



PAP SMEAR V/S VILI TEST IN SCREENING OF CERVICAL CANCER

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ABSTRACT

Background-Cervical cancer, despite being a preventable disease endangers the lives of significant number of women every year and also its incidence is growing with time. Cervical cytology which is a well accepted standard screening tool in developed countries but in developing countries like India it fails not only due to the lack of awareness but also due to financial and technical constraints visual inspection with Lugol's iodine (VILI) have been evaluated in a number of large clinical trials and is considered to be a possible alternative to cervical cytology for primary cervical cancer screening in low resource settings. **Aims and objectives:**To compare the results of VILI with that of Pap smear and further confirmation with colposcopic guided biopsy in the abnormal Pap smear and VILI test results. **Methods:**This clinical study was conducted in department of OBG Navodaya Medical College on 100 gynecological patients. After taking informed and written consent each woman who fulfilled the inclusion criteria were subjected to Pap smear examination and VILI. A biopsy was taken in patients with abnormal findings or suspicious findings on VILI. **Results:**In the present study sensitivity of PAP smear and VILI was 80% and 88% respectively and specificity was 55% and 80% respectively with biopsy as a reference standard **Conclusion:**The advantages of VILI are its low cost, easy to do and can be done by paramedical workers an immediate results are obtained which can be treated at the same visit. Sensitivity and specificity of VILI were higher than Pap, which were statistically significant. Thus, VILI is reliable as a screening test for detecting preinvasive lesion for cervix.

KEYWORDS : cervical cancer, Pap smear ,visual inspection with lugols's iodine, Pre-invasive lesions

INTRODUCTION

Cervical cancer is a public health problem in developing countries like India, so much so that India alone accounts for one-quarter of the worldwide burden of cervical cancers¹. It is estimated that cervical cancer will occur in approximately 1 in 53 Indian women during their lifetime compared with 1 in 100 women in more developed regions of the world²

It is the one of the leading cause of cancer mortality, accounting for 17% of all cancer deaths among women aged between 30 and 69 years. Every year, 122,844 women in India are diagnosed with cervical cancer, and 67,477 women die from the disease³.

80% of cervical cancers in developing countries, are untreatable at the time of discovery due to their advanced stage⁴.

- Since over 70% of the Indian population resides in the rural areas, cancer cervix still continues to be the number one cancer, which can be identified and treated in a timely manner⁵. Carcinoma cervix is one cancer which has a treatable, curable precursor lesion which is easily detectable by routine screening and can be treated effectively by simple methods⁷. One such screening method is Pap smear, which is well-known to be effective in reducing the population-wide incidence of invasive cervical carcinoma⁸. However, in low-resource settings, screening of carcinoma cervix by Pap smear can be replaced by cheaper and easily available visual methods such as VILI and VIA (visual inspection of acetic acid) which has high sensitivity to detect any grade of dysplasia⁹.
- One simple low technique screening test namely visual inspection with lugol's iodine (VILI) which is based on the ability of the trained health care personnel to detect yellow non iodine uptake areas in the cervical transformation zone are currently being evaluated in the experimental setting as potential alternative to cervical cytology, allowing the use of "screen and treat" protocol¹⁰.

AIM OF THE STUDY

- To find out whether Pap smear and VILI is a simple, cost effective easy and reliable procedure to screen women for precancerous lesion and early cancer of cervix.
- To compare the results of VILI with that of Pap smear and further confirmation with colposcopic guided biopsy in the abnormal Pap smear and VILI test result.

METHODOLOGY

SOURCE OF DATA: After obtaining ethical committee clearance, All gynaecological patients attending to OPD of Navodaya medical college after the age of 21 yrs who gave consent. From October 2020 to April 2021. the data processed by SSSP with version 16.0.

Institutional Ethical committee clearance has been obtained. Methods of collection of data:

Study site: Navodaya Medical College, Hospital and Research Centre, Raichur
Study design: prospective study
Sample size: 100

(d) Inclusion criteria:

All newly registered women attending gynaecology opd who gave consent.

- Apparently healthy.
- All women after the age 21 or earlier if she is sexually active.
- With intact cervix.
- With no history of cervical neoplasia.

(e) Exclusion criteria:

- Active bleeding pv
- Profuse cervical and vaginal discharge
 - Obvious cervical growth
 - History of hysterectomy
 - Surgical treatment of the cervix
 - Iodine allergy
 - Pregnant patient

Pre-requisites for Pap smear

- 1.it should be done in postmenopausal phase or anytime away from menstruation.
- 2.abstinence for 48 hours.
- 3.no douching,no vaginal tampon use,no intravaginal cream or contraceptive creams for 24-48 hours.
- 4.any associated cervicitis or vaginitis should first be treated before pap smear.

- The patient was explained about the procedure and its screening value.
- Consent was taken for the procedure
- The patient was put in the lithotomy position
- Unlubricated sim's speculum was inserted into the vagina and cervix is examined.
- Two smears were taken from each patient from the ectocervix and endocervix using Ayers spatula and cytobrush
- Smears were fixed with cytofix spray fixture.
- The patient was subjected to VILI test .
- Lugol's iodine was applied to the cervix and within 30 s direct visualization of the cervix was done
- If any abnormality detected in visual inspection of the cervix with Lugol's iodine, punch biopsy was taken from that area
- Biopsy specimen were fixed in formaldehyde and was sent for histopathological examination



Picture depicting Iodine positivity

RESULTS

- In our study, 13% of the cases were in the age group of 18-29 years, 32% in the age group of 30-39 years, 34% in the age group of 40-49 years and 22% in the age group of 50-59 years. (TABLE-1)

TABLE-1-Age distribution in our study

Age	CIN	No	total	Chi-square value	p-value
18-29	13%	13%	13	1.484	0.002
30-39	13%	32%	30		
40-49	50%	34%	35		
50-59	25%	22%	22		

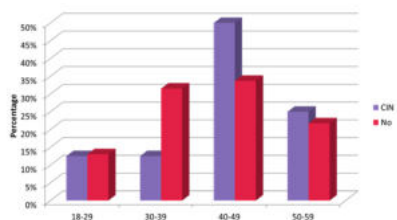


TABLE 1.1-Age distribution in our study

- In our study 56 cases were illiterate and 44 were literate.
- Incidence of CIN is 5(63%) in illiterate and 3(45%) in literate.

- In our study 55 cases belong to low socioeconomic class,35 belong to middle class and 10 belongs to higher class based on modified kuppuswamy classification.(TABLE-2)
- Incidence of CIN is found to be higher in (63%) low class

TABLE-2-Distribution of cases as per socioeconomic status

	CIN	No	total	Chi-square value	p-value
low	63%	54%	55	0.02	0.004
Middle	38%	35%	35		
High	0%	11%	10		

In our study 70 cases were married at age of 18 yrs or less and 30 cases were married at more than 18 yrs age.

- Incidence of CIN was more 6 (75%) in cases of married at 18 yrs or less.
- In the present study, shows that total 8 cases were detected positive on Pap smear examination. Out of those 8 cases, 4 cases were low-grade squamous intraepithelial lesion and 3 cases were reported as high-grade squamous intraepithelial lesion and 1 case was ASC-US Another 32 cases were reported as inflammatory smear.(TABLE 3)

TABLE-3-Pap smear findings in our study

PAP smear	No. of cases
No	60
Inflammantory	32
LSIL	4
HISL	3
ASC-US	1

From out of the total of 100 patients, VILI was positive in 14 cases. This constitutes 14% of the total study group. Nearly 86% of the study groups were reported normal on VILI (figure-1)

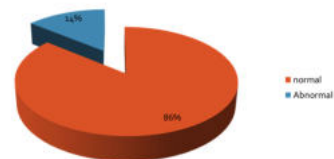


Figure-1 Showing results of VILI test.

Number of VILI positive cases are 14. Out of those 14 VILI positive cases,8 cases were showing abnormality even on biopsy. These 8 cases comprise of 53% of the total VILI positive cases.

From this table(TABLE-4) total of cases screened were 100. Out f 100 cases, 14 cases showed VILI positive. Out of these 14 VILI positive cases, 8 cases were positive even on biopsy. 6 cases did not show any premalignant lesions.

TABLE-4-Cases showing biopsy result.

Biopsy	VILI
Positive	8
Negative	6

For comparing the efficacy, from VILI negative cases group 25 patients were randomly selected. Out of these 39 cases, biopsy was positive in 9 cases. From the randomly selected 25 cases of VILI negative group, 1 cases was positive on cervical biopsy.(TABLE-5)

TABLE-5

VILI	Biopsy		Total
	Positive	Negative	
Positive	8	6	14
Negative	1	24	25
Total	9	30	39

From table, we can see that among 14 VILI positive case, 8 patients had positive cytology report. Among them, 4 patients were reported positive for biopsy. One case which was missed by Pap smear, was detected biopsy positive(TABLE-6)

TABLE-6

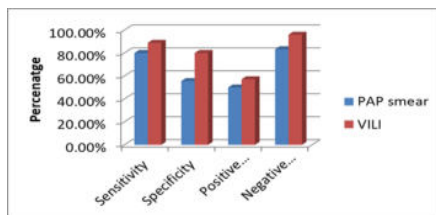
PAP smear	Biopsy		Total
	Positive	Negative	
Positive	4	4	8
Negative	1	5	6
Total	5	9	14

This table highlights and compares the statistical outcomes of the two tests Pap's and VILI.(TABLE 7 and 7.1)

TABLE-7

Statistic	PAP smear	VILI
	PAP smear	VILI
Sensitivity	80.00%	88.89%
Specificity	55.56%	80.00%
Positive Predictive Value	50.00%	57.14%
Negative Predictive Value	83.33%	96.00%

TABLE-7.1



DISCUSSION

Cervical cancer, despite being a preventable disease endangers the lives of significant number of women every year and also its incidence is growing with time. It is preceded by premalignant lesions which may take 5–15 years to progress to invasive cancer. If detected and treated timely, pre-invasive disease has nearly 100% cure rate with the simple surgical procedure while advanced cancers have <35% survival rate.

In the present study, high incidence of CIN was found in the age group of 40-49 years (50%) which was comparable with similar study by Juneja A et al5 who reported CIN in >40 yrs of age. In the present study it was found that the incidence of CIN was higher in lower socio economic class 5(63%), This study is similar to Sherwanti et al6. the sensitivity of VILI is 88.89%,

specificity 80.00%, positive predictive value was 57.57%, and negative predictive value was 96.00% with biopsy as the reference standard.

The sensitivity and specificity of cytology in our study are 80% and 55.56%, respectively. The study is comparable to study done by Agrawal et al7. in which the sensitivity of VILI was 94.70%, and specificity was 48.30%, and the sensitivity of cytology was 84.20%, and specificity was 62% In a study by Yadav et al., VILI when compared with histopathological report (HPR) had sensitivity and specificity of 80% and 87% respectively.

In India, even with a major effort to expand cytology services, it will not be possible to screen even one-fourth of the population once in a lifetime as universal screening has not been achieved. Moreover, screening programs in India are mostly institution based and are restricted to urban centers. Thus, in developing countries, there is a need for alternative strategies for early detection of premalignant cervical lesions. In low-resource settings, cervical cancer screening by Pap smear can be replaced by visual methods like VILI, which has the highest sensitivity (100%) to detect any grade of dysplasia, and a good specificity (93.3%).

An attempt has been made in the present study to increase awareness of women about cervical cancer and preventive health-seeking behavior, screen all women of the reproductive age group at least once a year and motivate them for annual screening until three negative Pap smears. Also effort has to be made to target the disease before its onset at the level of primary prevention by providing education and counseling and secondary prevention by effective screening and treatment.

A very recent study by Kaur et al8. concluded that in low resource settings, screening by Pap smear has not been successful in reducing incidence of cervical cancer. VIA and VILI are cheaper and easily available and can be used by medical and paramedical personnel on a large scale basis. Women continue to ignore symptoms of irregular bleeding, postmenopausal bleeding, and postcoital bleeding. Therefore, educating women about these signs and symptoms and to seek immediate medical care is effective.

CONCLUSION

Carcinoma cervix is more prevalent among women living in poor conditions with low income and limited education and awareness. In our study, comparing the results of VILI and Pap smear the sensitivity of VILI was comparable to Pap smear. Hence, VILI can be used as an alternative for the screening of carcinoma cervix even in periphery. The majority of women in India who belong to the low socioeconomic status of society remain devoid of any screening test as Pap smear has its own limitations like it is difficult to reach remote areas which comprise the majority of Indian population. Through screening tools such as VILI a large number of population that go undetected can be screened and reported at the same visit at an affordable cost with higher sensitivity and specificity.

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