

Screening for pre-malignant lesions of the cervix among rural women in Southern India

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ABSTRACT

Background: Cervical cancer, despite being a preventable disease claims the lives of significant number of women every year. Cervical cytology which is a standard screening tool in developed countries fails as a screening method in low-resource countries due to financial and technical constraints.

Objective: To determine the prevalence of pre-malignant lesions of the cervix by visual inspection with Lugol's iodine (VILI) and cervical cytology method (Pap smear) among rural married women.

Materials and Methods: A community based cross-sectional study was carried out among 30-65 years old married women in the field practice area of a tertiary health care center. A pre-designed questionnaire was administered to collect information on socio-demographic and reproductive characteristics from 316 women. They were tested for the presence of pre-malignant lesions of the cervix using Pap smear and VILI as screening tools.

Results: The VILI test was positive among 24 (7.6%) women and positivity was found to be more in the age group of 50 years and above, and among women from low socio-economic status. But the observed variations were statistically insignificant. None of the Pap smears showed any epithelial cellular abnormalities.

Conclusion: The prevalence of pre-malignant lesions of the cervix by VILI was 7.6 % while no pre-malignant lesion was detected by Pap smear method.

Keywords: cervical cancer, pre-malignant lesion, Pap smear, VILI, screening

INTRODUCTION

Cervical cancer is the third commonest cancer worldwide. India accounts for the quarter of the world's burden (126,000 cases out of 450,000 new cases each year) with up to 80% of the women presenting with an advanced disease. The age-standardized incidence rate ranges from 16 - 55/100,000 women in different regions of India with particularly high rates in rural areas.¹ Cervical cancer is a preventable disease as it can be diagnosed in its precancerous stage. Screening by cervical cytology is the most common method used for detection of the disease in an early stage. Developed countries with centralized cytology screening programs have shown a dramatic decrease in the invasive cervical cancer incidence and mortality.² The cytology screening program has failed in developing world due to financial constraints, lack of expertise and lack of

prioritization.³ These limitations have prompted the evaluation of simple and inexpensive methods such as Visual Inspection of the cervix after the application of 3-5% Acetic Acid (VIA) and after the application of Lugol's Iodine (VILI) to downstage the cervical cancer at an early stage when it can be still treated.⁴

These techniques are less expensive, simpler to perform, do not need any equipment and can be mastered in a short period by the health workers. They can provide the results immediately which make them suitable for the wide screening in regions with a high incidence of cervical cancer.⁵

Various published studies with VILI and VIA report that they are equally or more sensitive compared to cytology even though the specificity is low and they do seem to have an advantage over conventional screening techniques in developing countries with limited resources.^{4,6,7,8,9}

Limited studies have been conducted in this coastal area of Karnataka, India to detect pre-malignant lesions of the cervix using VIA or VILI. The present study was undertaken to determine the prevalence of pre-malignant lesions of the cervix by VILI and by conventional cytology method.

MATERIALS AND METHODS

A community based cross-sectional study was carried out in the field practice area of a tertiary care teaching hospital in southern Karnataka, which is spread over 11 villages covering a population of about 50,000 people. The study protocol was approved by the Institutional Ethics Committee.

Married women aged 30-65 years who were not pregnant or lactating and were not using any intra vaginal medications, with an intact uterus and without history of cervical neoplasia were included in the study. As the studies have shown that incidence of cervical dysplasia peaks high at 20-29 years of age, but the risk of progression to invasive cancer at these ages is very low¹⁰ and as WHO has recommended to screen every woman in the age-group of 35-55 years every ten or fifteen years¹¹; screening was concentrated on married women aged 30 years and above.

A sample size of 316 was selected for an estimated prevalence of pre-malignant lesions of cervix of 16.4% in Kerala⁴ and a precision of 25%. Sampling was done in two stages. In the first stage one village was selected from the field practice area based on convenient sampling. In the second stage stratified random sampling was done based on the age groups and the required number of women to be screened in each stratum was estimated by proportional allocation method. The selected village had 1932 married women in the age group of 30 -65 years. Their names were arranged in the ascending order according to the numbers given to their family folders which is maintained at the rural health centers of the field practice area. By using random number tables the required sample size, i.e., 316 women were identified for the study.

These selected subjects were contacted at their houses and the objectives of the study were explained to them. After obtaining a written informed consent the women were interviewed with respect to their socio-demographic and reproductive characteristics, using a pre-designed, structured questionnaire. Socio-economic status was assessed by using Modified Udai Pareek's Scale.¹²

The women were also informed about the causes of cervical cancer, signs and symptoms, prevention, early detection and treatment. They were given a card indicating the date, time and place of screening. The tests were performed by the investigator who was trained in performing and interpreting VILI test and in collecting cervical smears under the guidance of a gynecologist for a period of one month.

Women were screened in rural health centers, panchayat halls, schools and anganwadis based on their convenience. The screening process, investigations, and treatments were explained to the study participants.

Eligible individuals not available during the first house visit were contacted on another pre-informed date as per their convenience. Even after two such visits if the women were not available/non-compliant, then they were considered as non-respondents. The eligible women were selected till the sample size was reached.

The VILI test was performed by a single trained investigator on all 316 women to minimize the inter reader bias. All the Pap smears were examined in a single pathology laboratory.

Screening methods

Using an un-lubricated bivalve Cusco's speculum the cervix was exposed, excess mucus was cleaned when present and the cervix was visually inspected. A Pap smear was collected from the squamo-columnar junction (SCJ) of the cervix with Ayer's spatula. Following this, Lugol's iodine was applied on the cervix by using a 5 ml syringe. The results of VILI were recorded after one minute. A lack of iodine uptake on any area of cervix was

termed as VILI positive (malignant and pre-malignant cells have less glycogen and as a result do not take up iodine), if the whole of the cervix took up the iodine, it was termed as VILI negative as per the International Agency for Research on Cancer (IARC) criteria.¹³ Cervical smears were evaluated at the tertiary care hospital and reported according to the Bethesda 2001 system. The results of the study have been presented in percentages and Chi-square test has been used for data analysis.

Table.1 Socio-demographic characteristics of the study participants (n = 316)

Characteristics		No. (%)
Age-group (yrs)	30-39	140 (44.3)
	40-49	90 (28.4)
	50-59	66 (21.0)
	60-65	20 (6.3)
Education	Illiterates	33 (10.2)
	Literates	283 (89.8)
Marital Status	Married	262 (83.0)
	Widowed	49 (15.5)
	Separated	5 (1.5)
Socio-Economic Status	Low	169 (53.5)
	Middle	146 (46.2)
	High	1 (0.3)

RESULTS

Three hundred and sixteen women were subjected to cervical cancer screening methods—Pap smear test and VILI. The baseline characteristics of the study population are depicted in Table-1.

The majority of the women (72.7%) were in the age group of 30-49 years. The mean age was 42.8 years. Ninety percent of the women were literate. More than half of the women (53.5%) were from low socio-economic background.

Among 316 women, VILI finding was positive for 24 women (7.6%) but no pre-malignant lesions were detected by Pap smear method. It is evident from Table-2 that the VILI positivity increased with an increase in age of the study population and it was found maximum in the age group of 50 years and above. VILI positivity rate was higher among women from low socio-economic status (8.3%) as compared to those from middle and high socio-

economic status (6.8%), but the observed variation in this study was not statistically significant ($p = 0.82$). The gynecological complaints reported by the study subjects were backache (38.9%), discharge per vaginum (24.5%), irregular menstrual cycles (2.3%), h/o genital lesions (2%) and post coital bleeding (1%). Table -3 depicts that among 24 VILI positive women, 14 had normal cytology smears, 7 had inflammatory smears followed by one each with a report of atrophic smear, candidiasis and an unsatisfactory smear.

Table-2: Distribution of VILI results based on age group of study population (n = 316)

Age group (in years)	No. of women	VILI Positive No. (%)
30-39	140	7 (5.0)
40-49	90	8 (8.9)
50-59	66	7 (10.6)
60-65	20	2 (10.0)
Total	316	24 (7.6%)

(Chi-square for trend = 2.44; $p = 0.12$)

Table-3: Correlation of cervical cytology reports based on VILI findings of study population (n = 316)

Cervical Cytology report	VILI positive No. (%)	VILI Negative No. (%)
Normal	14 (58.3)	152 (52.1)
Inflammatory smear	7 (29.1)	95 (32.5)
Atrophic smear	1 (4.1)	11 (3.7)
Candidiasis	1 (4.1)	12 (4.1)
Unsatisfactory smear	1 (4.1)	22 (7.5)
Total	24	292

DISCUSSION

In our study prevalence of pre-malignant lesions of the cervix was 7.6% by VILI and no pre-malignant lesion was detected by Pap smear method. However, in various other studies the prevalence by VILI and Pap smear ranged from 8.7 to 58.65% and 3.3 to 14.5% respectively.^{3,14,15,17}

A study conducted by Sankarnarayanan et al., in Kerala reported that sensitivity of VILI was 87.2% whereas specificity was 84.7%.¹⁶ A meta-analysis in which the Pap test accuracy was compared with the histology reports showed that the sensitivity of Pap test could vary from 11 to 99% and the specificity from 14 to 97%; this analysis recommended that an optimum method of screening for cervical cancer has to be developed.¹⁸

In our study none of the Pap smears showed any cytological abnormality. This could be due to the fact that the test was done among women in the community, not on symptomatic patients and the study was done on a small sample. The Pap test is less accurate among post-menopausal women due to the anatomical and hormonal changes in them¹⁹ and also due to the wide variation in the sensitivity of the test.¹⁸

In the present communication it was found that VILI positivity increased as the age of the study population increased and the maximum VILI positivity was observed among women in the age group of 50- 65 years. This trend could be attributed to the fact that after menopause, the production of glycogen reduces and the color pattern resulting from iodine application during this period could be misleading.²⁰ Similar finding was reported in an IARC multi-centric study conducted by Sankarnarayanan et al., in India and Africa.⁴ It was also observed in a Chinese study that the average age of Cervical Intraepithelial Neoplasia (CIN)1, CIN2, CIN3 and cervical cancer were 38.65, 40.61, 44.10 and 46.73 years respectively.²¹

In a knowledge and attitudinal study conducted by Machoki and Rogo in a hospital in Kenya, out of 85 women who had histologically confirmed invasive cervical carcinoma, 78.8% had abnormal vaginal bleeding and 34.1% had post-coital bleeding.²²

In another Hospital based study in Nepal, out of 300 women seeking consultation in the gynecological OPD 81% of the women had come with complaints of lower abdominal pain, 62%

with vaginal discharge, 47% with backache, 26.7% with irregular bleeding, 11% with dyspareunia and 4.3% with post coital bleeding.¹⁷ One of the study carried out in India reports that among the 214 symptomatic patients attending cancer awareness camps, discharge per vagina (28.5%) and pain in lower abdomen(20.1%) were the common complaints followed by backache, irregular menstruation, dysuria, dyspareunia and post-menopausal bleeding.²³

However, the present study was carried out in a rural community and the most common complaints were severe backache and vaginal discharge followed by irregular bleeding, genital lesions and post coital bleeding.

Our cytology reports do agree with the findings of other studies^{3,21,24,25} with respect to the number of normal smears, inflammatory smears, atrophic smears and unsatisfactory smears but we did not find any smear with epithelial cellular abnormalities.

This was a community based cross-sectional study conducted among rural married women who were never screened before for premalignant lesions of cervix. Under the prevailing situation and within 6 months of time it was the maximum number that could be studied.

Very few community based studies on cervical cancer screening methods have been done in this part of India. This was the first time such a study was carried out in this area and we also do not have any previous reported data on the prevalence of pre-malignant lesions of the cervix from this region. Considering the socio-demographic characteristics of the participants and a setting with limited resources available, only the screening tests could be performed on these women and it is difficult to carry out confirmatory tests in the field setting. Keeping these factors in mind, VILI and Pap smear tests were considered as reliable tests to detect pre-malignant lesions of the cervix in the field. The VILI positive women were advised to visit the tertiary health care center for further evaluation, but they could not be followed up due to time and resource constraints.

CONCLUSION

In our study, the prevalence of pre-malignant lesions of the cervix among rural married women was 7.6% by VILI test and no pre-malignant lesions were detected by Pap smear method. As there is no baseline data on prevalence of pre-malignant lesions of the cervix among women from this area, further research studies are needed in this direction.

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