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LONG TERM HEALTH CONSEQUENCES OF VASECTOMY

Surgical sterilisation is the most effective, safe and economical long-term contraceptive method for both men and women. With increasing global awareness about these advantages, sterilisation has become the most widely used method of contraception. The number of couples using sterilisation is now estimated to be 170 million; the figure is expected to reach 270 million by the year 2000. Ample data exist to show that vasectomy is simpler and safer than tubectomy; in spite of this the estimated number of couples using vasectomy the world over is only 42 million. In the last two decades specific efforts have been made to inform the population of the safety of vasectomy and reassure them that vasectomy does not affect sexual performance. This has resulted in an increase in the acceptance of vasectomy in some of the developed and developing countries.

In the sixties it was generally assumed that the surgical excision of a small portion of the vas would not have any systemic effects. Immunological studies in men who had undergone vasectomy showed that over 50 per cent developed antisperm antibodies which persisted for ten years or longer. There have been conflicting reports of the changes in hormonal profile in vasectomised men. Concerned over the potential long-term consequences of these changes on prevalence of cardiovascular and autoimmune diseases

and malignancies, several investigators initiated studies on the long-term health consequences of vasectomy. In the early eighties data pertaining to follow up for periods upto a decade were obtained and reported. In the late eighties, data on substantially large numbers of men followed up for periods upto 20 years or longer became available from some of the developed and developing countries. Results from these studies indicated that overall morbidity and mortality rates in men who had undergone vasectomy were essentially similar to or even lower than that of controls drawn from the same community. However, two studies in USA showed that the risk of cancer of the prostate, the second most common malignancy in men in USA, was higher in men who had undergone vasectomy. A study from South Korea reported an increase in the risk of myocardial infarction in vasectomised men. Publication of and public debate on the conflicting global data regarding long-term risks and benefits of vasectomy have raised the question of the applicability of these findings in the Indian context.

In the nineties India will witness the impact of the ongoing demographic transition, in terms of the substantial increase in the proportion and number of persons above 50 years of age. The prevalence of cardiovascular diseases (CVD), cerebrovascular accidents (CVA) and

malignancies including cancer prostate is higher in men beyond 50 years of age; hence physicians will be seeing more patients with these illnesses even if the prevalence of all these diseases remain unaltered. Added to this is the fact that most of the estimated 13 million Indian men who had undergone vasectomy did so prior to 1977 and will be 50 years or older in the nineties and some may develop CVD, CVA or cancers. It is therefore essential that epidemiological studies are carried out in India to assess the long-term risks and benefits associated with vasectomy and draw balanced conclusions regarding the safety of vasectomy in the Indian context, so that informed choices among the available contraceptive options could be made. Global data on health consequences of vasectomy, their relevance to the Indian situation and the ongoing ICMR studies to obtain data on the long-term risks and benefits associated with vasectomy in India are reviewed here.

Prevalence of Vasectomy

For couples who have completed their family, vasectomy is a simple, effective, safe procedure which provides permanent protection against conception. Ample global data clearly demonstrate that vasectomy has no short-term adverse effect on health or sexual performance of men. Improved awareness about these advantages has led to increased acceptance of vasectomy in both developed and developing countries. The most spectacular increase had occurred in New Zealand and UK. Between 1976 and 1986, vasectomy rate increased from 9 to 23 per cent in New Zealand and from 2 to 11 per cent in UK. China, South Korea, Sri Lanka, Nepal and Thailand among developing countries have also shown a progressive increase in prevalence of vasectomy during the eighties. It is estimated that (as of 1992) nearly 42 million couples depend on vasectomy for contraception (Table I)¹ and the number is growing.

China and India have the largest number of vasectomised men in the world. In India, in spite of the fact that both vasectomy and tubectomy were introduced in the National Family Welfare Programme from its inception and vasectomy was well accepted in the fifties and sixties, only 7 per cent of the eligible couples are currently protected by vasectomy. Contrary to the global trend there had been a progressive decline in vasectomy acceptance in India during the last 20 years.

Table I. Prevalence of vasectomy

Regions/Countries	No. of couples using vasectomy (%)	No. of couples relying on vasectomy (millions)	No. of couples using tubectomy (%)
Asia	6.0	23.0	
China	8.0	18.1	28.0
India	7.0	13.0	22.0
Thailand	6.0	2.3	
S.Korea	11.0		
Near East, North Africa	0.5	<0.5	
Sub-Saharan Africa	0.5	0.5	
Latin America	0.7	0.4	
Australia and New Zealand	13.0	0.4	
Australia	10.0		28.0
New Zealand	23.0		19.0
Europe	3.0		
UK	12.0		
Netherlands	11.0		
North America	13.0	5.2	
All developing countries	5.0	32.3	
All developed countries	5.0	9.2	
Global	5.0	41.5	17.5

Source: Ref. 1

Changing Trends in Vasectomy in India

From inception to date, the major focus of India's National Family Welfare Programme has been on sterilisation, both in men and women. In the fifties and sixties, efforts were directed mainly to provide hospital-based vasectomy and tubectomy services. Health education through mass media or inter personal channels was minimal. Literacy rates were low and the outreach of mass media was limited. In spite of these, acceptance of vasectomy was quite high. With improved outreach through the camp approach, vasectomy formed 74 per cent of all sterilisations in 1970. However, during the last two decades, there has been a sharp and progressive decline in the

contribution of vasectomies to the total number of sterilisations in India (Table II)². The reasons for this decline have not been clearly documented.

Table II. Changing trends in vasectomy in India

Year	No. of vasec- tomy	No. of tubec- tomy	Total	Vasectomy (as % of total sterilisation)
1960	37,596	26,742	64,338	58.4
1969-70	10,55,860	3,66,258	14,22,118	74.2
1979-80	4,72,687	13,05,237	17,77,924	26.6
1989-90	3,41,581	38,46,582	41,88,163	8.2
1990-91	2,54,982	38,67,648	41,22,630	6.2
1991-92	1,74,008	39,15,170	40,89,178	4.2

Source: Ref. 2

Figures for 1991-92: Provisional unpublished data from Ministry of Health & Family Welfare.

The All India Post Partum Programme began in 1971 and with it the availability of tubectomy, as a part of Maternal and Child Health (MCH) services, from primary health centres (PHCs) to tertiary care hospitals, improved. Vasectomy services, however, did not get integrated into routine surgical practice. Unlike tubectomy services, vasectomy services did not reach out for potential clients, address their anxieties, problems or conveniences. The fact that the health infrastructure has the potential for carrying out vasectomy and acceptance of the method among men does exist in India was proved in 1976 when over six million vasectomies could be done. Obviously the potential for vasectomy to play the key role in the National Family Welfare Programme has not yet been fully exploited. Currently the Government of India is taking steps to popularise vasectomy and persuade men to participate in the Planned Parenthood movement through improved acceptance of this simple procedure.

Short -Term Sequelae of Vasectomy

Vasectomy is an easier, simpler and safer procedure than tubectomy^{1,3}. Every practicing physician with minimal additional training can develop the skills required for performing vasectomy safely and providing follow up care. Immediate complications following vasectomy are

rare. Reported incidence of complications range from 0.1 to 3.0 per cent¹. Haematoma and infections are the two immediate complications; neither is life threatening and both respond readily to treatment. With training and adequate attention to asepsis, these complications can be minimised. Thus, the procedure is ideally suited for use in the primary health care set up.

Vasectomised men have to be specifically reassured that the surgery will not in any way impair their sexual performance. There is a lag period of 3-6 months before all the sperms disappear and the contraceptive effect of vasectomy can be relied upon; hence vasectomised men have to be clearly instructed to use additional reliable contraception for the subsequent six months to prevent inadvertent pregnancies.

Biochemical Changes Following Vasectomy

Effect of vasectomy on the function of the pituitary-gonadal axis, epididymis and prostate had been extensively investigated in the seventies both in India and abroad. Most of these studies⁴⁻⁶ indicate that there is no alteration in the pituitary-gonadal axis, testicular function or androgen levels in vasectomised men. Semen analysis in these men indicated that there was some reduction in the secretory function of the prostate; however, the reduction was not progressive^{7,8}. The exact reasons for these changes are not known. No adverse health consequences attributable to these changes have as yet been reported.

Immune Changes Following Vasectomy

Antibodies to spermatozoa have been detected in over 50 per cent of men 3 to 6 months after vasectomy. These antibodies persist for a long time⁹. There have been speculations as to whether these antibodies may form circulating immune complexes which may result in adverse health consequences. It has been postulated that the immune complex may (i) get deposited in the arterial wall leading to intimal injury and accelerated atherosclerosis; (ii) lead to or hasten the progress of a variety of autoimmune diseases such as rheumatoid arthritis; (iii) heighten allergic disorders; and (iv) alter the risk or progression of some malignancies. Data from epidemiological studies have not substantiated any of these hypothesis.

Epidemiological Studies on Long-Term Health Consequences Associated with Vasectomy

Following the publication of conflicting results regarding hormonal changes and consistent finding of immune changes in vasectomised men, concerns were expressed about the potential health consequences of these changes. Therefore during the eighties several attempts were made to obtain information on the long-term health consequences of vasectomy through epidemiological studies.

Two approaches have been extensively used by epidemiologists to obtain data on the long-term health status of vasectomised men. In one, the starting point is the factor under investigation (vasectomy). Efforts were made to identify well defined population groups where accurate records of vasectomy status and major morbidity and mortality data were available for all the members for the last decade or more. From the existing records, persons who had undergone vasectomy were identified; one or more persons matched for age, race and socioeconomic status, were selected from the same population group. Through record linkage, information on the morbidity and mortality in these two groups of individuals was extracted from existing records and relative risk of morbidity computed. For obvious reasons matching for behavioural and life style variables was not possible, even though it is known that life style variables influence both the acceptance of vasectomy and morbidity profile. Yet another problem in all these studies was the fact that even when morbidity/mortality data were extracted from the records of over 10, 000 persons, the number of persons suffering from any specific morbidity was very small; consequently computed RR tends to have very wide confidence intervals (CIs). Because of the ready availability of computerised records of events related to health of the individuals this type of epidemiological investigation (variously termed as retrospective/historical cohort studies or as record linkage studies) is used to explore association, if any, between vasectomy and CVD, CVA and cancers in developed countries. Because of the absence of these types of records, such studies are not possible in developing countries.

In the second approach, individuals suffering from specific diseases under investigation is the starting point. Patients with the disease (eg. acute myocardial infarction) were identified either in well defined

communities or among persons attending hospitals; controls were individuals who did not suffer from these disease and were drawn from the same community or the hospitals after matching for age, race and socio-economic factors. Information on the presence or absence of the factor under investigation (vasectomy) in the cases and controls is collected. The relationship between the disease and the factor under investigation is computed by comparing the frequency of the factor in the cases and the control group. This type of case control study had been extensively used to investigate the possible association between specific diseases and vasectomy both in developed and developing countries, because it is relatively easy to collect information on the vasectomy rates in relatively large numbers of persons suffering from the specific diseases and the controls who are free from these diseases, within the existing constraints of availability of accurate hospital records, time and money.

The major problem in interpreting the results from the studies of either type is the accuracy with which controls have been "matched" and the elimination of any bias in the selection of the controls. It is well known that life style differences influence both vasectomy acceptance and prevalence of CVD, CVA and some malignancies, but it is not possible to match the life styles. As the etiological factors for many of the malignancies and autoimmune diseases are still poorly understood, matching except for obvious socio-demographic factors, is not possible. Even when all care is taken to match for the known factors, the possibility that some as yet unidentified factor might account for the observed association cannot be ruled out. Because of all these problems, interpretation of the reported associations between specific diseases and vasectomy from epidemiological studies using either the "retrospective cohort" or the "case control" approach is difficult and at times an unproductive exercise; detected associations can at best be taken as indication of a possible relationship, not necessarily causal, which needs to be confirmed.

Cardiovascular Diseases

Baboons fed on lipid rich diet when repeatedly immunised with foreign proteins have been shown to develop more severe atherosclerosis than the pair fed controls¹⁰. In 1978, Alexander and Clarkson¹¹

reported that diet induced atherosclerosis developed more extensively in the abdominal aorta, carotid arteries, distal segments of coronary artery and the intracranial cerebral arteries in vasectomised cynomolgus monkeys than in sham vasectomised control monkeys fed on the same diet. They postulated that the rapid progression of the lesion could be due to deposition of circulating immune complexes to sperms in the vessel wall and consequent endothelial damage and increased permeability¹¹. A decade later the same investigators reported that long-term follow up studies in these monkeys did not reveal any association between development of CVD and vasectomy¹².

In 1981, the WHO reviewed the available data and concluded that there was no clinical or epidemiological evidence to indicate that there is any increase in cardiovascular, endocrine or autoimmune diseases in vasectomised men¹³. However, concern about these potential risks following vasectomy persisted and several investigators attempted to obtain data on long-term health consequences associated with vasectomy. The focus of the initial studies was on CVD, because in the seventies cardiovascular and cerebrovascular diseases were the major causes of death in men in developed countries. Studies conducted in the UK and USA in the eighties in men who had undergone vasectomy two to ten years earlier, showed that the risk of CVD was either unaltered or lower in vasectomised men¹⁴⁻¹⁷.

By the late eighties and early nineties, in many of the developed and developing countries, there were sufficient numbers of men who had undergone vasectomy 15-20 years earlier and were in their fifties and sixties, making it possible to undertake large scale studies to obtain information on long-term cardiovascular disease risk in men who had undergone vasectomy¹⁸⁻²³. Data from USA involving 14,540 men who had undergone vasectomy prior to 1978 and 12,392 controls showed that the overall mortality rates in vasectomised men were lower and this was mainly due to lower CVD mortality rates in vasectomised men¹⁸. There were no differences in the risk of fatal or non-fatal myocardial infarction rates between the vasectomised men and controls. Both coronary artery disease and myocardial infarction (fatal and non-fatal) were lower in men who had undergone vasectomy 20 years earlier¹⁸. But the fact that even in the same studies there were no consistent time trends in the association between

CVD and vasectomy¹⁸, and not all studies showed a similar reduction in the CVD, suggests that the association is not causal, but might have been mediated by the self selection bias of the men who had undergone vasectomy. Healthier men may choose to undergo vasectomy and hence the lower morbidity and mortality rate.

Among the developing countries, South Korea where vasectomy acceptance had risen steeply in the last decade and China where the largest number of vasectomised men live have undertaken large scale studies to assess the CVD risk. A community based study on farmers from rural communes in Sichuan province from China showed that age specific death rates for all causes including CVD were lower in vasectomised men (RR 0.39; 95% CI 0.3-0.5). The investigators had, however, reported that there were some difficulties in the identification of the exact cause of death in this study. Simultaneously a community based study was undertaken to assess 'risk factors' for CVD in 4596 vasectomised men and 4340 men from the same community who had not undergone vasectomy. Vasectomised men were 'healthier' when compared to controls as assessed by prevalence of hypertension (RR 0.8; 95% CI 0.7-1.0), ischaemic heart disease (RR 0.5; 95% CI 0.3-0.7), biochemical parameters, resting ECG (RR 0.7; 95% CI 0.5-0.9) and stress test ECG (RR 0.9; 95% CI 0.6-1.2)²¹.

The South Korean study which was based on the analysis of death certificate in four major cities did not find any difference in risk of death due to cardiovascular or cerebrovascular disease between vasectomised men and controls (adjusted odds ratio 1.0; 95% CI 0.4-2.4)²². However, the same investigators reported an increased risk of acute myocardial infarction (adjusted odds ratio 2.6; 95% CI 1.1 - 6.1), 10-14 years after vasectomy in a hospital based case control study. In this study 163 men with acute myocardial infarction were compared with controls who were admitted to the same hospital for other ailments including cancers²³. The excess risk disappeared (adjusted odds ratio 1.1) when only the controls with digestive tract disorders were considered.

To sum up, available evidences suggest that the risk of CVD and cerebrovascular diseases in vasectomised men is either unaltered or is lower. The conflicting time trends found in the same study¹⁸ and differences between studies in the same country^{22,23} suggest that the reported lower risk of CVD in vasectomised men might be due

to the differences in the life styles of the vasectomy acceptors and is not a consequence of the procedure *per se*.

In India, the ICMR had carried out a case control study on several biochemical parameters including lipid profile in vasectomised men among industrial workers in Maharashtra in the early eighties. There were no significant differences in any of the biochemical parameters between cases and controls²⁴. So far, epidemiological studies exploring association, if any, between vasectomy and cardiovascular or cerebrovascular diseases have not been carried out in India.

India has the second largest number of vasectomised men in the world. Majority of them had undergone vasectomy more than 15 years earlier and are likely to experience in the nineties, some of the long-term risks/benefits associated with vasectomy. Data from some studies carried out in India indicate that there is an increasing prevalence of CVD in the country²⁵. Reported prevalence of hypertension is between 2.3-15.4 per cent depending upon the type of population studied; prevalence of ischaemic heart disease ranged from 1.7-6.5 per cent. It is estimated that in India there are 22.5 million persons suffering from hypertension and 12 million from ischaemic heart disease²⁵. Of these, approximately two thirds are men. Studies in non-resident Indians settled abroad have shown that CVD rates in Indians in these countries are higher than those of Caucasian citizens²⁶. In view of the large number of vasectomised men in India and relatively high prevalence of CVD in Indians, even a relatively small reduction in CVD risk (RR 0.8-0.9) in vasectomised men will benefit relatively large number of individuals. ICMR has initiated a hospital-based case control study to obtain data regarding CVD risk in vasectomised men in India.

Malignancies and Vasectomy

Two major hypotheses have been proposed linking vasectomy with altered prevalence of malignancies. These are (i) that the presence of antisperm antibodies may alter the immune response and hence alter the risk or progression of malignancies; and (ii) the altered sex hormone profile in vasectomised men may modify the prevalence or progression of hormone dependent tumours. The possibility that men who had undergone vasectomy may differ in their life styles and habits from

those who have not, and hence may have different malignancy risk should also be kept in mind while interpreting the results of studies investigating the risk of malignancies in vasectomised men.

Most of the available data on morbidity and mortality due to cancer in vasectomised men come from record linkage studies in UK and USA. A large retrospective cohort record linkage study in USA, involving over 10,000 vasectomised men and a similar number of controls revealed that though both groups had similar incidence rates for 98 diseases including various cancers, the death rate from cancers in vasectomised men was half that seen in the control group¹⁷. Almost all medium and long-term follow up studies have shown that the risk of morbidity and mortality due to cancers in vasectomised men were either similar to or lower than that in the control groups.¹³⁻²⁰ However, isolated findings of an increased risk of lymphomas, lung cancer and cancer prostate in vasectomised men have been reported from some studies^{18,27}. These conflicting reports on association between vasectomy and specific malignancies could be because of the fact that even when morbidity data over one or two decades in over 10,000 men who had undergone vasectomy and matched controls are extracted and analysed, the number of persons suffering from any given specific disease is so small that it is not possible to rule out that the association might be due to chance. Yet another reason for the variations in the reported trend might be problems in selecting appropriate "controls". Thus while overall data suggest that there is no association between cancers and vasectomy, further studies are needed to explore association, if any, between specific types of malignancies and vasectomy.

In India the prevalence of malignancies is very low as compared to developed countries^{28,29}. Cancer cervix and cancers of the oral cavity account for nearly half of all the malignancies. Prevalence of cancer prostate, lymphomas and hormone dependent tumours is low. It is therefore, essential to find out whether the findings from the developed countries regarding the association between malignancies and vasectomy are applicable to the Indian population. The ongoing ICMR case control study on cancers other than genito-urinary tract malignancies and vasectomy, is expected to provide some leads in this aspect during the next two years.

Specific Malignancies

Cancer testis

Cancer testis is a relatively rare malignancy, incidence being highest in men in their thirties. It has been postulated that vasectomy might protect against testicular tumours through enhanced immunological surveillance¹⁹, but there is no evidence to support this or to suggest that vasectomy may lead to increase in the incidence or hasten the progression of testicular cancer.

Strader *et al*³⁰ reported an association between vasectomy and testicular cancer in a case control study undertaken through telephone interviews. The association was seen only in Catholics and was most probably due to under-reporting of vasectomy by Catholics in the control groups. Cale *et al*³¹ who undertook a retrospective study of all patients who had been diagnosed as having testicular cancers in West Lothian district in the UK reported that the age standardised incidence of testicular tumours was 4.2 times higher in vasectomised patients. All the tumours were detected between 3 months to 4 years (mean 1.9 years) after vasectomy suggesting that some of these might have been present at the time of vasectomy. Subsequently two large record linkage studies, one from the UK¹⁹ and the other from the USA¹⁸, failed to detect any increase in the risk of testicular tumours in vasectomised men.

There are no sound biological reasons to suspect a causal relationship between vasectomy and testicular tumours. The conflicting reports might in part be attributed to one or more of the following confounding factors: (i) vasectomised men are a self selected group with as yet not clearly known factors associated with low prevalence of testicular cancer; (ii) men with small testicular tumours who wanted to undergo vasectomy might have been 'rejected', so that those who underwent vasectomy were a screened selected group with no testicular tumours; and (iii) testicular cancers are more often seen in Caucasians with higher education and income, a group which in UK and USA was more likely to seek vasectomy.

Cancer prostate

Very little is known about the etiology of cancer prostate. It is known that 'silent' prostate cancers are

detected during autopsy in 50 per cent or more men over the age of 60 years and in this group the incidence is similar in all countries³². However, there are marked differences in prevalence of clinically obvious cases of cancer prostate between developed and developing countries. Part of the observed differences could be due to inclusion of a large number of subclinical cases of cancer prostate detected in biopsy tissues obtained from patients with benign prostatic hyperplasia and the screening by prostate specific antigen and other tests for early diagnosis of prostate cancer, in the developed countries. However, there appear to be real differences both in the prevalence and progression of the tumour not only between countries but also between different races in the same country^{33,34}.

Over the last decade there has been a substantial increase in the prevalence of cancer prostate in some of the developed countries like the USA and UK. Currently cancer prostate is the second most common cancer in USA and some European countries. Globally it ranks as the fifth most common cancer in men³². However, reported prevalence in several developing countries including India and China is low. Incidence of cancer prostate in USA is 91.2/100,000; in India incidence ranges between 1.9 to 7.1/100,000^{28,29,33}. It is estimated that there are only about 100,000 patients with cancer prostate in India. Among the developed countries there are substantial differences in the incidence and mortality due to cancer prostate between USA and New Zealand and between the Whites and Blacks in USA^{28,34}. The reasons for the observed large differences are not known.

Reports exploring the association between vasectomy and cancer prostate date back to the mid eighties. Prior to 1990, two case control studies^{35,36} and one record linkage study³⁷ had reported that there was no association between cancer prostate and vasectomy; while another case control study reported that vasectomised men were at a higher risk³⁸.

In 1990 two hospital-based case control studies reported an increased risk of cancer prostate in vasectomised men^{39,40}. Rosenberg *et al*³⁹ reported an age adjusted RR of 5.3 (95% CI 2.7-10.0) in a study comparing 220 patients of cancer prostate and 571 men without any cancer; when the same patients were compared with 960 controls with cancers other than cancer prostate the RR was 3.5 (95% CI 2.1-6.0).



Mettlin and coworkers⁴⁰ reported that the RR was 2.2 (95% CI 1.0-4.6) in another hospital-based case control study of 614 cancer prostate cases and 2588 controls with cancers other than cancer prostate.

Subsequently four record linkage studies explored the association. Two of these studies conducted on health personnel or their spouses in USA showed a small but significant increase in the risk of cancer prostate in vasectomised men^{27,41}. In the Nurses Health Study involving 14,607 vasectomised men and age matched controls, the RR was 1.56 (CI 1.0-2.4). In the Health Professionals follow up study data on 10,005 vasectomised men and 37,800 age matched controls were compared; the RR was 1.66 (95% CI 1.25 - 2.21). Data from another study in USA (involving the general population availing the Kaiser Permanente Medical Care Programme) on 5119 vasectomised men and 15,357 controls showed that the RR was 1.0 (95% CI 0.7-1.6)⁴². The Oxford record linkage study reported RR of 0.44 (95% CI 0.0-4.0) in a comparison of 13,246 vasectomised men and 22196 controls¹⁹.

A review in 1993 by the National Institutes of Health, USA and WHO of all the available data (both published and unpublished) on cancer prostate in vasectomised men, endorsed the earlier WHO Expert Committee's conclusion that there is no biological mechanism to explain the association between cancer prostate and vasectomy and a causal relationship between the two is unlikely. The Expert Group noted that there was no consistency between reports and the reported associations were weak; hence there was no basis to change clinical and public health practices regarding vasectomy. The Group recommended that studies should be taken up in countries like India and China where the prevalence of cancer prostate is low⁴³. The ICMR has initiated a hospital-based case control study to explore the association, if any, between cancer prostate and vasectomy in India. India will be one of the countries participating in the proposed WHO multicountry study on evaluation of the risk of cancer prostate in vasectomised men.

Overall Morbidity and Mortality Rates

Record linkage studies on morbidity and mortality rates in vasectomised men have been carried out mainly in the UK and the USA¹⁴⁻²⁰. During the last

decade some attempts were also made to obtain these data in developing countries through hospital and community-based case control studies^{21,23}. All the available data indicate that the overall morbidity rates in vasectomised men were either similar to or lower than those reported in the control groups. There is no evidence of any increase in autoimmune diseases or urinary tract morbidities in vasectomised men^{14-20,23}. Two large record linkage studies from USA^{17,18} and one community-based case control study from China²¹ have shown that vasectomised men had lower age specific morbidity and mortality rates than the control group. In one US study¹⁸ and the study in China²¹, the difference was due to reduced CVD morbidity and mortality rates in men who had undergone vasectomy. In the other US study the reduction was due to lower malignancy rates¹⁷.

In the UK and USA most men who underwent vasectomy in the seventies were 'elitist' health professionals, their spouses or 'health conscious' persons. It has been suggested that the observed lower age specific morbidity and mortality rates might at least in part be due to the 'self selection' bias. 'Healthier' persons with healthier life styles might have undergone vasectomy and hence had lower morbidity and mortality rates. It is, however, difficult to define 'healthy person' and 'health conscious behaviour' in readily measurable parameters. Hence proof for the hypothesis that the lower morbidity rates could be attributed to these behavioural patterns remain elusive.

In developing countries like China such a self selection bias is unlikely. The fact that even in China the vasectomised men have lower age specific morbidity and mortality rates is, therefore, a very interesting observation. Whether this beneficial effect on CVD could be due to the freedom from anxiety over unwanted pregnancies or stresses inevitable to the problems of bringing up a large family within the existent resource constraints in developing countries, is not known. Studies need to be undertaken to explore whether similar findings are present in other developing countries like India. Whatever may be the reason for the observed beneficial effect, the association if found consistently, becomes important in view of the fact that health benefits of vasectomy have to be weighed against the risks and an assessment regarding the long-term safety of vasectomy has to be made.

Needs of the Family Welfare Programme in India

The ideal contraceptive totally free of risks does not exist and is unlikely to be discovered in the near future. In view of the ease, safety, low cost and feasibility in the primary health care set-up vasectomy is an eminently suitable permanent method of contraception in India. The Government of India is making specific efforts to popularise vasectomy.

The conflicting publications on the long-term health consequences of vasectomy and ensuing debate have to be viewed in this context. It can be argued that even if the risk of cancer prostate in vasectomised Indians is similar to the highest reported in USA (RR of 1.7) the number of vasectomised individuals affected by the disease will be small, as there are only about 100,000 cases of cancer prostate in India. In contrast even a small reduction in the magnitude of the risk of CVD (RR of 0.7-0.9) would benefit a very large number of men who had undergone vasectomy, because it is estimated that 23 million men suffer from CVD (hypertension and ischaemic heart disease). However, this argument may fail to satisfy the public because these computations are not based on Indian data on the magnitude of risks and benefits associated with vasectomy. It is therefore essential to find out the pattern and magnitude of the association between vasectomy and these diseases and compute country specific data on risks and benefits.

Ongoing ICMR Research Studies and Future Research Plans

The ICMR has recently initiated a comprehensive hospital-based case control study to assess the risk of CVD, CVA and cancers including cancer prostate in vasectomised men. The "subjects" for the study are married men beyond 50 years of age who are admitted to the chosen hospital/ group of hospitals with ischaemic heart disease, cerebrovascular accidents, cancer prostate, and cancers other than those of the genito-urinary tract. The "controls" are age matched, married men admitted to similar wards in the same hospital/group of hospitals within a month after admission of the "case" with ocular problems such as cataract and glaucoma, orthopaedic problems such as arthritis and fractures other than pathological fractures, and chronic infections or surgical problems other than those already listed.

It is expected that in about two years this study will provide preliminary data on the magnitude of the long-term risks and benefits associated with vasectomy in men beyond 50 years of age. Based on these data further studies can be planned and a balanced assessment of long-term health consequences of vasectomy could be presented to policy makers, physicians and potential clientele, so that they could make an informed choice based on Indian data.

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This write-up is contributed by Dr. C.R. Ramachandran, Senior Dy. Director-General and Dr. P. Ramachandran, Deputy Director-General (Sr. Grade), ICMR Hqrs, New Delhi.

ABSTRACTS

Some Research Projects Completed Recently

Ultrastructural changes in early leprosy:

A total of 70 clinically early, unclassifiable and doubtful cases of leprosy with disease of less than 12 months duration and with upto five lesions were studied to elicit fine structural changes in early lesions of leprosy, to identify definite criteria for early diagnosis and understand the pathological mechanism involved in the development of early lesions in the leprosy.

All patients were subjected to skin biopsy. Light microscopy revealed histologically developed granulomas in 18, indeterminate leprosy in 14 and no lepromatous changes in 38 subjects. Electron microscopy in 25 subjects who had no specific changes on light microscopy, showed nonspecific inflammatory changes in 20 patients. Five patients revealed derangement in the fine structure of the dermal nerve twigs in the form of oedema of the nerve fiber with separation of Schwann cells and swelling of the axons and splitting of myelin sheath. In addition, fragments of electron dense material which could be of bacillary origin were also found within the Schwann cell cytoplasm.

It is concluded that as the electron microscopy of patients with negative histological finding on light microscopy showed specific changes of leprosy in only 20 per cent of subjects, it is not of significant use to confirm the disease.

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Role of fine needle aspiration as an effective diagnostic tool in lymphadenitis affecting children:

The study was carried out in 200 children (132 boys and 68 girls) in the age group of one month to 12 years with lymphadenopathy to determine the etiopathogenesis of lymphadenitis and evaluate the accuracy of fine needle aspiration technique as a diagnostic aid. The major presenting symptoms were loss of appetite and weight (73%), fever (60%), swelling in the neck (55%) and cough (36%); duration of symptoms varied from 3

days to 2 yr. Among the lymph nodes involved, cervical nodes were the commonest (66%), followed by the axillary nodes (10%). Involvement of both cervical and axillary lymph nodes was seen in 13 per cent and generalized lymphadenopathy in 8 per cent of patients.

Fine needle aspiration cytology (FNAC) showed reactive hyperplasia in 134 (67%), tuberculosis in 48 (24%), lymphoma in 10 (5%) and tumour in two. In six patients FNAC was inconclusive.

Of the 200 patients, 120 were subjected to surgical biopsy of the same lymph node and the FNAC diagnosis was compared with the histopathological diagnosis. There were 74 patients with reactive hyperplasia, all of whom could be diagnosed both by FNAC and histopathology. Of the 28 patients of tuberculosis, 14 of Hodgkin's and 4 of non-Hodgkin's disease (diagnosed by histopathology) only 20, 8 and 2 patients were diagnosed by FNAC, giving accuracy rates of 71.4, 57.1 and 50 per cent respectively. Thus, a correct cytodiagnosis was obtained by aspiration biopsy cytology in 104 of 120 patients giving an accuracy rate of 86.6 per cent.

In four patients of tuberculosis lymphadenitis and two of Hodgkin's disease FNAC was inconclusive necessitating biopsy for an etiological diagnosis, whereas in four patients of histopathologically proven tuberculous adenitis and two of non-Hodgkin's lymphoma cytology revealed evidence of reactive hyperplasia. In four patients of Hodgkin's disease, there were false positive results on FNAC, two being diagnosed as tuberculous adenitis and two as red cell tumour.

It is thus concluded that aspiration cytology is, by and large a simple, safe, rapid and fairly accurate procedure. It is a low cost outpatient technique requiring no hospitalization or anaesthesia. It has a potential of being adopted as a routine screening investigation in palpable and accessible swellings.

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ICMR NEWS

The following meetings of various technical committees/groups of the Council were held at New Delhi:

Expert Group on Goitrogens.	August 17-18, 1994
Central Ethical Committee	August 18, 1994
Toxicological Review Panel	August 18, 1994
Expert Group on Assisted Reproductive Technology	September 12, 1994
Expert Group on Earthquake Disaster of Marathwada.	September 13, 1994

Participation of ICMR Scientists in Scientific Events:

Dr. K. N Panicker and Dr. S. P. Pani, Dy. Directors, Vector Control Research Centre (VCRC), Pondicherry and Dr. V. Kumaraswami, Asstt. Director, Tuberculosis Research Centre, Madras, participated in the Informal Consultation Meeting on the development of new strategies for the control of lymphatic filariasis at Penang, (August 20-28, 1994).

Dr. Leela Raman, Dy. Director (Sr. Grade), National Institute of Nutrition (NIN), Hyderabad, participated in the International Nutrition Program Seminars at Ithaca, New York (August 22-30, 1994).

Dr. K.N. Panicker, Dy. Director, VCRC, Pondicherry, Participated in the WHO meeting of the Control of Tropical Diseases at Geneva (September 1-2, 1994).

Dr. G. Ghafoorunissa, Dy. Director, NIN, Hyderabad, participated in the UNESCO/COSTAM/SFRR-Asia Workshop on Nutrition, Lipids, Health and Disease at Penang as also in the Oils and Fats International Congress 1994 at Kuala Lumpur (September 1-3 and 5-8, 1994 respectively).

Dr. Veena Shatrugna, Asstt. Director, NIN, Hyderabad, participated in the International Conference

on Population and Development at Cairo (September 3-13, 1994).

Dr. Jayashree Nandi, Research Officer, National Institute of Virology (NIV), Pune, participated in the VIII MRC AIDS Workshop at Manchester (September 4-7, 1994).

Dr. Aruna Dewan, Dy. Director, National Institute of Occupational Health, Ahmedabad, participated in the VII meeting of the IPCS/INTOX Poisons Centre Working Group (INTOX-7) at Sao Paulo (September 5-9, 1994).

Dr. M.S. Malhotra and Dr. Aruna Srivastava, Senior Research Officers, Malaria Research Centre, Delhi, participated in the International Workshop on Health and Environment at Colombo (September 5-10, 1994).

Dr. Kalyan Banerjee, Director, NIV, Pune, participated in a meeting of WHO Ad-hoc Committee on Orthopoxvirus Infection at Geneva (September 9, 1994).

Dr. G.V. Satyavati, Director-General, ICMR, delivered a special lecture on "Whither Medical Research in India" at the A.P. Academy of Sciences, Hyderabad where she was honoured as a distinguished scientist (September 12, 1994). She delivered the inaugural address at the symposium on Laboratory Animal Resource Development Experimentation and Welfare — Which Way to Go? at Hyderabad (September 13, 1994). Dr. Satyavati also delivered the Decennary Oration of the JSS Medical College, Mysore on "Medical Research vis-a-vis Medical Education in India" at Mysore (September 14, 1994).

Hindi Day Celebrations:

As part of Hindi Day celebrations by the ICMR Headquarters, a popular lecture (in Hindi) on Treatment of Gall Stones was delivered on September 13, 1994 by Dr. R.K. Tandon, Professor and Head, Department of Gastroenterology, All India Institute of Medical Sciences, New Delhi.

ICMR AIDED SYMPOSIA/SEMINARS/WORKSHOPS/COURSES/CONFERENCES

Symposium/Seminar/Workshop/ Course/Conference	Date & Place	Contact Address
National Workshop on Neuroepidemiology.	September 1-4, 1994; (at Bangalore)	Dr. M. Gourie-Devi, Organising Secretary of the Workshop, Department of Neurology, National Institute of Mental Health and Neurosciences, Bangalore.
XII Annual Conference of ISMS on Evaluation Technology in Medical Education and Health Care Delivery System.	September 5-7, 1994; (at Sevagram)	Dr. N.K. Tyagi, Organising Secretary of the Conference, M.G. Institute of Medical Sciences, Sevagram, Wardha.
Continuing Medical Education in Psychiatry.	September 10-11, 1994; (at Manipal)	Dr. P.S.V.N. Sharma, Organising Secretary, 4th Annual Conference of the Indian Psychiatry Society, Department of Psychiatry, Kasturba Medical College, Manipal.
Symposium on Complex Carbohydrates.	September 15-16, 1994; (at Roorkee)	Dr. Ritu Barthwal, Organising Secretary of the Symposium, Department of Biosciences and Biotechnology, University of Roorkee, Roorkee.
Satellite Symposium on Free Radicals in Biology.	September 15-17, 1994; (at Chandigarh)	Dr. N.K. Ganguly, Organising Secretary of the Symposium, Department of Experimental Medicine and Biotechnology, Postgraduate Institute of Medical Education and Research, Chandigarh.
VI National Symposium on Ultrasonics and One Day Workshop on Ultrasound in Medicine.	September 15-17, 1994; (At Tirupati)	Prof. L. Rama Murthy, Convenor, NSU-VI-94, Department of Physics, S.V. University, Tirupati.
National Update on Nutrition in Children.	September 24-25, 1994; (at New Delhi)	Dr. H.P.S. Sachdev, Secretary, Indian Academy of Pediatrics, Department of Pediatrics, Maulana Azad Medical College, New Delhi.
International Conference on Molecular and Metabolic Endocrinology and Contraceptive Technology.	September 26-27, 1994; (at Madras)	Dr. M. Michael Aruldas, Organising Secretary, Silver Jubilee International Conference, Department of Endocrinology, Dr. A.L. Mudaliar Postgraduate Institute of Basic Medical Sciences, Madras.
MICON-International' 94.	November 9-12, 1994; (at Mysore)	Dr. R. Shankaran, Chairperson of the Organising Committee, MICON-International'94, Defence Food Research Laboratory, Siddhartha Nagar, Mysore.
III International Conference on DNA Fingerprinting.	December 13-16, 1994; (at Hyderabad)	Dr. Lalji Singh, Organising Secretary of the Conference, Centre for Cellular and Molecular Biology, Hyderabad
International Symposium on Atherosclerosis, Thrombosis and Transfusion Medicine.	December 15-20, 1994; (at Bombay)	Dr. D. Mohanty, Director, Institute of Immunohaematology, Parel, Bombay.

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COUNCIL'S TRAINING PROGRAMMES

Reproductive Biology

At the Institute for Research in Reproduction, Bombay:

- ... Workshop on Gynaecologic Cytology and Immunocytochemistry (September 26-October 1, 1994).

Nutrition

At the National Institute of Nutrition, Hyderabad:

- ... Annual Training Course in Nutrition (December 1, 1994-February 28, 1995).

Occupational Health

At the National Institute of Occupational Health, Ahmedabad:

- ... Orientation Course on Occupational Health for Industrial Medical Officers (September 19-24, 1994).

... Training Course on Air Pollution Monitoring and Risk Assessment (October 19-25, 1994).

- ... Training Course in Pesticide Residue Analysis (December 5-9, 1994).

Laboratory Animal Technology

At the Laboratory Animal Information Service Centre, National Institute of Nutrition, Hyderabad:

- ... Training Course for Laboratory Animal Supervisors (September 12- December 10, 1994).

Haematology

At the Institute of Immunohaematology, Bombay:

- ... Training Course in Blood Group Serology and Blood Bank Methodology for Medical Officers (August 9-October 7, 1994).

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