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COMPARATIVE STUDY OF EFFECTIVENESS OF PAP SMEAR VERSUS VISUAL INSPECTION WITH ACETIC ACID AND VISUAL INSPECTION WITH LUGOLS IODINE FOR MASS SCREENING OF PREMALIGNANT AND MALIGNANT LESION OF CERVIX WITH COLPOSCOPY AS GOLD STANDARD

Obstetrics & Gynaecology

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ABSTRACT

Objective: To compare the effectiveness and sensitivity, specificity, positive predictive value and negative predictive value of visual inspection with acetic acid, Lugols iodine, PAP smear and colposcopy for screening of cancer cervix. **Methods:** Comparative cross-sectional study was conducted on 209 women were attending the Obstetrics and Gynecology OPD in tertiary care hospital for 18 months. Every patient has undergone Papanicolaou smear (PAP), visual inspection with 5% acetic acid (VIA) and with 5% Lugol's iodine (VILI) as well as Colposcopy. Analysis of the sensitivity, specificity and predictive values of the results using colposcopic directed biopsy as reference was done. **Results:** Out of total 209 participants, PAP was positive in 48 [22.9%] cases with 25[11.96%] ASCUS, 14 [6%] LSIL, 8[3.83%] HSIL, 1[0.47%] squamous cell carcinoma. VIA was positive in 131 cases [62.6%] and VILI in 66 cases [31.5%], both VIA and VILI were positive in 57 cases [27.2%]. From the above results, for PAP smear sensitivity was 66.7%, specificity 80.5% , positive predictive value 61.5% and negative predictive value 83.8%. For VIA sensitivity was 100%, specificity 13% , PPV 34.9% and NPV 100 % and for VILI sensitivity was 77.8%, specificity 74%, PPV 48.3% and NPV 85.4%. When VIA and VILI both were used for screening sensitivity was 77.8%, specificity 74%, PPV 51.8% and NPV 96.6%. **Conclusions:** From the results of current study, it was concluded that effectiveness of PAP, VIA and VILI is equally effective for screening of premalignant and malignant lesions of cervix, VIA and VILI can be use for mass screening of pre malignant and malignant lesion of cervix where facilities for PAP smear are not available.

KEYWORDS

PAP, VIA, VILI

Cervical cancer is the fourth most common cancer in women worldwide[1]. It is also the fourth most common cause of cancer death (311 365 deaths in 2018) in women worldwide[1]. More than 85% of these deaths occurred in low- and middle-income countries[1]. About 1,23,907 new cervical cancer cases are diagnosed annually and 77348 die from the disease in India [estimations from 2020][1]. The WHO's Global Strategy for the Elimination of Cervical Cancer a Public Health Problem provides a roadmap, through the following 90-70-90 targets for 2030:[2]

1. 90% of girls fully vaccinated with the HPV vaccine by age 15
2. 70% of women are screened with a high-performance test by 35 and 45 years of age
3. 90% of women identified with cervical disease receive treatment (90% of women with pre-cancer treated; 90% of women with invasive cancer managed).

Cervical screening programs implementing the use of pap smear cytology have shown a reduction in the incidence of cervical carcinoma greatly. Visual inspection of acetic acid (VIA) is an attractive alternative to pap smear cytology for its ease to usage, lower cost than pap smear, and fewer physician visits required.[3]

METHOD AND MATERIALS

Women attending to Gynecology OPD with complaints of vaginal discharge, postmenopausal bleeding, intermenstrual bleeding, abdominal pain, itching in genital region detailed history of these patients was taken, the details of the study were explained to these women and those who were willing to participate were enrolled as a participant and informed consent was taken. All the socio demographic details noted in a predesigned proforma. All women underwent PAP smear, VIA and VII followed by colposcopy and guided biopsy if required. In current study out of all 209 participants, colposcopy guided biopsy where taken in 113 cases.

Criteria for Study enrollment Inclusion Criteria:

all women attending Gynecology OPD group who are nonpregnant women i.e., women in sexually active reproductive age group, perimenopausal and postmenopausal women.

Exclusion Criteria:

1. Pregnant women
2. Women with - severe ill health
3. Women with puerperal period
4. Previous treatment of cancerous lesion
5. Women with h/o surgery on the cervix.

OBSERVATIONS AND RESULTS

Socio demographic observations

Parameter	Majority of patients belongs to	Percentage
Age	31-40 years	35.4%
Socio economical class	Lower middle socio economic class	41.1%
Area	Rural	52.6%
Menstrual status	Menstrual age group	83.3%
Parity	Para 2	46.40%

In the current study, White discharge per vagina (52.6%) had been observed to be the most common complaint. Other complaints reported are postmenopausal bleeding 17[8.1%], intermenstrual bleeding 14[6.7%], postcoital bleeding 14[6.7%], menorrhagia 13[6.2%], vulval pruritus 5[2.4%] and infertility 4[1.9%].In the study group, maximum number of PAP smear reports i.e. 99 [47.36%] of PAP smear report were suggestive of inflammation, 62[29.66%] normal, 25[11.96%] ASCUS, 14 [6%] LSIL, 8[3.83%] HSIL, 1[0.47%] squamous cell. On Colposcopic examination according to Swedes score majority of patients were under CIN1 (76.55) i.e., score between 0 to 4, 34 [16.26%] under CIN2 i.e. score between 5-6 and 15 [7.1%] belongs to CIN 3 i.e. score > 7. According to Swedes score CIN 1 is considered negative and CIN 2 and CIN 3 are considered positive. In present study, out of 209 women 113 colposcopic guided biopsy taken, out of which 70 patients were having cervicitis [61.9%] ,7 [6.2%] cases no pathology, 18 [15.9%] cases CIN1 , 9 [7.9%] cases CIN2 and 9 [7.9%] cases CIN 3. In the present study, out of 209, 113 (62.67%) are VIA positive and 66 (31.57%) are VILI positive. 57 cases (27.27%) are both VIA and VILI positive. From the above results, for PAP smear sensitivity was 66.7%, specificity 80.5% , positive predictive value 61.5% and negative predictive value 83.8%. For VIA sensitivity was 100%, specificity 13% , PPV 34.9% and NPV 100 % and for VILI sensitivity was 77.8%, specificity 74%, PPV 48.3% and NPV 85.4%. When VIA and VILI both were used for screening sensitivity was 77.8%, specificity 74%, PPV 51.8% and NPV 96.6%.

DISCUSSION

In the current study, the age of patient ranged from 21 to 77 years with maximum i.e., 35.4% of women belong to 31-40 years of age group. These findings are similar to study done by John Egede et al[4] in which majority of women belongs to 31-40 [44%] years of age group. In the

current study, majority of women 97 (46.41%) were para 2 which is similar to the study done by Hend S Saleh et al[5] mean parity was 2.4 . Current study maximum number of PAP smear reports i.e. 99 [47.36%] were suggestive of inflammation, 62[29.66%] normal, 25[11.96%] ASCUS, 14 [6%] LSIL, 8[3.83%] HSIL, 1[0.47%] squamous cell carcinoma. These observations are comparable with the study done by Rashmi Jain et al[6], 41.42% (87/210) cases of cervical lesions were diagnosed as NILM, 11.42%(24/210) cases ASCUS, 32.85% (69/210) cases were LSIL, 12.85% (27/210) cases as HSIL, Only 1.42% (3/210) case of SCC. Out of total 46 positive cases on colposcopy 27 cases are biopsy proven, giving sensitivity and specificity of 75% and 75% respectively. In the study done by Kabin Bhattachan et al[7], finding of colposcopy was interpreted using Swede score, giving sensitivity of 100%, specificity of 85.5%. In our study, out of total 209 women colposcopy guided biopsy taken in 113 cases with 70 [61.9%] cases of cervicitis, 7 [6.2%] cases of no pathology, 18 [15.9%] cases of CIN1, 9 [7.9%] cases of CIN 2 and 9 [7.9%] cases of CIN 3 . These observations are similar to study done by Ashish Kumar Bhattacharya et al[8], out of total 62 cases biopsy taken, 19 cases [30.6%] are suggestive of CIN and carcinoma. Out of total 209 cases VIA test is positive in 131 [62.67%] and negative in 78 [37.32 %] women, VILI is positive in 66 [31.57%] and negative in 143 [68.42%] women. Both test are positive in 57 [27.27%] and negative in 152 [76%]. In the study done by Rashmi Jain et al[6], out of total 210 cases 150 cases [71%] are positive in VIA test ,60 cases [28%] are negative. In study done by Kamal Patil et al[9], On VIA, 96 (48%) women were found to have a positive result. The sensitivity, specificity, PPV and NPV calculated from above data in our study and other studies compared in following table -

Pap smear	Histopathological finding		Total	P value
	Positive	Negative		
Positive	24	15	39	X2 =24.166
Negative	12	62	74	<0.001
Total	36	77	113	
VIA				X2 =5.129
Positive	36	67	103	0.024
Negative	0	10	10	
Total	36	77	113	
VILI				X2 =14.795
Positive	28	30	58	<0.001
Negative	8	47	55	
Total	36	77	113	
VIA+VILI [any 1 positive]				X2 =3.489
Positive	36	70	106	0.062
Negative	0	7	7	
Total	36	77	113	
PAP+VIA+VILI [any 2 positive]				X2 =28.243
Positive	34	32	66	<0.001
Negative	2	45	47	
Total	36	77	113	
VIA+VILI [both positive]				X2 =21.859
Positive	28	26	54	<0.001
Negative	8	57	59	
Total	36	77	113	

Sensitivity, Specificity, PPV and NPV of screening tests in other studies

STUDY	Test	Sensitivity	Specificity	PPV	NPV
Present study	PAP	66.7	80.5	61.5	83.8
	VIA	100	13	34.9	100
	VILI	77.8	61	48.3	85.4
Hend S Saleh et al5	PAP	78	96	75	97
	VIA	91	85	40	98
	VILI	66	91	43	98
Shuchi Consul et al10	PAP	84	62	59	85
	VIA	84	55	53	84
	VILI	89	75	70	91
Satyanarayan L et al 11	PAP	63	98	12	99
	VIA	84	96	4.2	99
	VILI	63	95	3.8	99

Both visual techniques (VIA, VILI) have high negative predictive value (100, 85.4). This means, a woman negative by VIA/VILI does not need further investigation at present but, these women are advised to undergo a VIA or VILI after a minimum interval of 3 years.

CONCLUSIONS

According to current study, majority of patient with malignant and pre malignant lesions of cervix presented with vaginal discharge, but postmenopausal bleeding, intermenstrual bleeding, postcoital bleeding, abdominal pain, vulval pruritus can also be presenting complaints. Thus, these symptoms should not be ignored and should be thoroughly investigated. The primary prevention of cervical cancer by vaccination is low in low resource countries. Thus, secondary prevention by screening became important in low resource country. High incidence of cervical cancer in low resource countries is due to lack of effective implementation of screening programme which aims at detecting premalignant conditions before they progress into invasive cancer. Cytology based screening programmes are difficult to establish and maintain in low resource nations due to lack of resources, trained man power, lack of refresher training, infrastructure and requirement of follow up. As results of PAP, VIA and VILI for detection of premalignant and malignant lesions of cervix are comparable, VIA and VILI can be recommended for mass screening of pre malignant and malignant lesion of cervix were facilities for PAP smear are not available

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