

CONTRACEPTIVE CHOICE : SAFETY VS EFFICACY.

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- Sathyamala

There is a general belief that contraceptives reduce maternal mortality rates considerably. Statements such as -

"Like all medicines, birth control pills occasionally cause serious problems in certain persons.... Of the 15,000 women who become pregnant, 75 are likely to die from problems of pregnancy or child birth; of the 15,000 women who take the birth control pills only one is likely to die from problems related to having taken the pill. Conclusion: It is much safer to take the pill than to become pregnant."

are made to highlight what a boon the modern day contraceptives are to the procreating women. Even when attempts are made to discuss complications or mortality rates in relation to contraceptive methods, they are usually rationalised as "...It may be emphasised that though the mortality of interval sterilization is much higher than that of post partum sterilizations, the mortality of either of the two procedures is much lower than the maternal mortality for this country (India) which is the risk the patient (emphasis added) would be exposed to if she were not sterilized." (2). Complacency is also expressed in statements like-contraceptive 'X' has no life threatening side effects and therefore it is safe. The underlying assumption in all these statements is that the contraceptive methods that are currently being promoted are far safer than the 'risk' of becoming pregnant.

While it may be true that child bearing adds a certain risk to the woman population, it becomes a definite risk in only those population which has an already high overall mortality rate : and it is the purpose of this paper to present the hypothesis that while contraceptive use may theoretically decrease the possibility of pregnancy related deaths, the quantum of morbidity it produces is far too high to justify its wide use in developing countries where the very factors responsible for the high maternal mortality rate would lead to an increase in mortality due to contraceptive use as well.

Morbidity load due to the currently available female methods of contraception:

An estimate of the probable morbidity load can be made on the basis of the data available on the incidence rates of complications arising from the use of contraceptive methods. The morbidity rates have been calculated on the number of acceptors in 1980-81.

Contraceptive method	Morbidity	Incidence	No. of acceptors in 1980-81	No. of women who would have suffered ill health
IUCDs	Bleeding and pain	10-15/100 users	6,00,000	60,000 to 90,000.
	PID	10/100 users	"	60,000
	Infertility	10/100 users	"	60,000
	Ectopic pregnancies	0.8 to 4% of method failure	"	240 to 1200
	Spontaneous abortions	50% of method failure	"	15,000
	Perforation of uterus	1/2500 users	"	240
Tubectomy	Post op. menorrhagia	5.1%	1,550,000	79,050
	Pelvic infections	12.42/1000	"	19,251

Total morbidity due to these two methods : 293781  
 Total number of acceptors : 2150000  
 Morbidity rate due to these two methods : 137/1000 acceptors  
 Morbidity rate due to IUCD alone : 326-337/1000 acceptors  
 (ref No.3)

The incidence rates used in these calculations are probably an underestimation of the actual incidence in rural areas. The calculations have also not taken into account the total morbidity subsequent to contraceptive failure. It should be noted that the complication rates for tubectomies are from surgeries performed in teaching hospitals. The incidence rates in the field situation ie. Primary Health Centres and FP Camps would probably be much higher than the ones quoted.

The morbidity due to oral pill use was not included in the table because the acceptance and the continuation rate for oral pill use in India has generally been very low. Infact it is so low that oral pill use rate is not included in the assessment of eligible couple protection rate. In 1983, to overcome the problem of the non acceptance of the pill, the Health Ministry came up with the bright idea of distributing the pills through the Village Health Workers. This plan was dropped later because of the opposition from the Indian Women's Scientists Association on the grounds that such a plan would neither be safe nor effective. However from the report of the 'Revised Strategy for National Family Welfare Programme', it appears that there are definite plans to expand the use of the pills through

social marketing and by using a new cadre of workers, the 'Village Level Women Volunteers Corps'. Reports have also come from several parts of the country that this new cadre has swung into action and that the pill is being promoted through the door to door sales technique. An even more worrying aspect of the strategy is for the first time an official policy states "acceptance of oral pills in rural areas can be expanded if medical consultation is not prescribed." (4) The potential morbidity and mortality due to oral pill use should this scheme become successful can be seen from data available from other countries. The following table presents the episodes of hospitalization and mortality rates in a group of oral pill users from UK.

Serious side effects associated with the use of combined oral contraceptive.

Side effect	Excess morbidity and mortality per year 100,000 users		
	<u>Diagnosis</u>	<u>Hospitalizations</u>	<u>Deaths</u>
Stroke	31	35	9.7
Deep Vein Thrombosis or Pulmonary Embolism	91		
Superficial or unspecified thrombosis	125	70	3.4
Heart attack and other non-rheumatic heart Dis.	17	17	8.0
Gall bladder Disease (surgically confirmed)	79	79	-
Kidney Infection	383	-	-
Benign liver tumor	1	1	0.1
Hypertension	406	-	1.7
Total	1133	202	22.9

(Ref. No.5)

This data indicates that "one out of every 500 pill users are hospitalized annually due to serious side effects caused by this method. An estimated one out of every 5000 users die annually from pill caused strokes, thromboses and heart attacks... roughly two thirds are among smokers and one third among non smokers". (5)

It is generally alleged that these risks do not apply to Asian Women because they do not have the same problems of heart attack and thrombotic disease. This assumption is unfounded because according to the ICMR report of 1981, "...Available data on Indian women with CVD (cardiovascular disease) show that though their lipid levels were higher than the normal Indian women, the levels were far below their Western counterparts". (6) and concludes that epidemiological studies are needed to confirm if Indian women using oral contraceptive might be at a lower risk of developing CVD. Epidemiological studies from Hong Kong have

shown that there has been an increase in heart ailments among women between 1969-75 or since the pill was introduced. If the pill programme indeed becomes successful one could still expect complacency because Indian women especially from the rural areas will neither be diagnosed nor hospitalized to the same extent as their British counterparts for obvious reasons. But one can say with surety that should the programme become successful the mortality and morbidity rate in women users under unsupervised conditions will be very high.

A recently released report (1982) from the Centre of Disease Control USA has shown that for the first time in the USA contraceptive-related deaths outnumber pregnancy - related deaths. This could very well be the situation in India if the trend towards pushing even more hazardous contraceptives persist.

The report of the 'Revised Strategy for National Family Welfare Programme' makes its intentions very clear. Under 'Family Planning Research' it states

"New technologies like injectables, sub-dermal implants, etc., are currently undergoing trials before introduction in the programme. The procedures and the protocols and the time scales of induction of new technologies will be revised to enable faster introduction of such technologies in the programme." "Development of simple, reversible, safe and long acting contraceptives such as the anti-fertility vaccine would seem to offer great potential. Research efforts in developing such a vaccine will receive high priority." (7)

Anyone with even a rudimentary knowledge of the mechanism of action of these methods would know that the complications arising out of their wide-use will be of a magnitude never witnessed before in contraceptive history. An added problem with these contraceptives is that the morbidity and mortality risks will not be confined to the women alone but is going to be extended to their progeny as well.

The question that gets posed is why then this strange attachment to hazardous contraceptives when available data already indicates that they are a definite threat to women's lives. This is when the red herring in the form of "effectiveness" is thrown up to confuse everyone. It is stated that more and more invasive a method is better and better is its effectiveness because it will act at so many levels that conception will not stand a chance!

The following table shows that if one compares the lowest observed failure rates for the currently available methods, the effectiveness is almost similar.



<u>Method</u>	<u>Lowest observed failure rate(%)</u>
Tubal sterilization	0.4
Vasectomy	0.4
Combined pills	0.5
IUD	1.5
Condom	2
Diaphragm with spermicide	2
Cervical cap	2
Fertility awareness	2 -20
(Ref. No.8)	

That means that theoretically at least in a well 'controlled' situation the effectiveness of invasive contraceptives are very similar to the non-invasive barrier methods. The problem comes when effectiveness is discussed in terms of actual use. For instance, if a woman takes the pill everyday and does not miss even once then the theoretical effectiveness would apply to her. But in a real situation in a group of pill takers the effectiveness would be influenced by the irregularity or the regularity with which each member takes the pill. Hence the actual failure rate can range from 5 (IUD) to 10 (Condom) to 19 (Diaphragm). This is what the population experts are really concerned about: the performance of a method in a population which they may not be able to "control". Hence the attachment to invasive methods which hopefully will not be affected by the vagaries of human nature.

The medical establishment however rationalises in a different way the need for a method whose theoretical use comes closer to the actualise. It is argued that if the failure rate is high with contraceptive use, the women accepting a method with the high failure rate would continue to run the risks of pregnancy. A comparison of cumulative risk of deaths associated with fertility control methods which includes both maternal deaths subsequent to contraceptive failure and method-related deaths show that despite the additional risk of high failure rates, condoms backed by abortion is the safest method available.

Cumulative Risk of Death Associated with Fertility Control Methods  
(per 100,000 nonsterile women)

Method	15-34	35-39	40-44	15-44
Pill/smoker	132	257	588	977
Pill/nonsmoker	21	70	160	251
Rhythm	36	14	18	68
Diaphragm/spermicide	28	11	14	53
IUD	25	10	10	45
Abortion	26	9	6	41
Condom	19	2	2	23
Condom/abortion	1	1	1	1
No method	192	129	141	462

(Ref. No.9)

It is obvious that if a Family Planning policy is really concerned with the health of the women, then it would stop viewing hysterically, the possibility of an inadvertant pregnancy due to contraceptive failure as a national disaster. Till such time it does that, the attempt of the population controllers will be to develop methods which tend towards the mythical 100% effectiveness leaving the concept of safety to the four winds.

The question that remains to be answered is -- is pregnancy really such an enormous risk that the wide use of hazardous contraceptives can not only be justified but should in fact be promoted in the interests of women? In this context it must be remembered that while comparing mortality and morbidity risks in contraceptive use and pregnancy there are two different populations at risk. Only women who become pregnant can die of pregnancy related causes. A much larger number of women is at a risk of death from contraception related causes, and this population would have already faced the risks of becoming pregnant before they accept a method. Finally it must also be remembered the complications arising from contraceptive use are generally long-term effects and could lead to permanent disability.

#### Notes and References:

1. "Where there is no doctor", Indian adaptation, by Sathyamala, VHAI.
2. ICMR Bulletin, June 1982, P 59.
3. (a) Incidence Rate (IR) for bleeding and pain, 'Contraceptive Technology, 1986-1987,' 13th Revised Edition, Irvington Publishers, p 202.
- (b) IR for PID, 'Population Reports, 'Series B, No.4, July 1982, p. B-121, "Other recent studies in developed countries have found the relative risk of developing PID ranges from 1.5 to 10 for IUD users." I have taken the higher figure because in developing countries it must be higher than this.
- (c) IR for infertility, population Reports, Series B, No.4, July 1982, "Thus, ectopic pregnancy or infertility may occur even after only one episode (of PID in the fallopian tubes)"
- (d) IR for ectopic pregnancies, Population Reports, Series B, No.4, p, B-125.
- (e) IR for spontaneous abortions, Population Reports, Series B, No. 4 p. B 124. "About 50% of uterine pregnancies spontaneously abort if the device is not removed". In some studies over half of the spontaneous abortions in IUD users is in second trimester and a spetic second trimester abortion is 26 times more likely in women with an IUD in place. The failure rate in actual users of IUD is 5/100.

- (f) IR for perforation of uterus, Contraceptive Technology, 1986-1987, p 208.
- (g) IR for post op. menorrhagia and Pelvic infections, ICMR Bulletin June 1982, p 59.
4. "Revised Strategy for National Family Welfare Programme," GOI, 1986 (?) p. 6.
  5. "Contraceptives and Developing Countries : the role of Barrier Methods," Bruce and Schearer, International Symposium on Research on the Regulation of human fertility, Sweden, Feb.1983, p 407.
  6. ICMR Bulletin, Dec. 1981.
  7. "Revised Strategy for National Family Welfare Programme," GOI 1986(?), p 123.
  8. Contraceptive Technology, 1986 - 1987, p 102.
  9. "Out look", Vol 1, No. 3, Sept. 1983, p 4, Figures adapted from Ory of the US Centres of Disease Control.