Pap Smear and Colposcopic Examination of the Cervix in Pelvic Inflammatory Disease and other Gynaecological Conditions: A Prospective Analytical Study

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ABSTRACT

Introduction: Pap smear and colposcopy are commonly done procedures in gynaecology practice. The Pap test is a low-cost, straight forward, and widely used tool for detecting cervical cancer and preinvasive cervical abnormalities. Colposcopy is also widely used to detect Cervical Intraepithelial Neoplasia (CIN) to guide cervical biopsy sites with clinical symptoms of suspected cervical diseases.

Aim: To evaluate the diagnostic implications of Pap smear and colposcopy in inflammatory cellular changes and to estimate the incidence of Cervical Intraepithelial Neoplasia (CIN)/invasive carcinoma in the study population through biopsy.

Materials and Methods: This prospective analytical study was conducted at JNU Medical College, Jaipur, India, where Pelvic Inflammatory Disease (PID), and other gynaecology Out Patient Department (OPD) patients without any previous diagnosis of cervical malignancy, were included in the study. A total of 150 study patients, underwent Pap smear and colposcopic examination with biopsy as the gold standard. Descriptive analysis of data was done using means and standard deviation for continuous variables and nominal variables as frequencies. The Chi-square test was applied to categorical variables to find out the association and Receiver Operating Characteristic (ROC) analysis was done to predict the diagnostic ability of Pap smear, and colposcopy in cervical pathology.

Results: The mean age of the patient population was 36±3 years. The mean age at first coitus and marriage of all the women were 18.9±2.7 years and 19.5±3.4 years, respectively. Twenty (13.3%) and 5 (3.3%) cases were reported as CIN and carcinoma, respectively after colposcopic biopsy. Pap smear results showed a sensitivity of 87.7% and a specificity of 78.2%. The Positive Predictive Value (PPV) and Negative Predictive Value (NPV) were 72.8% and 68.7%, respectively. Sensitivity of the colposcopic report was 89.4% and the specificity was 98.8%. The PPV is 96.6% and NPV is 82.3% for colposcopic report.

Conclusion: This study suggested that PID and gynaecology OPD patients can be better targeted with a good opportunity for screening the potential premalignant changes in the cervix by using Pap smear and colposcopy.

INTRODUCTION

It is estimated that atleast 10-15% of women have atleast one episode of Pelvic Inflammatory Disease (PID) in their lifetime (1). Most of the patients in gynaecology Out Patient Department (OPD) who complain of white discharge per vagina and pain in the lower abdomen are usually diagnosed with vaginitis or PID [1].

Cervical cancer accounts for 26.1-43.8% of all cancers in Indian women [2]. The major aetiological agent of cervical cancer, the human papillomavirus (HPV), has a long latent precancerous phase. HPV spreads with agents, resulting in PID with symptoms and compelling the patient to seek medical attention. Early identification and treatment at its preinvasive stage may benefit the patients, by decreasing the burden of morbidity and mortality resulting from cervical cancer [3].

Though Pap smear is the preferred screening modality, there are few screening programmes available. Pap smears are typically taken in the outpatient sections of public and private hospitals when patients appear with gynaecological symptoms. As a result, Pap smear is an essential component of women's comprehensive healthcare in India and other countries [4]. Pap smears are done commonly in PID patients and most of them are reported as inflammatory [5]. In the Bethesda system, when the type of infection is not specified, it is classified under benign cellular changes [6]. After prescribing antibiotics if repeat pap smears persist as inflammatory smears, then colposcopy is recommended [7].

Colposcopy is widely used to detect Cervical Intraepithelial Neoplasia (CIN) to guide cervical biopsy sites with clinical symptoms of suspected cervical diseases [8]. So, this seems quite logical that routine use of PAP smears and colposcopy in PID may help to identify preinvasive and invasive cervical carcinoma.

Hence, the purpose of the study was to evaluate the diagnostic implications of Pap smear and colposcopy in inflammatory cellular changes and to estimate the incidence of CIN/invasive carcinoma in the study population through biopsy.

MATERIALS AND METHODS

A prospective analytical study was conducted in the Department of Obstetrics and Gynaecology at a tertiary care centre in Jaipur, Rajasthan, India for a period of 15 months from January 2021 to March 2022. Institute ethical committee approval was taken and all study participants had given informed consent. Patients reporting to Gynaecology OPD were enrolled using convenient sampling.

Inclusion and Exclusion criteria: Patients with PID, Abnormal Uterine Bleeding (AUB), postcoital bleeding and a lump in the abdomen (pelvic mass) were included. Women with diagnosed

pregnancies were excluded from the study. Also, Women who had previously been treated for cervical cancer or had undergone hysterectomy were not eligible.

A total of 200 women, in the age group of 25-75 years were included in the study, however, 150 patients were finally analysed as 50 patients could not complete the required work up.

Study Procedure

Patients with PID were advised to use Clotrimazole or Betadine vaginal pessaries and antibiotics for a minimum of seven days. After one week of the antibiotic course, a Pap smear was performed with Ayer's wooden spatula. Then patients were subjected to colposcopy examination and biopsy with any positive clinical findings, after taking informed consent.

A Pap smear report comprises five components for reporting according to the 2014 Bethesda System for reporting cervical cytology: specimen type, adequacy, general category, interpretation, and additional testing [6,9]. Atypical squamous cells of uncertain significance (ASC-US), Low-grade squamous intraepithelial lesion (LSIL), High-grade squamous intraepithelial lesion (HSIL), and Squamous cell cancer are all used to interpretate epithelial cell abnormalities.

The gold standard in the diagnosis of cervical dysplasia was colposcopic examination with biopsies for pathologic investigation. A comprehensive colposcopy examination should include documentation of the cervix, squamocolumnar junction, presence of acetowhitening, existence of a lesion(s), visibility of the lesion(s), size and location of the lesions, vascular alterations, other aspects of the lesion(s), and Colposcopic impression [10].

STATISTICAL ANALYSIS

The collected data were tabulated and analysedusing Microsoft excel and SPSS software (version 26.0). Descriptive analysis of data was done using means and standard deviation for continuous variables and nominal variables as frequencies. The Chi-square test was applied to categorical variables to find out the association and ROC analysis was done to predict the diagnostic ability of Pap smear, and colposcopy in cervical pathology. p-value <0.05 was considered statistically significant.

RESULTS

The mean age of the patient population was 36±3 years.The mean age at first coitus and marriage of all the women were 18.9±2.7 years and 19.5±3.4 years, respectively.

The majority (53.3%) of patients belonged to the middle social-economic status. Socio-economic status was defined by using the Revised Kuppuswamy scale [11]. The most common complaint was per vaginal (PV) discharge with lower abdominal pain, which was seen in 56 (37.3%) patients [Table/Fig-1].

The majority (75.3%) of pap smears were reported as inflammatory as most of the patients belonged to PID and vaginitis group. But on colposcopy, only 34.7% of patients showed evidence of

cervicitis and 27.3% of colposcopies were reported as normal [Table/Fig-2].

The ROC analysis was done to assess the diagnostic utility of Pap smear and colposcopic examination for the determination of malignant and premalignant cervix changes. The AUC of the Pap smear value was 0.420 and with an observed cut-off value 2.5 with a sensitivity of 87.7% and specificity of 78.2% [Table/Fig-3]. Similarly, the AUC of the colposcopic report was 0.929 and with an observed cut-off value of 2.5, the sensitivity of the colposcopic report was 89.4% and the specificity was 98.8% [Table/Fig-3].

Colposcopy had a larger area under the curve than Pap smear testing, as seen in [Table/Fig-4], indicating greater test sensitivity and specificity. Colposcopy is a more robust test for identifying

| Clinical characteristics	Characteristics	Number	Percentage
Age group (years)	25-35	41	27.3%
	36-45	53	35.3%
	46-55	33	22.0%
	56-65	15	10.0%
	66-75	8	5.3%
Social status	Low	39	26.0%
	Middle	80	53.3%
	Upper	31	20.7%
Symptoms	Discharge PV with pain in the lower abdomen	56	37.3%
	Discharge PV	47	31.3%
	AUB, Postcoital bleeding	27	18.0%
	Other (Lump abdomen)	20	13.3%
Clinical diagnosis	PID	97	64.7%
	Vaginitis	18	12.0%
	AUB	20	13.3%
	Postcoital bleeding	7	4.7%
	Fibroid/Ovarian mass	8	5.3%
Pap smear	Inflammatory	113	75.3%
	ASCUS/AGUS	14	9.3%
	LSIL	6	4.0%
	HSIL	17	11.3%
Colposcopic examination	Normal	41	27.3%
	Cervicitis	52	34.7%
	CIN-I	44	29.3%
	CIN-II and III	13	8.7%
Biopsy report (n=109)*	Normal tissue	11	9.3%
	Cervicitis	28	18.7%
	Squamous metaplasia	45	30%
	CIN	20	13.3%
	Carcinoma	5	3.3%

[Table/Fig-1]: Clinical profile of the study population.
*-Colposcopic examination was normal in 41, hence it was 109

Clinical diagnosis	Pap smear findings n (%)				Colposcopic examination n (%)				Total
	Inflammatory	ASCUS/AGUS	LSIL	HSIL	Normal	Cervicitis	CIN-I	CIN-II and III	
PID	77 (51.3)	11 (7.3)	3 (2)	6 (4)	25 (16.7)	32 (21.3)	33 (22.0)	7 (4.7)	97 (64.7)
Vaginitis	15 (10)	2 (1.3)	1 (0.67)	0	7 (8.7)	8 (15.3)	2 (12.0)	1 (2.7)	18 (12.0)
AUB	13 (8.67)	1 (0.67)	2 (1.3)	4 (2.67)	4 (2.7)	7 (4.7)	7 (4.7)	2 (1.3)	20 (13.3)
Postcoital bleeding	6 (4.0)	0	0	1 (0.67)	2 (1.5)	1 (0.67)	1 (0.67)	3 (2)	7 (4.7)
Fibroid/Ovarian mass	2 (1.3)	0	0	6 (4.0)	3 (2.0)	4 (2.7)	1 (0.67)	0	8 (5.3)
Total	113 (75.3)	14 (9.3)	6 (4.0)	17 (11.3)	41 (27.3)	52 (34.7)	44 (29.3)	13 (8.7)	150

[Table/Fig-2]: Distribution of clinical diagnosis with Pap smear and colposcopic examination.
χ^2=57.452, p<0.001*; χ^2=33.988, p=0.001*

Parameters	Pap smear values	Colposcopic report values
Area under curve (AUC)	0.420	0.929
Standard error	0.057	0.021
p-value	0.042	<0.001
Lower bound (95% CI)	0.307	0.887
Upper bound (95% CI)	0.532	0.970
Cut-off value	2.5	2.5
Sensitivity	87.7%	89.4%
Specificity	78.2%	98.8%
Positive Predictive Value (PPV)	72.8%	96.6%
Negative Predictive Value (NPV)	68.7%	82.3%

[Table/Fig-3]: ROC analysis of Pap smear and colposcopic report with respect to biopsy finding.
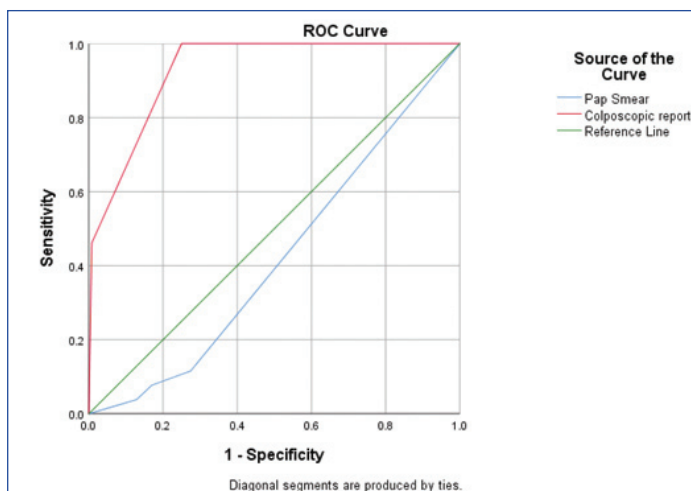
[Table/Fig-4]: ROC Curve for Pap smear and colposcopic report with respect of positive biopsy finding.

premalignant or malignant alterations in diseased patients, and its high specificity indicates that people who do not have a finding do not have the disease.

DISCUSSION

The PID is a clinical diagnosis; laboratory data or imaging studies are usually not required, though microscopic examination of a sample of cervicovaginal discharge is helpful in determining the presence of T. vaginalis, bacterial vaginosis, and/or leukorrhoea [12]. Pap smear and colposcopic examination, can help to plan the management in these clinical situations, as well as, can give an opportunity to pick the malignant changes in the cervix.

Misra JS et al., [12] studied the cervical cytology which was performed on 503 women with PID and revealed an alarmingly high proportion of SIL (144 cases-28.6%), despite the fact that 134 of them were of low-grade. There was no evidence of

cervical carcinoma. In the present study, Pap smear squamous intraepithelial lesions were seen in 23 cases (15.3%); most of them 17/23 were HSIL.

Hegde D et al., [13] did a comparative study of visual inspection by acetic acid (VIA) and Pap smear in a total of 225 women of the reproductive age group. Out of 225 patients, VIA was positive in 27 (12%) patients and the Pap smear was abnormal in 26 (11.7%). The Pap smear had a sensitivity of 83%, a specificity of 98%, and positive predictive value of 80%, and a negative predictive value of 97.9%. In the present study, we found these values 87.7%, 78.2%, 72.8%, and 68.7%, respectively.

Prasad D et al., [14] did a prospective observational study of 150 symptomatic women attending the gynaecology OPD at the Indira Gandhi Institute of Medical Sciences in Patna from 2019 to 2020. In those cases, a Pap smear, colposcopy, and biopsy were used to assess symptomatic women. In the study, Pap smear sensitivity and specificity were 91.7% and 45.45%, respectively, whereas colposcopy sensitivity and specificity were 83.3% and 72.72%, respectively.

Verma A et al., screened 200 women in the age group of 21-65 years by Pap smear testing [4]. Only 5% of women were aware that the various tests can diagnose cervical cancer. All of the women were married and in stable marriages. The average age was 38.6 years old. The most prevalent complaint was vaginal discharge, followed by menstrual bleeding. NILM was found in 56% of smears, 32.5% were inflammatory, and 1.5% had additional non specific results. ASC-US affected 1% of women, LSIL 5.5%, and HSIL 2.5%. Overall sensitivity and specificity for LSIL detection were 76.9% and 96.2%, respectively, whereas those for HSIL detection were 66.6% and 97.6%.

Shaki O et al., [15] also screened 1100 women in the age group of 21-65 years. The majority of the cases were benign, with 581 (52.8%) being negative for intraepithelial neoplasia (NILM), 203 (18.4%) being inflammatory, 45 (4%) being atypical squamous cells of undetermined significance, and 75 (6.8%) being high-grade squamous intraepithelial lesion (HSIL). Overall sensitivity and specificity for LSIL detection were 75.8% and 94.6%, respectively, while those for HSIL detection were 68.9% and 98.6%. A few other studies indicating epithelial cell abnormalities are described in [Table/Fig-5] [15-23] and compared with our study.

Similarly, we have tried to compare the sensitivity and specificity of colposcopy with other studies and the present study, which is tabulated in [Table/Fig-6] [24-27]. In contrast to the other studies, we have found a better specificity of colposcopy in finding the malignant and premalignant lesions of the cervix. This may be due to the ability of the colposcopy to directly visualise the suspicious areas and to take the targeted biopsies.

Giraud J et al., [28] study involved 298 patients hospitalised for PID, in whom smears and colposcopy were used to look for CIN.

Author name	Place and year of study	Total number of subjects	LSIL n (%)	HSIL n (%)	ASCUS n (%)	SCC n (%)
George P et al., [16]	Mangalore, India 2014)	1000	20 (2.0)	9 (0.9)	3 (0.3)	3 (0.3)
Sherwani R et al., [17]	Aligarh, India (2007)	242	8 (3.53)	8 (3.53)	3 (1.32)	8 (3.53)
Gupta K et al.,[18]	Western Uttar Pradesh, India (2013)	4703	64 (1.36)	42 (0.91)	24 (0.52)	18 (0.28)
Nayani ZS et al., [19]	Karnataka, India (2015)	104	1 (0.96)	1 (0.96)	2 (1.92)	-
Sengul D et al., [20]	Turkey (2014)	1032	4 (0.39)	1 (0.1)	12 (1.18)	2 (0.2)
Kothari et al., [21]	Ahmedabad, India (2014)	36740	293(0.83)	114 (0.31)	40 (0.11)	18 (0.05)
Nair GG et al., [22]	Kerala, India (2016)	2028	32 (1.58)	10 (0.49)	3 (0.15)	4 (0.2)
Bal M et al., [23]	Punjab, India (2012)	300	8 (2.7)	2 (0.7)	1 (0.3)	4 (1.3)
Shaki O et al., [15]	Mumbai, India (2018)	1100	75 (6.8)	66 (6)	44 (4)	35 (2.3)
Present study	Jaipur, India (2022)	150	6 (4.0)	17 (11.3)	14 (9.3)	(0)

[Table/Fig-5]: Comparison of epithelial cell abnormalities in Pap smear with other studies and the present study [15-23].

Author name	Place and year of study	Total number of subjects	NPD (%)	PPD (%)	Sensitivity (%)	Specificity (%)
Barut MU et al., [24]	Turkey, 2015	450	96	52	92	67
Dorji N et al., [25]	Bhutan, 2022	299	-	-	66.67	73.73
Gyawali P et al., [26]	Nepal, 2018	6109	-	62.6	96.44	34.98
Allameh T et al., [27]	Iran, 2022	94	-	-	97	41
Present study	India, 2022	150	82.3	96.6	89.4	98.8

[Table/Fig-6]: Comparison of sensitivity and specificity of colposcopy with other studies and the present study [24-27].

CIN was identified in 42 patients (14%), including 21 cases of low-grade CIN and 21 cases of high-grade CIN, as well as one case of early-stage micro-invasion. In the present study population authors found the CIN incidence of 13.3% and carcinoma in 3.3%. Similarly, Abdul MA et al., [29] also found 14% prevalence rate for CIN in PID. These findings indicate that CIN is more common in PID patients, implying that CIN should be studied more thoroughly in this population.

Wojciech's R et al., [8] study was done to determine the diagnostic value of cytology and colposcopy in women with CIN. The Pap smears demonstrated a sensitivity of 58.02% and a specificity of 63.28% in diagnosing CIN. The Positive Predictive Value (PPV) for cytology was calculated to be 75.38%, whereas the Negative Predictive Value (NPV) was calculated to be 43.75%. Colposcopy had an 89.21% sensitivity and a 98.8% specificity in the diagnosis of CIN, according to the study. Colposcopy had a PPV of 99.4% and a NPV of 82.6%. As a result, Pap smears have low diagnostic utility in the detection of CIN, whereas colposcopy offers good sensitivity and specificity in the identification of CIN. In the present study, the authors also found better PPV and NPV of colposcopy in comparison to Pap smear for detecting cervical malignant changes.

Tapisiz OL et al., [30] studied 105 patients that had an High-grade squamous intraepithelial lesion (HSIL) confirmed by excisional biopsy. At the time of colposcopy, 82 of these high-grade excisional pathology results were preceded by high-grade Pap cytology. The inclusion of a Pap smear during colposcopy offers the potential to detect high-grade cervical dysplasia. That adds the value of combined co-testing for better results.

Kuramoto H et al., [3], Nkwabong E et al., [5] and Jahic M et al., [31], also concluded that though the sensitivity of the Pap smear for detecting dysplasia is low in comparison to colposcopy, a colposcopy may not be suitable for primary screening due to its high chances of unsatisfactory colposcopic findings.

Limitation(s)

Though the results can be interpolated for general population, but larger in field screening trials will provide more authentic data for drafting the recommendations.

CONCLUSION(S)

It is well established that early detection helps in getting better cure rates. Though colposcopy and biopsy have shown better sensitivity and specificity in comparison to Pap smear, co-testing can overcome the inherent problems with colposcopy including the cases of unsatisfactory colposcopy. Even Pap smear alone can be an effective measure in cost constraints settings or where colposcopy facilities are not available.

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