

DISCUSSION

In contrast to a high prevalence of various reproductive factors in women in the west^{1,2} we found a low prevalence in our study. Almost similar trend has been in other reports from India as well. In our study, only 32.2% patients and 14.6 % of cases had menarche below 13 years of age. The means age of menarche in our and other studies had been reported to be around 14 to 14.5 years^{9,10}, in our study the average age at first live birth was 19.76 years in cases and 18.69 in controls. First live birth before 20 years of age was seen in 67.8% of cases and 79.8 % of controls respectively. Other studies to report an average age at first live birth as 19.5-20.5 years⁹⁻¹¹. Mean number of live births in our study were 3.63 and 4.26 in cases and controls respectively. Only four controls and 3 cases were nulliparous. An average parity of 3-5 has been reported in other studies as well,^{10,11} however the difference in number of live births in cases and control was statistically significant in our study as well as other studies. In our study majority in either group (i.e. 50.4% cases and 54.5% of controls) breast fed for 5-9 years. Other studies too report a high rate of breast feeding practice in Indian women¹⁰⁻¹². Thus it can be seen that though some reproductive factors are significantly more prevalent in breast cancer patients compared to controls, but their overall prevalence is much lower in Indian women than women in the west. In our study only few patients underwent breast biopsy before the onset of illness. (2.4% in the control group and 10.4% in the case group). The difference was found to be statistically significant. Women with one or more biopsy had 4.7 times risk of breast cancer compared to women with no biopsy. However a large proportion of Indian women do not have access to hospitals with facilities for breast biopsy. Illiteracy and poverty further add to the problem. In our population a history of lumpiness instead of history of biopsy should be given some place in risk assessment.

Percent breast density is an expression of the mammary gland mass as a fraction of the total breast area, and thus presumably the total number of breast cells at risk for malignant transformation. There is a significant positive relationship between dense mammographic patterns and subsequent risk of breast cancer and the association has been particularly strong when the exposure is defined as % breast density¹⁴. In our study we found that the premenopausal women with breast density of 0%. Thus the highest category of percent density was found to exceed the Odds ration of most other risk factors in the study population. In a multiethnic case control study it was found that women with breast density of more than 50% had 3.6 times higher risk of breast cancer than women with less than 10% density, but the risk varied with ethnicity. Whereas the odds ratio

was 5.3 for Caucasians and 4.2 for Native Hawaiians, it was only 3.2 for women of Japanese ancestry¹⁵. In other studies, it was seen that risk associated with dense patterns persisted for 8 years ad was greater in younger women than older women^{16,17}. Thus knowledge of a woman's breast density might be useful in determining the indication for screening.

Limitations of our study are that size of the study population is small and we were not able to do multivariate logistic regression analysis. However our study has identified mammographic density as an important risk factor which has not been investigated in Indian women in any other study so far. Benign breast biopsy and mammographic density need to be evaluated in larger studies for their potential role in risk assessment for breast cancer.

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ETHICAL GUIDELINES FOR BIOMEDICAL RESEARCH

The need for uniform ethical guidelines for research on human subjects is universally recognised. It has acquired a new sense of urgency as the critical issues in the area of biogenetic research involving human subjects have become acute. Apart from the mandatory clinical trials on new drugs, a number of diagnostic procedures, therapeutic interventions and prevention measures including the use of vaccines, are being introduced which involve human subjects. Further the advent of new medical devices and radio-active materials and therapeutic benefits of recombinant DNA products have added a new dimension to the ethical issues that need to be considered before evaluating these for their efficacy, utility and safety.

Any research using the human beings as subjects shall bear in

mind the following principles of : i) essentiality, (ii) voluntariness, informed consent, (iii) non exploitation, (iv) privacy and confidentiality, (v) precaution and risk minimisation, (vi) professional competence, (vii) accountability & transparency, (viii) maximisation of public interest and distributive justice (ix) institutional arrangements (x) public domain (xi) totality of responsibility and (xii) compliance.

Recent advances in the field of Assisted Reproductive technologies, organ transplantation, Human genome analysis, and gene therapy promise unquestionable benefits to mankind. At the same time, they raise many questions of law and ethics, stimulating public interest and concern.

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