Original Article

Implementation of cervical cancer screening: A demonstration in a rural community of North India

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ABSTRACT

Context: Strategies for implementation of cervical screening are the need of the hour while effective screening tests for early detection exist. **Aim:** To demonstrate the implementation of cervical cancer screening by aided visual tests in a North Indian rural community. **Setting and Design:** Cross-sectional study in a rural setting. **Subjects and Methods:** Baseline survey of community perspectives of screening and identification of eligible women of age 30-59 years was performed by Accredited Social Health Activists (ASHAs). Screening was targeted on 7604 women by the methods of visual inspection of cervix using acetic acid (VIA), by using lugol's iodine (VILI) tests and by Pap test. Screen positives were referred to colposcopy and further management. Data on evaluation parameters was collected. **Statistical Analysis:** Screening test performances were assessed by sensitivity, specificity and positive/negative predictive values (PPV/NPV) for detection of histological CIN II+. **Results:** Study showed coverage of 65.6% of total eligible women (7604). Extent of agreement of visual testes (VIA/VILI) between nurses and doctor was 77.3-100%. Screen positivity rates by VIA, VILI and Pap were 9.7%, 13.5% and 2.6%, respectively. Screen positives turned up for confirmatory diagnosis were 78%. Acceptance of treatment was 76%. Screen positivity of VIA and VILI declined ($P < 0.001$) with increase in age. Sensitivity, specificity, and PPV of VIA were 59.0%, 92.3% and 3.6% and of VILI were72.7%, 89.6% and 3.3% respectively. NPV was 99% in all the tests. **Conclusion:** Implementation of screening by aided visual tests was successfully demonstrated through utilization of ASHAs for motivation, achievement of good coverage and good response in clinical management of screen positives.

Key words: Aided visual screening, cervical cancer, health education, health infrasture, referral system

INTRODUCTION

Cancer of the uterine cervix is the leading cancer in India with estimated 134,420 new cases in the year 2008. This is one-fourth load of the total cancer cases in the year 2008 in India.[1] The present practice in India is hospital based opportunistic screening or screening in research setting in very few selected geographical areas of the country for the evaluation of screening methods such as Papanicolaou (Pap) test, aided visual inspection of the cervix and Human Papilloma virus (HPV) tests. Although the cytology screening reported evidence of reduction of this cancer in developed countries, its feasibility presents challenges in low resource settings. The role of Visual Inspection of cervix with Acetic acid (VIA) and Visual Inspection of cervix with lugols iodine (VILI) strategies for cervical cancer screening were widely studied. In recent years also, there were studies on evaluation of visual and cytology screening methods from India.[2-9]

Pooled analysis of the accuracy of five cervical screening tests assessed in 11 studies in Africa and India showed lowest sensitivity of 57% for Pap test and higher sensitivity of 79% for VIA for the outcomes of Cervical Intraepitheial Neoplasia (CIN) of grade CIN 2 + or CIN 3+. VILI was found to be on average 10% more sensitive than VIA and the HPV test by Hybrid Capture II (HCII) assay showed a sensitivity of CINII + as 62%.[10] VIA was demonstrated as a

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useful alternative if carefully monitored, HPV and cytology showed similar detection rate despite heavy investment as observed from an RCT conducted at Osmanabad district in India.[11] Although recent information supports the use of HPV DNA technology, however, until low-cost HPV-DNA testing becomes more widely available for low and middle-income countries, visual inspection methods, especially VIA will continue to provide a reliable and effective means for reducing the burden of cervical cancer.[12]

A study on review of randomized control studies addressing delivery of both breast and cervical screening, discussed on strategies for their implementation while effective screening tests for prevention and early detection exist.[13] A demonstration of implementation in this direction was a cluster RCT that reported interim results of VIA with high screening participation rate, good compliance for clinical management and significant downstaging.[14] Further demonstration of strategies for implementation is still need of the hour in low resource settings. A recent report in south India also stated on translating evidence into practice in low resource settings as the cervical cancer screening tests are only part of the solution in rural India, emphasizing the importance of operational aspects of screening services deliver and achieving adequate screening uptake.[15] In India, Tamil Nadu state recently took initiative for a VIA, VILI screening impementation on a pilot basis to demonstrate whether the program was appropriate and cost effective.[16] As the country does not have nation-wide screening facility available as yet as part of the national program because of various hassles in the methods, infrastructure and personnel, there is an urgent need to study feasible screening implementation models for the country. Thus, the present study aimed to demonstrate the implementation of feasible cervical cancer screening strategies focusing on operational issues of screening service delivery in a rural community of North India.

SUBJECTS AND METHODS

A pre-screening survey was done on 511 random samples of target group women from study area to evaluate community perspectives of screening prior to the launch of screening program. The study was cross-sectional in nature. Total duration of study was 3 years and 3 months from May 2009-July 2012. Total area of Dadri tehsil geographically was divided in two halves. One half of the area was chosen randomly which included 34 villages with estimated population of eligible women was 7604. All ever married women of age 30-59 years were targeted for screening. Women who had undergone hysterectomy, pregnant and previously diagnosed with cancer or precancer were excluded from screening. Medical officer and Auxiliary Nurse Midwife (ANMs) of the project were trained/retrained on cervical screening methods. Assessment of the trainee's skill of identifying the positivity in the visual tests was done by comparing with doctor's evaluation. Accredited Social Health Activists (ASHAs) were community health workers instituted by Government of India as part of the National Rural Health Mission (NRHM) used for motivation of women for cervical screening.

Per speculum examination of women was done in lithotomy position after inserting un-lubricated bivalve speculum with the help of torch having white light (halogen bulb). Result of per speculum examination was noted on prescribed and pretested schedule. This examination was followed by Pap smear sample collection of exfoliated cells by Ayres spatula. Glass slide was prepared and fixed by placing in jars containing 95% alcohol and transported for reporting. Lastly, ANM performed Aided visual examinations VIA followed by VILI in parallel and results were noted. VIA was done after applying 5% acetic acid with a cotton swab on cervix and by allowing sufficient time of 1 minute to see for colour change on transformation zone. VIA was considered to be positive if area became conspicuous with white color against the pinkish background of normal epithelium others and else considered to be negative. VILI was similar to VIA except the application of lugol's iodine instead of acetic acid. VILI was considered positive if yellow iodine non-uptake areas were visualized close to the squamo-columnar junction or a growth on the cervix turned yellow.[17] Bethesda system was followed for cytology in reading Pap smear.[18] Women with a report of Atypical Squamous Cells of Unknown Significance (ASC-US) or more were considered to be positive.

All screen positive cases were referred for colposcopy. Colposcopic diagnosis was made as per International Agency for Research on Cancer (IARC) guidelines and results were recorded by the doctor.[18] The colposcopy directed biopsy/Endocervical curettage (ECC) samples were sent for histology reporting. Reports were made available to the patients within 2-3 weeks. Histological CIN I and above were referred for appropriate treatment. The treatment of precancerous lesions was done as per IARC guidelines.[18] CIN I cases eligible for cryotherapy were treated at Community Health Center (CHC) by doctor else referred to tertiary care hospital for surgical procedures and radiotherapy. A strict monitoring mechanism was adopted to follow screen positives and confirmed positives. Consecutive three follow-ups were made to declare a woman to be labeled as lost to follow-up.

Various screening tests were assessed for detection CIN II + by the statistics such as sensitivity, specificity, and positive/negative predictive values (PPV/NPV). The crude estimates of these statistics were biased due to exclusion of

women who did not have the opportunity for full diagnostic verification. An adjustment was done after incorporating verification bias by inverse probability weighting to weight up women with observed biopsy report to women who refused for biopsy and also to screen positive women who do not turn for colpo and biopsy. Sampling strata were defined by all possible positive/negative combinations of VIA, VILI and Pap. First, women within the stratum of biopsy done were weighted and then results were projected in each combination of biopsy positive stratum to represent all the women screened with full screen results thus adjustment to nullify verification bias.[19] Analysis of data was performed by using SPSS version 16.0.

RESULTS

A door-to-door survey eliciting the name and age of women and her husband's name were collected on a proforma in each village. Of the total eligible women (7064) of age 30-59 year old surveyed and motivated, 4988 (65.6%) were reported for screening. Base line characteristics of information socio-demographic characteristics and clinical (Gynecological related) symptoms and signs of women screened in relation to screen positives by different modes of screening are given in Table 1. The overall screen positivity for Pap, VIA and VILI were 2.5%, 9.5% and 13.2%, respectively. Table 2 showing results of VIA, VILI and Pap in relation to the outcome of cervical screening in terms of arriving at confirmatory diagnosis.

Analysis for diagnostic evaluation was performed on 4148 out of 4988 observed in which all screening tests were performed and all screen positives with histology results available. The test criteria was to detect CIN II lesions by various modes of screening. The validity test statistics were computed after verification bias adjustments are given in Table 3. The sensitivity of cytology was though low (50%) followed by VIA with 59.1% and VILI with 72.7%. The PPVs were 3.6, 3.3 and 13.7 for VIA, VILI and Pap, respectively. NPV was about 99% in all the tests. If the Pap option is ignored being not feasible, VIA is marginally better as compare to VILI.

The details of parameters for assessing the implementation of screening program are given in Table 4. There were 168 screen-positive women who did not under go colposcopic evaluation. It was due to refusal or migrated from the area. Items 4 and 9 to 15 in Table 4 are assessed through an independently conducted random sample survey ($n = 474$) from the same area in the post-screening phase.

DISCUSSION

This demonstration study was to assess the implementation of screen services delivery where aided visual (VIA and VILI) and conventional Pap tests were used in a rural community North India. This study is first of its kind to demonstrate the implementation of screening methods in a rural setup in North India. The implementation is basically for visual tests (VIA and VILI) as this was research setting of demonstration the conventional Pap testing was considered as a third screening test. Sensitivity of VIA in the present study was 59.0% and 72.7% for VILI [Table 3]. On the other hand VILI was less specific N (Specificity of VIA 92.3% and VILI 89.6%) as compare to VIA. Considering PPVs, the overall performance was best

Table 1: Socio-demographic and clinical information of screened women

Age (in years)+	Screned women No (coverage %)	VIA positive No. (%)	VILI positive No. (%)	Pap positive No. (%)
Age (in years)+				
30-34	2103 (77.5)	240 (11.4)	334 (15.9)	49 (2.3)
35-39	1031 (59.7)	100 (9.7)	146 (14.2)	32 (3.1)
40-44	617 (57.1)	56 (9.1)	68 (11.0)	19 (3.1)
45-49	539 (61.5)	44 (8.2)	63 (11.7)	15 (2.8)
50-54	384 (66.6)	25 (6.5)	35 (9.1)	6 (1.6)
>55	314 (49.8)	10 (3.2)	13 (4.1)	3 (1.0)
Total	4988 (65.6)	475 (9.7)	659 (13.5)	124 (2.6)
		P<0.001	*P*<0.001	NS
Education status		NS	*P*<0.01	NS
Illiterate	3078	280 (9.1)	378 (12.2)	75 (2.4)
Literate	1813	195 (10.7)	281 (15.4)	49 (2.7)
Marital status		NS	NS	NS
Married	4763	468 (9.5)	648 (13.6)	122 (2.5)
Widowed/ separate/ divorced	128	7 (5.4)	11 (8.5)	2 (1.5)
Occupation		NS	*P*<0.001	NS
House wife	4672	457 (9.7)	629 (13.4)	120 (2.5)
Others	123	18 (14.6)	30 (24.3)	4 (3.2)
Religion		*P*<0.05	NS	NS
Hindu	4447	447 (10.1)	611 (13.7)	117 (2.6)
Other	444	28 (6.3)	48 (10.8)	7 (1.5)
Parity		NS	*P*<0.001	NS
<=2	1163	123 (10.6)	57 (4.9)	33 (2.8)
3+	3728	352 (9.4)	502 (13.4)	91 (2.4)
Menstrual history		*P*<0.001	*P*<0.001	NS
Regular	3408	367 (10.8)	508 (14.9)	87 (2.5)
Irregular	460	45 (9.8)	72 (15.6)	17 (3.69)
Menopause	1023	63 (6.1)	79 (7.7)	20 (1.9)
Clinical symptoms		*P*<0.001	*P*<0.001	NS
Present	4060	421 (10.4)	584 (14.4)	106 (2.6)
Absent	831	54 (6.5)	75 (9.0)	16 (1.9)
Clinical sign+		*P*<0.001	*P*<0.001	NS
Normal cervix	2362	90 (3.8)	139 (5.9)	54 (2.3)
Low-risks signs*	2475	368 (14.9)	501 (20.2)	70 (2.8)
High-risks signs**	54	17 (31.4)	19 (35.2)	0 (0.0)

NS: Indicate not significant at 5% level of significance+significance evaluated by trend Chi-square, *Low-risk signs: Cervicitis, cervical erosion, cervical polyp and prolapsed uterus, **High-risk signs: Erosions that bleed on touch, small growths and suspicious-looking cervix. VIA: Visual inspection of cervix using acetic acid, VILI: Visual inspection of cervix usiing lugol's iodine

Table 2: Outcome of cervical screening by aided visual tests (VIA/VILI) and Pap tests

Screening outcome	VIA	VILI	Pap
Eligible women screened	4891	4890	4795
Screen positive	475 (9.7)	659 (13.5)	124 (2.6)
Colpodone	381 (77.9	518 (78.6)	93 (75.0)
Biopsy done	138 (29.0)	184 (27.9)	55 (44.3)
Detected CINI	21	35	13
Detected CINII+	6	7	7
Screen Negative	4416 (90.3)	4231 (86.5)	4671 (97.4)
Screen positive by other tests	288 {6.5}	104 {2.4}	613 {13.1}
Colpodone	214 (74.3)	77 (74.0)	483 (78.8)
Biopsy Done	88 (30.5)	42 (40.4)	167 (27.2)
Detected CINI	22	8	30
Detected CINII+	5	4	3#

*Total eligible screened were 4988 out of total 7604 women invited. #One case was less due to inadequate Pap smear. (·) Indicate percent out of eligible women screened. [·] Indicate percent out of screen positive/scren positive by other tests. {·} Indicate percent out of screen negative

Table 3: Clincial performance of VIA, VILI, and Pap screening for detecting CIN-II+

Test characteristic (95% CI)	VIA	VILI	Pap
Sensitivity	59.1 (38.5,79.6)	72.7 (50.1,91.3)	50.0 (29.1,70.9)
Specificity	92.3 (91.5,93.1)	89.6 (88.6,90.4)	98.5 (98.1,98.8)
PPV	3.6 (1.7,5.6)	3.3 (1.7,4.9)	13.7 (6.2,21.3)
NPV	99.8 (99.6,99.9)	99.8 (99.7,99.9)	99.7 (99.6,99.9)

VIA: Visual inspection of cervix using acetic acid, VILI: Visual inspection of cervix usiing lugol's iodine, CIN: Cervical intraepithelial neoplasia, PPV: Positive predictive value, NPV: Negative predictive value, CI: Confidence Interval

for Pap followed by VIA and VILI. VIA is advised when Pap test option is ignored as not being feasible. The present study has successfully demonstrated the implementation of cervical screening in a rural community by VIA that is a feasible option for the low resource countries. VIA showed a marginally better overall performance as compared to VILI. A combined VIA and VILI performance may not achieve any additional benefit as compared single test in isolation. However, a pilot based implementation of combined VIA and VILI was recently initiated in Tamil Nadu state of India to assess the appropriateness.[16]

It has been identified that screening coverage component is a crucial component for gaining effective prevention of the disease.[20] Population based surveys indicated on average a low (19%) coverage of cervical cancer screening in developing countries as compare to developed countries (68%). Coverage of cervical cancer screening in developing countries ranges from 1% in Bangladesh to 73% in Brazil. They found effective screening rate in China was also very low 23%.[21] Present study demonstrated a good coverage and showed feasibility of involving health care infrastructure in the cancer prevention. Priority should be given to maximizing coverage within the at-risk target age group and assuring complete follow-up of those women

Table 4: Parameters for accessing the implementation of screening

Parameter	Result (%)
Percentage women turned up for initial screening	65.6
Extent of agreement between ANM and doctor for VIA/VILI	VIA: 77.3 VILI: 100
Screened positive rate by visual/cytology	
VIA	9.7
VILI	13.5
Cytology	2.6
No. did not turn up for initial screening	
Reasons	34.4
Fear	17.6
Feel healthy	29.9
Family not permitted	13.6
No time	7.7
Pregnancy	3.6
Others	8.1
Percent of screen-positive women turn up for colpo	78
No. of women did not turn up for colposcopy clinic	
Reasons	22.0
Refusal without giving reason	48.8
Migrated/Not traceable	41.7
Pregnant	3.6
Treatment outside project	5.9
Percent of women Biopsy done (out of total screen positive)	38
Treatment acceptance (CINI+54)	76
CIN I	32/43
CIN II/CIN III	6/8
Adeno/Squamous carcinoma	3/3
Information on screen facility reached in the community	
Yes	86.5
No	14.1
Informant about screen facility	
ASHA (Health system worker)	46.4
Project ANM	30.6
Information brochure/leaflet received	
Yes	77.2
No	22.7
Place of screening center	
Near village	86.9
Distant place	13.1
Neighbor woman got screened	
Yes	41.8
No	3.2
Unknown	55.1
Advise received to get screened	
Yes	48.5
No	51.5
Should healthy normal women be screened	
Yes	95.6
No	4.4

VIA: Visual inspection of cervix using acetic acid, VILI: Visual inspection of cervix usiing lugol's iodine, CIN: Cervical intraepithelial neoplasia

with abnormal screening test results rather than maximizing the number of tests performed in a woman's lifetime.[22] Coverage in the present study for at risk target age groups (33-55 years) ranged from 57.1 to 77.5% [Table 1]. A better follow-up observed for women with screen positives (78%) and of women with confirmed positives (76%) in the present setting [Table 4]. Different studies were reported with different coverage rates in India. A coverage of 41.6% was observed in a cross sectional study at Andhra Pradesh.[19] Tamil Nadu study and Rural Osmanabad study showed a good coverage of 63.6% and 72-74%, respectively.[11,12] In a

study at rural north India, only 2331/5603 (41.6%) enrolled for screening by one-to-one contact approach.[9] In a study on effectiveness, safety and acceptability of VIA screening along with see and treat with cryotherapy, of the 2513 women offered the procedure, 1879 (74.8%) accepted.[23] Our study [Table 1] demonstrated 65.6% coverage of eligible women of the target rural population. This good coverage was due to innovative tools of health education, motivation methods of training to staff and involvement of ASHAs to spread the message at the grass root level.

The test characteristics of various screening modes are well documented. In a study of concurrent evaluation of visual and cytology screening in rural India, sensitivity of VIA, VILI and Cytology to detect high grade CIN were 64.5%, 64.5% and 67.7%, respectively, specificity were 84.2, 85.5 and 95.4, respectively.[24] Present study showed 59% sensitivity for VIA, lower than VILI but more specific. This lower pickup might be due to lower case detection rate as such in our rural community. A cluster randomized trial demonstrated VIA to be an effective method to prevent cervical cancer in developing countries with sustainable quality assurance.[12] A study on providing updated estimation of accuracy of VIA based on meta-analysis reported a 80% sensitivity (range 79-82%) and a 92% specificity (range 91-92%) and positive predictive value of 10% (range 9-10%).[25]

In the present study with the use of innovative, simple and easy to understand health education material, utilization of ASHAs for inviting women for screening has yielded excellent results by covering about 66.0% of the eligible women from the rural community. Acceptance of referral by women was indicated with very good response of 78.0% of screen positives responding to colposcopy clinic for confirmatory diagnosis, and 76.0% of treatment acceptance for various precancerous and cancerous lesions. Post-screening surveys conducted at the end of the present study revealed successful implementation through spread of the screening information (77%) by ASHAs and ANMs, 77.2% women received information brochure and 95.6% women understanding the essential message of screening such as all normal and healthy women should undergo screening [Table 4]. A cluster randomized controlled trial demonstrated importance of visual method (VIA). In the VIA arm high screening participation rates, good compliance for clinical management and significant down staging was achieved.[14] A recent report indicated that the realistic sensitivity of a quality assured single visual inspection with acetic acid is around 50% and is associated with a 25-35% reduction in cervical cancer incidence and the frequency of cervical intra-epithelial neoplasia grade 2 or worse lesions in randomized controlled trials.[26] In the absence of HPV screening due to cost consideration and cytology being not practical to implement universal screening, VIA screening implementation to reduce the burden of the disease is the currently available alternative in low resource settings. For a successful implementation of cervical cancer screening some of the essentials are: (1) A prior evaluation of community perspectives of screening in the community, (2) Develop or use existing appropriate education messages for motivation and re-motivation of women of age 30-59 years for screening and follow up. (3) Adopt ways of communicating messages-Meeting stake holders and elders of the community, Group talks, announcements, and personal communication at the door step. (4) Use the extent possible help from Health care Infrastructure-ASHAs, ANMs and Lady medical officer (Gynecologist). (5) Provide training on motivation of women for three levels–initial and two times follow-up. (6) Provide training on VIA/VILI screening, referral, and adherence to quality control. (7) Advocate three visit approach for women to health care center-Screening visit, screen positive confirmation with colposcopy directed biopsy and treatment visit at referral hospital. (8) Adopt strict concurrent monitoring mechanism and (9) Concurrent evaluation of screening implementation.

Implementation of screening by aided visual tests was successfully demonstrated through utilization of ASHAs for motivation, achievement of good coverage and strict monitoring for good response for clinical management of screen positives.

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