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## **Cytomorphological spectrum of cervical Pap smear reports using the 2014 Bethesda system for reporting cervical cytology: A two year study in a tertiary care hospital at puducherry, India**

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***Abstract--Cancer cervix is fourth most common cancer in world and second most common in India. It is considered as a preventable disease when identified at an early stage by pap smear screening test. This study aims to explore the use of conventional pap smear for the diagnosis of various cytomorphological spectrum of cervical pap smear reports using The Bethesda System for reporting cervical cytology 2014 (TBSRC 2014), to analyze the clinical and demographic data of the patients, and also to characterize the age pattern of various pap smears findings/results and prevalence of abnormal pap smears among various age groups as well. In this retrospective study, a total of 1650 conventional pap smears of women who attended gynaecology OPD in our tertiary care hospital, Puducherry, India between July 2018 to July 2020 are evaluated and reported as per TBSRC 2014 and the results were tabulated and analysed accordingly. 1376 women had Negative for intraepithelial lesion/ Malignancy (NILM) and 33(2.3%) had Epithelial cell abnormality. Organisms (15.3%) is the one of the frequent patterns of NILM in the study involving predominantly 21-40 years age group (11%). Almost all cases of Epithelial cell abnormality (2.3%) involve >44 years of age. Though Distribution of ECA among 45-60 age group is less than >60 years age group, it doesn't show any significant statistical differences (p value-). ASC/SIL ratio is 0.37:1. Cervical cancer is the most common female cancer, for which pap smear screening test is done. TBSRC 2014 allows crisp reporting***

format and helps clinicians to appropriately manage through consensus guidelines. Epithelial cell abnormality increases with increase in age and parity. Awareness regarding vaginal hygiene practice and about Pap smear test should be implicated to every women through mass screening programmes and campaigns. Timely screening of pre-invasive lesion allows prevention from invasive cervical cancer.

**Keywords**---cytomorphological, Pap smear, cervical cytology, tertiary care hospital, puducherry.

## Introduction

Cervical cancer is one of the leading causes of cancer mortality among women worldwide and India accounts for almost 15.2% of global cervical cancer deaths [1]. In India, the national cancer registry program reveals higher incidence in the districts of Tamil Nadu and Puducherry [2]. The natural history of cervical cancer allows early detection of cervical epithelial lesions by simple and effective screening tool known as pap smear, discovered by George Papanicolaou which was way back at 1939 by studying the exfoliative cervical cytology. However, in an early era's the reporting terminologies of the same pap smear by different pathologists were different and hence created confusion in interpretation and management by treating physicians. The Bethesda System for Reporting Cervical Cytology at 1988 proposed a standard reporting terminology which are reproducible across different pathologists and communicates relevant information to the health care provider. The subsequent Bethesda workshops were conducted at 1991, 2001 and recently at 2014, during the course, TBS has undergone various refinements.

In the recent years, evidence-based consensus guidelines have proposed the concept of providing equal management for equal risks [3]. The 2014 Bethesda System for Reporting Cervical Cytology (TBSRC 2014) shows only minimal changes relative to terminologies itself, however includes refinement of morphological criteria, optional educational notes, and reporting Benign appearing Endometrial cells is now recommended for women aged >45years, as the predictive value for endometrial hyperplasia/ carcinoma is reliable only in postmenopausal women [4]. This study aims to explore the use of conventional pap smear for the diagnosis of various cytomorphological spectrum of cervical pap smear reports using TBSRC 2014, to analyze the clinical and demographic data of the patients, and also to characterize the age pattern of various pap smears findings/results and prevalence of abnormal pap smears as well. This would probably help to find the target group in the study population.

## Methodology

### Study Design

Retrospective descriptive study

### Criteria for inclusion

All the women more than 21 years attending the OPD with various gynaecology symptoms and also who come for routine screening, who had undergone pap smear test are included in the study. Institutional ethical committee clearance was obtained.

### Criteria for exclusion

Women who were pregnant, known or treated cases of Epithelial cell abnormality including cancer cervix and also unmarried women were excluded from the study.

### Study Period

July 2018 to July 2020.

### Sample Size

About 1650 cases are recruited over the study period. The medical records of the study participants are analyzed and complete clinical history including chief complaints, personal and marital history are noted. Per-speculum examination of cervix findings are included. Conventional pap smears obtained are evaluated and categorized as per the 2014 Bethesda system for reporting cervical cytology (TBSRC 2014). Reactive cellular changes associated with inflammation and atrophy are included in Negative for intraepithelial lesion/Malignancy (NILM). Epithelial cell abnormality (ECA) includes Atypical squamous cells of undetermined significance (ASC-US), Atypical squamous cell cannot exclude High grade squamous intraepithelial lesion (ASC-H), Low grade squamous intraepithelial lesion (LSIL), High grade squamous intraepithelial lesion (HSIL), and Squamous cell carcinoma (SCC). The data are tabulated and analyzed with Statistical Package for Social Sciences (SPSS) version 20 and descriptive statistics were presented as frequencies and percentages.

### Results

Table 1  
Clinico-demographic details (n=1650)

			NILM	ECA
AGE GROUP	21-30 years	373(22.6%)	332	-
	31-44 years	649(39.3%)	549	-
	45-60 years	528(32%)	430	12
	>60 years	100(6%)	65	21
PARITY	Nulliparous	154(9.3%)	154	-
	Living 1	198(12%)	196	2
	Multiparous	1298(78.6%)	1267	31
MARITAL (AGE AT	<21 Years	615(37.3%)	602	13

MARRIAGE)	>21 Years	1035(62.7%)	1015	20
CHIEF COMPLAINTS	White discharge PV	803(48.6%)		
	Abnormal uterine bleeding	222(13.4%)		
	Post coital bleed	20 (1.2%)		
	Lower abdominal pain	187(11.3%)		
	Prolapse uterus	110(6.6%)		
	Routine screening	308(18.6%)		
PERSPECULUM FINDINGS OF CERVIX	Healthy	1144(69.4%)		
	Erosion/ectropion	253(15.3%)		
	Discharge PV	253(15.3%)		

Table 2  
Age pattern of Pap smear results

Age group (Years)	Unsatisfactory	Negative for intraepithelial lesion/Malignancy (NILM) (n=1376(83.3%))				Epithelial cell abnormality (ECA) (ASCUS-3, ASCH-6, LSIL-9, HSIL-11, SCC-4)
		Organisms	Atrophy	Reactive cellular changes associated with inflammation	No other specific findings	
21-30	41	98	-	25	220	-
31-44	100	82	10	75	558	-
45-60	86	31	33	65	347	12
>60	14	-	12	-	53	21
	241(14.6%)	211(15.3%)	55(4%)	165(12%)	1178(85.6%)	33(2.3%)

Table 3  
Prevalence and comparison of pap smear results in various age groups

	≤ 45 years (n=1023)	>45 years (n=628)
NILM	1022	595
ECA	1	32
	45-60 years(n=12)	>60 years(n=21)
ASCUS	2	1
ASCH	4	1
LSIL	3	6
HSIL	1	10
SCC	1	3

A total of 1650 women between the age of 21-70 years are included in the study with the mean age of 37.5 years. 6 cases of post hysterectomy for benign etiology are also included. Majority (39.3%) of women were in age group of 31-44 years followed by 45-60 years age group (32%). The mean age at marriage is about 20 years. Out of 1650 women, 154(9.3%) were nulliparous and 1298(78.6%) were multiparous and rest had one living child. The most common chief complaints of women in our study were vaginal discharge 803(48.6%) followed by abnormal

uterine bleeding 222(13.4%), prolapse uterus 110(6.6%), post coital bleed 20(1.2%), and 308(18.6%) had come for routine screening. Per-speculum examination of cervix shows healthy cervix at 1144(69.4%) cases followed by erosion/ectropion in 253(15.3%) cases [Table1].

Out of 1650 pap smears examined, 1409(85.3%) were satisfactory according to TBSRC 2014, of which 74% showed presence of Transformation zone component. 241(14.6%) were unsatisfactory for evaluation- 160 were due to obscuration of squamous cells by dense inflammation more than 75%, and 81 due to low squamous cellularity. The rest of 1376 cases (83.3%) were reported as Negative for Intraepithelial lesion/ Malignancy (NILM). Organisms (15.3%) is the one of the frequent patterns of NILM in the study involving predominantly 21-40 years age group (11%)– 110 were of shift in flora suggestive of bacterial vaginosis, 80 cases were showing candida species with pseudo hyphae, and, 21 were of trichomonas vaginalis. The other patterns include 55(4%) cases of atrophic smear, 165(12%) cases of Reactive cellular changes associated with inflammation, and 3 cases with Benign appearing endometrial cells in a women age >45years. The epithelial cell abnormalities (ECA) constituted 2.3% of all cases which includes Atypical squamous cells- Undetermined Significance (ASC-US)-3(0.2%), Atypical squamous cells- cannot exclude HSIL(ASC-H)-6(0.4%), Low grade squamous intraepithelial lesion (LSIL)-9(0.6%), High grade squamous intraepithelial lesion (HSIL)-11(0.79%) and Squamous cell carcinoma-4(0.3%)[Table 2].

Almost all cases of ECA (2.3%) involves  $\geq 45$  years of age. 57% cases of ECA falls in 45–60-year age group, and rest 43% in >60 years age group. 25(75%) of these ECA cases presented with lower abdominal pain, 5(15%) with white discharge and the rest 3(0.9%) with history of post coital bleed. 20(62%) of cases with epithelial cell abnormality showed abnormal perspeculum finding such as erosion. ASC/SIL ratio in our study is 0.37:1.

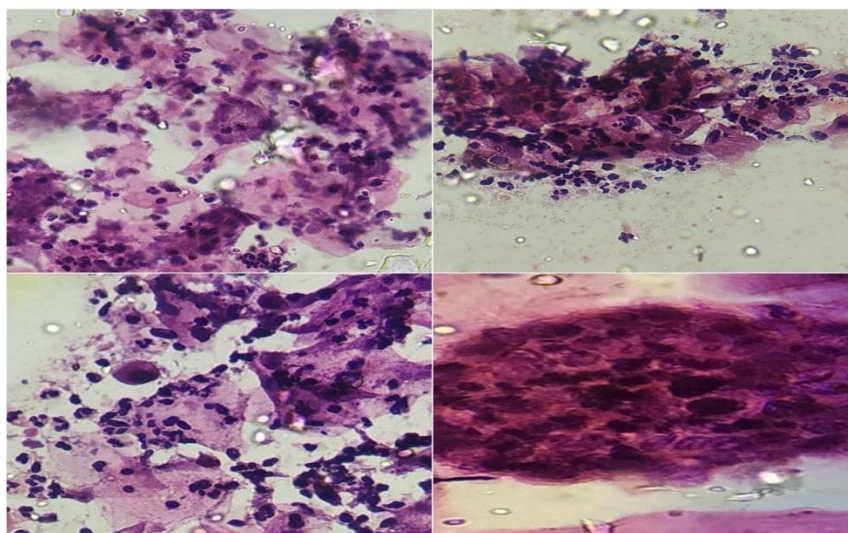


Figure 1. (a,b,c,d) Negative for Intraepithelial Lesion or Malignancy (NILM)- patterns a) Bacterial vaginosis b) Candida c) Trichomonas vaginalis d) Benign endometrial cluster

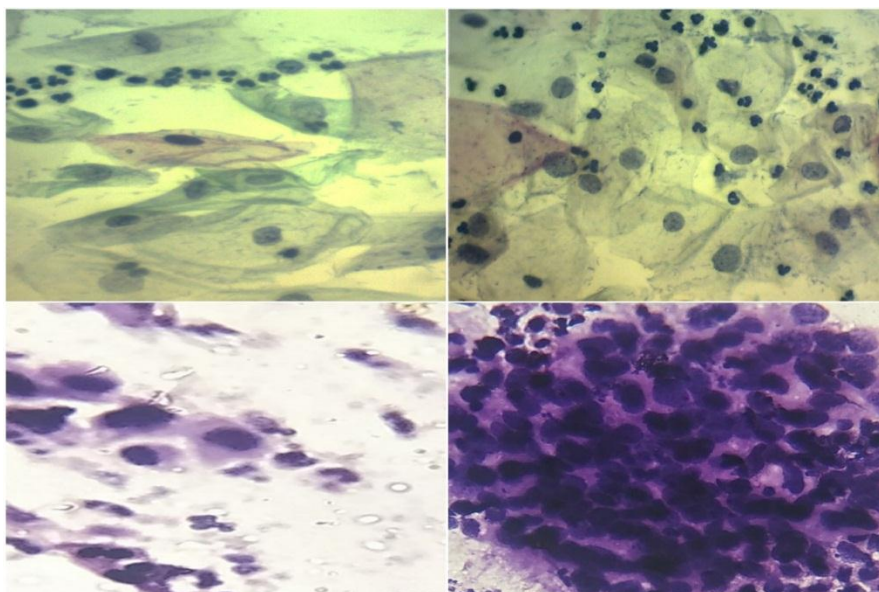


Figure 2. (a,b,c,d)- Epithelial cell abnormality -a)ASC-US b)ASCH c)HSIL d)SCC

## Discussion

Cervical cancer is one of the major public health problems in India and especially in rural settings (5). Pap smear is the most widely used screening tool to detect cervical precancerous lesions which do not present with obvious signs and symptoms [6] and also to detect cervical carcinoma at an early stage. Nowadays, incidence of carcinoma cervix has declined to more than 50% due to wide spread screening with cervical cytology [7]. TBSRC 2014 utilizes appropriately reproducible terminologies which are much informative to health care providers and allows efficient management through consensus guidelines. Majority (39.3%) of the women in the study were in age group of 31-40 years which is similar to study results done by Patel PCB et al., and Shekhar H et al. (8,9). Prevalence of squamous intraepithelial lesion (2%) is high among the 41-60 years age group which is similar to the study done by Gajasree S et al. (10 ).

The mean age of the study population is 37.5 years, which is appropriate, as it is the common age to develop carcinoma cervix between 40-50 years and its precursor lesions usually 5-10 years earlier. Our study results show concordance with similar studies done by Verma A et al., Bamanikar SA et al. which shows 38.6 and 38.5 years respectively(11,12). And so atleast one pap smear before the age of 45years is recommended at rural settings where the screening guidelines could not be followed due to some sociocultural factors(13, 14). The mean age at marriage in the study population is 20 years. Early age of marriage is relatively common at rural set-up which nowadays show declining trend; however, it is a known fact that early age of intercourse is one of the risk factors for cervical carcinoma. In our study 118(78.6%) were multiparous, which is one among the risk factor for carcinoma cervix. The most common chief complaints among the study population are vaginal discharge 803(48.6%), which is one of the commonest symptoms of infection/ inflammation. The results are similar to

studies done by Ranabhat SK et al., Sachan R et al and Pradhan B et al (7,15,16). Chronic persistent inflammation/ infections can predispose to neoplasia. 69.4%(1144) of cases reveals healthy cervix at per-speculum examination. Per-speculum findings of the cervix needs to be correlated with the cytology findings, since the reactive cellular change due to inflammation is one of the commonest diagnostic dilemmas with cervical intraepithelial lesion.

A total of 1650 pap smears were screened of which 241(14.6%) were unsatisfactory which was similar to the study done by Kulkarni et al. (14.8%) (17). The occurrence of epithelial cell abnormality (ECA) accounts for 2.3%, which is in agreement with studies conducted by Nayir et al, Chauhan et al and Kalyani et al(18.19.20). The known cases of carcinoma cervix were excluded in the study to know the true predictive nature of identifying the epithelial cell abnormality by the screening test of pap smear. The intraepithelial lesions identified in this study includes ASCUS, ASC-H, LSIL, HSIL and SCC. Almost all cases of ECA involves >40 years of age. This occurrence of ECA with increasing age and parity (100% >40 years) indicates increase risk of exposure to human papilloma virus, which is a potential risk factor for carcinoma cervix. However, majority of ECA had significant clinical history like lower abdominal pain (75%), postcoital bleed (0.9%) and perspeculum findings such as erosion (62%). This indicates that utmost invigilation of smears is demanding when cytopathologists screen the smear with clinical back-up. Bethesda system suggests that ASC/SIL ratio for an individual or laboratory should be less than 2:1 or 3:1 to avoid overuse of ASC category which actually reflects a kind of uncertainty in diagnosis. In our study the ASC/SIL ratio was 0.37:1 which is below the benchmark of Bethesda. (21)

## Conclusion

Cervical cancer is the most common female cancer, for which pap smear screening test is done. TBSRC 2014 allows crisp reporting format and helps clinicians to appropriately manage through consensus guidelines. Epithelial cell abnormality increases with increase in age (>40 Years) and parity, due to possible increase in risk of exposure to Human papilloma virus. Awareness regarding vaginal hygiene practice and about Pap smear test should be implicated to every woman through mass screening programmes and campaigns. Timely screening of pre-invasive lesion allows prevention from invasive cervical cancer. The target population in our rural setting is above 40 years which could help to identify precursor lesions early at stage.

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