Original Research Article

A clinico-pathological study to evaluate cervical cytology at tertiary healthcare hospital

Sonal[1*], Shalini Suman[1], Geeta Sinha[2]

[1]Junior Resident, Department of Obstetrics and Gynecology, Patna Medical College and Hospital, Patna, Bihar, India

[2]Professor, Department of Obstetrics and Gynecology, Patna Medical College and Hospital, Patna, Bihar, India

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Abstract

Aim: Clinico-pathological study to evaluate cervical cytology. **Material & Methods:** The present analytical study entitled was conducted in the Department of Obstetrics and Gynecology, Patna Medical College and Hospital, Patna, Bihar, India over the period of 1 year. The study includes total 100 subjects. **Results:** Mean age of the study population was 39.12 years. Majority belongs to 30-40 years of age group. Vaginal discharge was the major problem reported by the study subjects. There were statistically significant differences in diagnostic efficacy i.e sensitivity and specificity of LBC as compared to CPS for evaluation of cervical cytology. **Conclusions:** The present study concluded that LBC may improve the sample's quality, reduce the number of unsatisfactory smear and increases the diagnostic efficacy in comparison to CPS.

Keywords: Cervical cancer, Conventional Pap smear, Liquid-based cytology, Sensitivity, Specificity.

Introduction

Cervical cancer ranks second in incidence and mortality behind breast cancer in lower HDI settings. About 96,922 new cervical cancer cases are diagnosed annually in India (estimates for 2018). Cervical cancer is the second most common female cancer in women aged 15 to 44 years in India. Rural women are at higher risk of developing cervical cancer as compared to their urban counterparts.[1]

Persistent infection of the cervix with high-risk types of human papillomavirus (HPV) has been established as a necessary (but not sufficient) cause for the development of cervical cancer.[2] HPV is a very common sexually transmitted infection that is usually acquired soon after the initiation of sexual activity.

**Correspondence*

Dr. Sonal,

Junior Resident, Department. of Obstetrics and Gynecology,Patna Medical College and Hospital, Patna, Bihar, India.

E-mail: sonal6630@gmail.com

Most HPV infections clear spontaneously within 1–2 years but persistent infections with high-risk types of HPV (particularly HPV16 and HPV18) may progress to precursors of and ultimately to invasive cervical cancer.[3]

Although the conventional Pap test was responsible for the initial success in reducing the incidence of cervical cancer, however the clinical performance of the technology is not without limitations. A broad range of sensitivity (30%–87%) has been reported for the detection of high-grade lesions by the conventional Pap test. The conventional Pap test was also found to have a false-negative rate of about 14% to 33%, approximately two-thirds of which is due to limitations of sampling or slide preparation. Only a small portion of the sample taken from the patient is transferred to the conventional Pap smear slide; most of it is discarded along with the sampling device. These limitations may lead to inaccuracies and equivocal diagnoses when using this methodology.

To address these shortcomings, new technologies were introduced. In 1996, the ThinPrep® Pap test (Hologic, Inc, Marlborough, MA) became the first LBC approved by the US Food and Drug Administration (FDA). Implementation of this test, which uses LBC for

improved detection of abnormal cervical cells may be partially responsible for a further decline in cervical cancer following the plateau seen with use of the conventional Pap test. In 1999, a second LBC test was developed and approved by the FDA, the SurePath™ Pap test (Becton, Dickinson and Company, Franklin Lakes, NJ). [4,5]

There is a lack of quality studies to compare the test performance of Liquid Based Cytology and Conventional Pap smear in resource limited setup. Hence the present study was undertaken with the aim to evaluate the diagnostic efficacy of liquid based cytology compared with conventional Pap smear.

Materials and methods

The present analytical study entitled was conducted in the Department of Obstetrics and Gynecology, Patna Medical College and Hospital, Patna, Bihar, India over the period of 1 year.

Inclusion Criteria

Patients above 20 years of age coming with following complaints

1. Irregular menses
2. Postcoital bleeding
3. Discharge per vagium
4. Pain lower abdomen.

Exclusion Criteria

1. Sexually not active (nuns, virginal women)
2. Local cervical lesion causing BPV like cervical erosion, polyp, trauma
3. Women who are pregnant.

Ethical approval and Informed consent

The study protocol was reviewed by the Ethical Committee of the Hospital and granted ethical clearance. After explaining the purpose and details of the study, a written informed consent was obtained.

Methodology

The sample will be taken as part of routine hospital screening of patients for cervical epithelial lesions. Patient is made to lie in dorsal position with knees flexed. Speculum is inserted without cleaning the local area with an antiseptic. The samples would be taken with cervix brush which is broom like device and divided into two part (split–sample technique).

First, conventional Pap smear is prepared and immediately alcohol –fixed. After that smear brush will be detached and suspended in Liquid based cytology (LBC) vial containing preservative fluid, which is transferred to the pathology laboratory for further processing. Both liquid based cytology and conventional pap smear will be done on the same patient using this split method.

LBC uses a sedimentation process whereby samples are enriched to remove debris, followed by centrifugation to generate a pellet, a portion /subset of which is then applied to the slide for analysis. The automatic slide preparation is carried out by the Cell solution F50 processor to generate a thin-layer cell sample. Then both LBC smear and conventional Pap smear will be subjected to Papanicolaou staining following which both slide will be analysed by the pathologist.

Statistical analysis

The data was analyzed using SPSS 19 (SPSS Inc. Chicago, IL, USA) Windows software program. Descriptive frequencies were expressed using mean and standard deviation. Sensitivity and specificity were calculated with 95% confidence interval (CI) where relevant.

Table 1: Age distribution of the study population

Age (Years)	Frequency
20-30	21 (21%)
30-40	36 (36%)
40-50	23 (23%)
50-60	15 (15%)
>60	5 (5%)
Total	100
Mean±SD	39.12±3.43

Table 2: distribution according to presenting complaints

Complaints	N (%)
Discharge	42 (42%)
Pelvic Pain	33 (33%)
Vaginal Bleeding	17 (17%)
Postcoital Bleeding	**8 (8%)**

Table 3: Satisfactory smears in LBC as compared to CPS

Variables	LBC	CPS
Satisfactory	92 (92%)	70 (70%)
Unsatisfactory	8 (8%)	30 (30%)

Table 4: Diagnostic Accuracy of LBC and PAP

Variables	LBC	CPS
Sensitivity, % (95% CI)	87.0 (68.78, 97.45)	44.43 (14.66, 60.80)
Specificity, % (95% CI)	81.0 (28.36, 99.49)	73.0 (47.62, 92.73)

Discussion

In the present study majority of the cases were noted between 30-34 years. Similar finding of maximum number of patients presenting to age group of 30 to 35 years were observed by Ranjana H et al.[6]

In present study most common presenting complaint was white discharge per vagina (40%). Similar finding were observed by Sherwani RK et al.[7] they also found that most common presenting complaints in their study was white discharge per vagina, in (42.5%) cases.

Kenneth and Yao, have emphasized the significance of vaginal discharge and its association with neoplastic changes in the cervix.[8] These finding were also observed in our study i.e patients presenting with complaints of white discharge were associated with neoplastic lesions in cervix.

Our finding were found in disagreement with the findings of the study conducted by Karimi-Zarchi M et al who reported most common presenting complaint was post-menopausal bleeding in 30.7%.[9]

In the present study, LBC had more number of satisfactory smears than the conventional PAP smear. According to Monsanego et al.[10] the reason for unsatisfactoriness in conventional PAP smear is thick smear, obscuring blood and inflammatory cells. According to Sherwani et al.[7] in LBC, cytolysis and drying artifact are minimal or absent due to immediate fixation in a liquid fixative and lesser limited factors such as inflammatory cells, blood and mucus.

Our study showed a sensitivity of 44.43% in CPS and 87% in LBC and specificity of 81.0% and 73.0% in CPS and LBC. This was found in agreement with various studies like Sheets et al.[11], Sherman et al.[12], Roberts et al.[13], Papillo et al.[14] and Yeoh et al.[15] which also showed higher sensitivity and specificity for LBC than CPS.

Conclusion

The present study concluded that LBC can be considered superior to conventional pap smear with respect to adequacy of smear, clarity of background and increased sensitivity and specificity. The study confirmed previous reports of decreased numbers of unsatisfactory samples with Liquid based cytology.

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