



CERVICAL CANCER SCREENING BY PAP SMEAR TEST AND CLINICAL CORRELATION – A PROSPECTIVE OBSERVATIONAL STUDY.

Obstetrics & Gynaecology

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ABSTRACT

Background: Cervical cancer despite being mostly preventable, it is nevertheless a serious public health problem, particularly in areas with little resources. It can be diagnosed early at the premalignant stage with cervical cytological screening by papanicolaou (pap) smears. Diagnostic accuracy is improved and prompt action is made possible by correlating Pap smear results with clinical symptoms and examination findings. **Aims:** To determine the frequency of abnormal cervical cytology in women attending a tertiary care facility and to establish a correlation between cytological findings, clinical symptoms, and examination findings. **Methodology:** This prospective observational study was conducted in the Department of Obstetrics and Gynecology at Ballari medical college and research centre Ballari, from January 2024 to December 2024. Women aged 21–65 years with gynecological complaints or those seeking opportunity in screening program were included. Pap smears were collected using the conventional method and categorized using the 2014 Bethesda System. Abnormal findings were correlated with clinical presentations and per speculum examination. **Results:** A total of 1020 Pap smears were analysed. Most women were aged 41–50 years (48.3%) and from lower socioeconomic backgrounds (67.6%). Vaginal discharge (42.2%) was the most common symptom, followed by postmenopausal bleeding (13.3%). Cytology revealed NILM in 86.1%, ASCUS in 3.3%, LSIL in 3.4%, and HSIL in 0.98%. Unsatisfactory smears accounted for 6.1%. Severe abnormalities were more common in women with suspicious cervix on examination. **Conclusion:** Correlating Pap smear results with clinical symptoms improves early detection and triage of cervical lesions. This integrated approach is vital in optimizing cervical cancer screening, particularly in resource-limited settings.

KEYWORDS

Human Papillomavirus, Pap Smear, Cervical Intraepithelial Neoplasia, Cervical Malignancy

INTRODUCTION

Globally, cervical cancer remains one of the most common gynaecologic malignancies. It is the fourth most prevalent cancer in women globally and ranks 14th overall, according to current data [1]. Cervical cancer develops in the cells of the cervix, the lower part of the uterus that connects to the vagina.

Several risk factors for cervical cancer are associated with human papillomavirus (HPV) exposure. After the initial HPV-caused lesion, the invasive cancer growth process may take up to 20 years. However, there are also many additional risk factors (such as sexual and reproductive variables, behavioral factors, etc.) for cervical cancers, such as having infection with HIV, sex before the age of sixteen, having several partners, use of oral contraceptive pills for a long duration, smoking, having high parity, and having a low socioeconomic status [2].

Alterations in cervical tissue are typically benign and rarely lead to immediate issues. The progression from these cellular changes to cancer can span several years or even decades. If cancer does develop, it may present with symptoms such as unusual bleeding — including after sexual activity, between menstrual periods, or following menopause — as well as abnormal vaginal discharge, which may have a foul smell. Additional signs can include fatigue, unintended weight loss, abdominal or pelvic pain, and discomfort during urination. Often, by the time symptoms become noticeable, cervical cancer has already reached an advanced stage [3].

This issue remains critical as the frequency of HPV infection seems to be increasing consistently. Cervical cancer is one of the most common and preventable illnesses among women in low- and middle-income nations, however there are effective primary and secondary preventative measures, such as preinvasive disease treatment and HPV vaccination. In order to eradicate cervical cancer, the Ministry of Health has asked for a coordinated approach that involves a challenging set of steps at every level of a health service [4]. Implementing thorough screening can lead to early discovery and proper treatment. The most accessible, practical, and economical method for detecting premalignant and malignant lesions on the cervix is still the papanicolaou (Pap) smear. Cervical dysplasia and inflammatory lesions are two premalignant cervix lesions that can be

identified in the early stages of the disease using a pap smear. However, using the same technique of interpretation, other studies have found pap smear accuracy ranging from 53 to 78% [4, 5]. It has been demonstrated that the pap smear's sensitivity and specificity for identifying high-grade lesions of cervical intraepithelial neoplasia (CINII and CINIII) are 55.4 and 96.8%, respectively [6]. The early identification of such changes facilitates timely management, preventing the progression to invasive cancer.

The use of Pap smear screening is still inconsistent in many developing nations, including India's rural and semi-urban areas, despite its demonstrated advantages. Cervical cancer presents in its advanced stages due to low screening program participation rates caused by socioeconomic circumstances, cultural attitudes, ignorance, and a lack of adequate healthcare infrastructure. Clinical correlation with Pap smear results becomes essential in this situation to increase diagnostic precision and ensure proper therapy and follow-up [7]. A thorough assessment of the internal and external genitalia must be part of the physical examination. A friable cervix, visible cervical lesions, erosions, lumps, bleeding during the examination, and fixed adnexa are examples of positive exam results in women with cervical cancer [8]. Clinical evaluation improves the capacity to detect people at risk and directs choices about additional tests, such as a biopsy, colposcopy, or treatment options, when paired with Pap smear findings. The integration of cytology-based screening with clinical and demographic data has been a key component of recent attempts to enhance cervical cancer control, especially in areas with limited resources.

Optimizing resource allocation and prioritizing high-risk cases for referral can be achieved by comprehending the relationship between cytological abnormalities and clinical presentation. In light of this, the current study is to determine the frequency of abnormal cervical cytology in women who are enrolled in a tertiary care facility and to establish a correlation between these results and examination findings and clinical symptoms.

METHODOLOGY

This prospective observational study was conducted in the Department of Obstetrics and Gynecology at Ballari medical college and research centre, Ballari. The study began following approval from the

Institutional Ethics Committee and after obtaining written informed consent from all participants. Women aged between 21 and 65 years who attended the outpatient department from January 2024 to December 2024 were enrolled in the study. Participants presented with a range of gynecological complaints, such as vaginal discharge, blood-stained or foul-smelling discharge, postcoital bleeding, intermenstrual bleeding, postmenopausal bleeding, lower abdominal pain, and infertility. Additionally, asymptomatic women who visited the hospital and took part in cervical cancer screening program or routine Pap smear testing were also included.

Exclusion criteria included women with visible cervical growths suggestive of malignancy, those already diagnosed and undergoing treatment for cervical cancer, and pregnant women. Detailed patient histories were recorded using a structured proforma, which captured presenting complaints and findings from per speculum and bimanual vaginal examinations. Pap smear samples were collected using the conventional method. The patient was positioned in the lithotomy position, and the cervix was visualized using a Cusco's speculum. An Ayre's spatula was inserted such that the longer arm entered the cervical canal while the shorter arm remained on the ectocervix. A full 360-degree rotation was performed to ensure proper sample collection from the ectocervix. The collected specimen was then evenly spread onto a glass slide. A separate sample from the endocervix was obtained using a cytobrush. This sample was also smeared on a slide and immediately fixed with 95% ethanol. Each slide was labeled clearly with the patient's identifying information and accompanied by a requisition form detailing clinical findings. All samples were then sent to the cytology laboratory for evaluation.

Only those reports deemed satisfactory for evaluation were included and categorized according to the Bethesda System 2014 for reporting cervical cytology [9]. This included Negative for intraepithelial lesion or malignancy (NILM), atypical squamous cells of undetermined significance (ASCUS), Low grade squamous intraepithelial lesion (LSIL) and high-grade intraepithelial lesion (HSIL). Every woman with abnormal pap test findings was handled in accordance with WHO standard recommendations and encouraged to follow up. To find precancerous lesions, Pap smear data were analyzed using the Bethesda approach. The clinical association between each pap smear abnormality was examined.

Statistical Analysis

Data will be entered into Microsoft excel data sheet and will be analyzed using SPSS 22 version software. Categorical data will be represented in the form of Frequencies and proportions. Chi-square will be used as test of significance. Continuous data will be represented as mean and standard deviation. Independent t test will be used as test of significance to identify the mean difference. P value <0.05 will be considered as statistically significant.

Sample Size

Sample size was estimated by using the proportion of epithelial cell abnormality in subjects who were screened by Pap smear was 5.76% from the study by Paridhi Garg et al. using the formula.

Sample Size = Z1-α/2² P(1-P)/d²

Z1-α/2 = is standard normal variate (at 5% type 1 error (P<0.05) it is 1.96 and at 1% type 1 error (P<0.01) it is 2.58). As in majority of studies P values are considered significant below 0.05 hence 1.96 is used in formula.

P= Expected proportion in population based on previous studies or pilot studies d= Absolute error or precision

P = 5.76% or 0.0576

q = 94.24% or 0.9424

d = 1.5% or 0.015

Using the above values at 95% Confidence level a sample size of 927 subjects will be included in the study. Considering 10% Nonresponse a sample size of 927 + 92.7 ≈ 1020 subjects will be included in this study.

RESULTS

From January 2024 to December 2024, a total of 1020 Pap smears were examined. 48.3% of the women in the research were between the ages of 41 and 50, and 25.1% were between the ages of 51 and 60. More than half of the women (67.6%) came from lower socioeconomic backgrounds. Pap smears were performed for a variety of symptoms, such as post-menopausal bleeding (13.3%) and vaginal discharge (42.2%). The other details are depicted in the table 1.

Table 1: Clinico-demographic Details

Clinico-demographic parameter	Observation	Frequency (N=1020)	Percentage
Age distribution	21-30 years	31	3.1
	31-40 years	140	13.7
	41-50 years	493	48.3
	51-60 years	256	25.1
	61-65 years	100	9.8
Socio-economic status	Lower	690	67.6
	Middle	225	22.05
	High	105	10.35
Parity	P1	45	4.4
	P2	105	10.35
	P3	221	21.7
	P4	249	24.4
	>P4	400	39.2
Indications for PAP smear	Vaginal discharge	431	42.2
	Post-menopausal bleeding	136	13.3
	Vaginal itch	105	10.2
	Burning micturition	96	9.41
	Intermenstrual bleed	45	4.41
	Suspicious cervix	88	8.62
	Postcoital bleed	48	4.70
	As a routine screen (Asymptomatic)	71	6.96

Per-speculum Examination Findings

According to the speculum examination, hypertrophied cervix was evident in 9.3% of the subjects, and white discharge was often observed in 39.4%. Furthermore, the cervix seemed healthy upon inspection in 29.9% of cases. The per-speculum results are shown in Figure 1

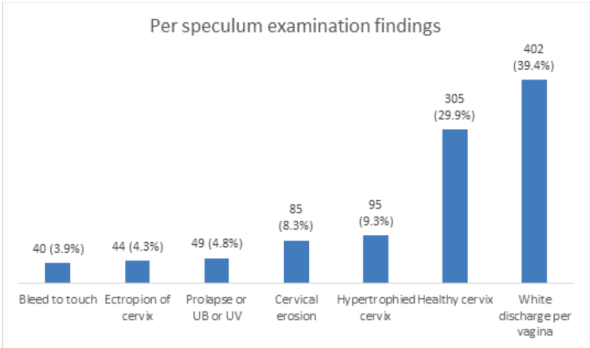


Figure 1: Per Speculum Findings Among 1020 Patients.

Cervical Lesion Cytology According to Epithelial Cell Abnormality:

In our study 86.1% reported as Negative for intraepithelial lesion or malignancy (NILM). A total of 3.3%, 3.4%, and 0.98% of the women had the epithelial abnormalities ASCUS, LSIL, and HSIL, respectively. 6.1% of reports were deemed inadequate. (Table 2)

Table 2: Pap Smear Report in 1020 Patients.

PAP report	Frequency (N=1020)	Percentage
Unsatisfactory sample	62	6.1
Negative for intraepithelial lesion or malignancy	879	86.1
Atypical squamous cells of undetermined significance (ASCUS)	34	3.3
Low-grade squamous intraepithelial lesion (LSIL)	35	3.4
High-grade squamous intraepithelial lesion (HSIL)	10	0.98

The study aimed to correlate the pap smear findings with clinical symptoms among the patients.

This analysis of 958 patients (excluding 62 with unsatisfactory samples) assessed the correlation between Pap smear findings and clinical symptoms. The majority (91.8%) had NILM (Negative for Intraepithelial Lesion or Malignancy), indicating benign cytology. Abnormal findings included ASCUS (3.5%), LSIL (3.7%), and HSIL

(1%). These abnormalities were most commonly seen in patients with vaginal discharge, postcoital bleeding, and suspicious cervix on examination. Vaginal discharge, the most frequent complaint, accounted for the highest number of abnormal smears. Notably, 10.3% of women with postmenopausal bleeding and 18.2% with a suspicious cervix had abnormal results. These findings highlight the importance of Pap smear screening, particularly in symptomatic women.

Table 3: Correlation of Clinical Presentations and Pap Smear.

	NILM (n=879)	ASCUS (n=34)	LSIL (n=35)	HSIL (n=10)	Total
Asymptomatic (n=71)	71	0	0	0	71
Vaginal discharge (n=369)	347	9	11	2	369
Post-menopausal bleed (n=136)	122	7	6	1	136
Vaginal itch (n=105)	96	3	4	2	105
Burning micturition (n=96)	90	2	3	1	96
Intermenstrual bleed (n=45)	39	1	3	2	45
Suspicious cervix (n=88)	72	6	8	2	88
Postcoital bleed (n=48)	42	6	0	0	48
Total	879	34	35	10	

DISCUSSION

Cervical cancer poses a serious but preventable risk to the health of women. When combined with meticulous clinical evaluation, the Pap smear test continues to be a useful tool for early detection and lowering the incidence of cervical cancer and increasing their survival time [10].

This research is particularly relevant in the Indian context, where organized nationwide screening programs are still in developmental stages, and opportunistic screening remains the norm, especially the utility of pap smear.

The Pap smear is a well-established cytological method for detecting cervical abnormalities [11]. The American Cancer Society (2012) states that the Pap smear test is a standard cancer screening procedure that has to be carried out every three years. Additionally, a Pap smear combined with an HPV DNA test is advised as a screening procedure every five years [12]. While the clinical symptoms frequently offer crucial contextual information that can assist prioritize high-risk patients, direct additional investigations, and increase diagnosis accuracy.

The majority of abnormal cytology results were found in women between the ages of 41 and 50, according to the study's findings. This is in line with previous research by Justa U et al in 2024 [13] and Sachan PL et al in 2018 [14]. It suggests the risk of cervical epithelial abnormalities rises with age, especially during the perimenopausal period. Cytological abnormalities are more common in this age group, which may be caused by hormonal changes, cumulative exposure to risk factors including HPV infection, and a decrease in immune surveillance.

Additionally, a sizable fraction of the women with abnormal Pap screening findings were from lower socioeconomic stratum, which is known to be a risk factor for cervical cancer. The findings corroborated with Broberg G et al in 2018 [15] and Akinyemiju T et al in 2016 [16]. Poor personal hygiene, a lack of knowledge about cervical screening, and restricted access to healthcare are all factors that contribute to the late diagnosis of cervical lesions in women from economically deprived families.

Furthermore, it is consistent with data indicating multiparity is a known risk factor for cervical cancer that the majority of women with abnormal cytology had high parity, or more than four children. Similar trend was highlighted in a systematic review and meta-analysis by Tekalegn Y et al in 2022 [17]. Prolonged exposure to high quantities of progesterone and oestrogen, as well as repeated cervical trauma during childbirth may render the cervical epithelium more susceptible to malignant transformation. In order to ensure early identification and prompt intervention, our findings highlight the significance of focused screening and health education initiatives in high-risk groups.

Present research highlighted that vaginal discharge followed by postmenopausal bleeding was the most encountered clinical presentations. Even the per speculum examination revealed that white discharge per vagina was most noted. This is due to the fact that changes in

hormones, particularly oestrogen, which promote the development of cervical mucus lead to discharge per vagina in women of reproductive age. Women go through cyclical changes, ovulation, and sexual activity throughout this stage of life, all of which can lead to a rise in vaginal secretions, both normal and pathological. Abnormal discharge is also caused by inadequate menstrual hygiene, the use of contraceptives, and an elevated risk of infections such as candidiasis or bacterial vaginosis. greater reporting is also a result of regular gynecological consultations and greater health awareness [18]. In line with results from previous population-based cervical screening programs [14, 19], where the majority of women exhibit normal cytology, 86.1% of Pap smear reports in this research were negative for intraepithelial lesion or malignancy. This illustrates how Pap smears are a useful screening method for determining if a woman's cervical epithelium is normal or at risk in those who are asymptomatic or very slightly unwell.

In this study, 86.1% of Pap smears showed negative for intraepithelial lesion or malignancy, ASCUS was seen in 3.3%, indicating minor abnormalities that often require follow-up or HPV testing. LSIL and HSIL were found in 3.4% and 0.98% respectively—though less common, these lesions are clinically significant and warrant timely management to prevent progression to invasive cancer.

The main aim of the study was to correlate between the clinical symptoms and pap smear in cervical cancer. The data shows a strong correlation between clinical symptoms and abnormal Pap smear findings. Women with symptoms, particularly vaginal discharge, suspicious cervix, and abnormal bleeding, had greater rates of cytological abnormalities, such as ASCUS, LSIL, and HSIL, whereas asymptomatic women tended to have normal reports. The largest percentage of severe lesions was found in the suspicious cervix, confirming its predictive significance. These findings highlight how crucial it is to combine cytological screening with clinical assessment in order to identify cervical abnormalities early. The findings were also consistent in Sachan PL et al in 2018 [14].

CONCLUSION

Cervical cancer poses a serious but preventable risk to the health of women. A more comprehensive clinical picture is generated by the association between Pap screening results and clinical symptoms, which facilitates earlier identification, better triage, and enhanced management of cervical abnormalities. This combination strategy greatly lowers the morbidity and mortality associated with cervical cancer and is particularly important in settings with limited resources. Hence, the study emphasises the importance of cervical cytology in standard gynaecological treatment and the necessity of thorough screening methods that take into account both laboratory and clinical results.

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