

A cluster randomized, controlled trial of breast and cervix-cancer screening in Mumbai, India: methodology and interim results after three rounds of screening

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Cervix and Breast cancers are the most common cancers among women worldwide and extract a large toll in developing countries. In May 1998, supported by a grant from the NCI (US), the Tata Memorial Hospital, Mumbai, India, started a cluster-randomized, controlled, screening-trial for cervix and breast cancer using trained primary health workers to provide health-education, visual-inspection of cervix (with 4% acetic acid-VIA) and clinical breast examination (CBE) in the screening arm, and only health education in the control arm. Four rounds of screening at 2-year intervals will be followed by 8 years of monitoring for incidence and mortality from cervix and breast cancers. The methodology and interim results after three rounds of screening are presented here. Good randomization was achieved between the screening ($n = 75360$) and control arms ($n = 76178$). In the screening arm we see: High screening participation rates; Low attrition; Good compliance to diagnostic confirmation; Significant downstaging; Excellent treatment completion rate; Improving case fatality ratios. The ever-screened and never-screened participants in the screening arm show significant differences with reference to the variables religion, language, age, education, occupation, income and health-seeking behavior for gynecological and breast-related complaints. During the same period, in the control arm we see excellent participation rate for health education; Low attrition and a good number of symptomatic referrals for both cervix and breast.

Of the estimated 470,000 new cases of cervix cancer diagnosed each year worldwide, 80% occur in developing countries and around 27% occur in India from where 126,000 new cases are diagnosed annually and over 71,000 deaths because of cervix cancer are reported each year.^{1,2} Nearly 70% of cervix cancer patients in India present at stages III and IV.³ Around 20% of women who develop cervix cancer die within the first year of diagnosis and the 5-year relative survival rate is 50%.⁴

Breast cancer is the most common cancer among women worldwide and is also the leading cause of cancer deaths in women. Breast cancer is responsible for an estimated 189,000 and 184,000 deaths in developed and developing countries

respectively thus accounting for 16% and 12% of all cancer deaths in women. Although the age-standardized incidence of breast cancer is generally lower in developing countries than in developed countries (23.1 vs. 63.2 per 100,000 women), incidence rates are seen to vary widely between and within countries. Breast cancer is already more common than cervix cancer in a number of developing countries.⁵ Data from developing countries suggests that age-standardized incidence rates of breast cancer are rising rapidly in low-incidence regions such as Africa and Asia.⁶

There are no organized screening programmes for cervix and breast cancers in India. Cervix Cytology and Mammography based screening programmes are difficult to organize in India because of issues related to absence of trained manpower, infrastructure, logistics, quality assurance, frequency of screening and costs involved. Simple tests like visual inspection of the cervix after application of 4–5% acetic acid (VIA) and Clinical Breast Examination (CBE) have generated considerable interest in several developing countries. VIA has been shown to have a sensitivity ranging from 67% to 90%.^{7–11} Much of what we know about the benefit of the CBE is derived from indirect evidence. The sensitivity of CBE

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