comparing the service performance of various institutions (4).

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MATERIALS AND METHODS

Data are reported on 14,043 women delivering 14,364 infants at nine centres in India from January 1977 to December 1978. All these institutions utilised the computerized and standardized MCM system of the India Fertility Research Programme (India FRP). Data on sociodemographic characteristics, obstetric history, antenatal, intranatal and postnatal status of the mother, management and outcome of delivery and neonatal status were recorded using standard definitions and criteria on standard, single page forms of the India FRP.

Definitions and Criteria

All deliveries, regardless of outcome were included in the study. However, induced and spontaneous abortions (with a foetus weighing less than 500 grams and gestation upto 19 weeks), molar pregnancies and false labour were excluded. The duration of pregnancy was estimated in completed weeks from the onset of the woman's last normal menstrual period to the day of delivery.

In cases with multiple complications, only the primary complication was reported. Women with haemoglobin less than 10 grams per 100 ml were categorized as anaemic. For defining low birth weight, 2500 grams and 2000 grams were taken as cut-off points.

For estimating mortality rates, stillbirths weighing 1000 grams or more and early neonatal deaths were included. Neonatal death was defined as infant death prior to discharge from the hospital. Mean postdelivery hospitalisation at the study centres ranged from 3.4 to 7.0 nights. Reported rates are lower for centres where women were discharged before 7 days of delivery and so the reported perinatal mortality rates do not include all deaths within 7 days of birth.

Except in the case of women who underwent sterilisation or IUD insertion during their hospital stay, postpartum contraception as reported in this paper, reflects the couples' intention to contracept and not the actual use of the contraceptive method.

Methodology

As recommended by Bernard et al, the authors have utilised the abacus to show the results of MCM at the study centres and have displayed the findings in a ranked manner (4). This method is recommended for evaluating and comparing centre performance as it provides a simple means for highlighting inter-centre differences. As these differences are seen by the service providers, peer review and discussion are stimulated and consequently recommendations for action are initiated from within the group that is responsible for service delivery. The centres from which data are reported in this paper were not essentially similar in character or locale as is frequently reflected in the findings. However, the objective of this paper is not to report the findings per se but to illustrate the methodology.

In this paper, the authors have further extended the use of this methodology by utilising the abacus to not only show the inter-centre differentials, but also to demonstrate associations between two or more variables. To do this, one variable, generally the independent variable is first ranked in descending order, by centre. When this is done, the range of this variable as well as the high and low ranking centres are immediately visualised. Next, the corresponding values for the dependent variable are plotted for each centre. A consistent association between variables plotted on the abacus is suggestive of a statistically significant correlation. In this analysis, apparent associations observed on the abacus, were statistically validated. The correlation coefficients for the corresponding variables were found to be statistically significant in the vast majority of the cases. The significant level (p value) of 0.05 was used.

RESULTS

Sociodemographic Characteristics

Generally young (mean age 25.7 years), low parity (mean 1.2) women attended these institutions which drew their clientele from urban and rural areas in the ratio of 3:2. Age and parity differentials between centres were minimal (Table I and Fig 1). A similar pattern of increasing parity with increasing maternal age was seen at all centres. Parity increased from 0.2 - 0.5 at ≤ 19 years, to 1.5 - 3.4 at 35 - 39 years, and 0.0 - 4.0 at 40+ years. In one centre, however, higher parity levels were noted for each age group; 4.9 at 35 - 39 years and 6.3 at 40+ years (Fig 2). This difference was probably due to the fact that this centre derived its clientele predominantly from rural areas. The educational level of women delivering at these centres differed widely and ranged from 1.4 to 13.1 mean school years (Table I).

TABLE I

MEAN AGE, PARITY AND EDUCATION OF WOMEN DELIVERED AT NINE CENTRES IN INDIA, JANUARY 1977 TO DECEMBER 1978

Centres	No. of Cases	Mean Age	Mean Parity	Mean Education
Bombay (1)	2874	25.4	1.2	1.4
Bombay (2)	1673	25.4	1.2	4.4
Bombay (3)	1234	26.4	1.3	8.7
Bombay (4)	729	25.3	1.2	3.4
Bombay (5)	907	26.9	0.8	13.1
Baroda	3388	25.0	1.4	4.6
Manipal	1851	27.0	1.7	5.7
Delhi	904	24.9	1.3	4.7
Calcutta	483	25.6	1.1	8.3

Note: In the figures these centres are designated as follows: Bombay 1-5 as B_1-B_5, Baroda as Bd, Manipal as M, Delhi as D and Calcutta as C.

TABLE II

PRESENT AND PAST MATERNAL AND PERINATAL LOSSES FOR WOMEN DELIVERED AT NINE CENTRES IN INDIA, JANUARY 1977 TO DECEMBER 1978

Centres	Maternal Mortality Rate/1000	Stillbirth Rate/1000	Neonatal Mortality Rate/1000	Perinatal Mortality Rate/1000	Stillbirth* Rate/1000	Infant Mortality* Rate/1000
$Bombay_1$	3.6	24.8	18.8	44.4	10.7	11.6
$Bombay_2$	1.9	27.3	39.0	65.2	13.5	21.5
$Bombay_3$	1.7	15.3	15.5	30.6	12.0	6.0
$Bombay_4$	0.7	16.2	33.0	48.7	18.6	23.8
$Bombay_5$	0.8	11.0	4.5	15.4	18.9	46.8
Baroda	7.8	67.0	48.0	111.9	19.8	45.5
Manipal	1.7	26.7	14.8	41.1	28.4	33.9
Delhi	0.9	29.5	0.0	31.7	16.5	28.4
Calcutta	2.2	30.4	41.8	70.9	17.0	15.1

Note: 1. Maternal and neonatal mortality rates are expressed per 1000 live births and the stillbirth and perinatal mortality rates per 1000 infants delivered.

2. Neonatal mortality includes deaths before discharge to infants born alive and perinatal mortality includes neonatal deaths plus stillbirths weighing at least 1000 grams.

* These rates pertain to past deliveries. The stillbirth and infant mortality rates are expressed per 1000 deliveries.

Mortality

While there were wide mortality differentials between centres, most of the centres that had a higher incidence of maternal deaths also had a higher incidence of stillbirths and neonatal deaths (Table II and Fig 3). However, although the maternal mortality and stillbirth rates correlated (r +.90) significantly, these variables did not correlate significantly with the neonatal death rate.

A positive association was observed for prior infant deaths and stillbirths (Fig 4), however, the correlation coefficient (r +.64) was not statistically significant. While infant mortality rates varied considerably between centres (6.0 –46.8 per 1000 deliveries), the stillbirth differentials were not so marked (10.7 - 28.4 per 1000 deliveries) (Table II and Fig 4).

Morbidity

There was a wide variation in the incidence of antenatal (4.4% - 57.5%) and intranatal complications (7.4% - 23.7%) between centres. The incidence of postnatal complications ranged from 0.5% to 11.1%. Centres reporting a higher incidence of antenatal complications also reported a higher incidence of intranatal and postnatal complications (Table III and Fig 5). However, the correlation coefficient (r +.80) was significant for intranatal and postnatal complications. Figure 5 shows a positive association for perinatal mortality and maternal morbidity. The correlation coefficients for perinatal mortality rate and antenatal (r +.62), intranatal (r +.26) and postnatal (r +.07) complication rates were, however, not statistically significant.

TABLE III

MATERNAL MORBIDITY RATES REPORTED FOR WOMEN DELIVERED AT NINE CENTRES IN INDIA, JANUARY 1977 TO DECEMBER 1978

Centres	Percent Complications		
	Antenatal	Intranatal	Postnatal
Bombay (1)	18.9	7.7	2.8
Bombay (2)	14.9	4.8	1.6
Bombay (3)	4.4	7.4	1.5
Bombay (4)	6.3	6.6	0.5
Bombay (5)	57.5	23.7	8.8
Baroda	52.1	11.5	2.4
Manipal	12.7	15.6	3.1
Delhi	7.0	17.2	2.5
Calcutta	34.1	19.8	11.1

Note: In the case of multiple antenatal, intranatal and postnatal complications only the primary complications are reported.

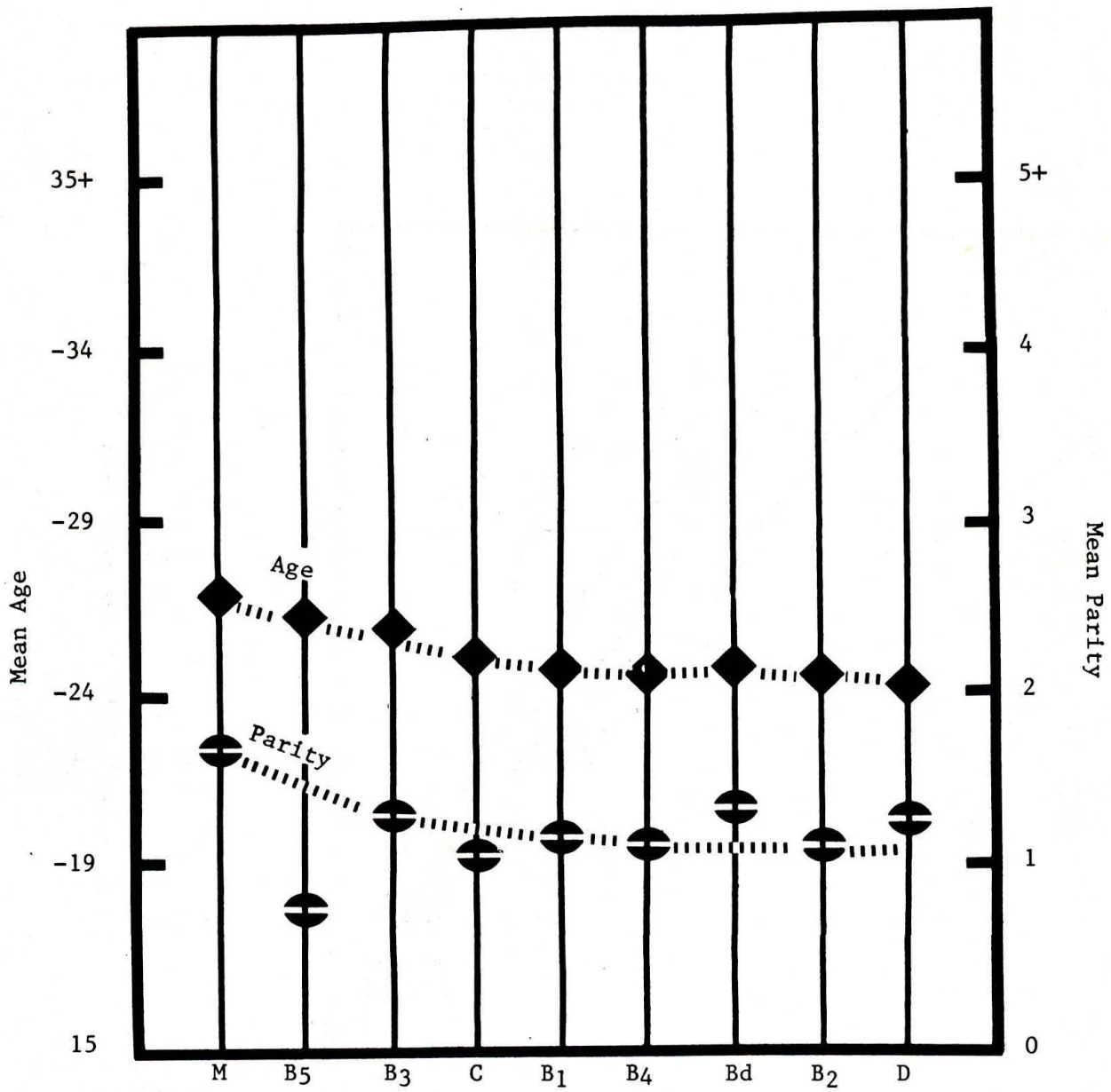

Fig 1

MEAN MATERNAL AGE AND PARITY FOR WOMEN DELIVERED AT NINE CENTRES IN INDIA, JANUARY 1977 TO DECEMBER 1978

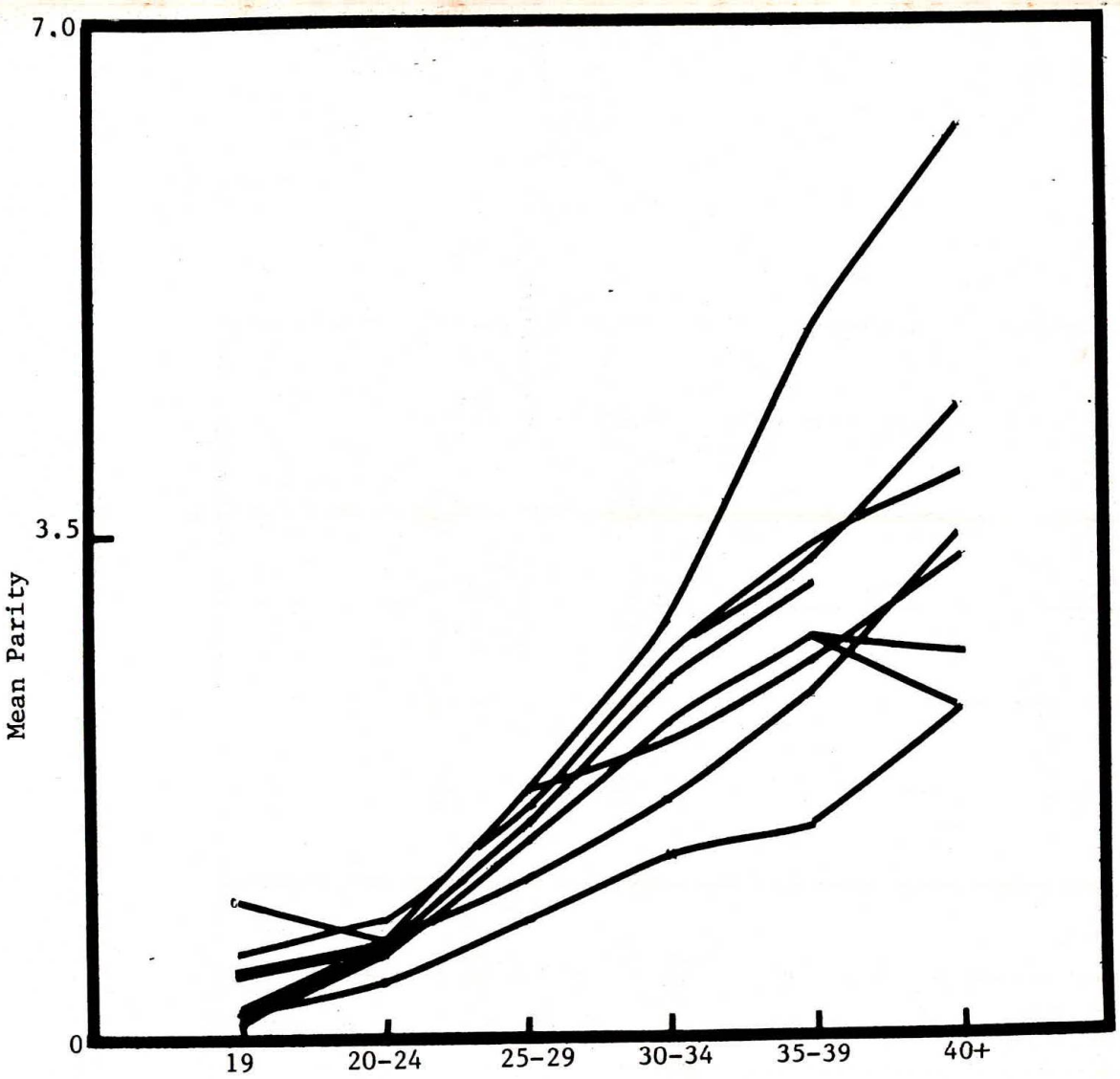

Fig 2

MATERNAL AGE BY MEAN PARITY FOR WOMEN DELIVERED AT NINE CENTRES IN INDIA, JANUARY 1977 TO DECEMBER 1978

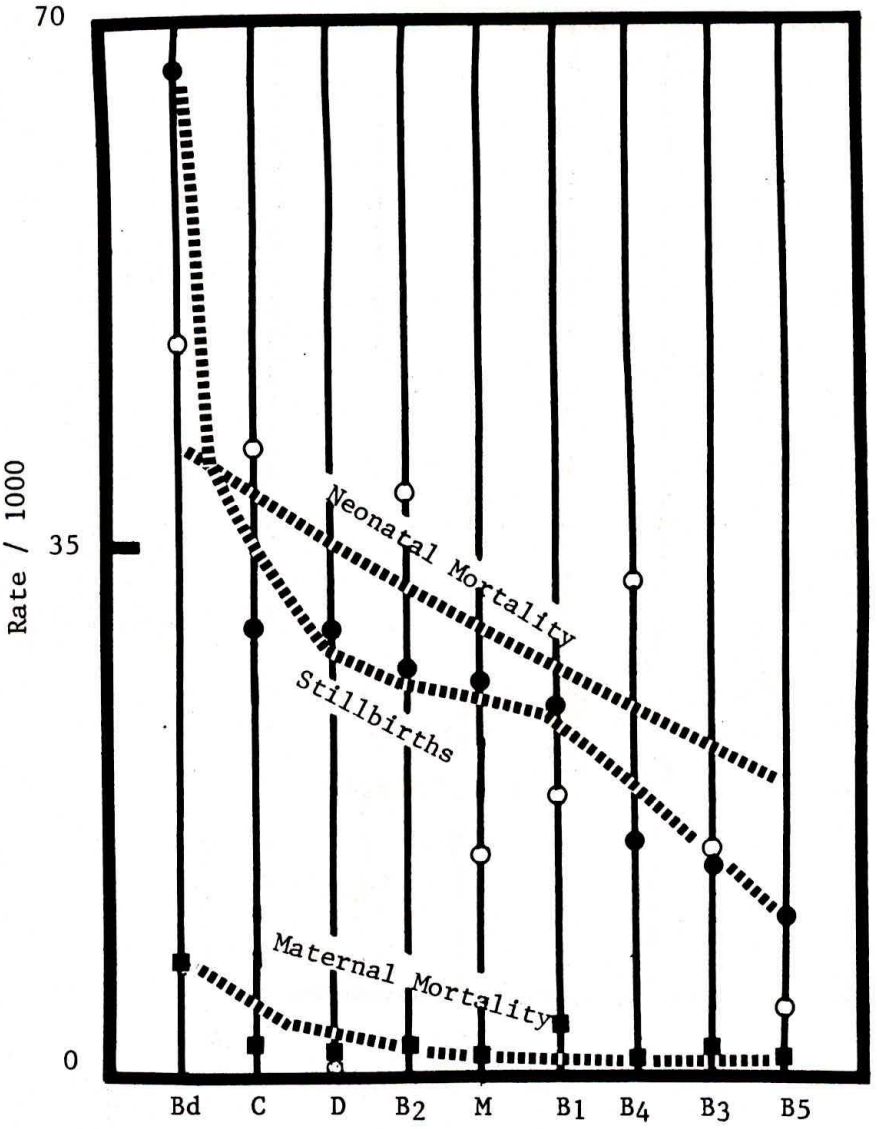

Fig 3

MATERNAL AND NEONATAL MORTALITY RATES AND STILLBIRTH RATES REPORTED FOR WOMEN DELIVERED AT NINE CENTRES IN INDIA, JANUARY 1977 TO DECEMBER 1978

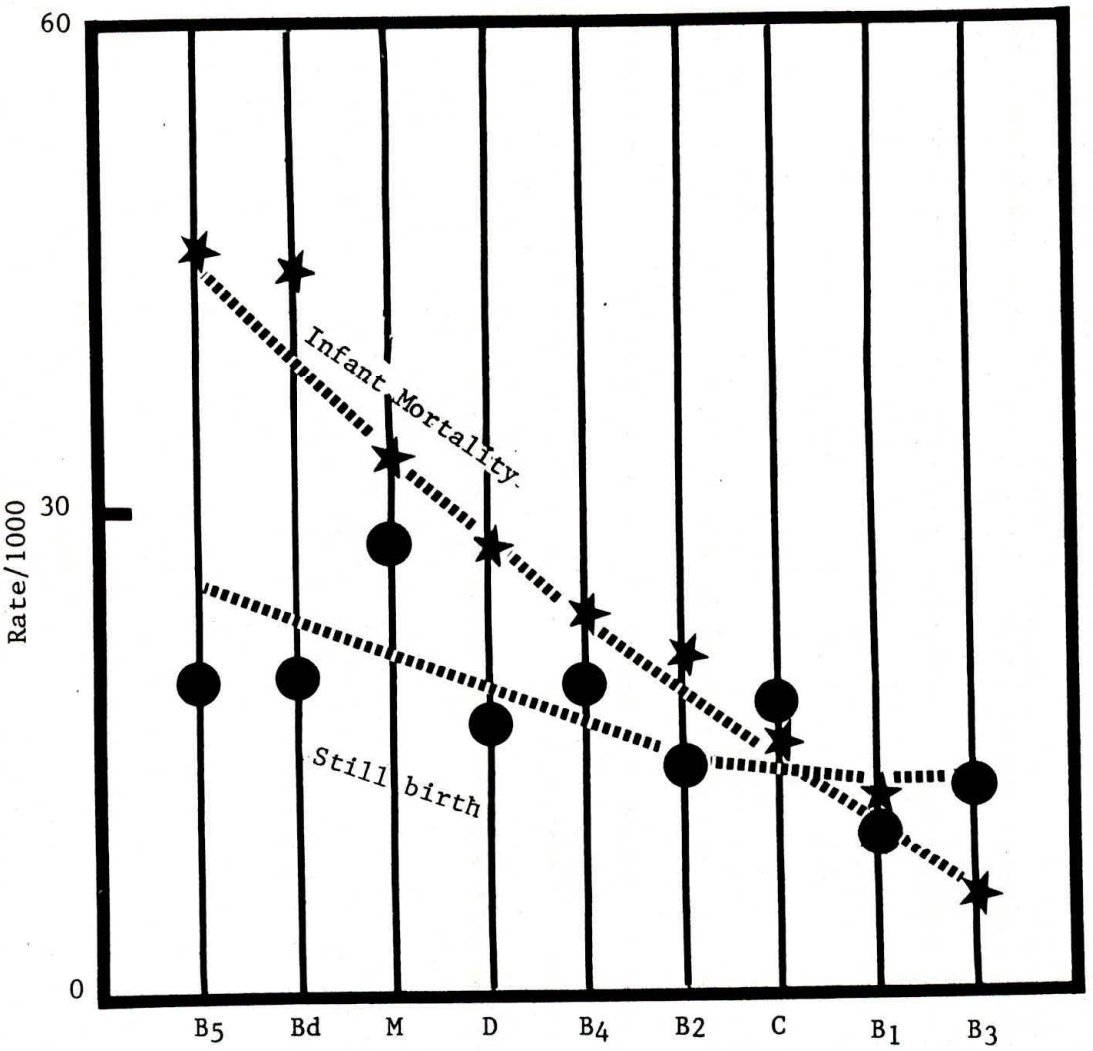

Fig 4

PREVIOUS INFANT MORTALITY RATES AND STILLBIRTH RATES REPORTED BY WOMEN DELIVERED AT NINE CENTRES IN INDIA, JANUARY 1977 - TO DECEMBER 1978

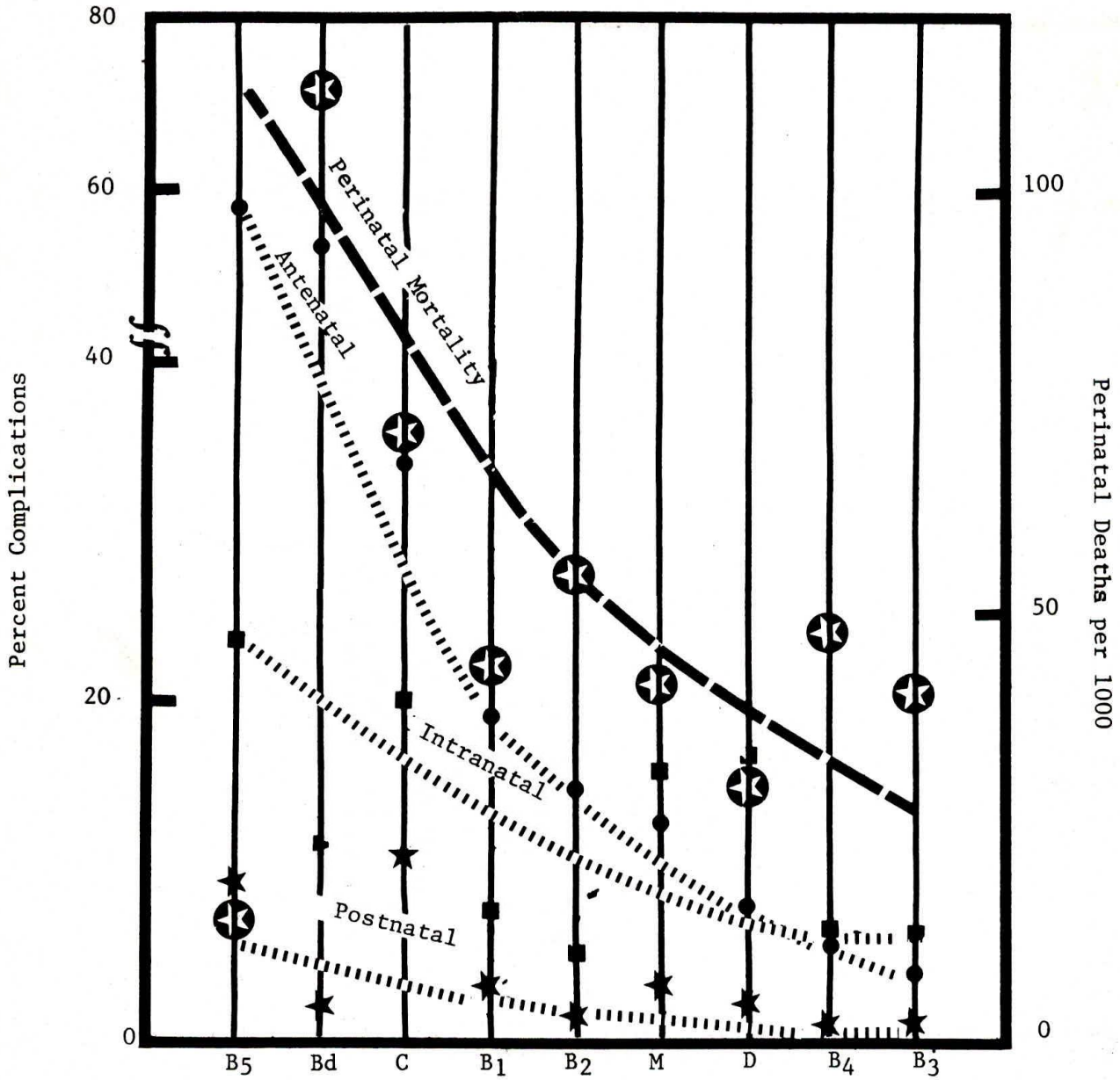

Fig 5

MATERNAL MORBIDITY RATES AND PERINATAL MORTALITY RATES FOR WOMEN DELIVERED AT NINE CENTRES IN INDIA, JANAURY 1977 TO DECEMBER 1978

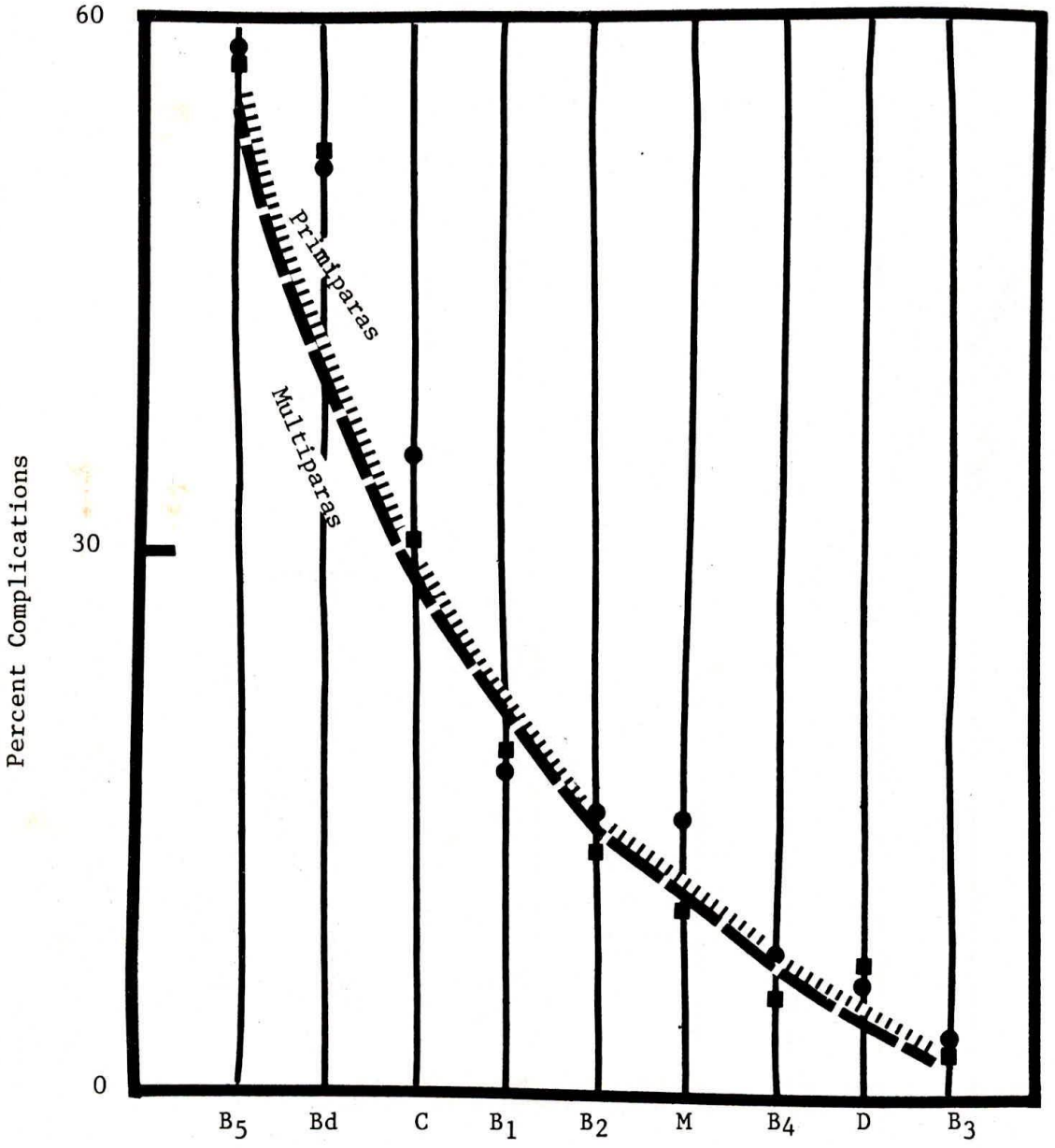

Fig 6

ANTENATAL COMPLICATION RATES REPORTED FOR PRIMIPAROUS AND MULTIPAROUS WOMEN DELIVERED AT NINE CENTRES IN INDIA, JANUARY 1977 TO DECEMBER 1978

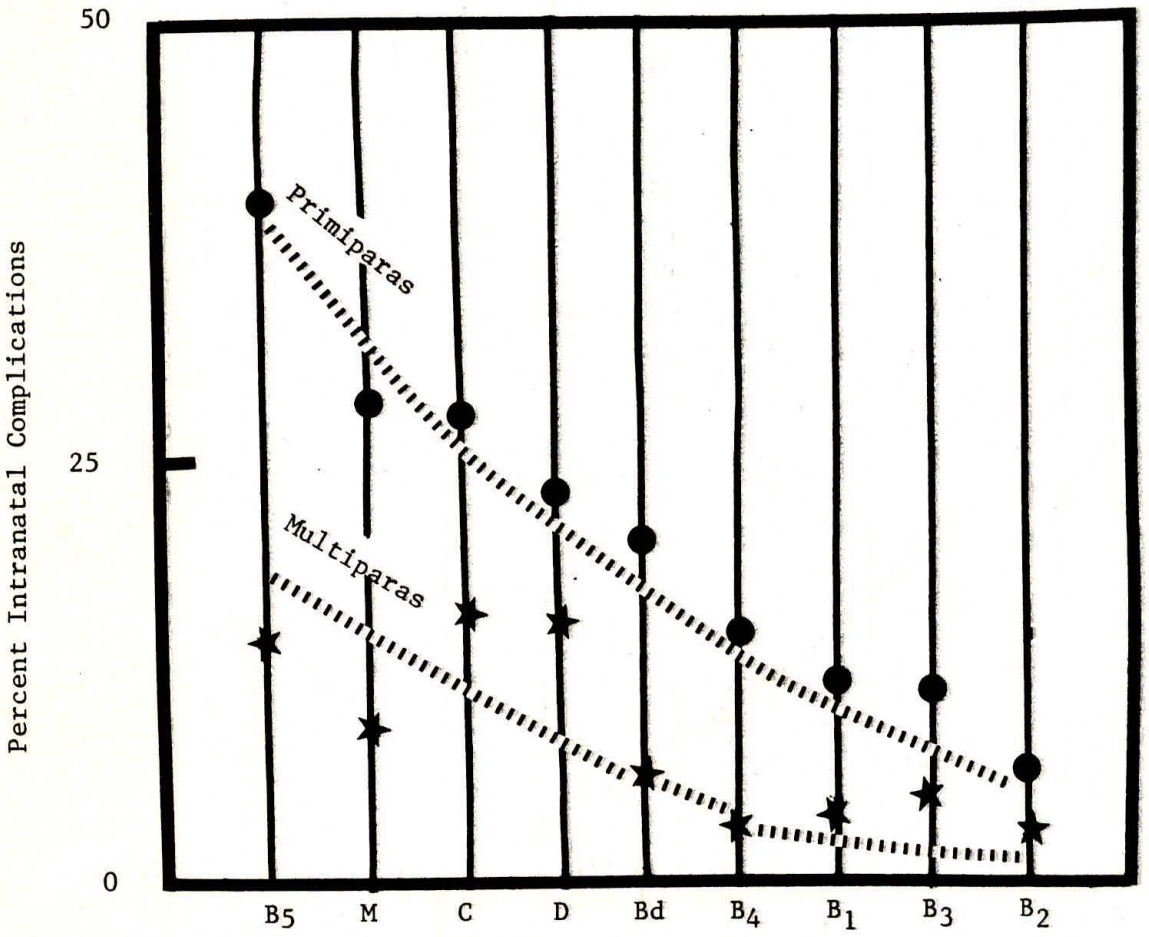

Fig 7

INTRANATAL COMPLICATIONS REPORTED FOR PRIMIPAROUS AND MULTIPAROUS WOMEN DELIVERED AT NINE CENTRES IN INDIA, JANUARY 1977 TO DECEMBER 1978

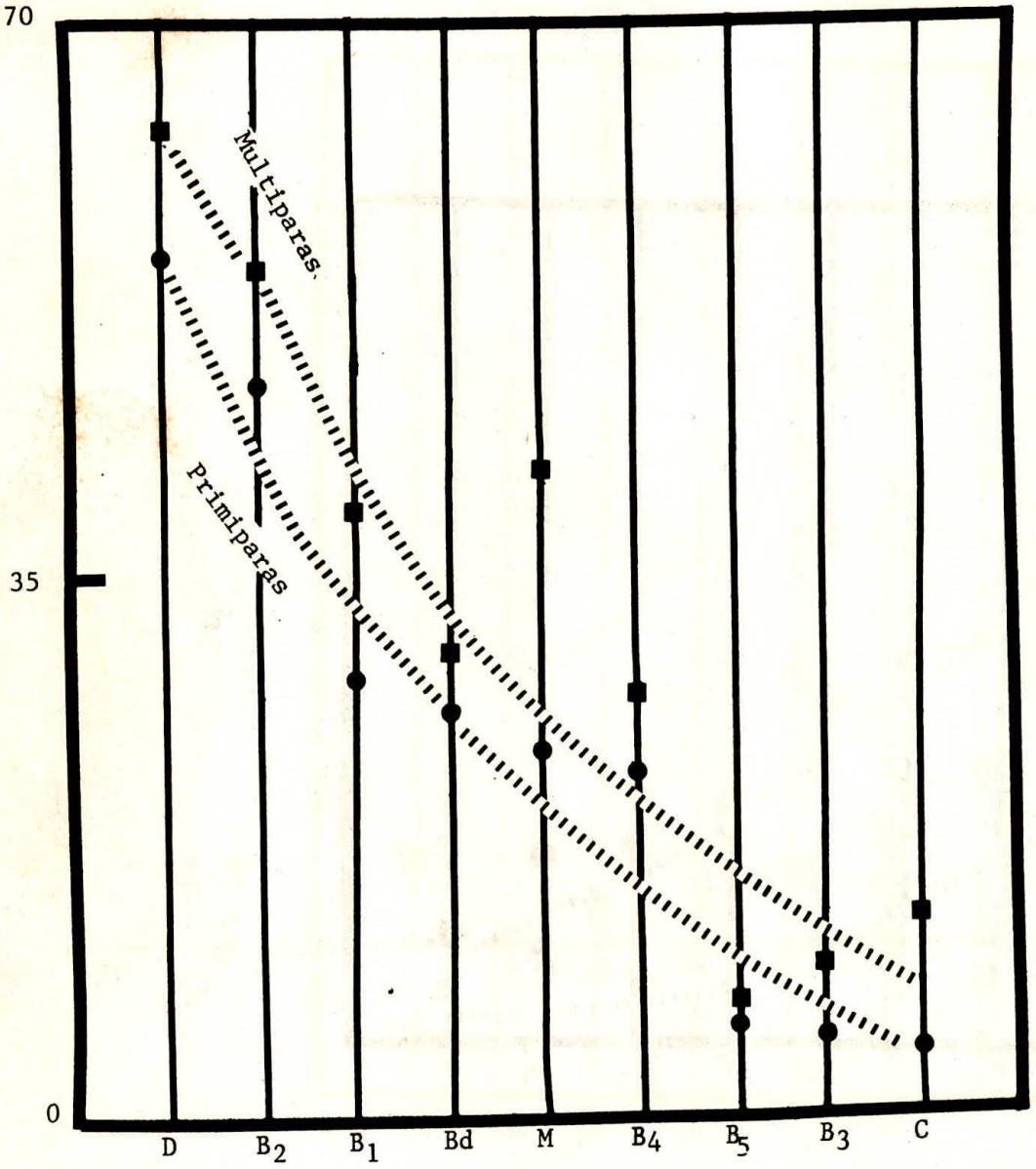

Fig 8

INCIDENCE OF ANAEMIA IN PRIMIPARAOUS AND MULTIPAROUS WOMEN DELIVERED AT NINE CENTRES IN INDIA, JANUARY 1977 TO DECEMBER 1978

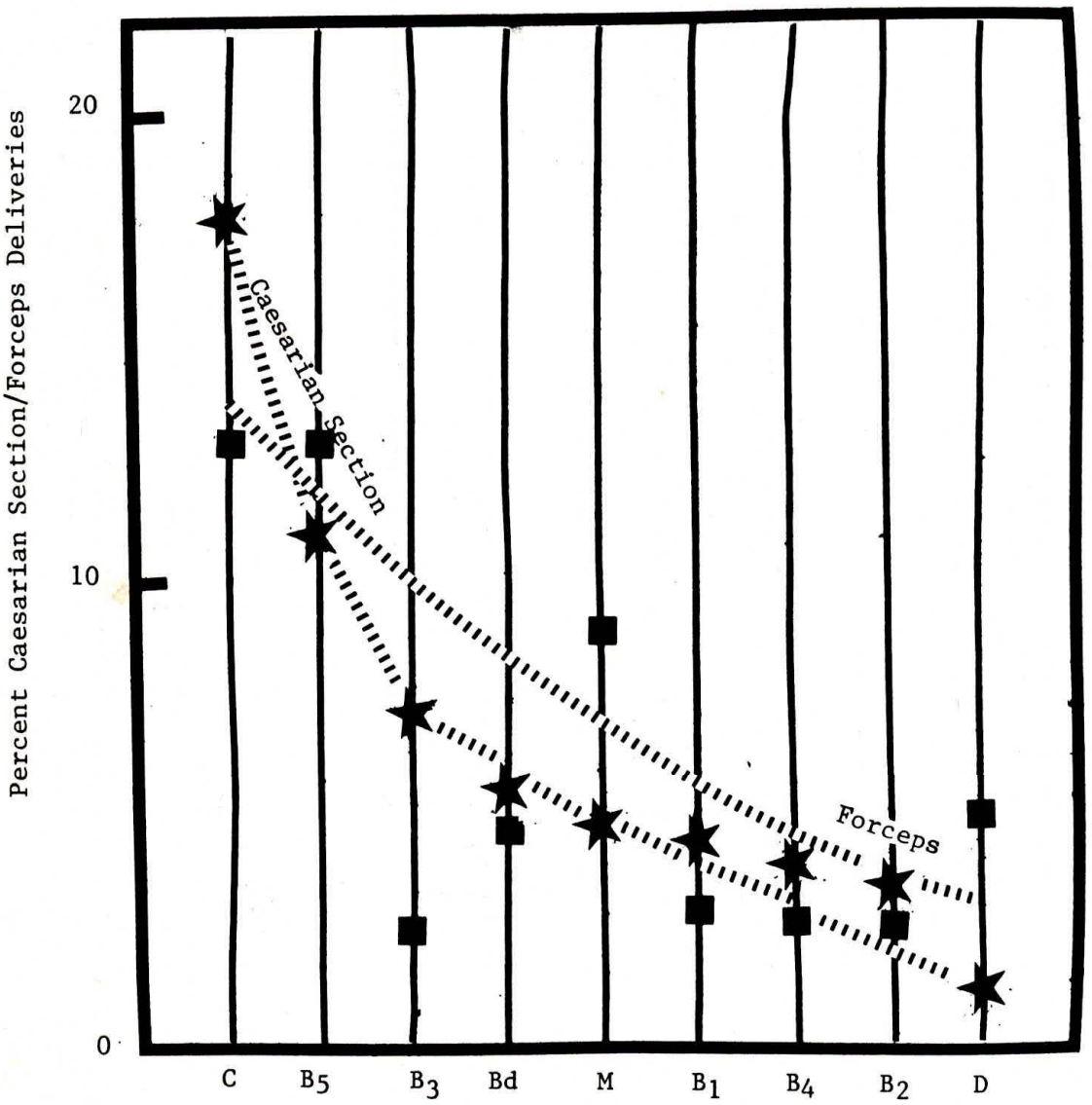

Fig 9

THE INCIDENCE OF CAESARIAN SECTION AND FORCEPS DELIVERIES FOR WOMEN DELIVERED AT NINE CENTRES IN INDIA, JANUARY 1977 TO DECEMBER 1978

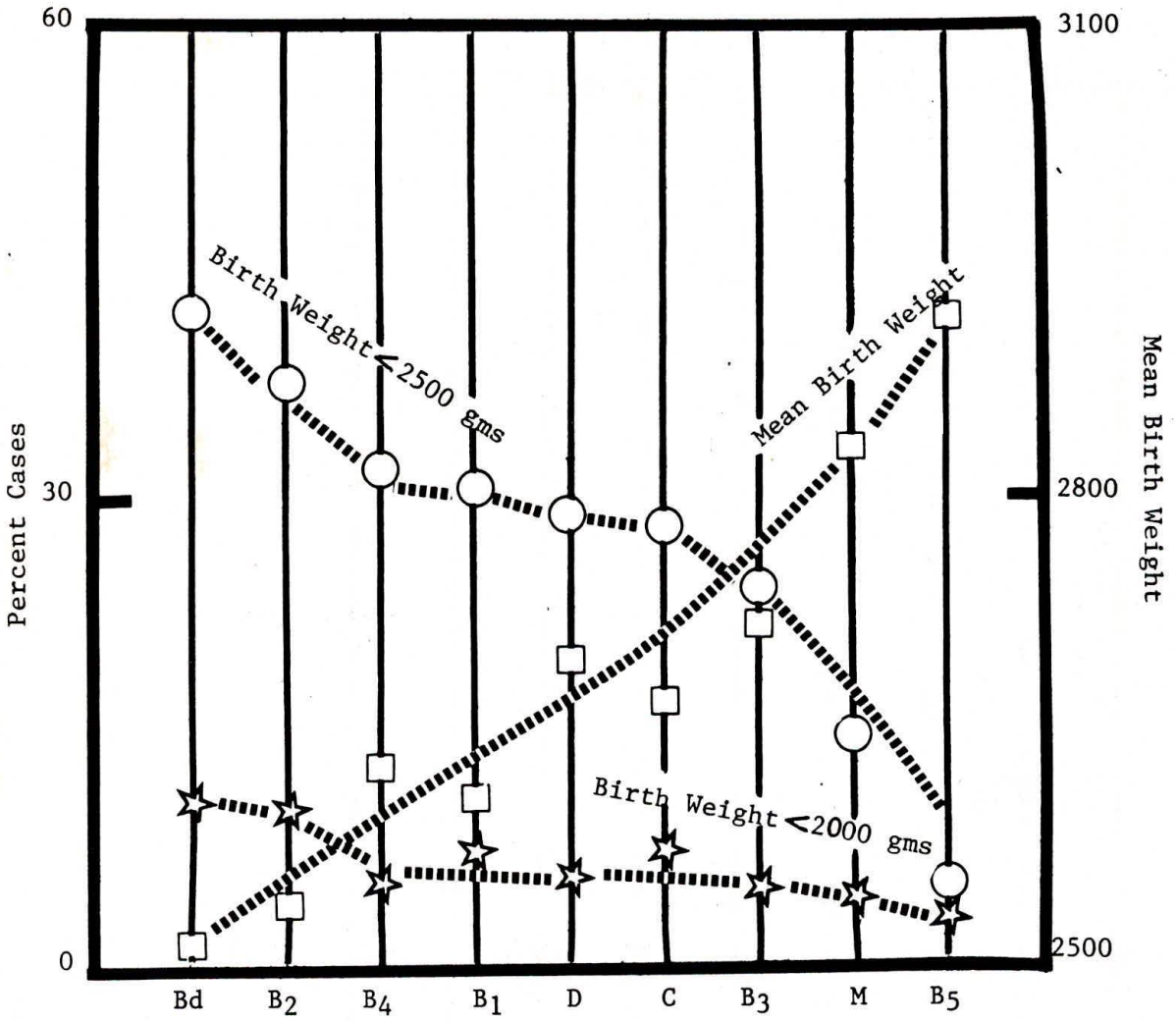

Fig 10

MEAN BIRTH WEIGHT AND PERCENTAGE OF LOW BIRTH WEIGHT INFANTS DELIVERED AT NINE CENTRES IN INDIA, JANUARY 1977 TO DECEMBER 1978

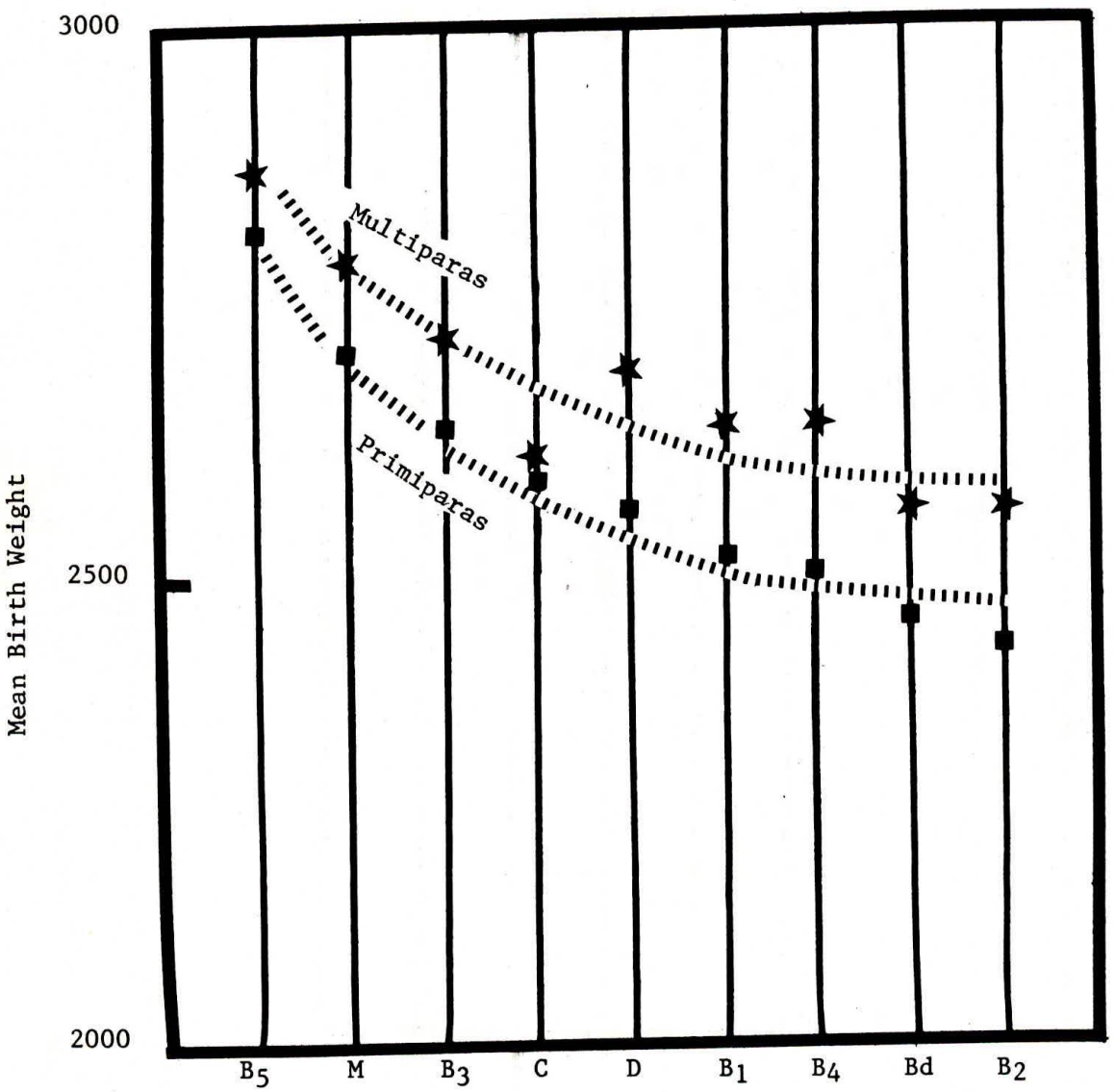

Fig 11

MEAN BIRTH WEIGHT FOR PRIMIPAROUS AND MULTIPAROUS WOMEN DELIVERED AT NINE CENTRES IN INDIA, JANUARY 1977 TO DECEMBER 1978

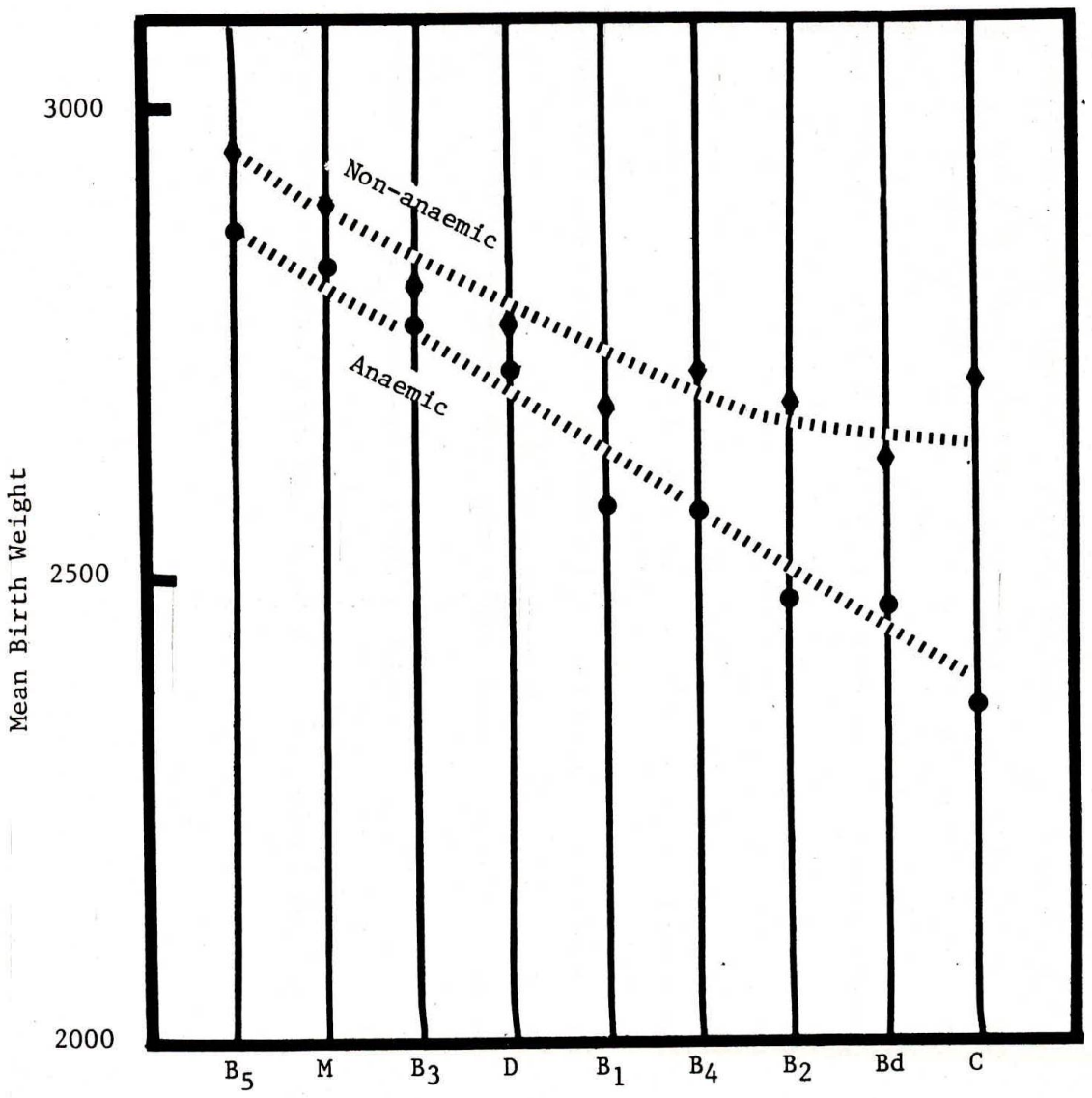

Fig 12

MEAN BIRTH WEIGHT FOR ANAEMIC AND NON-ANAEMIC WOMEN DELIVERED AT NINE CENTRES IN INDIA, JANUARY 1977 TO DECEMBER 1978

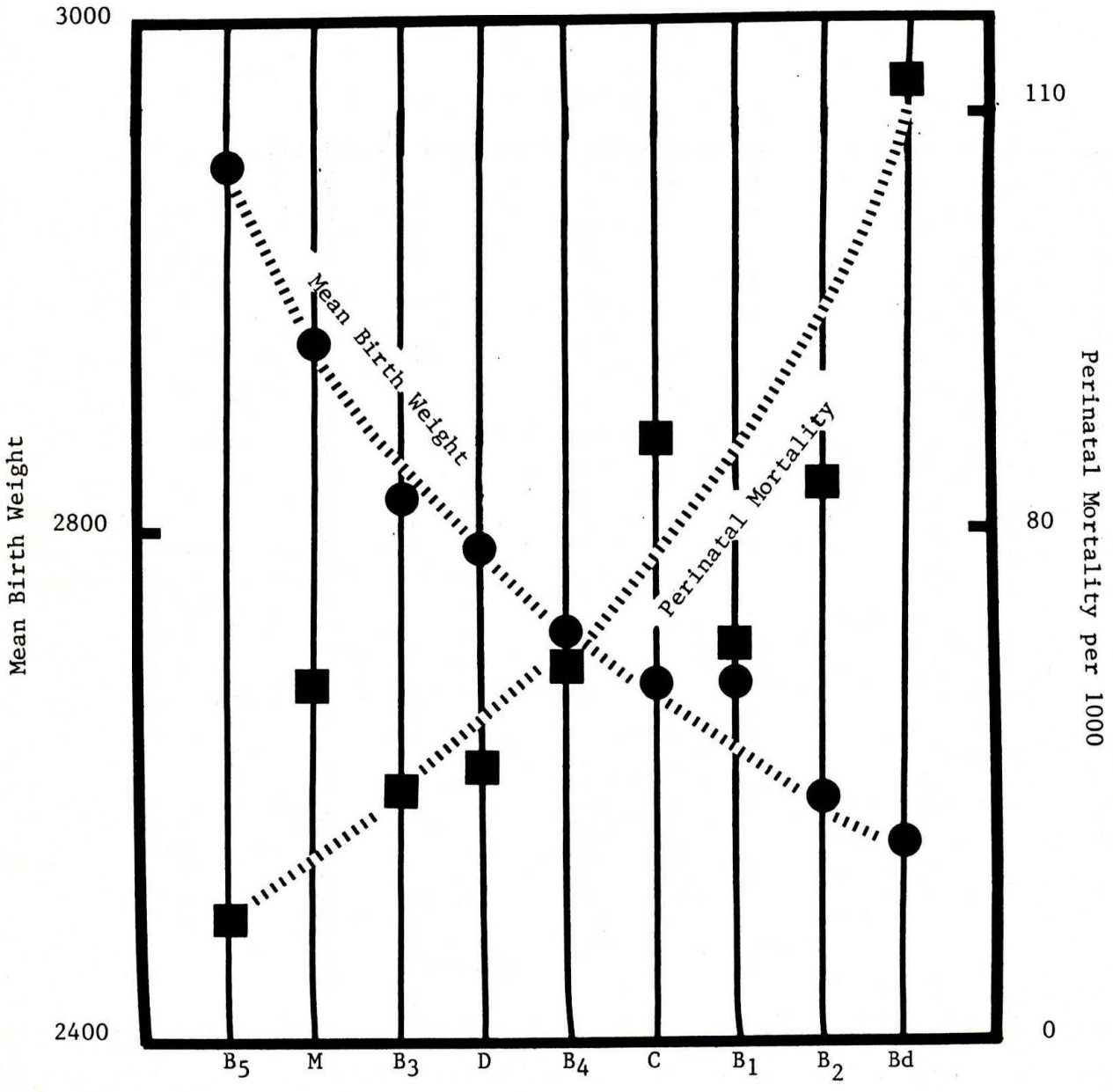

Fig 13

MEAN BIRTH WEIGHT AND PERINATAL MORTALITY FOR WOMEN DELIVERED AT NINE CENTRES IN INDIA, JANUARY 1977 TO DECEMBER 1978

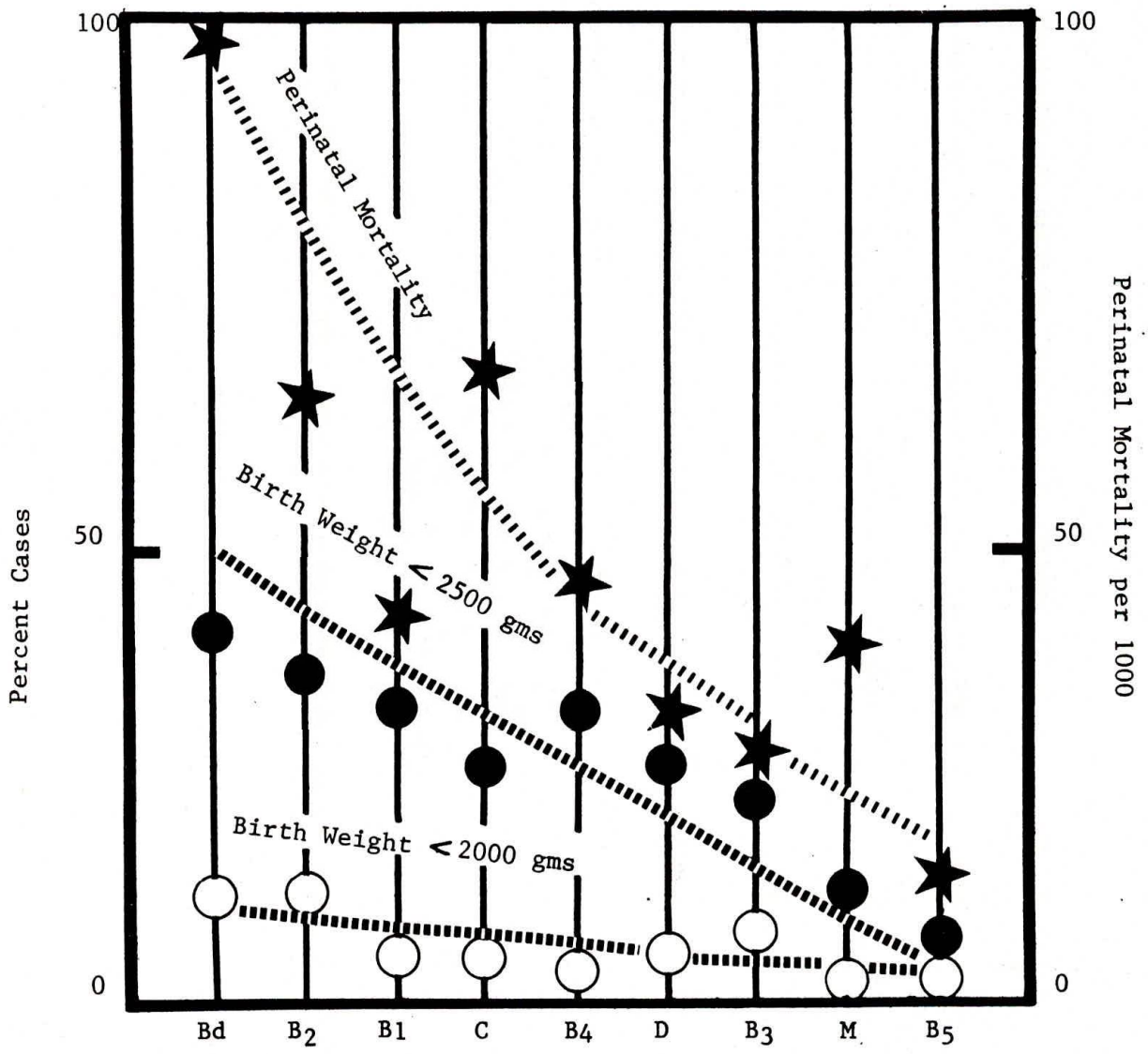

Fig 14

THE INCIDENCE OF LOW BIRTH WEIGHT AND PERINATAL MORTALITY FOR INFANTS DELIVERED AT NINE CENTRES IN INDIA, JANUARY 1977 TO DECEMBER 1978

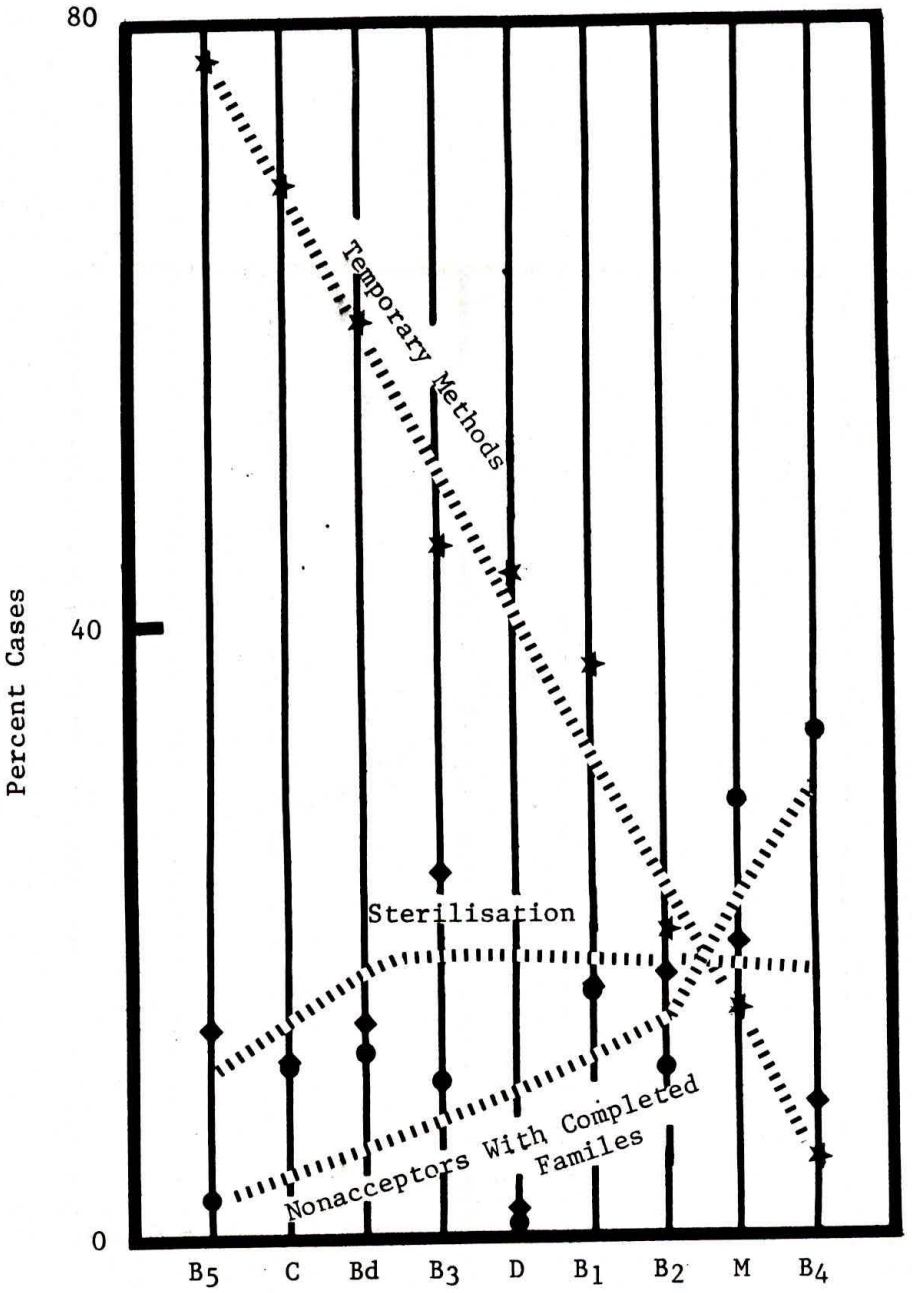

Fig 15

POSTPARTUM ACCEPTANCE OF PERMANENT AND TEMPORARY METHODS OF FERTILITY CONTROL AND NON-ACCEPTANCE OF FERTILITY CONTROL METHODS BY WOMEN WHO HAVE COMPLETED THEIR DESIRED FAMILY SIZE AT NINE CENTRES IN INDIA, JANUARY 1977 TO DECEMBER 1978

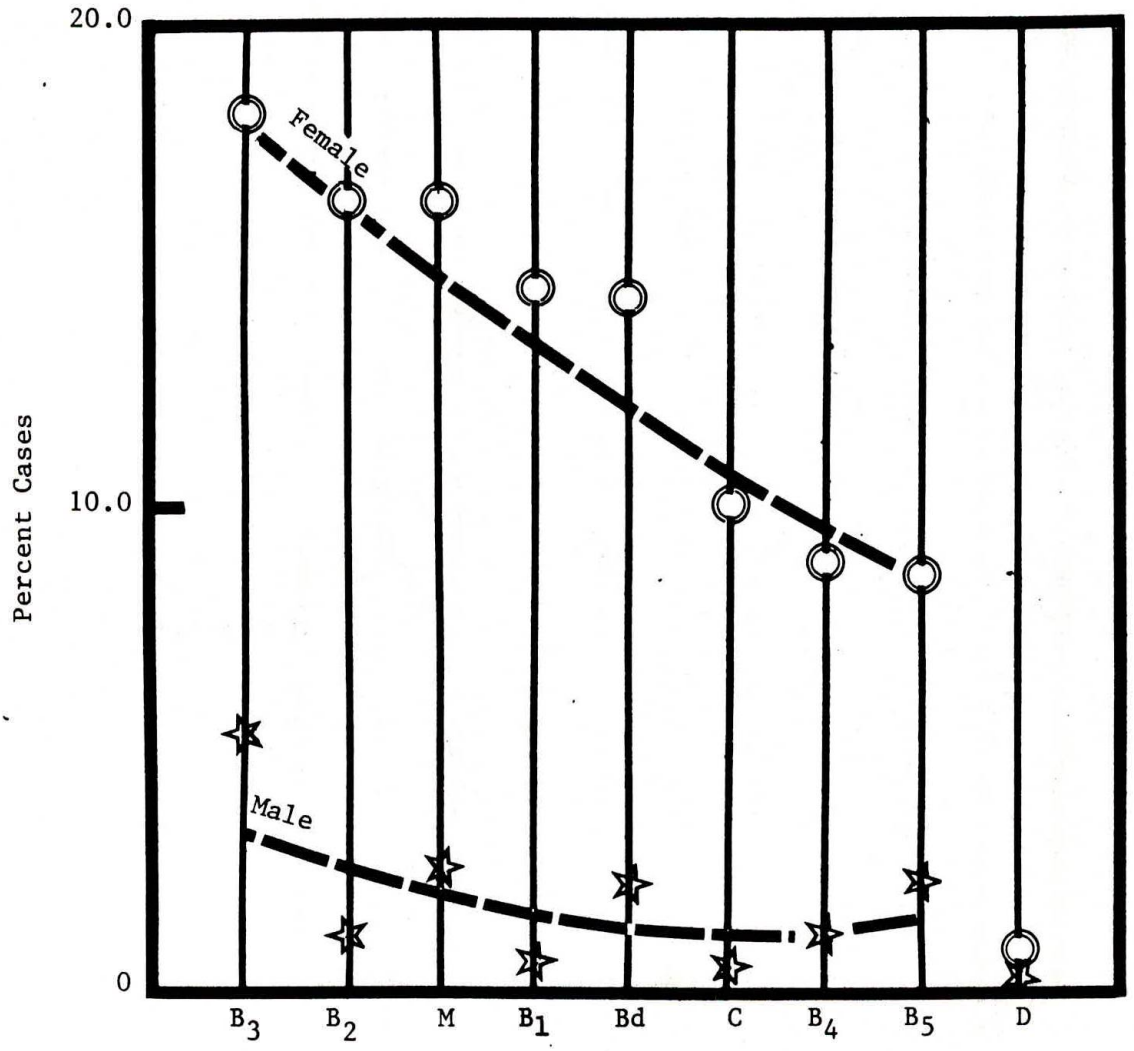

Fig 16

FEMALE AND MALE STERILISATION ACCEPTED BY WOMEN DELIVERED AT NINE CENTRES IN INDIA, JANUARY 1977 TO DECEMBER 1978

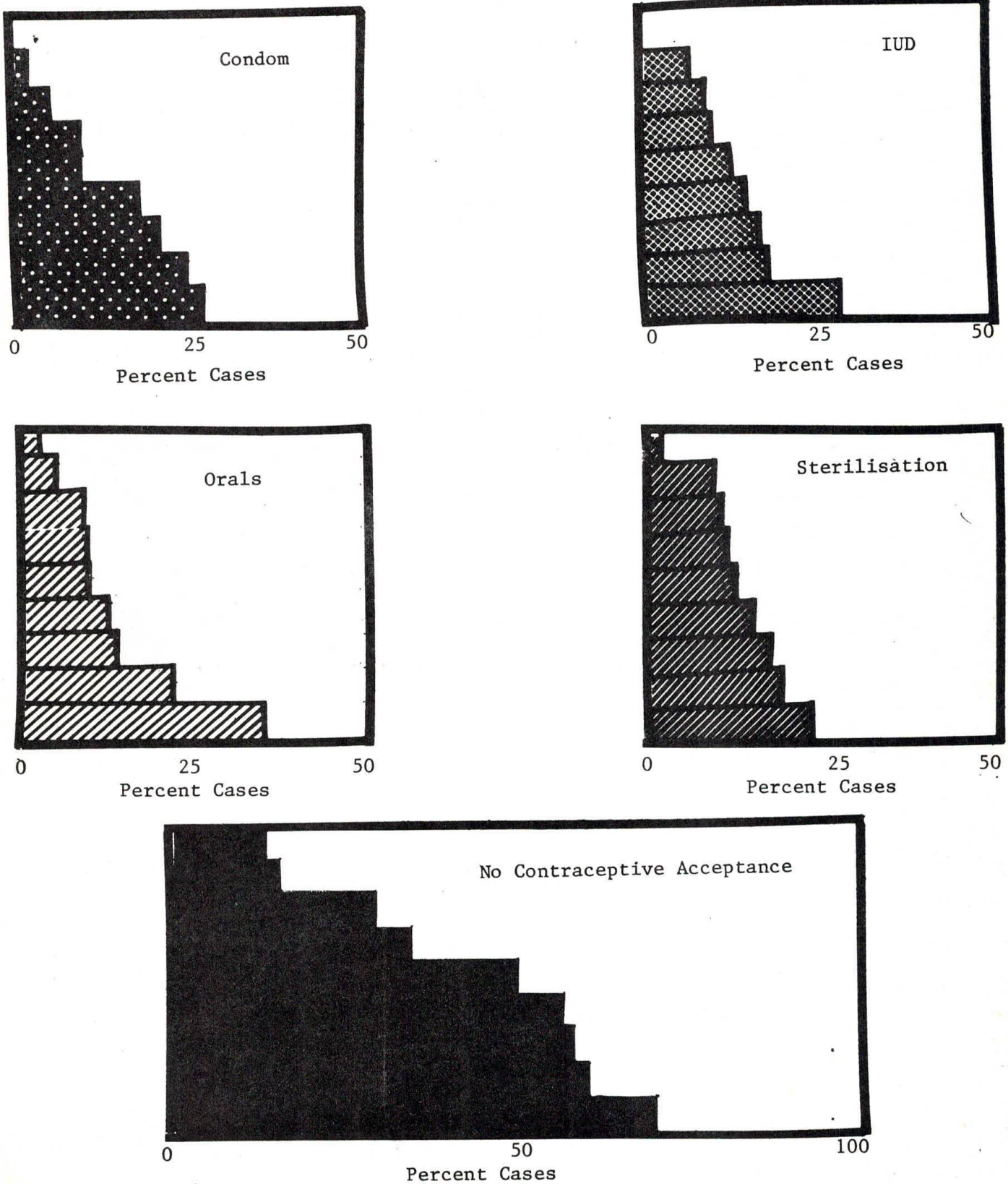

Fig 17

POSTPARTUM ACCEPTANCE OF THE CONDOM, STERILISATION, ORAL CONTRACEPTIVES AND IUD AND NON-ACCEPTANCE OF FERTILITY CONTROL METHODS AT NINE CENTRES IN INDIA, JANUARY 1977 TO DECEMBER 1978

The incidence of antenatal complications was similar among primiparas and multiparas (Fig 6). However, the incidence of intranatal complications was consistently higher for primiparas at all study centres (Fig 7). The incidence of anaemia was higher for multiparas than for primiparas (Fig 8). Although the incidence of caesarian section and forceps delivery varied markedly between centres there was a statistically significant positive correlation (r +.79) between these two methods of delivery (Fig 9).

Birth Weight

Mean birth weight ranged from 2527.9 grams to 2915.4 grams and the incidence of low birth weight infants ranged between 3.6% and 11.0% for < 2000 grams and from 5.4% to 42.5% for < 2500 grams at the study centres (Fig 10). As expected, highly significant negative correlations were noted for mean birth weight and incidence of low birth weight infants of < 2000 grams (r -.92) and < 2500 grams (r -.98) (Fig 10). Mean birth weight of infants born to primiparous women was lower than that of infants born to multiparous women (Fig 11) and mean birth weight for infants of anaemic women was lower than that for infants of non-anaemic women (Fig 12). These differentials were consistently evident at all centres.

Reported perinatal mortality rates ranged from 15.4 to 111.9 per 1000 infants delivered at the various centres. A statistically significant inverse correlation (r -.79) was demonstrated between perinatal mortality rates and mean birth weight (Fig 13). Similarly, centres with a higher incidence of low birth weight infants reported higher perinatal mortality rates (Fig 14); the correlations with perinatal mortality were highly significant for infants weighing < 2500 grams (r -.75) and < 2000 grams (r -.86).

Postpartum Contraceptive Acceptance

There were wide variations in the acceptance of postpartum contraception (21.0% to 74.9%) at various centres. The proportion of couples who stated that they had completed their desired family size but who did not accept any method of fertility control ranged from 0.0 to 33.3 percent at various centres (Fig 15). The percentage of couples accepting temporary methods ranged from 20.3% to 74.0%. While sterilisation acceptance was similar at most centres (Fig 15), female sterilisation was accepted more frequently than male sterilisation at all centres (Fig 16). Figure 17 shows that condoms were accepted by 0.0 to 26.5%, IUDs by 0.0 to 28.6% and oral contraceptives by 2.6 to 35.1 percent couples at the various centres. The percentage of couples who did not accept any method of fertility control ranged from 15.1 to 69.0 at the study centres (Fig 17).

DISCUSSION

Strategies for service delivery must vary in different countries as well as in different regions within the same country. To provide maximal benefits, local priority needs must be identified and services geared to first meet the needs of those who are at high risk. The priority accorded to each element of maternity care and the strategy for its delivery within primary health care, should be based on assessed local needs, socio-cultural characteristics of the population and available resources. Priorities should be determined in the light of criteria such as the magnitude and severity, as well as the health and social consequences of the problem; feasibility, cost and effectiveness of the health action; and demands for care and acceptance of services by the community.

MCM as a Managerial Tool

While there is an urgent need in developing countries to clearly define priorities for action in order to ensure the rational and optimal utilisation of limited resources, there is, unfortunately a paucity of reliable health and service statistics in these countries which makes it difficult to evaluate services for defining local priorities. MCM aims to bridge this gap by utilising the action-oriented or applied research approach for the collection of accurate local data on sociodemographic and clinical variables at all service levels and also provides a simple and reliable tool for evaluating these data and monitoring programme impact. A broad range of factors governing high risk groups, management and outcome of delivery as well as intervention to improve outcome can be evaluated and epidemiological comparisons can be made between the biological and socio-environmental factors which operate interactively to influence pregnancy outcome. Thus, MCM provides a managerial tool for the assessment of alternative approaches and priorities in the delivery of maternity services and, thereby, enables appropriate allocation and reallocation of resources for improved population coverage and effective implementation of integrated maternity and family planning services.

MCM as a Tool for Service Providers and Programme Planners

The present analysis focuses on inter-centre comparisons of key indices with the objective of evolving a simple to apply, and easy to use methodology for ranking the performance of different maternity centres by commonly defined indices. This analysis highlights characteristics, such as age, parity and education, of women delivering at these centres. Positive health indices such as birth weight, and negative health indicators such as the morbidity and mortality rates are also described. It also depicts trends and associations between patient characteristics, maternity services and pregnancy outcome. The findings are displayed on an abacus in a ranked manner so that the results can be easily interpreted and utilised by service providers for defining priorities. A national abacus, may similarly be used by programme planners for reviewing programme performance at the national level. A regional abacus would provide a comparison of programme performance between different geographical regions of the country. This method can thus be used by programme planners at the regional and national levels for developing programme strategy. It can also be used at the local level for programme implementation. Thus MCM provides a tool to enable programme planning and implementation based on reliable local data. The present analysis serves as an example to illustrate this. This analysis not only describes the type of women delivered at the study centres, her obstetric background and her morbidity and mortality experience, but highlights the causes of maternal and perinatal mortality at these centres and demonstrates the multiple interactions between the various causative factors. Such feedback especially when available on a periodic basis, can be effectively utilised for identifying priority problems, implementing appropriate health measures to combat them and evaluating such measures.

The present analysis shows that the sociodemographic characteristics of the women delivering at the study centres were similar. These women were generally young, of low parity and varying educational background. Several different clinical patterns were seen. While there were wide morbidity and mortality differentials between centres, the morbidity and mortality patterns were consistent within centres. This indicates that certain aetiological factors were operational within certain institutions causing

high complication rates in the antenatal, intranatal, postnatal and neonatal periods and resulting in high maternal and perinatal losses. By examining the data, some causative linkages were established. Parity, anaemia, morbidity experience, gestational age and birth weight were identified as the key factors influencing pregnancy outcome. Centres with infants of lower mean birth weight showed higher perinatal losses. In turn, standards of birth weight at various centres were determined by several factors. Thus, mean birth weight was lower for infants born to anaemic women than for those born to non-anaemic women, indicating the need for implementing antenatal care programmes that emphasize the prevention and treatment of anaemia at these centres. Primiparous women clearly constituted a high risk group. Intranatal complications were consistently higher, and mean birth weight was consistently lower for primiparous women than for multiparous women at all centres. The fact that more than a third of the women delivering at these centres were primiparous, further emphasized the need for special services for this group. Another high risk group identified through this analysis were women exposed to the risk of unwanted pregnancy. The need for emphasizing postpartum contraceptive programmes at centres with a high proportion of non-acceptors and especially at centres with a high proportion of women who have completed their desired family size but do not accept any method of fertility control, was highlighted.

MCM at Various Levels of Maternity Care

For MCM to be effectively utilised, it should be incorporated within the framework of existing maternity health care services of the country. Standard record systems, that can be practically utilised by personnel at various service levels, should be implemented. These record systems must, neccessarily vary in complexity depending on the category of personnel for whom they are meant. The type of feedback provided through this system must also be specifically designed for the user so that personnel at different service levels can effectively interpret data and translate results into appropriate and effective health measures.

A sophisticated, computerized system may be considered for teaching institutions to enable investigators to conduct scientific, indepth studies on various aspects of maternity care and seek answers to the many unknowns in maternal health. While such studies, undoubtedly, have considerable merit, in developing countries the greatest need for MCM exists at the peripheral service levels--in district hospitals, and peripheral health centres (PHCs) where deliveries are conducted primarily by trained midwives, and even more so, at the traditional birth attendant (TBA) level as the vast majority of the deliveries in these countries are conducted by TBAs.

The present analysis is based on a system of MCM that is designed for large maternity institutions. This system has been modified for use at PHCs, where pertinent data on selected key variables can be obtained by the midwife for monitoring maternity services at this level. However, since the problems of maternity care in developing countries relate primarily to service provided by TBAs, high priority should be assigned for developing simple, cost-effective and practical systems of MCM at this service level.

MCM as a Research Tool

MCM may be used as a research tool to scientifically explore areas of special interest such as causes of maternal or perinatal morbidity and mortality, epidemiology of low birth weight (5,6), related aspects of postpartum contraceptive acceptance (7,8), obstetrical problems (9) and a host of other unknowns in maternity care. Feedback through this system permits evaluation of health indicators within institutions (10)

or group of institutions (11,12) and when such feedback is periodic, the effect of control measures on these health indices can be measured. In addition to periodic evaluation within and between institutions, MCM may be used for making comparisons between maternity care programmes operating in different parts of a country (8) and also in different countries (2,13).

MCM for Providing Referral Linkages

Within a country, MCM should eventually be operational at all the three service levels including the large maternity institutions, the peripheral hospitals and PHCs and also the non-institutional level where deliveries are conducted by TBAs. For services to be effectively coordinated at these levels, there should be a referral chain which extends from the periphery (TBAs) to the hospitals via the PHCs. For the system to be effective, the referral centre, whether a large maternity institution or a PHC must, provide feedback to the referral source. MCM provides a linkage for two-way communication between the various service levels and thus, assists in establishing greatly needed, referral systems. It provides a means for systematically chanelling data to regional and central levels and feedback to peripheral levels. While institutional MCM provide important clues to programme planners for developing service strategy, the regular feedback of data to the peripheral levels assist service providers in assigning and when needed, reassigning priorities for programme implementation.

MCM for Staff Supervision and Training

Although basic education and training for health personnel is needed at all service levels, in-service training and continuing education must receive priority in maternity care programmes. Regular feedback made available through MCM, can be effectively utilised as a tool for inservice training of field personnel. Problem-solving and joint evaluation of specific interventions and service coverage, can be effectively used for imparting training. The added benefit of this approach is that it can be used locally and does not require staff to stay away from work, which is a common impediment in implementing training programmes.

CONCLUSIONS AND RECOMMENDATIONS

In developing countries, the overwhelmingly high incidence of maternal and infant mortality and morbidity are causes of top national concern. Service strategies for meeting the challenge of minimizing maternal and perinatal losses must be based on careful evaluation to determine what approaches are most effective in various settings and what methods are best suited to meet the specific needs of the high risk groups. In the context of limited resources in developing countries, priorities must be clearly defined to ensure the appropriate allocation and optimal utilisation of available resources. This requires that an efficient monitoring system be built into service programmes so that present needs can be adequately assessed and future trends anticipated and planned for thorough continuous measurement and evaluation. Maternity Care Monitoring (MCM) provides a managerial tool for the assessment of alternative approaches and priorities in the delivery of maternity services. It assists service providers in determining priorities for action and programme planners in developing programme strategy, based on reliable local data.

To be effectively utilised at the national level, MCM should be incorporated within the framework of existing service programmes, at all three service levels including large maternity institutions, peripheral hospitals and health centres, as well as non-institutional deliveries conducted by TBAs. The system utilised for MCM must, necessarily, vary in complexity depending upon the service level at which it is implemented so that the feedback through this system can be correctly interpreted by the user and then effectively translated into appropriate health measures.

Thus, by establishing a standardized system of data collection and analysis and providing regular and systematic feedback in a meaningful and cost-effective manner, MCM facilitates improvements in maternity care. Feasible and effective methods of service delivery, adapted to the socio-cultural and environmental needs, can thus be implemented to extend health coverage to the vulnerable groups of the population through the optimal utilisation of local resources.

National health programmes may utilise consultant services offered by the International Federation for Family Health (Federation) to design and implement systems for MCM relevant to meet their specific needs. The Federation will assist in developing Country Projects for implementing MCM which may be eligible for financial support from the United Nations Fund for Population Activities (UNFPA) and other donor agencies.

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FERTILITY CONTROL PRACTICES AMONG 15,221 WOMEN UNDERGOING HOSPITAL DELIVERY

Saroj Pachauri, MD, DPH, PhD[1] *Armin Jamshedji, MA*[2]

ABSTRACT

Data on 15,221 women delivering 15,424 babies at hospitals participating in the Maternity Care Monitoring Programme of the India Fertility Research Programme (India FRP) are reported. The majority of the cases were young, married, low parity women with varying levels of education. About sixty percent were urban residents. The mean age of the youngest living child for the series was 3.2 years. Reported rates for induced and spontaneous abortions and stillbirths were 7.2, 69.4 and 24.0 per 1000 pregnancies. The mean number of children desired was 3.4. Desired family size as related to age and number of living children is discussed. The maternal and perinatal mortality rates were 1.3 and 47.9 per 1000 deliveries.

While 88.8 percent of the couples had not used any method of fertility control prior to the present delivery, only 34.8 percent did not agree to accept any fertility control method after delivery. Female sterilisation (17.3%), oral contraceptives (15.7%) and condoms (14.1%) were the most popular methods; IUDs were accepted by 10.2 percent cases. Acceptance of fertility control methods correlated positively with age and number of living children and inversely with desire for additional children. While oral (18.8%) and conventional (17.4%) contraceptives were the methods of choice among the younger couples (wife's age < 19 years), sterilisation (43.8%) was the method of choice among the older couples (wife's age 30+ years). Most (62.0%) of couples with four or more living children selected sterilisation. /Postpartum fertility control acceptance in relation to age, living children and desired family size is discussed.

INTRODUCTION

In recent years in India as in other countries facing population pressures, there has been an emphasis on organizing postpartum programmes for hospitals. It is hypothesized that the postpartum period presents a unique opportunity to provide family planning services since it brings the potential client in contact with health personnel who can provide her with an appropriate method for spacing or limiting family size at a time when she is more likely to be motivated to accept fertility control methods. This report discusses the sociodemographic characteristics, reproductive history and postpartum fertility control acceptance among women undergoing delivery.

MATERIALS AND METHODS

This is a pooled analysis of data on 15,221 women delivering 15,424 babies at selected hospitals in India during the period January 1976 to January 1978. Data on all cases were recorded on the single-page maternity record of the India FRP. At these institutions, maternity services are being concurrently monitored by the Maternity Care Monitoring system of the India FRP. This system is designed for concurrent computerized monitoring and evaluation and ensures rapid feedback of results to enable hospital administrators to suitably modify policies for the management of programmes for maternity care and postpartum postpartum fertility control.

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Fertility control acceptance as discussed in this study, includes contraceptive methods planned and provided and, therefore, except in the case of women undergoing concurrent sterilisation or IUD insertion there is no evidence that the planned method was infact used.

Standard definitions were used for all rates and events reported. Neonatal and perinatal mortality rates reported in this study include stillbirths and infant deaths prior to discharge from the hospital.

RESULTS

Sociodemographic Characteristics

The study group comprised predominantly of young (mean age 25.9 years), low parity (mean parity 1.5) women with varying levels of education (mean number of school years 6.2). In this series, 26.5 percent of the women were primiparas (Table I). There was a sharp increase in mean parity with increasing age (Fig 1). While 62.2 percent of the women were from urban areas, 33.9 percent were from rural areas and 3.7 percent were from slum areas (Table I).

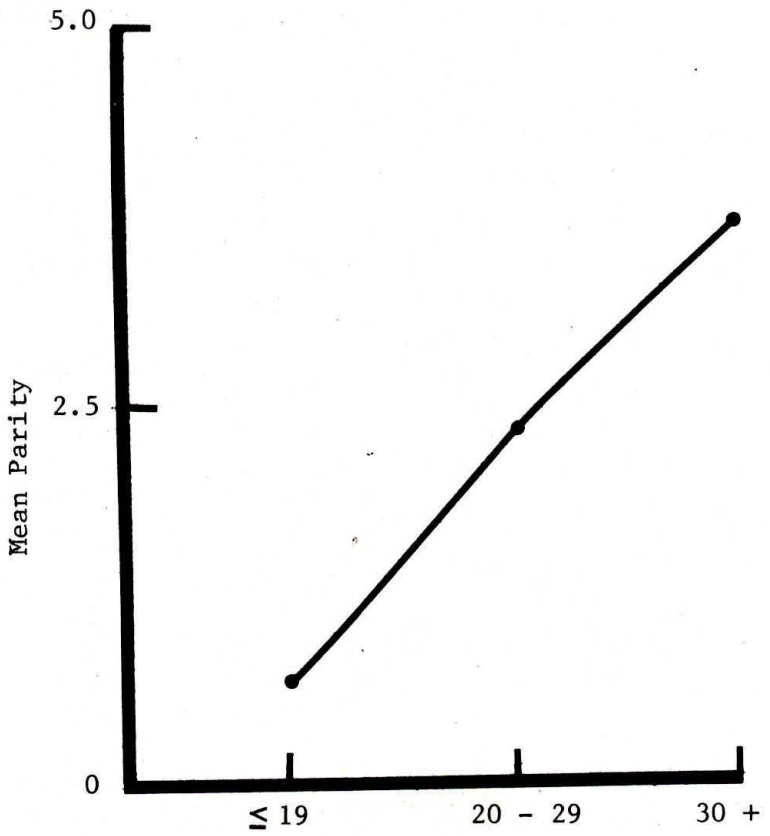

Fig 1

MEAN PARITY BY MATERNAL AGE FOR 15,221 WOMEN UNDERGOING HOSPITAL DELIVERY IN INDIA, JANUARY 1976 TO 1978

TABLE I

SOCIODEMOGRAPHIC CHARACTERISTICS OF 15,221 WOMEN UNDERGOING HOSPITAL DELIVERY IN INDIA, JANUARY 1976 TO 1978

Characteristics	Number	Percent
Age (Years)		
≤ 17	133	0.9
18 - 19	851	5.6
20 - 24	5944	39.1
25 - 29	5107	33.6
30 - 34	2210	14.5
35 - 39	838	5.5
40 +	121	0.8
Unknown	17	0.1
Mean	25.9	
Parity		
0	5215	34.3
1	4027	26.5
2	2768	18.2
3	1589	10.4
4	815	5.4
5+	767	5.0
Unknown	40	0.3
Mean	1.5	
Living Children		
0	5481	36.0
1	4015	26.4
2	2647	17.4
3	1404	9.2
4	669	4.4
5+	565	3.7
Unknown	440	2.9
Mean	1.3	
Sex Ratio	99.7*	
Age of Youngest Child		
< 1	312	2.0
1	910	6.0
2	3509	23.0
3	2033	13.4
4	899	5.9
5+	942	6.2
No children	4840	31.8
Unknown	1776	11.7
Mean	3.2	

*Sex Ratio = Number of males per 100 females.

TABLE I (CONTD)

Characteristics	Number	Percent
Patient's Education (School Years)		
0	1527	10.0
1 - 2	302	2.0
3 - 4	769	5.0
5 - 6	986	6.5
7 - 8	972	6.4
9 - 10	812	5.3
11 - 12	783	5.1
13 +	530	3.5
Unknown	8540	56.1
Mean	6.2	
Marital Status		
Never married	56	0.4
Currently married	14640	96.2
Formerly married/other	498	3.3
Unknown	27	0.2
Residence		
Urban	9472	62.2
Rural	5161	33.9
Slum	560	3.7
Unknown	28	0.2

Reproductive History

The mean age of the youngest child was 3.2 years; it was 2 years in about a fourth of the cases and 4+ years in 12.1 percent cases (Table I).

The live birth rate was 899.4 per 1000 pregnancies. Reported rates for induced and spontaneous abortion were 7.2 and 69.4 per 1000 pregnancies respectively. The stillbirth rate was 24.0 per 1000 pregnancies (Table II).

Desired Family Size

The desired family size was 3.4 children. For women below 20 years of age it was 2.9 children; for those at 20 - 29 years and above 30 years it was 3.3 and 5.0 children respectively (Fig 2). As the number of living children increased from one to four, the desire for additional children declined sharply--Figure 3 shows a

TABLE II

PREVIOUS REPRODUCTIVE HISTORY OF 15,221 WOMEN UNDERGOING HOSPITAL DELIVERY IN INDIA, JANAURY 1976 TO 1978

Reproductive History	Number of Events	Rate/1000 Pregnancies
Induced abortion	205	7.2
Spontaneous abortion	1963	69.4
Stillbirth	678	24.0
Live birth	25436	899.4
Unknown	55	0.8

a steeply rising curve which plateaus off after four living children. While 32.1 percent of the women with one living child wanted one more child, 64.7 percent of these women wanted two or more additional children. About sixty percent of the women with two living children wanted another child and 15.8 percent wanted two or more additional children. While 39.2 percent of the women with three living children wanted another child, 16.9 percent with four living children desired one more child (Fig 3).

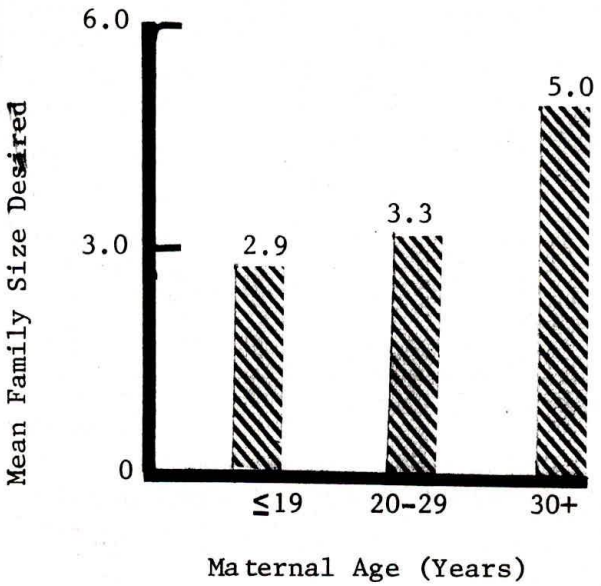

Fig 2

MEAN TOTAL DESIRED FAMILY SIZE BY MATERNAL AGE FOR 15,221 WOMEN UNDERGOING HOSPITAL DELIVERY IN INDIA, JANUARY 1976 TO 1978

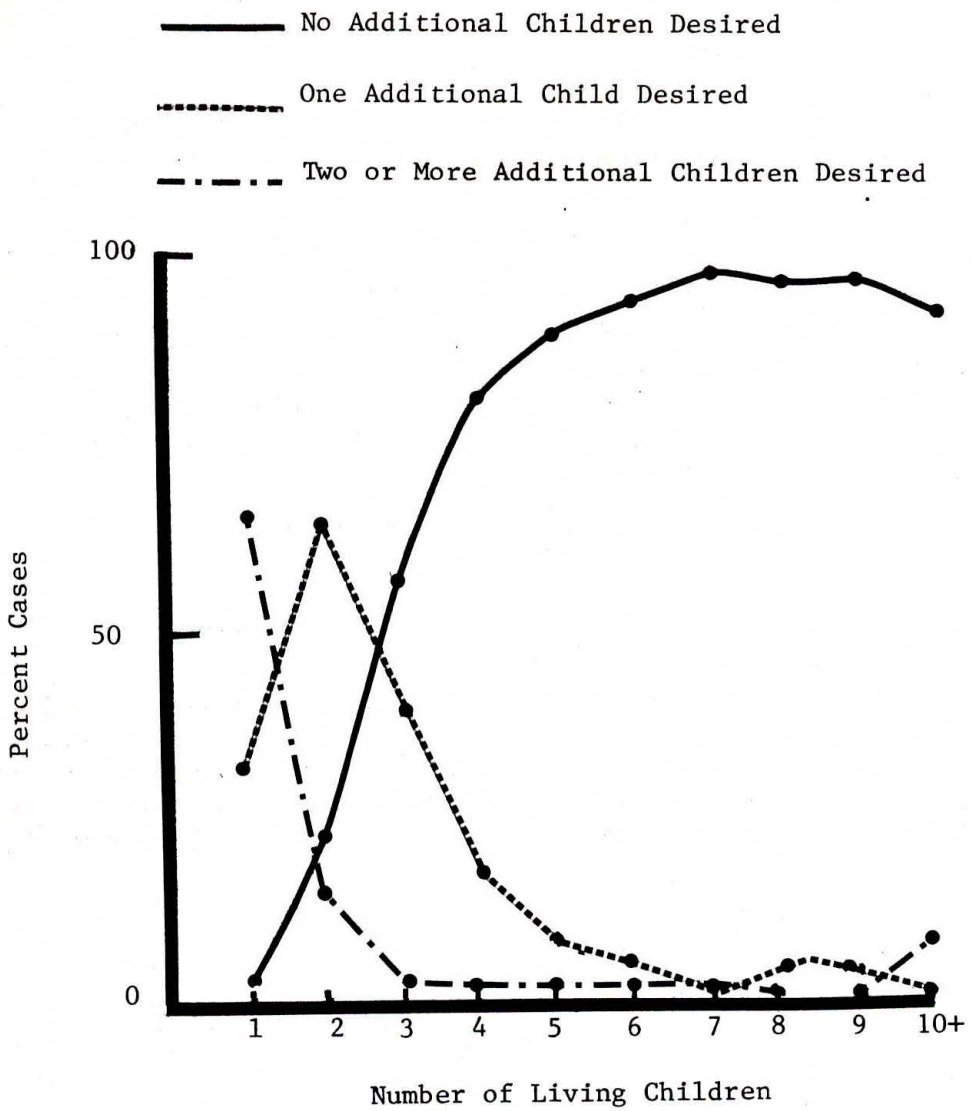

Fig 3

NUMBER OF LIVING CHILDREN BY ADDITIONAL CHILDREN DESIRED FOR 15,221 WOMEN UNDERGOING HOSPITAL DELIVERY IN INDIA, JANUARY 1976 TO 1978

Mortality Rates

There were 20 maternal deaths in this series; the maternal mortality rate was 1.3 per 1000 deliveries. The stillbirth and neonatal mortality rates were 30.5 and 21.1 per 1000 deliveries respectively. The perinatal mortality rate for the series was 47.9 per 1000 deliveries (Table III).

TABLE III

MORTALITY RATES FOR 15,221 WOMEN UNDERGOING HOSPITAL DELIVERY IN INDIA, JANUARY 1976 TO 1978

Mortality	Number	Rate/1000 Deliveries
Maternal mortality	20	1.3
Stillbirths	470	30.5
Neonatal mortality*	315	21.1
Perinatal mortality	739	47.9

*Deaths before discharge to infants born alive.

Acceptance of Fertility Control Methods

While 88.8 percent of the couples had not used any method of fertility control prior to the present delivery, only 34.8 percent did not agree to accept any fertility control method after delivery. After delivery, there was an increase in the acceptance of all methods of fertility control except conventional contraceptives. Female sterilisation (17.3%), oral contraceptives (15.7%) and condoms (14.1%) were the most popular methods; IUDs were accepted by 10.2 percent cases (Fig 4).

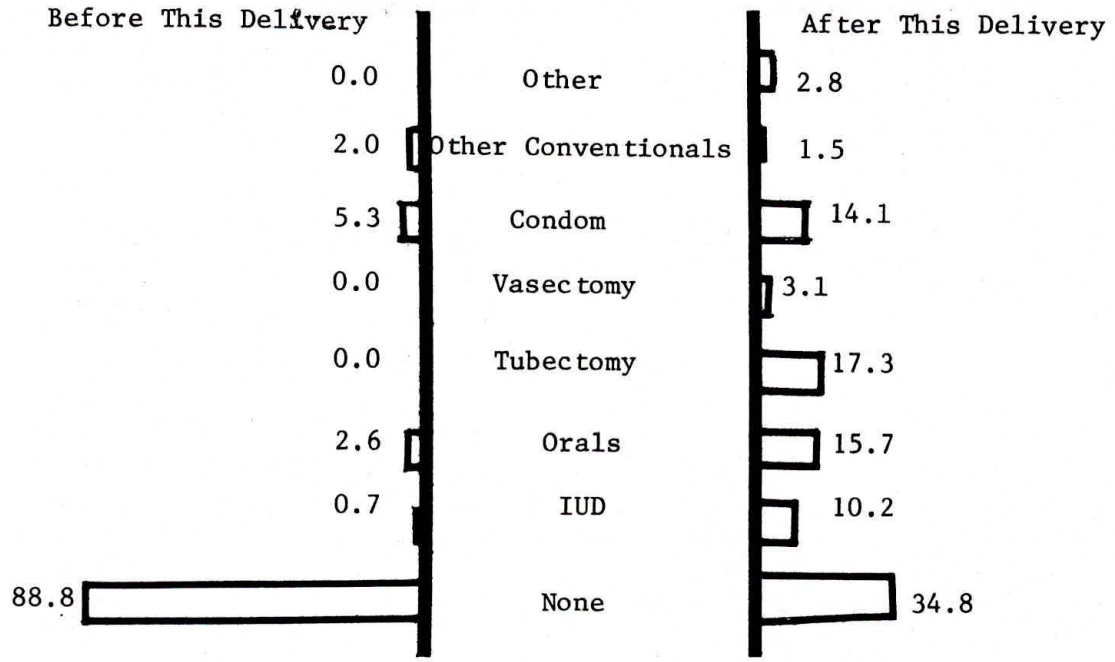

Fig 4

CONTRACEPTIVE ACCEPTANCE BEFORE AND AFTER DELIVERY FOR 15,221 WOMEN UNDERGOING HOSPITAL DELIVERY IN INDIA, JANUARY 1976 TO 1978

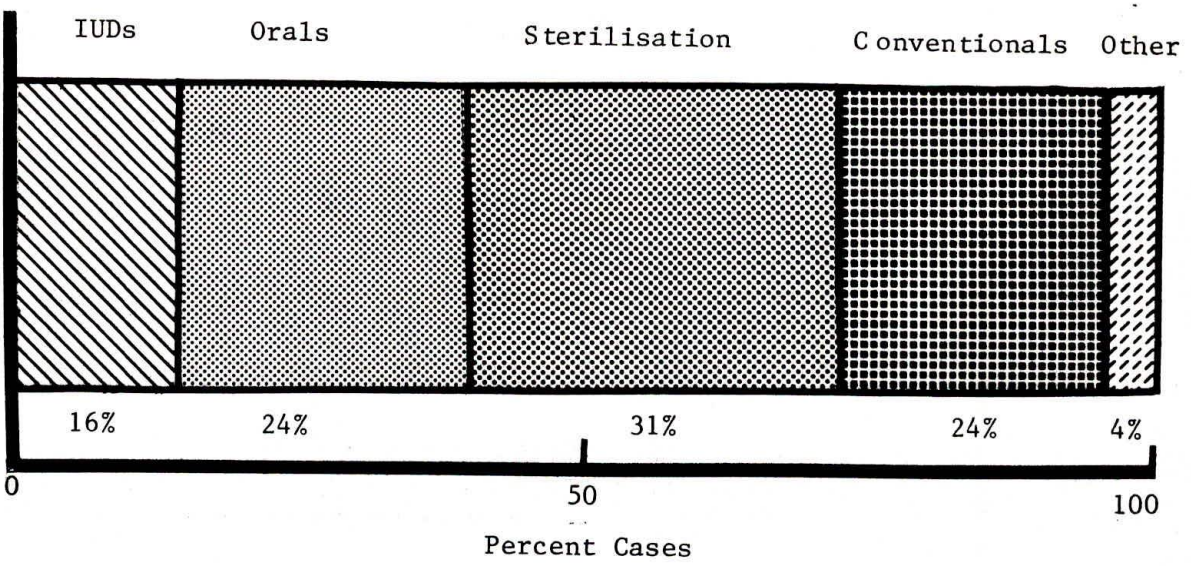

Fig 5

POSTPARTUM FERTILITY CONTROL ACCEPTANCE BY METHOD FOR 15,221 WOMEN UNDERGOING HOSPITAL DELIVERY IN INDIA, JANUARY 1976 TO 1978

Figure 5 shows that among couples accepting fertility control, about a fourth selected oral and conventional contraceptives and 31.5 and 15.8 percent respectively selected sterilisation and IUDs. Among couples accepting sterilisation, the majority desired female sterilisation (84.7%); 81.5 percent of the women accepting sterilisation underwent concurrent sterilisation. Among the conventional contraceptive acceptors, the vast majority (90.6%) accepted the condom.

Postpartum Fertility Control Acceptance by Age, Living Children and Additional Children Desired

Acceptance of fertility control methods correlated positively with age (Table IV and Fig 6) and number of living children (Table V and Fig 7) and inversely with desire for additional children (Table VI and Fig 8).

TABLE IV

PREVALENCE OF FERTILITY CONTROL METHODS BY MATERNAL AGE FOR 15,221 WOMEN UNDERGOING HOSPITAL DELIVERY IN INDIA, JANUARY 1976 TO 1978

Fertility Control Method	Maternal Age (Years) ≤19 N=982	20 - 29 N=11016	30 + N=3162
IUD	10.6	11.2	7.3
Orals	18.8	17.5	8.8
Sterilisation	1.4	15.5	43.8
Conventionals	17.4	17.3	9.3
Other	4.1	2.9	2.2
TOTAL	52.3	64.4	71.4

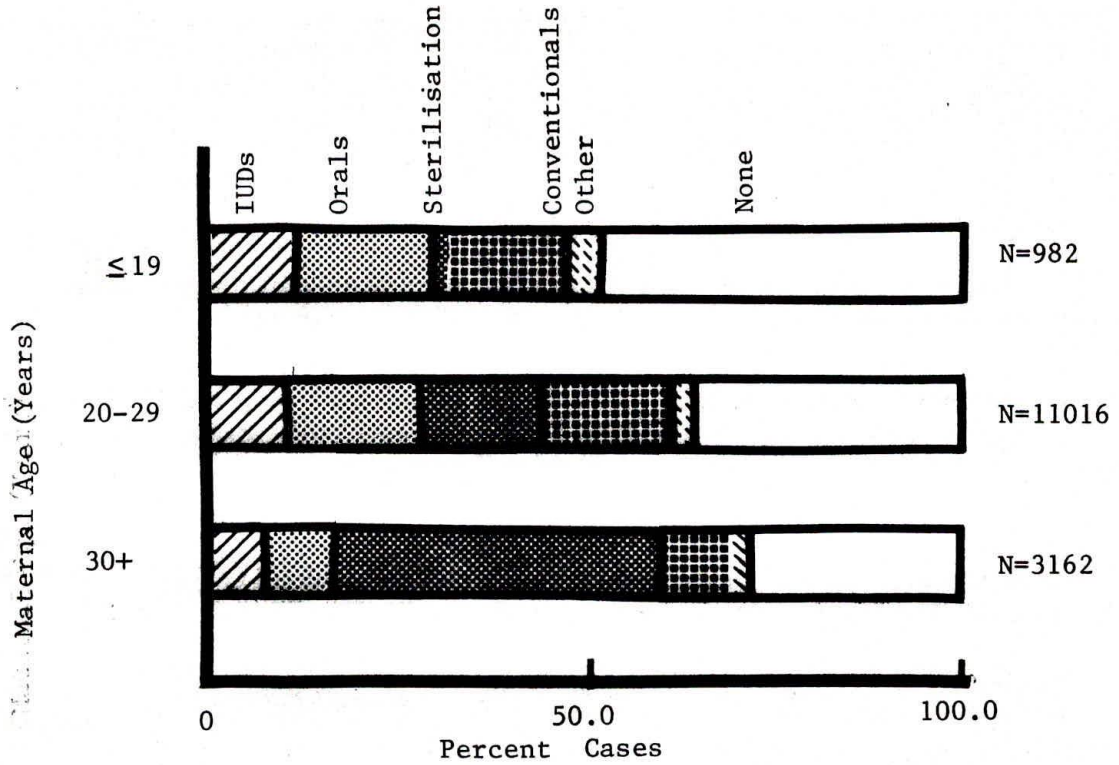

Fig 6

PREVALENCE OF FERTILITY CONTROL METHODS BY MATERNAL AGE FOR 15,221 WOMEN UNDERGOING HOSPITAL DELIVERY IN INDIA, JANUARY 1976 TO 1978

While oral (18.8%) and conventional (17.4%) contraceptives were the methods of choice among the younger couples (wife's age ≤19 years), sterilisation (43.8%) was the method choice among the older couples (wife's age 30+ years). At 20 to 29 years of age, oral (17.5%) and conventional (17.3%) contraceptives and IUDs (11.2%) were the most prevalent methods (Table IV and Fig 6).

TABLE V

PREVALENCE OF FERTILITY CONTROL METHODS BY NUMBER OF LIVING CHILDREN FOR 15,221 WOMEN UNDERGOING HOSPITAL DELIVERY IN INDIA, JANUARY 1976 TO 1978

Fertility Control Method	Number of Living Children ≤ 3 N=11802	4+ N=2589
IUD	11.7	4.3
Orals	18.0	7.2
Sterilisation	11.9	62.0
Conventionals	18.3	4.6
Other	3.1	2.0
TOTAL	63.0	80.1

When the number of living children was three or less the prevalence of oral contraceptives was about 18 percent in each case and that of IUDs and sterilisation was about 12 percent in each case. Most (62.0%) of couples with four or more living children selected sterilisation (Table V and Fig 7). Sterilisation (63.7%) was the method of choice among couples who did not desire additional children. However, 12.0 percent of these couples did not accept any method of fertility control. Acceptance rates for methods were similar among couples desiring one or two additional children (Table VI and Fig 8).

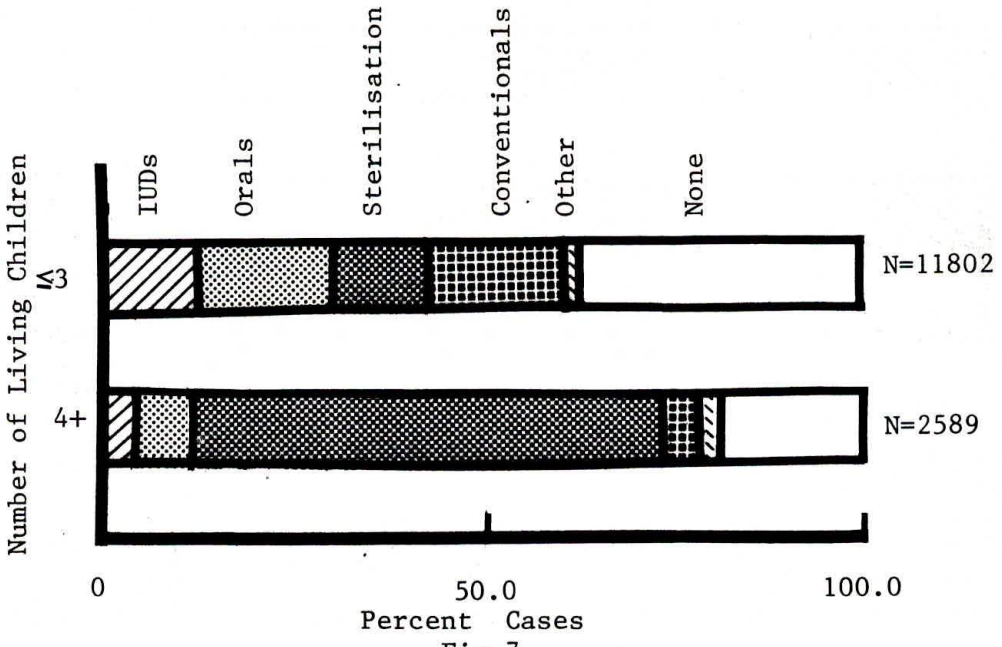

Fig 7

PREVALENCE OF FERTILITY CONTROL METHODS BY NUMBER OF LIVING CHILDREN FOR 15,221 WOMEN UNDERGOING HOSPITAL DELIVERY IN INDIA, JANUARY 1976 TO 1978

TABLE VI

PREVALENCE OF FERTILITY CONTROL METHODS BY NUMBER OF ADDITIONAL CHILDREN DESIRED FOR 15,221 WOMEN UNDERGOING HOSPITAL DELIVERY IN INDIA, JANUARY 1976 TO 1978

Fertility Control Method	Additional Children Desired 0 N=4779	1 N=5627	2+ N=4493
IUD	7.6	13.7	13.9
Orals	7.9	22.3	25.2
Sterilisation	63.7	0.7	0.7
Conventionals	6.5	22.3	27.9
Other	2.3	2.7	6.8
TOTAL	88.0	61.7	74.5

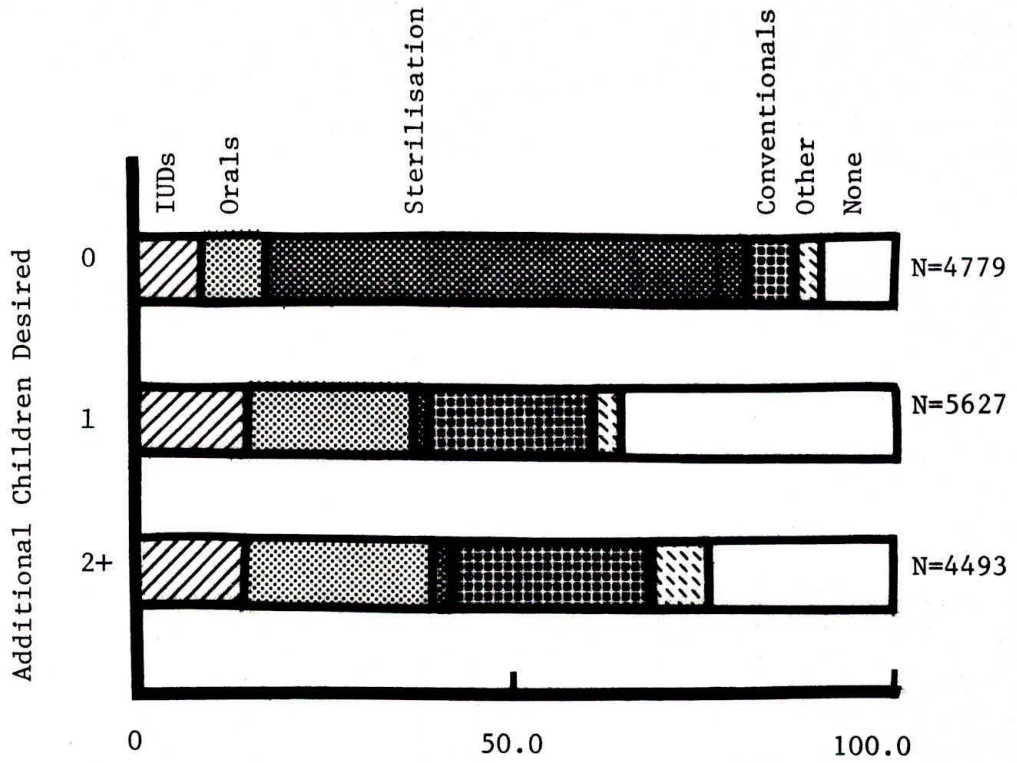

Fig 8

PREVALENCE OF FERTILITY CONTROL METHODS BY ADDITIONAL CHILDREN DESIRED FOR 15,221 WOMEN UNDERGOING HOSPITAL DELIVERY IN INDIA, JANUARY 1976 TO 1978

DISCUSSION

Studies show that there is an increase in the acceptance of fertility control methods after menstrual regulation (1,2) abortion (3,4) and delivery (5,6). Several hospitals organize programmes for providing contraceptive information and services to women in the postabortion and postdelivery period on the assumption that women are likely to be receptive to methods for limiting family size or spacing future children.

In this analysis, the authors have attempted to isolate factors which determine fertility control acceptance for women undergoing hospital delivery in India. The results of this analysis indicate that in this group of relatively young, low parity women representing both urban and rural areas, there was a marked increase in fertility control acceptance. Six out of every ten women chose a method after delivery even though nine out of ten had not used any method of fertility control before delivery. However, a little over a third of this group did not agree to accept any method of fertility control. These were predominantly the younger, low parity women desiring additional children. Contraceptive counselling programmes should aim to motivate these women to accept spacing methods. Oral contraceptives and condoms were the methods of

choice among couples who wished to space their future children and female sterilisation was the method of choice among those who had completed their desired family size. While one out of every six couples who had completed their families selected sterilisation for control of fertility, there remained a hard chore of 12 percent couples who did not agree to accept any method even though they had completed their desired family size. More intensive contraceptive counselling is needed for this group of cases.

This analysis indicates that younger women desire smaller families and that the number of additional children desired is inversely related to the number of living children. The association with the sex of the living children is not examined. While data on the mortality experience of the study population are provided in this report, no attempt has been made to evaluate the effect of previous pregnancy outcome on the decision to use contraceptive methods. In a subsequent analysis, the authors propose to test the hypothesis that women experiencing more favourable pregnancy outcome are more likely to desire fewer children and accept fertility control methods.

ACKNOWLEDGMENT

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PRETEST OF THE MATERNITY CARE MONITORING CORE QUESTIONNAIRE FOR PERIPHERAL HEALTH CENTRES

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ABSTRACT

This is a report of a pretest of the Core Questionnaire recommended for Maternity Care Monitoring (MCM) at peripheral health centres. Data on 100 maternity cases attending the Padra Primary Health Centre in Baroda District were recorded by medical interns. High maternal morbidity and perinatal mortality rates and low birth weight are reported. Recommendations are made to improve the record. It should be pretested by midwives on a larger series of cases.

INTRODUCTION

The major goal of Maternity Care Monitoring (MCM) is to assist in establishing a standardized system of data collection and analysis which provides systematic feedback of programme performance and highlights priorities for action at various levels of maternity care provided through hospitals, peripheral health centres and traditional birth attendants (TBAs). In response to the need expressed by several developing countries, a standardized system for monitoring maternity care at hospitals was conjointly developed and pretested by the International Fertility Research Program (IFRP) and the International Federation of Gynaecology and Obstetrics (FIGO).

While there are obvious advantages in using internationally standardized record systems, it is nevertheless, most important to ensure that they are designed to meet specific local needs. The International Federation for Family Health (Federation) is presently assisting its member countries to consititute national Task Forces for MCM. The Task Force for each country will review the experience of local investigators with the international record systems and modify them for local use. While this will ensure adherence to standard definitions and comparability across countries, it will also make it possible to specifically adapt the system for the needs of each country.

The record system for MCM at hospitals is standardized and computerized and has been extensively pretested (1-5). There is, however, an urgent need to develop and pretest record systems for the peripheral health centre and TBA levels of maternity care as in developing countries the vast majority of the deliveries are not conducted in hospitals.

After carefully reviewing the internationally standardized hospital record system, members of the Federation, FIGO, and national Task Forces from several countries recommended a Core Questionnaire for peripheral health centres (Page 179). This record will be pretested by member countries of the Federation. This is a report of a pretest of the Core Questionnaire which was conducted in Baroda, India.

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MATERNITY CARE MONITORING RECORD

Please circle appropriate choices and fill in boxes and blanks.

PATIENT IDENTIFICATION: 1. Maternity service _____ 2. Admission date _____ *day month year*

3. Patient's name _____ Husband's Name _____

4. Address _____

STUDY IDENTIFICATION

5. Center name _____ and number: [ ][ ][ ] 1-3
6. Study number: [8][0][1] 4-6
7. Patient order number: [ ][ ][ ][ ][ ] 7-11
8. Delivery date: [ ][ ] *day* [ ][ ] *month* [ ][ ] *year* 12-17

PATIENT CHARACTERISTICS

9. Patient's age: *(completed years)* [ ][ ] 21-22
10. Patient's education: *(school year completed)* 0) 0 1) 1-2 2) 3-4 3) 5-6 4) 7-8 5) 9-10 6) 11-12 7) 13-14 8) 15+ [ ] 23
11. Patient's height in cm: [ ][ ][ ]

PAST OBSTETRIC HISTORY

12. Total live births: [ ][ ] 27-28
13. Children now living: number of males *(8 or more = 8)* [ ] 29; number of females [ ] 30
14. Number of stillbirths: *(8 or more = 8)* [ ] 32
15. Number of infant deaths: *(less than 12 completed months; 8 or more = 8)* [ ] 33
16. Outcome of last pregnancy: 0) not previously pregnant 1) live birth, full term, still living 2) live birth, full term, deceased 3) live birth, premature, still living 4) live birth, premature, deceased 5) stillbirth 6) induced abortion 7) spontaneous abortion 8) other _____ [ ] 36
17. Number of months since last pregnancy ended: *(98 or more = 98)* [ ][ ] 37-38

CURRENT PREGNANCY AND DELIVERY

18. Number of antenatal visits: *(8 or more = 8)* [ ] 40
19. Estimated duration of pregnancy: *(menstrual age in completed weeks)* [ ] 46-47
20. Type of delivery: 0) spontaneous 1) outlet forceps 2) vacuum extractor 5) breech extraction 6) cesarean section 7) destructive procedure 8) other _____ [ ] 54
21. Attendant at labor/delivery: 0) none 1) nurse 2) qualified midwife 3) student nurse/midwife 4) auxiliary/TBA 5) medical student 6) general physician 7) OB/GYN physician 8) other _____ [ ] 59

THE NEWBORN

22. Birthweight in grams: *(888 if referred before delivery)* [ ][ ][ ][ ] 60-62
23. Sex of infant(s) born at this delivery: number of males [ ] 63; *(write number of each)* number of females [ ] 64
24. Primary fetal/neonatal condition: 0) normal, or stillbirth with no apparent pathology 1) fetal distress during labor 2) malformation 4) respiratory distress syndrome 7) trauma 8) other *For codes 2), 7), 8), specify* _____ [ ] 67
25. Status of fetus/newborn: 0) living 1) died before admission 3) died after admission-ante/intrapartum 5) died postpartum 8) other _____ [ ] 69

THE MOTHER

26. Primary puerperal condition: 0) normal 1) fever requiring treatment 2) bleeding requiring treatment 7) death *(complete Death Report)* 8) other _____ [ ] 70

SPECIAL STUDIES

27. Source of referral [ ] 73
28. Appropriateness of referral [ ] 74
29. Risk assessment score [ ] 75

FAMILY PLANNING

COMPLETE THESE ITEMS AT TIME OF DISCHARGE

30. Female sterilization: 0) none 1) before this delivery 2) at cesarean section 3) immediately after delivery 4) same day 5) 1-2 days later 6) 3-4 days later 7) 5-9 days later 8) 10 or more days later [ ] 77
31. Number of additional children wanted: *(8 or more = 8)* [ ] 78
32. Contraceptive method planned or provided: 0) none 1) IUD 2) orals/injectables 3) female sterilization 4) male sterilization 5) condom 6) withdrawal/rhythm 7) foam/diaphragm/jelly 8) other [ ] 79

Recorder's name _____ [1] 80

PLEASE MAIL TO:

MATERIALS AND METHODS

Data on 100 maternity cases attending the Padra Primary Health Centre in Baroda District, India between November 1979 to January 1980 were recorded by medical interns on the Core Questionnaire. Data were obtained on patient characteristics, obstetrical events, antenatal care, delivery, foetal/neonatal status, puerperal status, desire for additional children and postpartum fertility control.

Definitions and Criteria

All deliveries conducted at the health centre, regardless of outcome were included. Induced and spontaneous abortions (with a foetus weighing less than 500 grams and gestation upto 19 weeks), molar pregnancies and false labours were excluded. The duration of pregnancy was estimated in completed weeks from the onset of the last normal menstrual period to the day of the delivery.

For estimating the perinatal mortality rate, stillborn infants weighing 1000 grams or more and early neonatal deaths of infants were included. Neonatal death was defined as infant death prior to discharge from the health centre.

RESULTS

Sociodemographic Characteristics

The average woman delivering at this centre was 27.7 years of age, 156.4 centimetres tall and had 1.4 years of school education. Ten percent of the women were below 19 years, 60.0 percent were between 20 to 29 years and 30.0 percent were above 30 years of age. The majority (74.0%) were 150-159 cms tall. While 38.0 percent were illiterate, 50.0 percent had 1 to 2 years of formal education (Table I).

Obstetric History

While 15.0 percent of the women were nulliparous, 30.0 percent had 1 to 2 live births and 55.0 percent had 3+ live births. Mean parity was 2.9; 53.0 percent had 2 to 3 living children, 20.0 percent had 4 or more living children and 17.0 percent had no living child. The sex ratio for the study group was 122.8. Stillbirths and child loss were experienced by 18.0 and 20.0 percent of the women respectively (Table II).

Outcome of Previous Pregnancy

The last pregnancy ended in a live birth, stillbirth and abortion in 68.0, 7.0 and 13.0 percent of the cases respectively. Among the livebirths, 46.0 percent were fullterm deliveries and 22.0 percent were premature deliveries. Twelve percent of the women had not experience a prior pregnancy (Table III).

TABLE I

SELECTED PATIENT CHARACTERISTICS OF 100 WOMEN ATTENDING THE PADRA PRIMARY HEALTH CENTRE IN BARODA DISTRICT, BARODA, NOVEMBER 1979 TO JANUARY 1980

Patient Characteristics	Percent Cases
Age (Completed years)	
≤ 17	6.0
18 - 19	4.0
20 - 24	34.0
25 - 29	26.0
30 - 34	27.0
35 +	3.0
Mean	27.7
Education (School years)	
0	38.0
1 - 2	50.0
3 - 4	11.0
5 - 6	1.0
Mean	1.4
Height (Cms)	
≤ 149	5.0
150 - 155	31.0
156 - 159	43.0
160 +	21.0
Mean	156.4

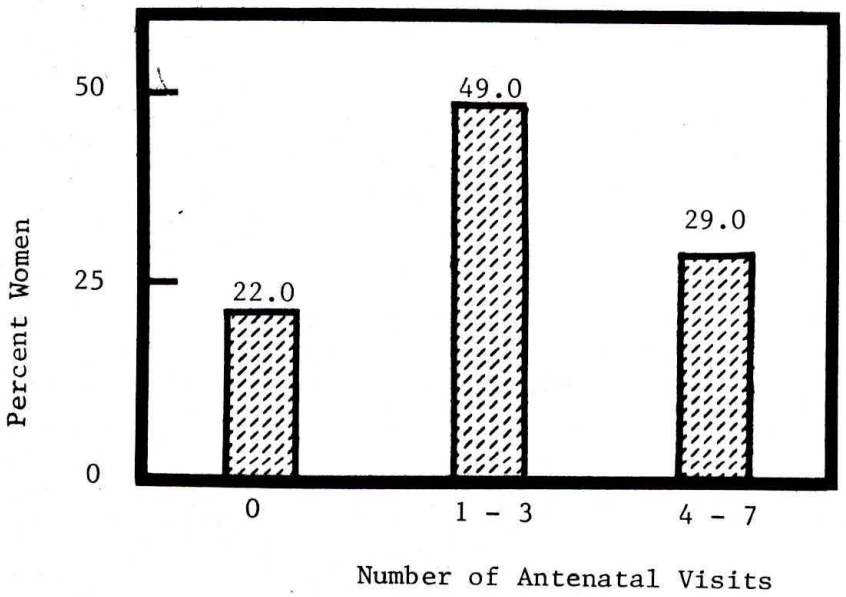

Fig 1

NUMBER OF ANTENATAL VISITS REPORTED FOR 100 WOMEN ATTENDING THE PADRA PRIMARY HEALTH CENTRE IN BARODA DISTRICT, BARODA, NOVEMBER 1979 TO JANUARY 1980

TABLE II

OBSTETRIC HISTORY OF 100 WOMEN ATTENDING THE PADRA PRIMARY HEALTH CENTRE IN BARODA DISTRICT, BARODA, NOVEMBER 1979 TO JANUARY 1980

Obstetric History	Percent Cases
Parity	
0	15.0
1 - 2	30.0
3 - 4	47.0
5 +	8.0
Mean	2.9
Number of Living Children	
0	17.0
1	10.0
2	27.0
3	26.0
4 +	20.0
Mean	2.7
Sex ratio	122.8*
Stillbirth	
0	82.0
1	16.0
2	2.0
Child loss	
0	80.0
1	19.0
2	1.0

*Number of males per 100 females.

TABLE III

OUTCOME OF PREVIOUS PREGNANCY FOR 100 WOMEN ATTENDING THE PADRA PRIMARY HEALTH CENTRE IN BARODA DISTRICT, BARODA, NOVEMBER 1979 TO JANUARY 1980

Outcome	Percent Cases
Never pregnant	12.0
Full-term live birth still living	46.0
Premature live birth still living	12.0
Premature live birth deceased	10.0
Stillbirth	7.0
Induced abortion	1.0
Spontaneous abortion	12.0

Antenatal Care

Twenty two percent of the women in the study group received no antenatal care; 49.0 percent had 1 to 3 antenatal visits and 29.0 percent had 4 to 7 antenatal visits (Fig 1).

Labour and Delivery

Mean duration of pregnancy was 39.3 weeks. Delivery was spontaneous in 90.4 percent cases. Breech extractors and forceps were used in 5.3 and 4.2 percent cases respectively (Table IV). There were no multiple deliveries. In this series, 56.4 percent of the deliveries were conducted by a nurse and 12.8 percent by a midwife. Student nurses and midwives conducted 21.3 percent and only 3.2 percent cases were delivered by a general physician. No assistance was available during pregnancy in 5.3 percent cases (Table IV).

TABLE IV

ATTENDANT AT DELIVERY AND TYPE OF DELIVERY FOR 94 WOMEN DELIVERED AT THE PADRA PRIMARY HEALTH CENTRE IN BARODA DISTRICT, BARODA, NOVEMBER 1979 TO JANUARY 1980

Attendant at Delivery	Type of Delivery: Spontaneous No.	%	Outlet Forceps No.	%	Breech Extractor No.	%	Total No.	%
Nurse	52	61.2	0	0.0	1	20.0	53	56.4
Student nurse/ midwife	18	21.2	0	0.0	2	40.0	20	21.3
Qualified midwife	10	11.8	0	0.0	2	40.0	12	12.8
Medical student	0	0.0	1	25.0	0	0.0	1	1.1
General physician	0	0.0	3	75.0	0	0.0	3	3.2
None	5	5.9	0	0.0	0	0.0	5	5.3
TOTAL	85	100.0	4	100.0	5	100.0	94	100.0

Note: As six cases were referred to a hospital, data on 94 cases are reported in this and all subsequent tables.

Birth Weight

The male-female sex ratio was 224.1. Mean birth weight of the infants in this series was 2379.5 grams. Mean birth weight of male infants (2580.3 gms) was significantly higher than that of female infants (2421.9 gms). However, the percentage of low birth weight (< 2500 gm) was not significantly higher among female infants (55.2%) than among male infants (35.3%) (Fig 2).

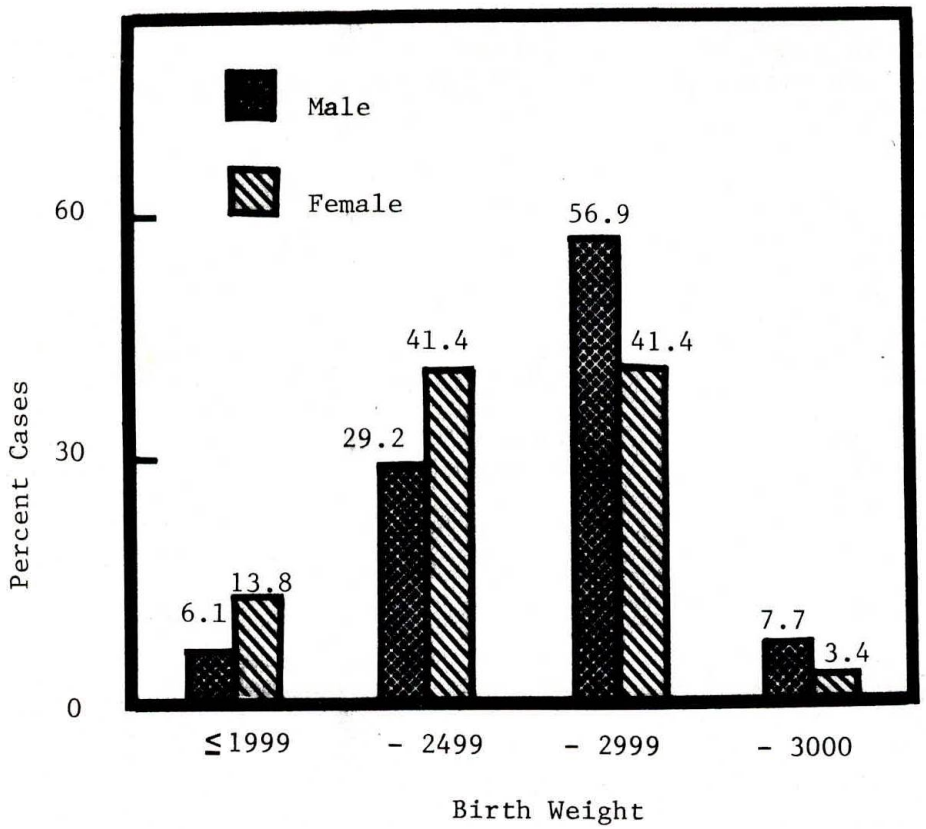

Fig 2

BIRTH WEIGHT BY SEX OF 94 INFANTS DELIVERED AT THE PADRA PRIMARY HEALTH CENTRE IN BARODA DISTRICT, BARODA, NOVEMBER 1979 TO JANUARY 1980

Complications and Referrals

Postpartum complications were reported for 16 (17.0%) women. Fever requiring treatment (11.7%) was the most commonly reported puerperal complication. Urinary tract infection was reported for 3 (3.2%) cases. One woman developed mastitis and another developed phelebitis (Table V). Six women were referred to the district or to the general hospital. The reasons for referral were placenta previa, cord prolapse, ecclampsia, antepartum haemorrhage and shoulder presentation with hand prolapse.

Perinatal Mortality

There were no maternal deaths but high perinatal losses. There were 2 (2.1%) foetal deaths before admission and 8 (8.5%) after admission. The stillbirth rate was 106.4 per 1000 pregnancies. The neonatal and perinatal death rates were 95.7 and 202.1 per 1000 pregnancies respectively (Table VI).

TABLE V

PRIMARY POSTPARTUM COMPLICATIONS REPORTED FOR 94 WOMEN DELIVERED AT THE PADRA PRIMARY HEALTH CENTRE IN BARODA DISTRICT, BARODA, NOVEMBER 1979 TO JANUARY 1980

Postpartum Complications	Number	Percent
Fever requiring treatment	11	11.7
Urinary tract infection	3	3.2
Mastitis	1	1.1
Phelebitis	1	1.1
TOTAL	16	17.0

TABLE VI

MORTALITY RATES REPORTED FOR 94 WOMEN DELIVERED AT THE PADRA PRIMARY HEALTH CENTRE IN BARODA DISTRICT, BARODA, NOVEMBER 1979 TO JANUARY 1980

Mortality	Number	Rate/1000 Deliveries
Maternal mortality	0	0.0
Stillbirth	10	106.4
Neonatal mortality*	9	95.7
Perinatal mortality**	19	202.1

*Deaths before discharge to infants born alive

**Neonatal deaths plus stillbirths.

Desire for Additional Children and Postpartum Fertility Control Acceptance

The majority (71.6%) of the women in this study wanted additional children. While 40.0 percent wanted one additional child, 8.4 percent wanted 3 more children (Table VII).

More than half (57.5%) of the women in the series did not accept any method of fertility control after delivery. However, 23.4 percent underwent postpartum sterilisation. Four (4.2%) accepted IUDs and 9.6 and 2.1 percent of the husbands respectively accepted the condom and sterilisation (Table VII).

TABLE VII

NUMBER OF ADDITIONAL CHILDREN WANTED AND PLANNED CONTRACEPTIVE METHOD FOR 94 WOMEN DELIVERED AT THE PADRA PRIMARY HEALTH CENTRE IN BARODA DISTRICT, BAORDA, NOVEMBER 1979 TO JANUARY 1980

Number of Additional Children	None		IUD		Orals		Female Sterilisation		Male Sterilisation		Condom		Total	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	
0	1	3.8	0	0.0	1	3.8	22	84.6	2	7.7	0	0.0	26	100
1	29	76.3	3	7.9	1	2.6	0	0.0	0	0.0	5	13.2	38	100
2	18	81.8	0	0.0	0	0.0	0	0.0	0	0.0	4	18.2	22	100
3+	7	87.5	1	12.5	0	0.0	0	0.0	0	0.0	0	0.0	8	100
TOTAL	55	57.5	4	4.2	2	2.1	22	23.4	2	2.1	9	9.6	94	100

COMMENT

The present pretest of the Core Questionnaire highlighted the following aspects.

- The analysis results showed extremely high stillbirth and neonatal mortality rates prevailing in this area. The women included in the pretest reported high pregnancy wastage and foetal loss. The incidence of postpartum complications reported for this group was considerably higher (17.0%) than that reported in a pooled analysis of data from several centres (2.5%) in India (6) and was also higher than that reported (3.1%) from a rural area (7). Mean birth weight was lower and percentage of low birth weight (< 2500 gms) infants was higher for this series than for other series (6,7). Thus, high levels of mortality and morbidity were demonstrated despite the small sample pretested indicating the immense potential of the Core Questionnaire as a monitoring tool. However, inorder to scientifically evaluate the quality of feedback and to finalize the record, a pretest of a larger series is suggested.

- This analysis provided data on the incidence of perinatal mortality which was found to be very high in this series. However, data on causes of death were not available. To obtain this important information, the PHC doctor must complete the Perinatal Mortality Record for all stillbirths and neonatal deaths and the Death Report for all Maternal deaths.

- For effective, continued use at the PHC, the Core Questionnaire should be in the form of a register.

- Training in data recording is necessary to ensure that data are completely and accurately recorded by health personnel.

- An instruction manual is needed to facilitate accurate recording of data and to ensure adherence to standard definitions and uniformity in data recording.

- A suitable referral record with clear instructions is needed for reporting referrals from the PHC to the district or other hospitals.

- Addition of items should be considered for recording data on method of last delivery, antenatal conditions and complications of labour/delivery.

- As this record is intended to be used by the nurse and midwife, it should be translated into the local language. In the present pretest, the record was not translated and data were recorded by the medical intern. It is recommended that another pretest be conducted after translating the record to evaluate its practicability when it is used by the nurse and midwife.

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PREGNANCY TERMINATION WITH THE BATTELLE HAND PUMP - STUDIES IN INDIA

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ABSTRACT

A hand pump was developed by Battelle in the USA with the objective of providing equipment for rural areas which is safe, effective and efficient, is easy to use, repair and maintain, and does not require the use of electrical energy. The results of studies conducted by the India Fertility Research Programme (India FRP) indicate that the Battelle Hand Pump can be used safely, effectively and efficiently for terminating first trimester pregnancies. The design of the hand pump has been replicated locally and this equipment will be now manufactured in the country soon.

INTRODUCTION

For the successful implementation of rural programmes for termination of pregnancy, it is necessary to equip rural health centres providing these services with equipment which not only satisfies the criteria of low cost, safety and effectiveness but is also easy to use, maintain and repair and most importantly, is such that it does not require the use of electrical energy. With these criteria in mind, a hand pump was developed by Battelle in the USA. This is a report of studies conducted by the India FRP at five centres with the objective of evaluating the safety, effectiveness and technical efficiency of the Battelle Hand Pump for terminating first trimester pregnancies.

MATERIALS AND METHODS

Data on 878 pregnancy termination procedures performed with the Battelle Hand Pump at five centres in India from August 1976 to April 1978 were reported on standard forms of the India FRP.

Definitions and Criteria

Physically healthy women with pregnancies upto 10 weeks' gestation were included in the study. Gestational age was calculated as the number of completed weeks from the first day of the patient's last normal menstrual period to the day her pregnancy was terminated. Technical failure was defined as a case in whom the uterus could not be successfully evacuated with the hand pump technique and another method had to be used for completing the abortion. Procedure time was the time from the first insertion to the last removal of the speculum and cannula time was the time from the first insertion to the last removal of the cannula. Cannula obstruction was defined operationally by the number of times it was removed from the uterine cavity. Complications and complaints were categorised into the immediate and follow-up categories. Immediate complications and complaints were defined as those occurring from the time the procedure was initiated to the time the patient was discharged. Follow-up complications and complaints were defined as those occurring between the patient's discharge and her follow-up contact 2 to 4 weeks after pregnancy termination. Blood

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loss during the procedure was estimated by the operator from the aspirated uterine contents. Blood loss of 100 ml or more was defined as excessive.

The equipment was evaluated using the following criteria:

1. Procedure and cannula time
2. Incidence of technical failures and difficulties.
3. Frequency of cannula obstruction.
4. Incidence of complications and complaints

The recommended period of follow-up was from 2 to 4 weeks after the procedure. In this study 94.6 percent cases returned for follow-up history and examination. All statistical tests were performed using a significance level (p value) of 0.05.

The Abortion Procedure

The procedures were performed without anaesthesia at all except one centre where paracervical block anaesthesia with 10 ml of 1 percent xylocaine was used for terminating pregnancies of 6 to 10 weeks' gestation. At one of the centres no analgesia or anaesthesia was used. At the other three centres, however, analgesia was used. At one centre premedication in the form of 100 mg of pethidine and 0.6 mg of atropine was administered intramuscularly half an hour prior to the procedure. At another, the patient received 5.0 to 7.5 mg of intravenous diazepam and 500 mg of analgin.

Cold sterilisation was used for sterilising the equipment. The patient was placed in the dorsal lithotomy position and draped. A pelvic examination was performed and the vulva was cleansed. A Sim's speculum was introduced to retract the posterior vaginal wall and the cervix was grasped with a tenaculum or volsellum. The uterus was sounded and the length of its cavity was measured to determine the degree of cervical dilatation and the size of cannula needed. The cervix was then dilated upto the required size and the appropriate size of cannula was introduced into the uterus while the hand pump was kept precharged. The cannula was then connected to the hand-operated vacuum pump assembly. The pinch valve was released, the cannula was gently rotated through 180° and gradually withdrawn to the middle of the uterine cavity. Aspiration was considered complete if air bubbles appeared in the cannula. After aspiration, a check curettage was routinely performed. Prophylactic antibiotics were routinely administered at 4 centres. The material collected in the flask was first visually examined and was then sent for histo-pathological examination. A detailed description of the Battelle Hand Pump and its operating mechanism has been reported in an earlier publication (1).

RESULTS

Sociodemographic Characteristics

The mean age of the women undergoing abortion was 26.8 years. Their mean parity was 2.2; 12.2 percent had no live births. Their mean education was 9.0 school years; 57.7 percent had 10 or more years of school education (Table I).

TABLE I

SOCIODEMOGRAPHIC CHARACTERISTICS OF 878 WOMEN UNDERGOING FIRST TRIMESTER ABORTION WITH THE BATTELLE HAND PUMP AT FIVE CENTRES IN INDIA, AUGUST 1976 TO APRIL 1978

Sociodemographic Characteristics	Number	Percent
Age (Years)		
≤ 19	42	4.8
20 - 24	292	33.3
25 - 29	286	32.6
30 - 34	169	19.2
35 +	89	10.1
Mean	26.8	
Parity		
0	107	12.2
1 - 2	539	61.4
3 - 4	180	20.5
5 - 6	52	5.9
Mean	2.2	
Patient's Education (School Years)		
0	75	8.5
1 - 3	27	3.1
4 - 6	125	14.2
7 - 9	144	16.4
10 - 12	353	40.2
13 +	154	17.5
Mean	9.0	

Gestational Age

Pregnancy was terminated at 5 to 6 weeks' gestation in 49.3 percent, at 7 to 8 weeks' gestation in 39.7 percent and at 9 to 10 weeks' gestation in 10.9 percent cases (Fig 1).

Procedure Time and Hospitalisation

There was an increase in procedure time with increase in gestation; it was 4.7, 5.8 and 6.4 minutes at 5-6, 7-8 and 9-10 gestational weeks respectively. (Table II) and Fig 2). These differences were not statistically significant. Mean cannula time was similar for varying periods of gestation; it was 2.4, 3.1 and 3.3 minutes for gestations of 5-6, 7-8 and 9-10 weeks respectively (Table III and Fig 2).

All pregnancy termination procedures were performed on an outpatient basis. Only women who underwent concurrent sterilisation were hospitalised.

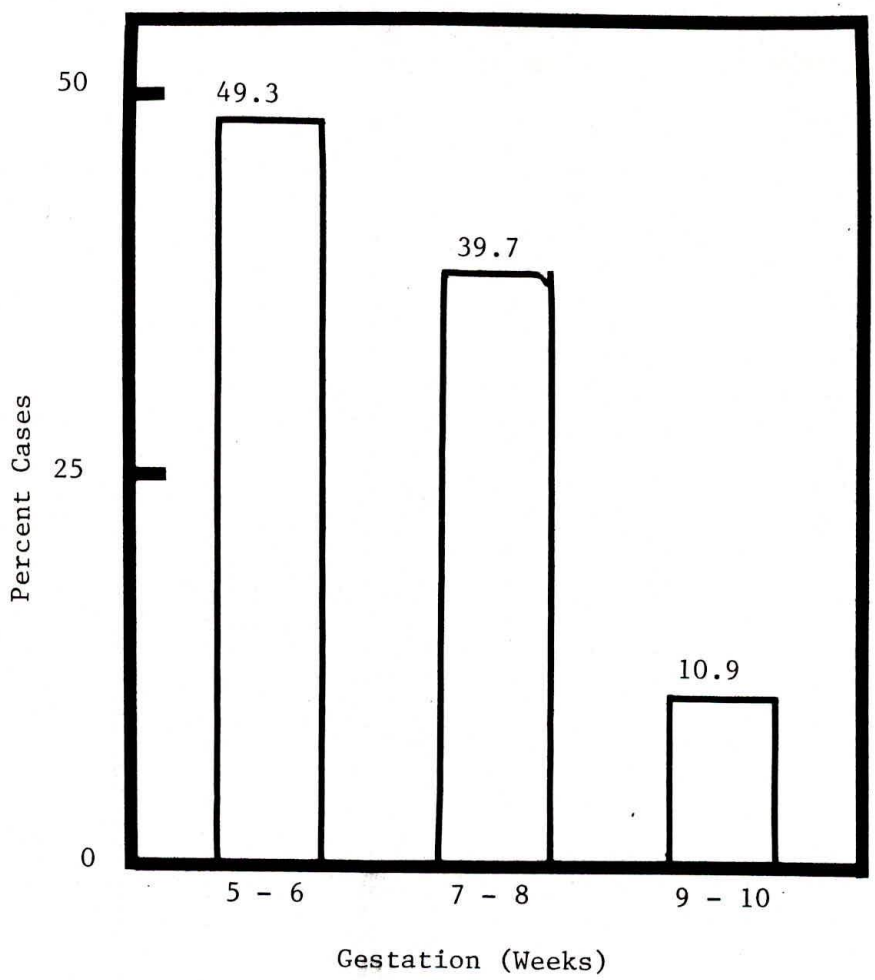

Fig 1

GESTATIONAL AGE OF 878 WOMEN UNDERGOING FIRST TRIMESTER ABORTION WITH THE BATTELLE HAND PUMP AT FIVE CENTRES IN INDIA, AUGUST 1976 TO APRIL 1978

TABLE II

PROCEDURE TIME BY GESTATION FOR 847 WOMEN UNDERGOING FIRST TRIMESTER ABORTION WITH THE BATTELLE HAND PUMP AT FIVE CENTRES IN INDIA, AUGUST 1976 TO APRIL 1978

Procedure Time (Minutes)	Weeks' Gestation					
	5 - 6 N = 416		7 - 8 N = 336		9 - 10 N = 95	
	No.	%	No.	%	No.	%
≤ 1	4	1.0	1	0.3	0	0.0
2 - 3	201	48.3	91	27.1	21	22.1
4 - 5	67	16.1	67	19.9	11	11.6
6 - 7	43	10.3	49	14.6	17	17.9
8 +	101	24.3	128	38.1	46	48.4
Mean	4.7		5.8		6.4	

Note: Data not reported for 31 cases.

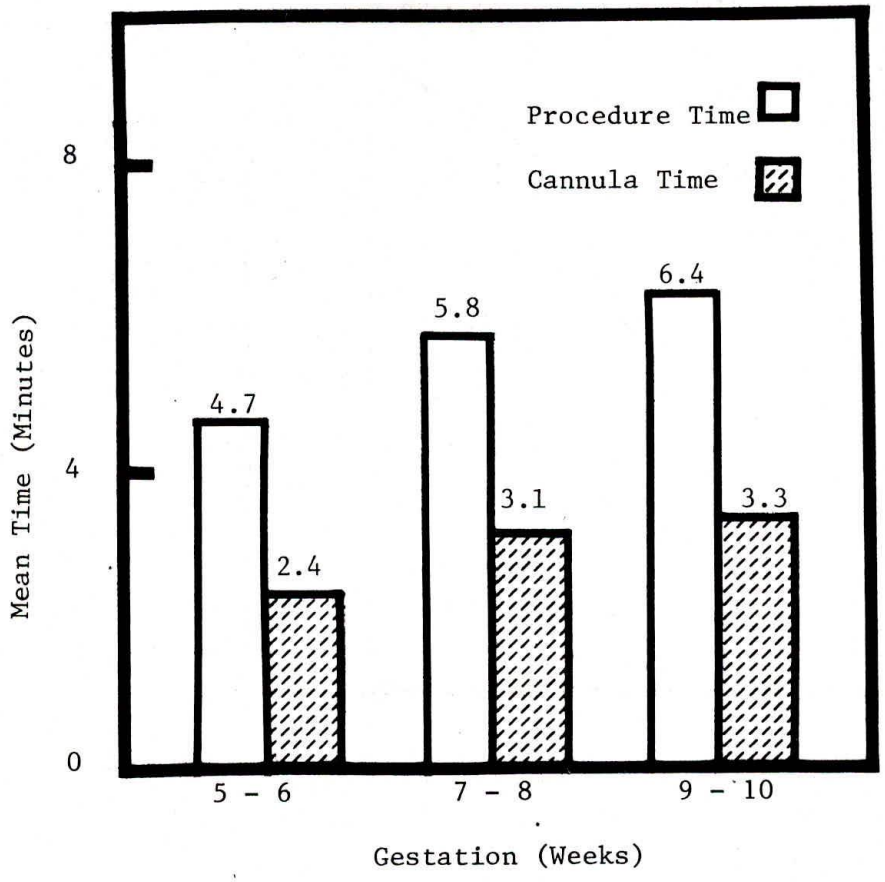

Fig 2

GESTATION BY PROCEDURE AND CANNULA TIME FOR 847 WOMEN UNDERGOING FIRST TRIMESTER ABORTION WITH THE BATTELLE HAND PUMP AT FIVE CENTRES IN INDIA, AUGUST 1976 TO APRIL 1978

TABLE III

CANNULA TIME BY GESTATION FOR 847 WOMEN UNDERGOING FIRST TRIMESTER ABORTION WITH THE BATTELE HAND PUMP AT FIVE CENTRES IN INDIA, AUGUST 1976 TO APRIL 1978

Cannula Time (Minutes)	Weeks' Gestation 5 - 6 N = 416		7 - 8 N =336		9 - 10 N = 95	
	No.	%	No.	%	No.	%
≤ 1	169	40.6	81	24.1	19	20.0
2 - 3	165	39.7	144	42.9	44	46.3
4 - 5	16	3.8	32	9.5	9	9.5
6 - 7	66	15.9	79	23.5	23	24.2
Mean	2.4		3.1		3.3	

Note: Data not reported for 31 cases.

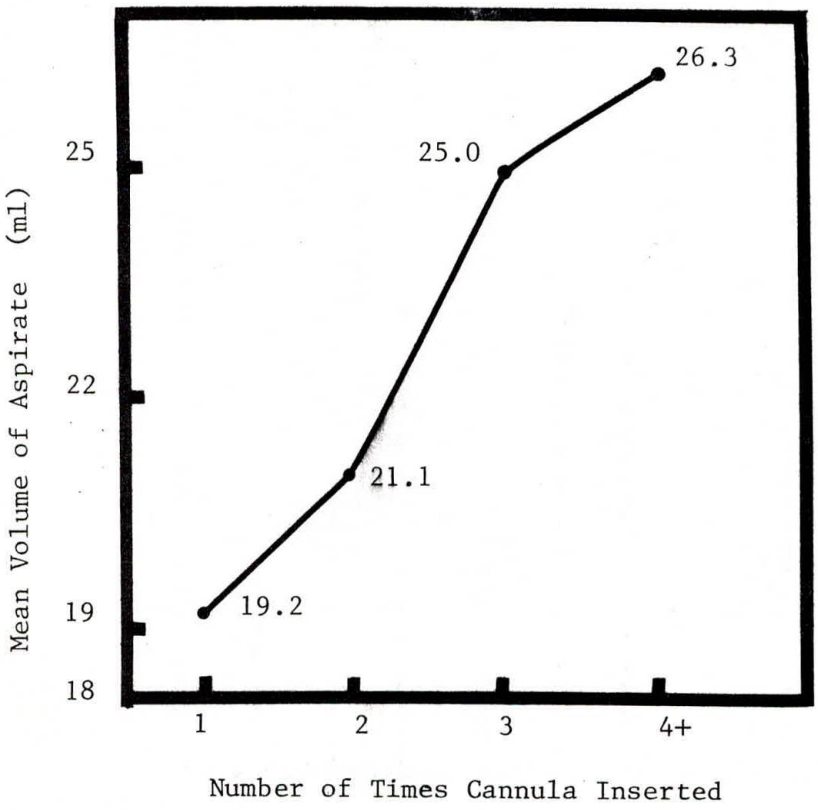

Fig 3

NUMBER OF TIMES CANNULA INSERTED BY MEAN VOLUME OF ASPIRATE FOR 847 WOMEN UNDERGOING FIRST TRIMESTER ABORTION WITH THE BATTELLE HAND PUMP AT FIVE CENTRES IN INDIA, AUGUST 1976 TO APRIL 1978

Technical Difficulties

Technical difficulties were reported for 8.8 percent cases. Leakage of air (5.4%) and blockage of the cannula (1.5%) were the most frequently reported technical difficulties (Table IV).

Technical Failures

There were 7 (0.9%) technical failures; pregnancy could not be successfully terminated with the hand pump and a second procedure was used to evacuate the uterine contents. Five of these technical failures were due to leakage of air and unsatisfactory vacuum. In one case incomplete abortion was diagnosed at the follow-up visit and in another the reason for technical failure was not reported.

TABLE IV

TECHNICAL DIFFICULTIES REPORTED FOR 878 WOMEN UNDERGOING FIRST TRIMESTER ABORTION WITH THE BATTELLE HAND PUMP AT FIVE CENTRES IN INDIA, AUGUST 1976 TO APRIL 1978

Technical Difficulties	Number	Percent
Leakage of air	47	5.4
Blockage of cannula	13	1.5
Valve not functional	5	0.6
Pinch valve broken/dislocated	3	0.3
Material aspirated in shorter plastic tube	2	0.2
Cannula came out of os	2	0.2
Push button adapter faulty	1	0.1
Dislocation of tube	1	0.1
Ring replaced	1	0.1
Gauge not showing pressure	1	0.1
Tube slipped from bottle	1	0.1
Connecter seal replaced	1	0.1
TOTAL	78	8.8

Cannula Obstruction

The cannula had to be reinserted in over 60 percent cases. The rates of cannula obstruction were similar at various gestational ages (Table V). The number of times the cannula was reinserted increased with increase in the volume of aspirate (Table VI and Fig 3).

TABLE V

NUMBER OF TIMES CANNULA INSERTED BY GESTATION FOR 878 WOMEN UNDERGOING FIRST TRIMESTER ABORTION WITH THE BATTELLE HAND PUMP AT FIVE CENTRES IN INDIA, AUGUST 1976 TO APRIL 1978

Number of Times Cannula Inserted	Gestation (Weeks) 5 - 6 N=433		7 - 8 N=349		9 - 10 N=96	
	No.	%	No.	%	No.	%
1	136	31.4	131	37.5	34	35.4
2	166	38.3	79	22.6	25	26.0
3	98	22.6	93	26.6	17	17.7
4	33	7.6	46	13.2	20	20.8
Mean	2.6		2.7		2.7	

TABLE VI

NUMBER OF TIMES CANNULA INSERTED BY VOLUME OF ASPIRATE FOR 847 WOMEN UNDERGOING FIRST TRIMESTER ABORTION WITH THE BATTELE HAND PUMP AT FIVE CENTRES IN INDIA, AUGUST 1976 TO APRIL 1978

Volume of Aspirate (ml)	Number of Times Cannula Inserted							
	1 N=300		2 N=271		3 N=182		4+ N=94	
	No.	%	No.	%	No.	%	No.	%
≤ 9	40	13.3	18	6.6	3	1.6	1	1.1
10 - 14	53	17.7	42	15.5	11	6.0	0	0.0
15 - 19	29	9.7	37	13.7	8	4.4	1	1.1
20 - 24	39	13.0	48	17.7	13	7.1	7	7.4
25 +	139	46.3	126	46.5	147	80.8	85	90.4
Mean	19.2		21.1		25.0		26.3	

Note: Data not reported for 31 cases.

Complications

Immediate complications were reported for 1.3 percent cases. Blood loss (more than 100 ml) was reported for 9 (1.0%) cases. Uterine perforation occurred in 2 (0.2%) and cervical laceration in 1 (0.1%) case (Table VII).

TABLE VII

COMPLICATIONS REPORTED FOR 878 WOMEN UNDERGOING FIRST TRIMESTER ABORTION WITH THE BATTELLE HAND PUMP AT FIVE CENTRES IN INDIA, AUGUST 1976 TO APRIL 1978

Complications	Number	Percent
Immediate:		
Blood loss	9	1.0
Uterine perforation	2	0.2
Cervical laceration	1	0.1
Total	12	1.3
Early Postoperative:		
Bleeding/spotting	39	4.5
Bleeding requiring curettage	15	1.8
Fever requiring antibiotics	1	0.1
Total	55	6.4

The incidence of follow-up complications was 6.4 percent. Bleeding requiring curettage was reported for 15 (1.8%) and fever requiring antibiotics for 1 (0.1%) case. In this series 4.5 percent of the women reported bleeding and/or spotting at the follow-up visit (Table VII).

Complaints

The incidence of early and follow-up complaints was 3.8 and 2.5 percent respectively. Abdominal pain (1.9%) and vomiting (1.0%) were the most commonly reported immediate complaints. Abdominal pain (1.3%) was the most frequently reported complaint at the follow-up visit (Table VIII).

TABLE VIII

COMPLAINTS REPORTED FOR 878 WOMEN UNDERGOING FIRST TRIMESTER ABORTION WITH THE BATTELLE HAND PUMP AT FIVE CENTRES IN INDIA, AUGUST 1976 TO APRIL 1978

Complaints	Number	Percent
Immediate:		
Abdominal pain	17	1.9
Vomiting	9	1.0
Vasovagal attack	2	0.2
Vertigo	2	0.2
Chest pain	1	0.1
Backache	1	0.1
Depression	1	0.1
Total	33	3.8
Early postoperative:		
Abdominal pain	11	1.3
Weakness	4	0.5
Leucorrhoea	2	0.2
Backache	2	0.2
Tender fornix	1	0.1
Discharge per vagina	1	0.1
Micturition	1	0.1
Total	22	2.5

Fertility Control Acceptance

While 75.6 percent of the women had not used any method of fertility control three months prior to the procedure, 64.7 percent accepted a method after termination of pregnancy. In this series, 28.0, 16.6 and 8.1 percent of the women accepted IUDs, oral contraceptives and sterilisation respectively and 3.1 percent of the husbands accepted sterilisation (Fig 4).

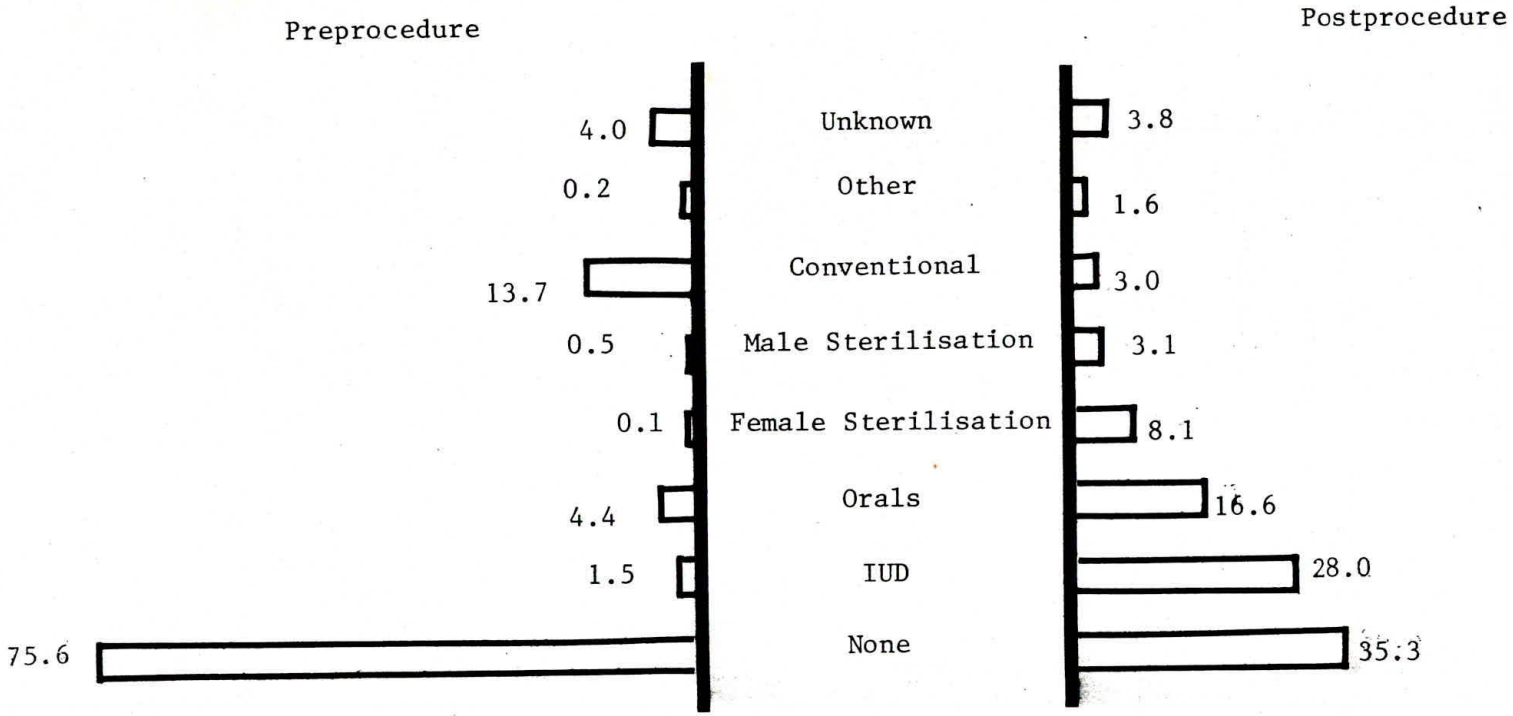

Fig 4

PRE AND POST PROCEDURE FERTILITY CONTROL ACCEPTANCE BY 878 WOMEN UNDERGOING FIRST TRIMESTER ABORTION WITH THE BATTELLE HAND PUMP AT FIVE CENTRES IN INDIA, AUGUST 1976 TO APRIL 1978

DISCUSSION

Pregnancy termination with vacuum aspiration is a widely accepted procedure as it has been extensively documented to be safe and effective (2-5). With this procedure, several variations in the type of cannula (6,7), source of vacuum, and vacuum pressure (8) have been evaluated. However, its application in developing countries has been limited essentially to urban institutions because of its dependence on electricity. For large-scale use in rural areas, equipment which can be operated efficiently without electrical power is needed.

Studies with the Battelle Hand Pump indicate that it can be used safely, effectively and efficiently for terminating first trimester pregnancies. The incidence of complications following pregnancy termination with the prototype equipment was low. Technical difficulties reported by workers testing this equipment were mostly minor. Certain improvement in the equipment have been suggested, such as modification of the adapter system to permit more cannula rotation without leakage of air (9). In order to make the equipment widely available, it was recommended that this design be replicated locally with suggested improvements. A hand pump of the same design is presently being developed in India.

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STUDY OF A POSTPLACENTAL INTRAUTERINE DEVICE AT THE NOWROSJEE WADIA MATERNITY HOSPITAL

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H.B. Nariman, MBBS, DGO[3]

ABSTRACT

This is a preliminary report of 50 postplacental insertions of the sutured copper T-200. No complications were reported. The expulsion rate of 6.0 percent with this device was considerably lower than that reported in literature. These results indicate that the chromic catgut sutures attached to the device provide an effective anchor to prevent the expulsion of the device in the immediate postpartum period. Larger studies are needed to document expulsion rates of the sutured Copper T-200.

INTRODUCTION

As the intrauterine device (IUD) requires one time motivation it is a suitable contraceptive for developing countries. Motivation for accepting contraception is high in the immediate postpartum period. However, the high rate of expulsion associated with postpartum IUD insertion has been a limiting factor in making this highly effective method available to women in postpartum programmes. Recent modifications of the IUD have been made with the idea of increasing retention by physiological embedding of the device in the endometrium. One such method is to provide chromic catgut sutures as biodegradable extensions for hinging the IUD to the endometrium. This study was undertaken to evaluate the effectiveness of the sutured copper T-200 when inserted immediately after placental expulsion.

MATERIALS AND METHODS

This is a preliminary report of 50 postplacental insertions of the sutured copper T-200 IUD in women delivering at the Nowrosjee Wadia Maternity Hospital in Bombay from June 1979 to February 1980. Informed consent was obtained from women who requested a spacing method and were willing to participate in the study.

The IUD was inserted within two hours of placental expulsion. In 47 (94.0%) cases the device was inserted by hand and in 3 (6.0%) cases the inserter was used for inserting the device into the uterus. In all cases care was taken to ensure that the device was placed at the uterine fundus. Postnatal care provided was similar to that for any normal case. The woman was re-evaluated prior to discharge on the fifth day after delivery and was requested to return for a follow-up visit 20 days after delivery and every three months thereafter. While all the study cases were examined five days after delivery, 84.0 percent were examined 20 days after delivery and 50.0 percent were examined at the three months follow-up visit.

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RESULTS

Sociodemographic Characteristics

More than half of the IUD acceptors were primiparous and were 21 to 25 years of age. While 20.0 percent of the women in the study group were illiterate, 52.0 percent had completed six to ten years of schoool education. The majority (94.0%) of the acceptors were Hindus (Table I).

TABLE I

SOCIODEMOGRAPHIC CHARACTERISTICS OF 50 WOMEN UNDERGOING POSTPLACENTAL INSERTION OF THE COPPER T-200 AT THE NOWROSJEE WADIA MATERNITY HOSPITAL, BOMBAY, JUNE 1979 TO FEBRUARY 1980

Sociodemographic Characteristics	Number	Percent
Age (Years)		
< 20	12	24.0
21 - 25	27	54.0
26 - 30	9	18.0
31 +	2	4.0
Parity		
1	27	54.0
2	13	26.0
3	9	18.0
4	1	2.0
Education (School years)		
0	10	20.0
1 - 5	4	8.0
6 - 10	26	52.0
11 - 15	9	18.0
16 +	1	2.0
Religion		
Hindu	47	94.0
Muslim	2	4.0
Parsee	1	2.0

Expulsions

The device was expelled in three cases. Thus the expulsion rate was 6.0 percent. In one case the device was expelled within three days of insertion. In the other two cases it was expelled within two weeks of insertion. The remaining 47 women continue to wear the IUD.

Complications and Complaints

No complications were reported in this series. The only complaint reported was the occurrence of a pricking sensation in the vagina. This complaint was reported by 12 (24.0%) cases and was due to the presence of the nylon thread of the device in the vagina. As the postpartum uterus is large, the thread, which was originally long, descended into the vagina when the uterus involuted, and created this pricking sensation. This symptom disappeared when the string was cut short at the first follow-up visit.

CONCLUSIONS

After reviewing our experience with IUD insertions in this and previous studies conducted at this institution we feel that postplacental IUD insertion is easier than subsequent insertion. However, motivation prior to insertion is difficult as the concept of postpartum IUDs is still new to the women attending this institution.

When 100 postpartum insertions with the multiload, Cu-250, postpartum T, and Lippes loop were evaluated at our institution, the expulsion rate was 40.0 percent. These preliminary results of this study showed that the expulsion rate was significantly lower. The expulsion rate with this device was also much lower than that reported in literature (1,2). It appears that the catgut sutures are effective for anchoring the device to the endometrium and prevent its expulsion in the postpartum period. Larger studies are needed to document the effectiveness of the sutured Copper T-200.

ACKNOWLEDGMENT

The authors wish to express their gratitude to the India Fertility Research Programme for sponsoring the study and providing the devices.

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MATERNAL AND NEONATAL MORBIDITY AND MORTALITY WITH PREMATURE RUPTURE OF MEMBRANES - THE ROLE OF PROPHYLACTIC ANTIBIOTICS

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ABSTRACT

This study was conducted to study the incidence of neonatal and maternal mortality and morbidity following premature rupture of the membranes and to evaluate the role of prophylactic antibiotics in preventing maternal and neonatal infection in such cases.

The neonatal and maternal mortality rates for the study group were 4.0 and 2.4 percent respectively. The incidence of neonatal and maternal infection increased with time after the rupture of membranes. For maternal infection rates these differences were statistically significant. The incidence of neonatal infection was lower by 20-50 percent and that of maternal infection was lower by 10-20 percent for cases who did receive antibiotics as compared to those who did. This suggests that prophylactic antibiotics are not indicated in these cases.

INTRODUCTION

Although premature rupture of membranes is a common obstetrical complication, its potential as a maternal and foetal hazard generally tends to be overlooked and undermined. Prolonged rupture of membranes has been incriminated as a major factor in maternal and neonatal morbidity. However, the degree of risk to the mother and to the infant from premature rupture of membranes, in the absence of other obstetrical difficulties, has never been satisfactorily assessed and established. Several methods which have been proposed for determining the presence or absence of infection, could be used as valuable screening devices for the early detection of this potentially hazardous condition which can be treated effectively.

This study was undertaken to: (1) determine the incidence of infection in the mother and the newborn based on bateriological and/or histopathological evidence and (2) evaluate the role of prophylactic antibiotics in preventing maternal and neonatal infection.

MATERIALS AND METHODS

Case Selection and Categorization

Data are reported on 125 women who delivered at the Kasturba Hospital in Delhi from August 1977 to January 1978 with uncomplicated rupture of membranes and no other obstetrical complications. The study cases were categorised into the following groups:

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[1]Medical Superintendent, [2]General Duty Medical Officer, Department of Obstetrics and Gynaecology, Kasturba Hospital, Delhi.

Group I - Group I was the control group which consisted of 25 cases in whom labour started within 12 hours of rupture of membranes.

Group II - Group II consisted of 50 cases in whom membranes had ruptured 12 to 24 hours prior to the onset of labour. This group was further subdivided into Group II-A and Group II-B each consisting of 25 cases.

Group III - Group III consisted of 50 cases in whom the membranes had ruptured 24 hours or more before the onset of labour. This group was further subdivided into Group III-A and Group III-B each consisting of 25 cases.

Antibiotics were administered to both the mother and the newborn in Groups II-A and III-A but not to those in groups II-B and III-B. To achieve a random pattern in as far as possible, every alternate mother and newborn received prophylactic antibiotics. The mother received 0.5 gm of streptomycin with 4 lac units of penicillin intramuscularly for 7 days (after a test dose). The newborn received one lac units/kg of body weight of crystalline penicillin 12 hourly after a test dose and 5 mg/kg of body weight of garamycin intramuscularly, 8 hourly for 7 days.

Infection Criteria:

Infection in the mother was detected by the following methods:

1. Culture of a high vaginal swab for aerobic and anerobic organisms. In case of a positive culture, an antibiotic sensitivity test was put up against the isolated organism.

2. Histopathological examination of the umbilical cord, placenta and membranes. Leucocytic infiltration was considered as histopathological evidence of infection.

Infection in the newborn was detected by the following methods:

1. Culture of the venous blood (taken from the femoral vein) for aerobic and anerobic organisms.

2. Culture of the gastric aspirate.

3. Cell count of the gastric aspirate. A smear was considered to be positive when there were 5 or more polymorphs per high power field.

Both the mother and newborn were followed up for seven days after delivery. The criteria for maternal infection was a temperature of $38^{o}C$ or more at any time and/or local infection in the form of a foul smelling lochial discharge. The criterion of neonatal infection was the presence of any sign or symptom of septicemia within the first seven days of birth.

All statistical tests were performed using a significant level (p value) of 0.05.

RESULTS

Neonatal Mortality and Morbidity

There were five neonatal deaths; of these 4 were from group II-A and one was a control case. The neonatal mortality rate for the series was 4.0 percent. Neonatal mortality increased with increase in time after rupture of membranes and was highest after 24 hours when the incidence was doubled.

The incidence of neonatal infection for the series was 26.4 percent. Infection rates for Groups I, II and III were 20.0, 26.0 and 30.0 percent respectively (Table I and Fig 1). However, the differences were not statistically significant. The neonatal infection rate was higher for infants who received prophylactic antibiotics than for those who did not (Fig 2).

TABLE I

INCIDENCE OF NEONATAL INFECTION IN VARIOUS GROUPS AT THE KASTURBA HOSPITAL, DELHI, AUGUST 1977 TO JANUARY 1978

Group	Number of Cases	Infection	
		No.	%
I - Control Group	25	5	20.0
II - Rupture of membranes within 12 to 24 hours	50	13	26.0
III - Rupture of membranes after 24 hours	50	15	30.0
TOTAL	125	33	26.4

Maternal Mortality and Morbidity

There were 3 deaths in this series; all 3 cases belonged to group III A. The maternal mortality rate was 2.4 percent.

The incidence of maternal infection for the series was 22.4 percent. Infection was documented bacteriologically in only 7 cases. The incidence of of maternal infection increased by time; it was 12.0, 16.0 and 34.0 percent in Groups I, II and III respectively (Table II and Fig 2). There was a significant difference in the incidence

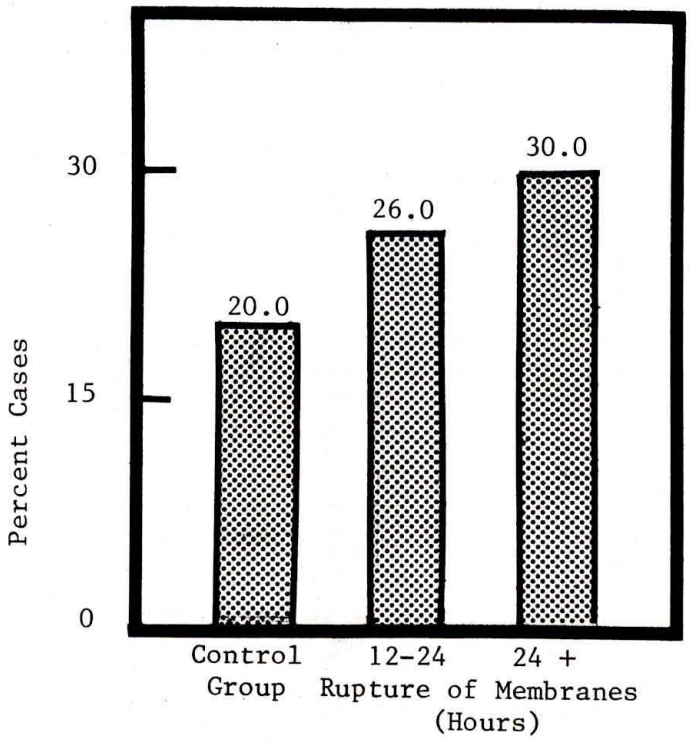

Fig 1

INCIDENCE OF NEONATAL INFECTION BY TIME IN VARIOUS GROUPS AT THE KASTURBA HOSPITAL, DELHI, AUGUST 1977 TO JANUARY 1978

TABLE II

INCIDENCE OF MATERNAL INFECTION IN VARIOUS GROUPS AT THE KASTURBA HOSPITAL, DELHI, AUGUST 1977 TO JANUARY 1978

Group	Number of Cases	Infection	
		No.	%
I- Control Group	25	3	12.0
II- Rupture of membranes within 12 to 24 hours	50	8	16.0
III- Rupture of membranes after 24 hours	50	17	34.0
TOTAL	125	28	22.4

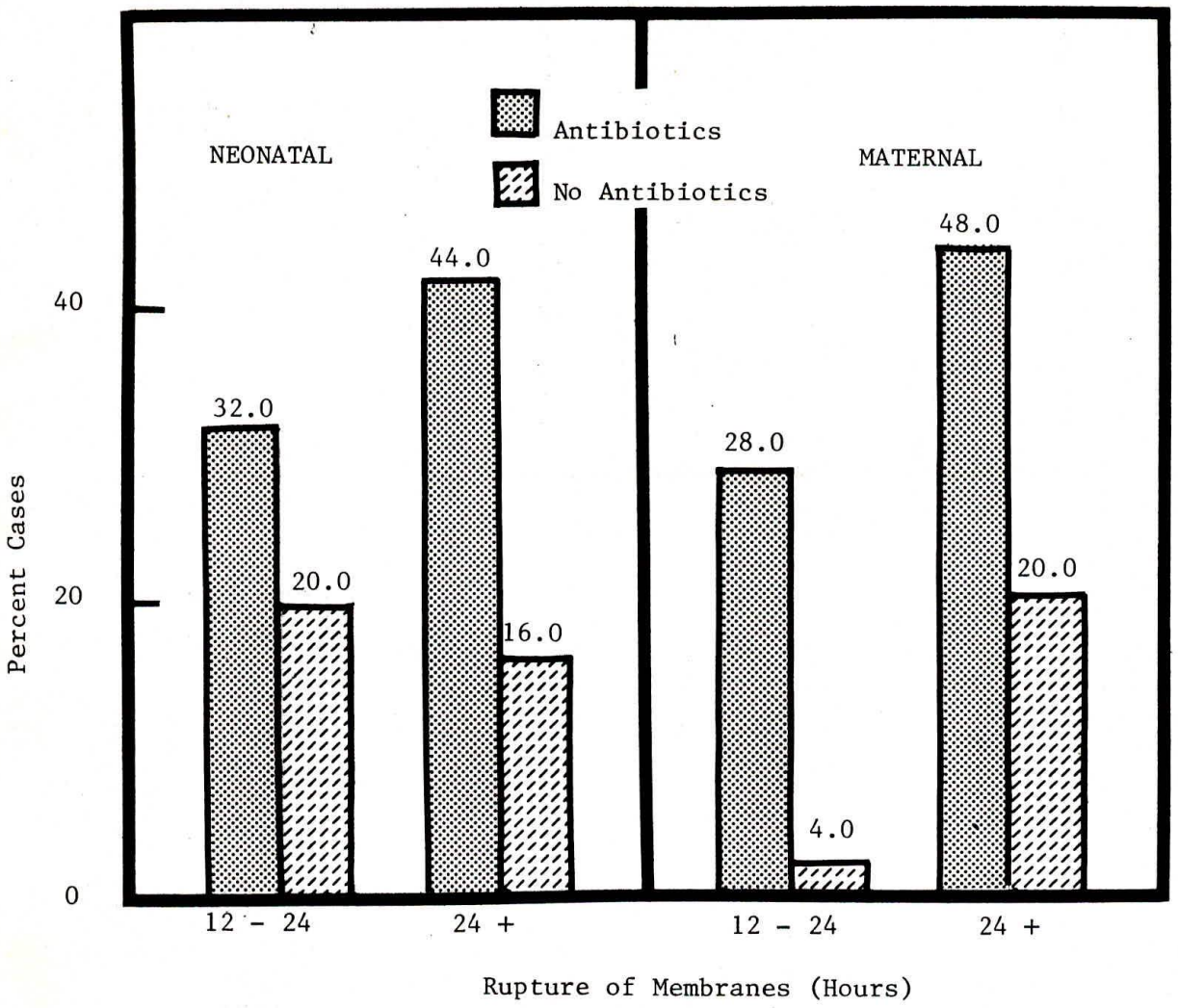

Fig 2

INCIDENCE OF NEONATAL AND MATERNAL INFECTION WITH AND WITHOUT ANTIBIOTICS BY TIME IN THE STUDY GROUPS AT THE KASTURBA HOSPITAL, DELHI, AUGUST 1977 TO JANUARY 1978

of infection in groups II and III (Table II and Fig 3). The incidence of maternal infection was significantly higher for women who received antibiotics than for those who did not (Fig 2).

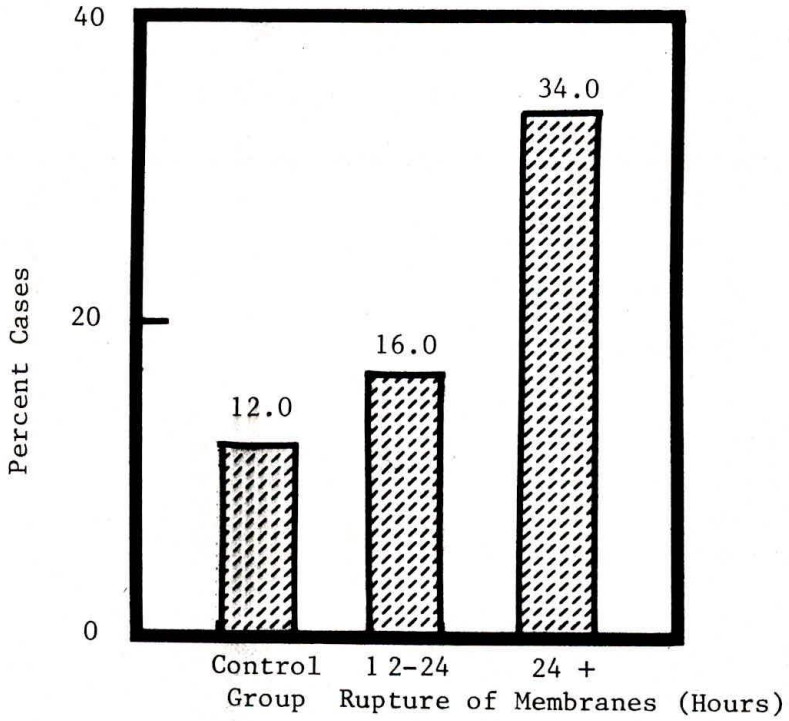

Fig 3

INCIDENCE OF MATERNAL INFECTION BY TIME IN VARIOUS GROUPS AT THE KASTURBA HOSPITAL, DELHI, AUGUST 1977 TO JANUARY 1978

DISCUSSION

A review of available literature, shows a considerable variation in opinion regarding risks related to premature rupture of membranes and to the management of this condition. Spontaneous rupture of membranes often heralds the onset of normal labour, but when the membranes rupture without prompt onset of labour, an entirely different set of consequences results.

In this study, the incidence of neonatal infection was found to be independent of time after rupture of membranes. Similar observations were made by Habel et al (1). The neonatal morbidity rate (26.4%) for the present series was lower than that reported by Pyrles et al (31.0%) (2) but was considerably higher than that reported by Taylor et al (4.3%) (3) and Habel et al (3.0%) (1). When the membranes ruptured before 24 hours, the neonatal infection rate was 30.0 percent in this series.

In this study, there was a 10 to 20 percent higher rate of infection among infants who received prophylactic antibiotics than among those who did not. While Pryles et al (2) made a similar observation, Calkins (4) observed a reduction in the incidence of foetal infection when penicillin was administered prophylactically. Equivocal results were reported by other workers (1, 5).

This study showed an increase in neonatal mortality with increasing time after rupture of membranes, especially after 24 hours when the mortality rate doubled. Burchell also showed a doubling of neonatal mortality after 24 hours, and a second doubling was reported during the next 24 hours (6). Breese (7) observed a three and a half times increase and Eastman (8) observed a three fold increase in neonatal mortality 48 hours after the membranes ruptured. Other workers also showed an escalation in the neonatal death rate every 12 hours (9-11). Bishop (12), however, observed a slight decrease in both stillbirth and neonatal death rates in cases of premature rupture of the membranes.

In this study, prophylactic antibiotic therapy did not decrease neonatal mortality. Similar results were reported by Breese (7) and Kent et al (13). Lebherz et al (14) showed very little difference in the mortality rates of patients who received or did not receive antibiotics.

In this series, the incidence of maternal infection was seen to increase as the time between the rupture of membranes and onset of labour increased. Similar reports were made by other researchers. In contrast to this, Lebherz et al showed that maternal morbidity did not increase significantly with premature rupture of membranes (15). Woltz observed that there was no maternal morbidity within 24 hours of rupture of membranes and after 24 hours, there was no definite relationship between duration of rupture of membranes and maternal morbidity (16).

In this study, the incidence of maternal infection was found to be significantly higher in patients who received prophylactic antibiotics as compared to those who did not, suggesting that prophylactic antibiotic therapy is not warranted in these cases. Similar observations were made by other workers who showed similar maternal morbidity rates for patients who received antibiotics and those who did not (6, 7, 16, 17). The maternal mortality rate (2.4%) in this series was higher than that reported by Schulze (18), who reported no maternal mortality, but was lower than that reported by Bishop (5.1%) (12). The study suggested that prophylactic antibiotics do not prevent maternal and neonatal infection in uncomplicated cases of premature rupture of membranes.

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DESIGN OF THE COMMUNITY-BASED PROJECT FOR SOUTH KANARA DISTRICT

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ABSTRACT

The project design for a community-based programme of contraceptive distribution and family planning surgical services for South Kanara District is described.

Oral contraceptives will be provided through 301 distribution outlets spread over the district. The role of depot workers and supervisors in the programme is explained. Menstrual regulation and other services will be provided at minimal charge by trained rural medical practitioners. It is envisaged, that after the initial inputs, the programme will become a self-supporting distribution system.

INTRODUCTION

The project is designed for community-based distribution of oral contraceptives and for provision of family planning surgical services to eligible couples in the South Kanara District. It aims to supplement the ongoing programmes and to saturate the area with family planning services by popularizing the use of IUDs, condoms, menstrual regulation (MR), oral contraceptives, and medical termination of pregnancy.

This project will be funded for 3 years by the Family Planning Foundation, will be implemented by the Kasturba Medical College, Manipal and will be monitored and evaluated by the Jan Mangal Samastha.

The South Kanara District has coastal, hilly and forest areas and thus provides a wide range of conditions for testing the system for future large-scale replication in the country. While 18.5 percent of the couples in this state are protected by sterilisation, only 1.3 percent use IUDs and 0.8 percent use other methods including oral contraceptives.

According to the 1971 census the population of this district was 1,939,315. It is expected to increase by 19.4 percent in 1981 when it will be 2,315,000. There are 8 taluks, 18 towns and 663 villages in this district which has two medical schools, 15 hospitals, 76 dispensaries and 20 primary health centres with a total bed strength of 2,934.

This Project aims to establish a self-sustaining distribution system for:

1. social marketing of oral contraceptives through trained community workers by using marketing management technique supported by reasonable cash sales commissions and

2. provision of family planning surgical services, specifically for MR through trained local medical practitioners who will receive fees which are within the capacity of the beneficiaries .

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PROJECT ORGANIZATION

Community-Based Distribution of Contraceptives

Through this project, 301 distribution outlets will be established to cover the entire project district. Each outlet will cover a population of 5,000 in sparsely populated areas and 10,000 in densely populated, coastal areas. Trained local women will serve as depot workers incharge of these outlets. These depot workers will register all eligible women in their areas. In low density areas, the depot workers will receive Rs. 0.75 per couple registration and Rs. 0.75 as sales commission for each pill cycle distributed. In the high density coastal areas, the depot workers will receive Rs. 0.50 per couple registration and Rs. 0.60 per pill cycle distributed. The monthly income of the depot worker from the sale of pills is estimated to be Rs. 283.00 in coastal areas and Rs. 177.00 in other areas.

There will be one supervisor to supervise ten depot workers. The supervisor will receive a monthly salary of Rs. 250.00 plus Rs. 100.00 for travel. He will also receive Rs. 0.05 to Rs. 0.10 (coastal/rural areas) as commission on sale of pills. It is estimated that the monthly income of the supervisor will be Rs. 486.00. At a later stage, sale at cost or with subsidy will be considered for other contraceptives such as condoms and foam tablets and for simple medicines used to treat common ailments. While the depot worker will receive two weeks training in family planning methods, marketing and record-keeping procedures, the supervisors will be trained for one week in family planning methods, marketing and management. Orientation training in the field will be provided to these personnel every six months.

Community-Based Services for Menstrual Regulation

MR services will be provided in the district through 75 rural medical practitioners who will be trained in family planning methods and specifically trained to perform the MR procedure. They will also be supplied with MR kits. These practitioners will receive a moderate remuneration for performing MR and MTP and for inserting IUDs. An expert medical team from the Kasturba Medical College Hospital will visit them periodically to ensure that they receive adequate medical support from the Government health agencies and also from enlisted medical practitioners.

Headquarters Office

The Medical Director of the Kasturba Medical College will be the Project Director. Other staff of the Headquarters Office will include a project manager, an assistant manager, a secretary, accounts assistant, typist, attendant and driver. There will be two technical advisory committees--A Biomedical Committee and a Marketing Committee--represented by senior members from the appropriate professions in the district and also government health representatives.

CONCLUSION

As it is privately managed, this project will have considerable flexibility. It is envisaged that by complementing present services in the district, this project will saturate the area with family planning services and will, thereby, assist in reaching as yet unreached rural populations in the district.

MONITORING AND EVALUATION OF A COMMUNITY-BASED DISTRIBUTION PROGRAMME

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ABSTRACT

The monitoring and evaluation system based on the Community-based Distribution (CBD) Programme for oral contraceptives in Howrah District in West Bengal is described. A simplified record keeping system is recommended. Data may be evaluated using manual and/or computer analysis to produce performance measures needed for assessing programme achievement.

INTRODUCTION

The monitoring and evaluation system for a programme for the community-based distribution (CBD) of oral contraceptives (OCs) described in this report is based on the record-keeping system designed and pretested by the India Fertility Research Programme (India FRP). This system generates routine service statistics necessary for the management and evaluation of CBD programmes. These service statistics can be produced by using a combination of manual and computer analyses and provide programme administrators with a simple and efficient means of producing the performance measures necessary for assessing the success of the programme in meeting its specific goals.

THE RECORD SYSTEM

In 1977, a pilot CBD programme of oral contraceptives (OCs) was conducted in the District of Howrah in West Bengal. Based on the evaluation results of this programme, a simplified system of record-keeping has been developed by the India FRP. This system requires the depot holder to maintain only two records--the Couple Contact Register for registering all couples contacted and an Issue Sheet for recording pill cycles distributed during the month. The Issue Sheet which comprises of the Admission and Follow-up Issue Sheets is the basic form used for programme evaluation. The following is a description of the record system recommended by the India FRP for monitoring and evaluation of CBD programmes.

The Issue Sheet

The depot holder completes the Admission and Follow-up Issue Sheets and submits them to the Project Office each month. Appendix I provides a sample of these forms and the instructions for completing them.

The Admission Issue Sheet is completed only for new acceptors starting OCs during the month. Data recorded for each new acceptor include her pill card number (a number assigned serially to acceptors), day of visit and number of pill cycles provided. Upto a maximum of three client characteristics such as age, parity and present contraceptive

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practice can also be recorded on this form. Specific client characteristics can be selected. In accordance with the legal requirements, the acceptor signs against each pill cycle received.

The Follow-up Issue Sheet is completed for all old cases who return for a resupply of OCs or are readmitted into the programme. The data recorded on this form include pill card number, day of visit, number of cycles supplied and the date of next visit. The pill card number is preprinted serially on the Follow-up Issue Sheet to enable the depot holder to detect clients who fail to visit the clinic on their due date during any specific month. Acceptors who fail to visit the clinic for a resupply of OCs within the month have blanks against 'day of visit', 'no. of cycles supplied' and 'the due date of next visit'. At the end of the month, the follow-up Issue Sheets are examined to note preprinted pill card numbers with blank data. Thus, the drop-outs can be identified. These constitute the priority group of cases who should be followed up by the depot holder. By matching their pill card numbers, these cases can be traced back on previous Issue Sheets to confirm the dates of their last visits and the due dates of their next visits. The depot holder makes home visits to contact cases who are overdue for a depot visit to motivate them to continue OCs. For clients who discontinue OCs, the reason for discontinuation is recorded by the depot holder on the Code Card (Appendix II).

Information on the stock of oral contraceptives are recorded by the depot holder on the lower section of the Follow-up Issue Sheet to account for supplies received. The contact number of the last eligible couple contacted by the depot holder is also recorded in this section of the Follow-up Issue Sheet.

The Couple Contact Register

A Couple Contact Register is indexed alphabetically like a telephone directory, so that couples contacted can be traced by name. This register is maintained by the depot holder to record particulars of all eligible couples (14 - 35 years) contacted. Information recorded in this register includes the name and address of the couple, their contact number and three client characteristics. The Pill Card Number is recorded only in case the woman accepts OCs (Appendix III).

The Pill Acceptor Card

A Pill Acceptor Card is provided by the depot holder to each new acceptor and is kept with the acceptor. It serves as an identity card which she is expected to produce each time she visits the depot for a resupply of pills. The depot holder records identification information, including the pill card number, the acceptor's name, and her husband's name and address on this card. The date of visit and the due date of her next visit are also recorded. Instructions on how to take the pill are printed on the Pill Acceptor Card (Appendix IV).

The depot holder completes the Couple Contact Register for all couples that he/she contacts. If neither the husband or the wife have been sterilised and if the wife is not using OCs or the IUD, the depot holder motivates her to use OCs. If the woman accepts the method and has no contraindications to OCs, the depot holder requests her to visit the depot during her next menstrual period or at the earliest possible in the event that she has lactational amenorrhoea. She is assigned a pill card number when she visits the depot for her first supply of OCs. This number is also

recorded in the Couple Contact Register. After disbursement of a cycle of OCs, the depot holder completes the Admission Issue Sheet and prepares a Pill Acceptor Card in duplicate. The client is advised the due date for her next visit in accordance with the visit calendar (Appendix V). Visits to the depot by old continuing cases or readmission cases for resupply of pills are recorded on the Follow-up Issue Sheet.

The following is a description of records maintained at the Project Office for the systematic monitoring of the CBD programme:

The Control Card

The Control Card, a key record for monitoring, summarizes the progress of the depot and shows at a glance, the various statistics of records and supplies as well as payments made to and revenue collected from the depot. The upper section of this card provides detailed particulars on the geographical location of the depot, its identification by state and district, opening date of the depot and hours the depot operates. The lower section of the card provides summary information on the cumulative number of couples contacted, number of new, continuing, readmission and discontinuing acceptors, stock of pills received and balance in hand, and accounts of payments and revenue (Appendix VI).

The Data Control Slip

Data Control Slip is attached to the Issue Sheets submitted by the depot holder and is completed every month at the Project Office to verify and note the number and types of records submitted by the depot holder (Appendix VII).

The CBD Records Flow Sheet

When documents are received at the Project Office for data processing and filing, the Records Flow Sheet is completed to log by Depot Number, all incoming sets of records during the month and to take note of those depots that fail to submit their records (Appendix VIII).

The Document Sheet

The Document Sheet when completed and tallied at the end of each month shows the total number of OC cycles distributed and the number of new acceptors for all depots included in the programme (Appendix IX).

PERFORMANCE MEASURES

The following performance measures are used to evaluate programme achievements:

The Monthly Progress Report

This report shows the cumulative number of couples contacted each month and the cumulative and monthly number of new acceptors and OC cycles distributed at all depots included in the programme. It provides statistics on the current status of the programme and compares it to achievements of past months (Appendix X).

Prevalence Rate

The prevalence rate specifies what proportion of the eligible women contacted are continuing OCs at given time intervals of programme operation. The prevalence rate after 'n' months of programme operation is calculated by dividing the number of continuing acceptors by the total number of eligible couples registered after 'n' months of programme operation.

Continuation Rate

The continuation rate indicates for a given point in time, what proportion of women in the programme are continuing OCs among women who ever accepted OCs. The continuation rate is calculated for each depot in the programme after 3, 6, 12, 18 and 24 months of operation.

Graphs for Programme Monitoring

The following six graphs are maintained at the Project Office to measure progress of the programme at the depot, thana and the district levels:

1. New and discontinuing acceptors of OCs by month and year for each depot.
2. Continuing users of OCs by month and year for each depot.
3. New and discontinuing acceptors of OCs by month and year for each thana.
4. Continuing users of OCs by month and year for each thana.
5. New and continuing acceptors of OCs by month and year for each district.
6. Continuing users and prevalence of use of OCs by month and year for each district.

The Monthly Programme Performance Indices (PPI) Record is maintained by state, district, thana and depot number (Appendix XI). This record enables calculation of monthly prevalence

rates and continuation rates and plotting of the above-mentioned graphs. The information on the PPI form is derived every month from the Issue Sheets.

If funds are available, the processing of the Issue Sheets may be computerized to produce monthly PPIs for each depot and the various performance rates. However, the Issue Sheet can also be processed by hand. In this event the Follow-up Issue Sheet is perforated beyond the column for 'Due Date of next visit'. It can be torn off from here to remove the columns for 'Day of visit' and 'Number of cycles supplied'. These columns are pasted against the appropriate Pill Card Number on the Acceptor Follow-up Chart (Appendix XII). The number of continuing, discontinuing and new acceptors can be calculated each month from the Acceptor Follow-up Chart. Thus, the various performance measures can be generated by computer or manually for programme monitoring and evaluation.

NEW ADMISSION ISSUE SHEET

(To be completed for New Acceptors only)

State No.	Dist. No.	Depot No.	Month	Year

Pill Card No.	Day of visit	Cycles supplied	Couple Characteristics	Name & Address/ Acceptor's Signature

INDIA FERTILITY RESEARCH PROGRAMME

CBD PROGRAMME

FOLLOW-UP ISSUE SHEET

State No. | Dist. No. | Depot No. | Month | Year

Pill Card No.	Acceptor's Signature	Due Date for next visit	Date of this visit	Cycles supplied/ reason for discontinuation

STOCK OF ORAL PILL — Oral Pills

A. At start of month .....
B. Received this month .....
C. Total this month (A+B) .....
D. Distributed this month .....
E. Balance at end of month .....

The Last Contact No. assigned this month/ completed couple contacts in area

Signature..... Date.....

INDIA FERTILITY RESEARCH PROGRAMME

Community Based Distribution of Contraceptives

CODE LIST

(কোডের তালিকা)

FOR

Reasons for discontinuation of pill

(বড়ি বন্ধের কারণ সমূহ)

Code No.	Reasons for discontinuation
1	Unplanned Pregnancy - অপরিকল্পিত গর্ভধারণ
2	Menstrual Side effects including pain - মাসিক সংক্রান্ত অসঙ্গতি, যন্ত্রনাসহ (যেমন মাসিক বন্ধ, অধিক মাসিক, অল্প মাসিক ইত্যাদি।)
3	Other medical reasons - অন্যান্য শারীরিক কারণসমূহ (যেমন রক্তস্বল্পতা, বমি হওয়া, মাথার যন্ত্রনা মাথা ঘোরা, শরীরে র‍্যাশ, অবসাদ বা দুর্বলতা, হাত পায়ের যন্ত্রনা, ইত্যাদি।)
4	Planning Pregnancy - পরিকল্পিত গর্ভধারণ
5	Personal reasons/husband away from home - ব্যক্তিগত কারণ — (যেমন বিবাহ বিচ্ছেদ, স্বামীর বিদেশ গমন, স্ত্রীর মৃত্যু ইত্যাদি।)
6	Moved from area - সেন্টারের অন্তর্গত অঞ্চল থেকে অন্যস্থানে চলিয়া যাওয়া
7	Programme Specific reasons(Lack of pills, cost of pills, Problems with services) বড়ি বিতরন ব্যবস্থা সংক্রান্ত কারন — (যেমন বড়ির অভাব, বড়ির দাম, বড়ি বিতরনের নানাবিধ সমস্যা, ইত্যাদি।)
8	Switched to another method - অন্য পদ্ধতি গ্রহন।
9	Unknown - বড়ি বন্ধের কারন জানা যায় নাই।

নির্দেশ:—

১। বড়ি স্যাইড থাইতে কেহ বড়ি খাওয়া বন্ধ করিলে, কি কারনে বন্ধ করিলেন কেবল তাহার কোড নং Follow Up Record এর পাতের দিকে বন্ধের কারন লিখিবার নির্দিষ্ট স্থানে বসাইবেন।

২। মাসের শেষে, যাহাদের বড়ি নিতে আসার নির্দিষ্ট তারিখ ৭ বা তার বেশী দিন পেরিয়ে গেছে, তাহাদের 'Discontinuation' বা বড়ি খাওয়া ছাড়িয়া দিলেন বলিয়া গন্য করা হইবে এবং 'ISSUE SHEET' এ মাসের শেষ তারিখে তাহাদের CR No ও Pill Card No তালিকাভুক্ত লিখিবেন ও 'Program Status' কলামে '3' লিখিবেন এবং 'Number Pill Cycles Supplied' কলামে '0' লিখিবেন।

Ind.F.R.P./CBD Project/ Follow-up Visit Calendar/1979.

প্রথমবারে মাসিক আরম্ভ হইলে (কোন যেকোন দিন) সন্তান হওয়ার পর মাসিক বন্ধের ক্ষেত্রে ক্লিনিকে ভর্তি হইতে হইবে এবং সেই দিন হইতেই পিল খাওয়া শুরু করিতে বলিতে হইবে। ১নং প্যাকেটের ১নং পিল যে বারে খাওয়া শুরু করিবেন ২৮ দিন পর ২৯ দিনের দিন, ২নং প্যাকেটের ১নং পিল সেই বারেই খাওয়া শুরু করিবেন। প্রতি বারে ২৮ দিনের মধ্যে পরবর্তী পিল প্যাকেট সংগ্রহ করিতে বলিবেন। [illegible] ভেলিয়া কোন দিনের মধ্যে পরবর্তী পিল প্যাকেট সংগ্রহ করিতে হইবে, সেই দিনের তারিখটি পিল প্যাকেটে লিখিয়া দিবেন।

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
MON	*J1	J29	F26	M26	A23	My21	Jul8	Jy16	Ag13	S10	Oct8	N5	D3	D31	J28
TUES	J2	J30	F27	M27	A24	My22	Jul9	Jy17	Ag14	S11	Oct9	N6	D4	J1	
WED	J3	J31	F28	M28	A25	My23	Ju20	Jy18	Ag15	S12	Oct10	N7	D5	J2	
THURS	J4	*F1	*M1	M29	A26	My24	Ju21	Jy19	Ag16	S13	Oct11	N8	D6	J3	
FRI	J5	F2	M2	M30	A27	My25	Ju22	Jy20	Ag17	S14	Oct12	N9	D7	J4	
SAT	J6	F3	M3	M31	A28	My26	Ju23	Jy21	Ag18	S15	Oct13	N10	D8	J5	
SUN	J7	F4	M4	*A1	A29	My27	Ju24	Jy22	Ag19	S16	Oct14	N11	D9	J6	
MON	J8	F5	M5	A2	A30	My28	Ju25	Jy23	Ag20	S17	Oct15	N12	D10	J7	
TUES	J9	F6	M6	A3	*My1	My29	Ju26	Jy24	Ag21	S18	Oct16	N13	D11	J8	
WED	J10	F7	M7	A4	My2	My30	Ju27	Jy25	Ag22	S19	Oct17	N14	D12	J9	
THURS	J11	F8	M8	A5	My3	My31	Ju28	Jy26	Ag23	S20	Oct18	N15	D13	J10	
FRI	J12	F9	M9	A6	My4	*Ju1	Ju29	Jy27	Ag24	S21	Oct19	N16	D14	J11	
SAT	J13	F10	M10	A7	My5	Ju2	Ju30	Jy28	Ag25	S22	Oct20	N17	D15	J12	
SUN	J14	F11	M11	A8	My6	Ju3	*Jy1	Jy29	Ag26	S23	Oct21	N18	D16	J13	
MON	J15	F12	M12	A9	My7	Ju4	Jy2	Jy30	Ag27	S24	Oct22	N19	D17	J14	
TUES	J16	F13	M13	A10	My8	Ju5	Jy3	Jy31	Ag28	S25	Oct23	N20	D18	J15	
WED	J17	F14	M14	A11	My9	Ju6	Jy4	*Ag1	Ag29	S26	Oct24	N21	D19	J16	
THURS	J18	F15	M15	A12	My10	Ju7	Jy5	Ag2	Ag30	S27	Oct25	N22	D20	J17	
FRI	J19	F16	M16	A13	My11	Ju8	Jy6	Ag3	Ag31	S28	Oct26	N23	D21	J18	
SAT	J20	F17	M17	A14	My12	Ju9	Jy7	Ag4	*S1	S29	Oct27	N24	D22	J19	
SUN	J21	F18	M18	A15	My13	Jul0	Jy8	Ag5	S2	S30	Oct28	N25	D23	J20	
MON	J22	F19	M19	A16	My14	Jul1	Jy9	Ag6	S3	*Oct1	Oct29	N26	D24	J21	
TUES	J23	F20	M20	A17	My15	Jul2	Jy10	Ag7	S4	Oct2	Oct30	N27	D25	J22	
WED	J24	F21	M21	A18	My16	Jul3	Jy11	Ag8	S5	Oct3	Oct31	N28	D26	J23	
THURS	J25	F22	M22	A19	My17	Jul4	Jy12	Ag9	S6	Oct4	*N1	N29	D27	J24	
FRI	J26	F23	M23	A20	My18	Jul5	Jy13	Ag10	S7	Oct5	N2	N30	D28	J25	
SAT	J27	F24	M24	A21	My19	Jul6	Jy14	Ag11	S8	Oct6	N3	*D1	D29	J26	
SUN	J28	F25	M25	A22	My20	Jul7	Jy15	Ag12	S9	Oct7	N4	D2	D30	J27	

*J-January, F-February, M-March, A-April, My-May, Ju-June, Jy-July, Ag-August, S-September, Oct-October, N-November, D-December.

INDIA FERTILITY RESEARCH PROGRAMME

CBD PROGRAMME

COUPLE CONTACT REGISTER

STATE [|] DISTRICT [|]

DEPOT NO. [| |]

FOR THE MONTH.......................

Name and Address	Couple Contact No.				Patient Characteristics						Pill Card Number			Day of Contact	

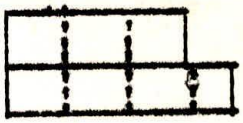
INDIA FERTILITY RESEARCH PROGRAMME

CBD PROGRAMME

PILL ACCEPTOR CARD

PILL CARD NO.

COUPLE CONTACT NO.



Wife's Name.....Husband's Name.....

Address.....

Depot Name & Address

Depot No.....

Name of Depot Holder.....Clinic Hours.....

Instruction on Pill Use:.....

.....

Instruction for Follow-up Visit:.....

.....

FOLLOW-UP VISIT

Today's Date	No. of Cycles	Remark	Due Date for next visit	Today's Date	No. of Cycles	Remark	Due Date for next visit.

Ind.F.R.P./CBD Project/ Follow-up Visit Calendar/1979.

প্রথমবারে মাসিক আরম্ভ হইলে (কোন দিন-সন্তান হওয়ার পর মাসিক বন্ধের ক্ষেত্রে) ক্লিনিকে আসিতে হইবে এবং সেই দিন হইতেই পিল খাওয়া শুরু করিতে বলিতে হইবে। ১নং প্যাকেটের ১নং পিল যে বারে খাওয়া শুরু করিবেন ২৮ দিনপর-২৯ দিনের দিন, ২নং প্যাকেটের ১নং পিল সেই বারেই খাওয়া শুরু করিবেন। প্রতি বারে ২৮ দিনের মধ্যে পরবর্তী পিল প্যাকেট সংগ্রহ করিতে বলিবেন। এই বার ২৮ দিনের মধ্যে পরবর্তী পিল প্যাকেট সংগ্রহ করিতে হইবে, সেই দিনের তারিখটি পিল প্যাকেটে লিখিয়া দিবেন।

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
MON	*J1	J29	F26	M26	A23	My21	Jul8	Jy16	Ag13	S10	Oct8	N5	D3	D31	J28
TUES	J2	J30	F27	M27	A24	My22	Jul9	Jy17	Ag14	S11	Oct9	N6	D4	J1	
WED	J3	J31	F28	M28	A25	My23	Ju20	Jy18	Ag15	S12	Oct10	N7	D5	J2	
THURS	J4	*F1	*M1	M29	A26	My24	Ju21	Jy19	Ag16	S13	Oct11	N8	D6	J3	
FRI	J5	F2	M2	M30	A27	My25	Ju22	Jy20	Ag17	S14	Oct12	N9	D7	J4	
SAT	J6	F3	M3	M31	A28	My26	Ju23	Jy21	Ag18	S15	Oct13	N10	D8	J5	
SUN	J7	F4	M4	*A1	A29	My27	Ju24	Jy22	Ag19	S16	Oct14	N11	D9	J6	
MON	J8	F5	M5	A2	A30	My28	Ju25	Jy23	Ag20	S17	Oct15	N12	D10	J7	
TUES	J9	F6	M6	A3	*My1	My29	Ju26	Jy24	Ag21	S18	Oct16	N13	D11	J8	
WED	J10	F7	M7	A4	My2	My30	Ju27	Jy25	Ag22	S19	Oct17	N14	D12	J9	
THURS	J11	F8	M8	A5	My3	My31	Ju28	Jy26	Ag23	S20	Oct18	N15	D13	J10	
FRI	J12	F9	M9	A6	My4	*Ju1	Ju29	Jy27	Ag24	S21	Oct19	N16	D14	J11	
SAT	J13	F10	M10	A7	My5	Ju2	Ju30	Jy28	Ag25	S22	Oct20	N17	D15	J12	
SUN	J14	F11	M11	A8	My6	Ju3	*Jy1	Jy29	Ag26	S23	Oct21	N18	D16	J13	
MON	J15	F12	M12	A9	My7	Ju4	Jy2	Jy30	Ag27	S24	Oct22	N19	D17	J14	
TUES	J16	F13	M13	A10	My8	Ju5	Jy3	Jy31	Ag28	S25	Oct23	N20	D18	J15	
WED	J17	F14	M14	A11	My9	Ju6	Jy4	*Ag1	Ag29	S26	Oct24	N21	D19	J16	
THURS	J18	F15	M15	A12	My10	Ju7	Jy5	Ag2	Ag30	S27	Oct25	N22	D20	J17	
FRI	J19	F16	M16	A13	My11	Ju8	Jy6	Ag3	Ag31	S28	Oct26	N23	D21	J18	
SAT	J20	F17	M17	A14	My12	Ju9	Jy7	Ag4	*S1	S29	Oct27	N24	D22	J19	
SUN	J21	F18	M18	A15	My13	Ju10	Jy8	Ag5	S2	S30	Oct28	N25	D23	J20	
MON	J22	F19	M19	A16	My14	Ju11	Jy9	Ag6	S3	*Oct1	Oct29	N26	D24	J21	
TUES	J23	F20	M20	A17	My15	Ju12	Jy10	Ag7	S4	Oct2	Oct30	N27	D25	J22	
WED	J24	F21	M21	A18	My16	Ju13	Jy11	Ag8	S5	Oct3	Oct31	N28	D26	J23	
THURS	J25	F22	M22	A19	My17	Ju14	Jy12	Ag9	S6	Oct4	*N1	N29	D27	J24	
FRI	J26	F23	M23	A20	My18	Ju15	Jy13	Ag10	S7	Oct5	N2	N30	D28	J25	
SAT	J27	F24	M24	A21	My19	Ju16	Jy14	Ag11	S8	Oct6	N3	*D1	D29	J26	
SUN	J28	F25	M25	A22	My20	Ju17	Jy15	Ag12	S9	Oct7	N4	D2	D30	J27	

*J-January, F-February, M-March, A-April, My-May, Ju-June, Jy-July, Ag-August, S-September, Oct-October, N-November, D-December.

INDIA FERTILITY RESEARCH PROGRAMME

Community Based Distribution of Contraceptives

CODE LIST

(কোডের তালিকা)

FOR

Reasons for discontinuation of pill

(বড়ি বন্ধের কারণ সমূহ)

Code No.	Reasons for discontinuation
1	Unplanned Pregnancy - অপরিকল্পিত গর্ভধারণ
2	Menstrual Side effects including pain - মাসিক সংক্রান্ত অসঙ্গতি, যন্ত্রণাসহ (যেমন মাসিক বন্ধ, অধিক মাসিক, অল্প মাসিক ইত্যাদি।)
3	Other medical reasons - অন্যান্য শারীরিক কারণসমূহ (যেমন রক্তাল্পতা, বমি হওয়া, মাথার যন্ত্রণা মাথা ঘোরা, শরীরে ক্লান্তি, অবসাদ বা দুর্বলতা, হাত পায়ের যন্ত্রণা, ইত্যাদি।)
4	Planning Pregnancy - পরিকল্পিত গর্ভধারণ
5	Personal reasons/husband away from home - ব্যক্তিগত কারণ— (যেমন বিবাহ বিচ্ছেদ, স্বামীর বিদেশ গমন, স্বামীর মৃত্যু ইত্যাদি।)
6	Moved from area - সেন্টারের অন্তর্গত অঞ্চল থেকে অন্যস্থানে চলিয়া যাওয়া
7	Programme Specific reasons(Lack of pills, cost of pills, Problems with services) বড়ি বিতরণ ব্যবস্থা সংক্রান্ত কারণ— (যেমন বড়ির অভাব, বড়ির দাম, বড়ি বিতরণের নানাবিধ সমস্যা, ইত্যাদি।)
8	Switched to another method - অন্য পদ্ধতি গ্রহণ।
9	Unknown - বড়ি বন্ধের কারণ জানা যায় নাই।

নির্দেশনা:—

১। বড়ি খাইতে আছেন কেহ বড়ি খাওয়া বন্ধ করিলে কি কারণে বন্ধ করিলেন কেবল তাহার কোড নং Follow Up Record এর নীচের দিকে বন্ধের কারণ লিখিবার নির্দিষ্ট স্থানে বসাইবেন।

২। মাসের শেষে, যাহাদের বড়ি নিতে আসার নির্দিষ্ট তারিখ ৭ বা তার বেশী দিন পেরিয়ে গেছে তাহাদের 'Discontinuation' বা বড়ি খাওয়া ছাড়িয়া দিলেন বলিয়া গন্য করা হইবে এবং 'ISSUE SHEET' এ মাসের শেষ তারিখে তাহাদের CR No ও Pill Card No তালিকাভুক্ত লিখিবেন ও 'Program Status' কলামে '3' লিখিবেন এবং 'Number Pill Cycles Supplied' কলামে '0' লিখিবেন।

INDIA FERTILITY RESEARCH PROGRAMME/COMMUNITY BASED DISTRIBUTION OF CONTRACEPTIVES/CONTROL CARD

D ot Holder.....P.O..... State [!] Dt.Pill Distbn.started.....19

Address.....Rly.Stn..... Dist. [!] Clinic Hrs.....m to.....m

C .....Bus Route..... Closed on.....Day

A ress.....Th.....An....Dist.. Depot No. [! !]

te Mth/Yr	Cumu.Couple contacted till this month	ACCEPTOR						PILL STOCK					Pay-ment to DH This month	Reve-nue to CBD this month	Remarks
		Contg. last Month	New Adm.	Re- Adm.	Total Accep	Dis-con-tng.	Conti -nuing	Start of Mnth	Rece-ived	Total	Disb.	Bal-ance			

INDIA FERTILITY RESEARCH PROGRAMME

DATA CONTROL SLIP

BATCH NO. ☐☐☐☐☐

STATE NO. ☐☐

DISTRICT NO. ☐☐

DEPOT NO. ☐☐☐

ENCLOSURES

1. **Total No. New Admission Issue Sheets**_____

2. **Total No. Follow-up Issue Sheets**_____

FOR MONTH OF ☐☐☐☐
Month Year

INDIA FERTILITY RESEARCH PROGRAMME

STATE ☐☐ DISTRICT ☐☐ CBD RECORDS FLOW SHEETS

Centre No.	Cum. Couples Contd.	New acceptors this month	Total cycles dis. this month	Remarks	Centre No.	Cum. Couples Contd.	New accep. this month	Total cycles dis. this month	Remarks	Centre No.	Cum. Couples Contd.	New accep. this month	Total cycles this month	Remarks
1					1					1				
2					2					2				
3					3					3				
4					4					4				
5					5					5				
6					6					6				
7					7					7				
8					8					8				
9					9					9				
0					0					0				
1					1					1				
2					2					2				
3					3					3				
4					4					4				
5					5					5				
6					6					6				
7					7					7				
8					6					8				
9					9					9				
0					0					0				
1					1					1				
2					2					2				
3					3					3				
4					4					4				
5					5					5				
6					6					6				
7					7					7				
8					6					8				
9					9					9				
0					0					0				

INDIA FERTILITY RESEARCH PROGRAMME
CBD DOCUMENT SHEET

Page ____

Centre No.	NEW ACCEPTOR ISSUE SHEET Year 19.. Months submitted												FOLLOW-UP ISSUE SHEET Year 19.. Month submitted											
	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D
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CED PROGRAMME

MONTHLY PROGRESS REPORT

Month	no.of Centres opened till this month	Cumulative CR completed till this month	PILL ACCEPTORS		Pill Distributed this Month	Cumulative Pills distributed till this month
			New acceptors this month	Cumulative acceptrs. this month		

CBD PROGRAMME (HOWRAH)
PROGRAMME PERFORMANCE INDICES

APPENDIX XI

State	Dist.	Thana	Depot		1977 July	A	S	O	N	D	1978 J	F	M	A	M	J	J	A	S	O	N	D	1979 J	F	M	A	M	J
Couple Registration																												
ACCEPTORS				Old Contng.																								
				Re-Adm.																								
				New Acceptors																								
				Total																								
Acceptors discontinuing																												
Continuing Acceptors																												
Prevalence of Use																												

State	Dist.	Thana	Depot		1977 July	A	S	O	N	D	1978 J	F	M	A	M	J	J	A	S	O	N	D	1979 J	F	M	A	M	J
Couple Registration																												
ACCEPTORS				Old Contng.																								
				Re-Adm.																								
				New Acceptors																								
				Total																								
Acceptors discontinuing																												
Continuing Acceptors																												
Prevalence of Use																												

ACCEPTOR FOLLOW-UP CHART

State | Dist. | Thana | Depot

Calander Month

Page -

Pill Card No.	C.R. No.																		
1																			
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8																			
9																			
0																			
1. OLD																			
2. NEW																			
3. READMISSION																			
4. DISCONTINUATION																			
5. CONTINUING USERS (1+2+3-4)																			