

A Randomized Comparison of Three Pap Smear Collection Methods

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Abstract

Cervical cancer is a significant health care problem worldwide. Cervical cancer ranks as fourth most common gynecological cancer and is mainly related as a result of the effectiveness of screening. As India being a developing country, an easy and low cost screening procedure with good detection rate will play great role in reducing the mortality and morbidity associated with it, one such method is cytologic examination.

BACKGROUND AND OBJECTIVES:

1. To compare effectiveness of smear quality of endocervical cells by three Papanicolaou smear collecting devices (Ayre's spatula and cytobrush, Ayre's spatula and cotton swab, Ayre's spatula alone)
2. To determine which method produces the high quality smear.
3. To study the prevalence of risk factors of cancer cervix in these women.

METHODS:

The study was done over a period of 1 year for all women who visited the outpatient gynecology clinic at Apollo Hospitals, Aragonda, CHITTOOR DISTRICT, ANDHRA PRADESH, INDIA. A total of 300 women who were sexually active and over 21 years of age were enrolled in the study. A complete history is taken and clinical examination, an examination p/s,p/v examination were performed. One of the Pap smear technique was used to take Pap smear from women. All unmarried women with acute cervical infection, patients after total hysterectomy, women with invasive cancer cervix, patients who have previously been treated for cervical cancer where excluded from study.

RESULTS:

Randomization of comparison of the adequacy of smear collection with cytobrush and Ayre's spatula, cotton swab and Ayre's spatula, and Ayre's spatula alone. The number of adequate, marginal and inadequate smears by three different methods differs significantly. Number of adequate smears was higher in Cyto brush + Spatula (80%), cotton swab + spatula (76%) and Ayre's spatula (65%).

INTERPRETATION AND CONCLUSION:

Use of Cytobrush + Ayre's spatula in routine Pap smear screening is effective in obtaining adequate smears when compared to smears taken with Cotton swab + Ayre's spatula or Ayre's spatula alone. According to present study taking Pap smear with Ayre's spatula alone, as it used to be done before is not a very satisfactory method for collecting endocervical cells. Keeping in mind that ours is a developing country, cotton swab along with Ayre's spatula may be recommended for improving the percentage of adequate smears. However, to reduce the percentage of false negative smears, Cytobrush along with Ayre's spatula should be used.

Keywords- Pap smear-papanicolaou smear, p/v-per vaginal ,p/s –per speculum.

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I. Introduction

Worldwide cervical cancer is a significant health care problem. Cervical cancer ranks as third most common gynecological cancer and is mainly related as a result of the effectiveness of screening program.¹ In developing countries, where health care resources are limited, ca cervix is the second most frequent cause of cancer causing mortality and morbidity¹. As cancer cervix can be treated if detected early, it is very important that all the gynecologists, and other primary health care providers of women be familiar with screening techniques, vaccination programmes and diagnostic procedures and risk factors for cervical cancer and management of preinvasive disease.

According to WHO ,In 2018, an estimated 570 000 women were diagnosed with cervical cancer worldwide and about 311 000 women died from the disease, when diagnosed early cervical cancer can be treated effectively as cervical cancer has a long preinvasive stage which can be treated effectively. With a comprehensive approach to prevent, screen and treat, cervical cancer can be eliminated as a public health problem within a generation.

The burden of cervical cancer falls on the women who lack access to health services, mainly in low- and middle income countries. In India, cervical cancer contributes to approximately 6–29% of all cancers in women

"Cancer cervix is the fourth most common cancer with estimated 1 lakh new cases in 2016 and about 1.04 lakh during 2020 ". The ICMR said, one woman dies of cervical cancer every 8 minutes in India

As India being a developing country an easy and low cost screening procedure with good detection rate will play great role in reducing the mortality and morbidity associated with it, one such method is cytologic examination.

In recent reports concerning the standard of adequacy of the cytologic examination; two main sources have been considered, one related to the adequacy of cell collection by the gynecologists and other connected with the screening by the cytopathologist.

In an attempt to decrease the false negative rates, and insufficient endocervical cells, several new collection techniques have been developed.

II. Materials And Methods:

This prospective study was carried out over 1 year at the Department of Obstetrics and Gynecology in Apollo Hospital, Aragonda, Chittoor district, ANDHRA PRADESH, India. We screened 300 sexually active women who were more than 21 years of age. Women with different complaints, attending the gynecology OPD were included in this study. Those not willing to participate in the study and had a frank growth, had been treated for cervical cancer, post hysterectomy women and pregnant women were excluded from the study. A detailed history was taken using a predetermined proforma that included the chief complaint and the findings of per speculum and vaginal examinations.

Informed written consent was obtained from all women. Patients were placed in the lithotomy position, and a sterile bivalve speculum was inserted into the vagina. The posterior vaginal wall was retracted posteriorly and the anterior vaginal wall anteriorly to allow proper visualization of the cervix and vaginal wall. Samples are collected accordingly.

In the first group of 100 patients, Pap smear was taken with cytobrush and Ayre's spatula. Per speculum examination was done with good source of light. Two smears were taken.

I. From endocervical canal with cytobrush: Cytobrush gently inserted into the endocervical canal, rotated 360 degrees. The sample applied to the slide with stroke of each side of the bristles.

II. From transformation zone with Ayre's spatula, which was rotated circumferentially over the transformation zone. The sample applied to the slide from both sides of the spatula.

• In the second group of 100 patients Pap smear done with cotton swab and Ayre's spatula. Two smears were taken.

I. From endocervical canal with sterile cotton swab dipped in saline. The sample is applied to the slide.

II. From transformation zone (ectocervix) with Ayre's spatula which was rotated circumferentially, the samples applied to the slide.

• In the third group of 100 patients Pap smear done with only Ayre's spatula from ectocervix (single slide).

I The smears are immediately fixed in the fixative 95% ethyl alcohol. Then pelvic examination done.

II The slides were submitted to pathology department for Papanicolaou study. All the smears were evaluated by the same cytopathologist, who was blinded to the sampling device.

Laboratory results were reported according to the new Bethesda System for Reporting Cervical Cytology 2014. The smears showing adequate number of endocervical cells and not obscured by blood or air drying were reported as ADEQUATE smears. The smears showing few endocervical cells, obscured by blood or inflammatory cells were reported as MARGINAL smears. While those showing no endocervical cells, too thick or obscured by blood or inflammatory cells were reported as cells, too thick or obscured by blood or inflammatory cells were reported as INADEQUATE SMEARS.

III. Results

In this study conducted among total 300 persons, the number of adequate, marginal and inadequate smears by three different methods differ significantly. Number of adequate smears was higher in Cyto brush + Spatula (80%), cotton swab + spatula (76%) and Ayre's spatula (65%) table(2).

When pair wise comparison is made with respect to adequacy, it is found that for Cytobrush + Spatula Vs. Spatula, P value is significant (p=0.0124). Whereas Cytobrush + Spatula Vs. Cotton swab + Spatula compared p-value was 0.136, so p-value is not significant. Similarly, Spatula Vs. Cotton swab + Spatula when compared p-value is not significant table (12).

The Prevalence of risk factors associated with cancer cervix in the present study are as a shown below. (table 1)

Figure 2: Socio economic status

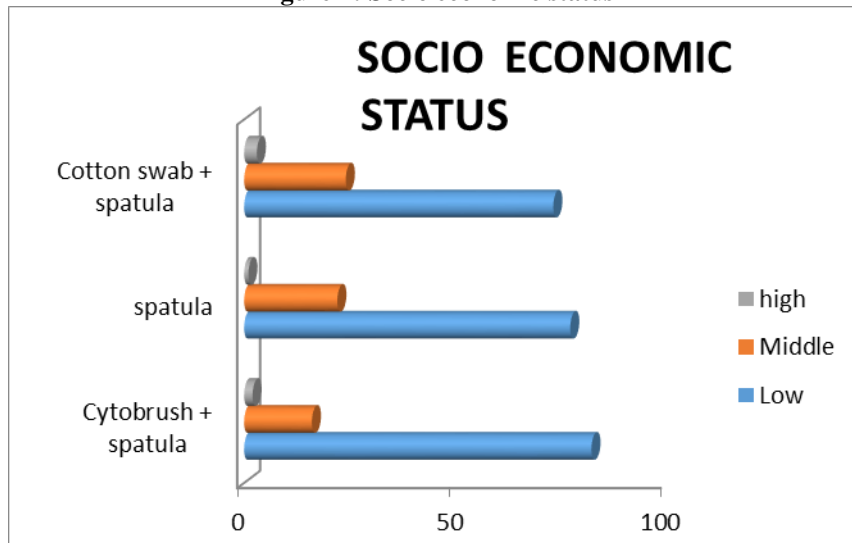


Figure 4: Education status

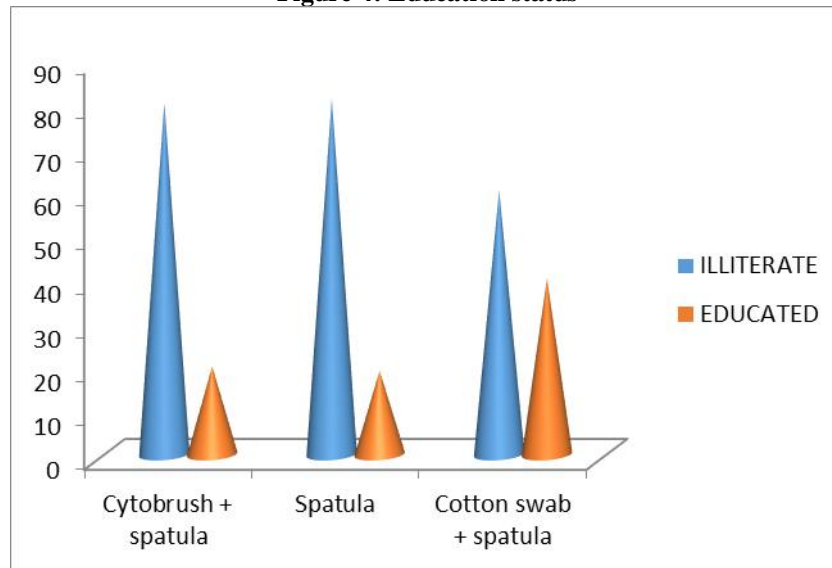


Figure 7: Presenting complaints

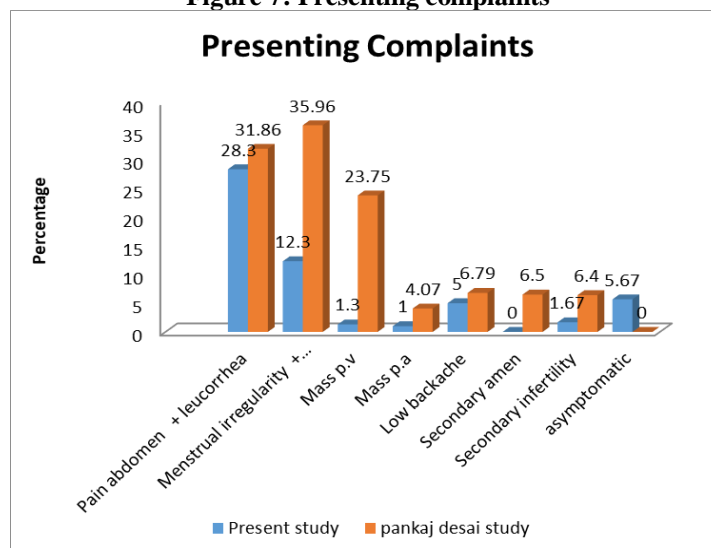


Table 1
Socio demographic characteristics

Age group	
Less than 30	55%
31-40	28.66
41-50	14%
More than 50	2.33
Economic status	
Low	77.3%
Middle	20.67
High	2%
Contraception usage	
Never used	27.3%
Barrier methods	5%
Ocp	5.6%
Iucd	13%
Tubectomy	48%
Parity distribution	
Less than 2	22%
2-4	71%
Greater than 4	7%
Education level	
Illiterate	73.6%
Educated	26.33%
Age of marriage/age of first coitus	
Less than 15	8%
16-20	81%
21-25	9%
26-30	1%
Greater than 31	1%
Complaints	
Asymptomatic	5.67%
Leucorrhea	44%
Pain abdomen and leucohorea	28.3%
Menstrual irregularity	12.3%
Mass pv	1.3%

Mass pa	1%
Low back ache	5%
Secondary infertility	1.67%

Comparison regarding the quality of Pap smear by three collecting methods, it is noted that adequate smear was higher in cytobrush + spatula (80%) and cotton swab + spatula (76%) compared to Ayre’s spatula alone. The number of inadequate smear and marginal smear was less with cytobrush + spatula (10%) and cotton swab + spatula (24%) compared to spatula alone (35%).

Table 2
Comparison of pap smear quality by three collecting methods

Findings	Cytobrush + spatula	Spatula	Cotton swab + spatula	PERCENTAGE
ADEQUATE	80	65	76	73.67%
MARGINAL	10	12	13	11.67%
INADEQUATE	10	23	11	14.67%

$\chi^2 = 12.542$ $p = 0.023$

Since p value is significant in this table, so the three groups differ significantly with respect to the degree of adequacy.

Table 3
Pairwise comparison of three groups with respect to adequacy

	χ^2	P
CYTOBRUSH + SPATULA VS SPATULA	12.213	0.0124*
CYTOBRUSH + SPATULA VS COTTON SWAB + SPATULA	9.52	0.136
COTTON SWAB + SPATULA VS SPATULA	6.473	0.247

* indicate significant value.

When compared pairwise with respect to adequacy, cytobrush + spatula Vs. Spatula P-value is 0.0124 (p-value is significant). There is significant difference with respect to adequacy of cervical smear between groups.

When compared between CytoBrush + Spatula Vs. CottonSwab+ Spatula p-value is 0.0136(p-value is not significant). So there is not significant difference with respect to adequacy.

Similarly when Ayre’s spatula Vs. Cottonswab + Spatula was compared p= value is 0.247 (p- value is not significant). So there is no significant difference with respect to adequacy.

Table 4 Presence of Endocervical Cells

Devices Compared	No. of Smears		No. of Endocervical Cells		Odds ratio	95% CL for population odds ratio
	Device 1	Device 2	Device 1	Device 2		
CytoBrush + Spatula(Device 1) Vs Spatula (Device 2)	100	100	80	65	2.15	1.82, 2.886
CytoBrush + Spatula(Device 1) Vs Cotton Swab Spatula (Device 2)	100	100	80	71`	1.63	1.343, 2.174
Cotton Swab Spatula(Device 1) Vs Spatula (Device 2)	100	100	65	55	1.5194	1.106, 1.624

When cytobrush + spatula(device 1) vs spatula (device 2) is compared the odds ratio is 2.15,so device 1 is 2.15 times more likely to get adequate smears than device 2.

When cytobrush + spatula (device 1) vs cotton swab+ spatula (device 2) is compared the odds ratio is 1.63,so device 1 is 1.63 times more better than device 2.

In Cotton Swab + Spatula (device 1) vs Spatula (device 2) odds ratio is 1.34 here device 1 is superior to device 2. So Ayre’s Spatula is ineffective device for collecting endocervical cells.

Table 5 Detection of Dyskaryosis

Devices Compared	No. of Smears		No. of Dyskaryotic Cells		Odds ratio	95% CL for population odds ratio
	Device 1	Device 2	Device 1	Device 2		
CytoBrush + Spatula(Device 1) Vs Spatula (Device 2)	100	100	20	6	3.916	2.353, 4.99
CytoBrush + Spatula(Device 1) Vs Cotton Swab Spatula (Device 2)	100	100	20	8	2.42	1.772, 3.303
Cotton Swab Spatula(Device 1) Vs Spatula (Device 2)	100	100	10	6	1.42	0.885, 2.263

With respect to detection of abnormal cells cytobrush + spatula (device 1) vs Spatula (device 2) odds ratio is 3.916 so device 1 is 3.916 times more likely to detect abnormal cells than device 2.

With cytobrush + spatula (device 1) vs Cotton Swab + Spatula (device 2) is odds ratio is 2.42, so device 1 is 2.42 times better than device 2.

When Cotton Swab + Spatula (device 1) vs Spatula (device 2) compared, odds ratio is 1.42, so device 1 is 1.42 times better than device 2 in detecting abnormal cells. So Ayre's spatula alone gives lower yield of dyskaryosis.

IV. Discussion

As shown by large studies, the adequacy of a smear judged by the presence of endocervical cells is very important to achieve higher sensitivity. The collecting devices that are better at collecting endocervical cells, were also likely to produce adequate smears. Use of Cytobrush and Cotton swab along with Ayre's spatula, rather than the Ayre's spatula alone may be more expensive. But repetition of inadequate smears increases the cost of screening and generates anxiety for affected women.

It is found that dyskaryosis was more likely to be detected in smears that contained endocervical cells than in those without such cells.

Since cervical adenocarcinoma is preceded by preinvasive diseases, smears that lack endocervical cells do not allow screening for glandular atypia. The Ayre's spatula is ineffective in detection of glandular epithelial neoplasia, whereas collection devices designed to improve endocervical cell collection are likely to detect glandular abnormality.

The number of adequate smear found in the present study is 80% by cytobrush plus spatula as compared to 76% by cotton swab plus Ayre's spatula and 65% by Ayre's spatula along. The difference is statistically significant as shown in table.

To avoid the fallacy in the present study, separate slides were taken for ecto and endocervical smears. Hence, the number of adequate smears were more.

Though there is significant statistical difference between cytobrush + spatula Vs spatula with regard to adequate smears (80% Vs. 65%). There is no significant statistical difference between cytobrush + spatula Vs. cotton swab + spatula. (80% Vs. 76%)

As the use cytobrush is not feasible due to financial constraints for our routine screening of a large number of women, cotton swab along with Ayre's spatula may be recommended for the increase of percentage of adequate smears.

V. Conclusion

The adequacy of a smear judged by the presence of endocervical cells is very important to achieve higher sensitivity. The collecting devices that are better at collecting endocervical cells, were also likely to produce adequate smears. Use of Cytobrush and Cotton swab along with Ayre's spatula, rather than the Ayre's spatula alone may be more expensive. But repetition of inadequate smears increases the cost of screening and generates anxiety for affected women.

- Use of Cytobrush + Ayre's spatula in routine Pap smear screening is effective in obtaining adequate smears when compared to smears taken with Cotton swab + Ayre's spatula or Ayre's spatula alone.
- According to present study taking Pap smear with Ayre's spatula alone, as it used to be done before is not a very satisfactory method for collecting endocervical cells. Keeping in mind that ours is a developing country with financial problems, cotton swab along with Ayre's spatula may be recommended for improving the percentage of adequate smears. However to reduce the percentage of false negative smears, Cytobrush along with Ayre's spatula should be used.
- Assessment of endocervical cells (Bethesda system) should be the way to audit the overall quality of a cervical smear screening program.
- The prevalence of abnormal smears is more among women with risk factors. Since majority of these factors are preventable, women must be given health education regarding legal age of marriage, local hygiene, contraception and sexually transmitted disease.
- The presence of vaginal infection increases the number of inadequate smears and there by increases the false negative reports. Hence treatment of vaginal infections is of utmost importance before taking a Pap smear.

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