



A randomized clinical trial comparing cytobrush - spatula with cotton swab - spatula for Papanicolaou smears

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OBJECTIVE(S) : To compare the quality of smear and the rate of pick up of positive pathology from smears obtained from cytobrush spatula and from cotton swab spatula.

METHOD(S) : Five hundred and fourteen women were randomized into cytobrush with cotton swab group with 257 women in each group. Wooden Ayres spatula was used in both the groups for ectocervical sampling. Cytobrush or cotton swab was used for endocervical sampling. All the slides were reported following the Bethesda system (1991) of reporting.

RESULTS : Both the groups were matched with respect to age, parity, age at menarche, years of married life and years after last delivery. Significantly more number of satisfactory smears were seen in cytobrush group. Inadequate smears in the form of absent endocervical cells occurred in 3.12% patients of the cytobrush group as compared to 8.56% in the cotton swab group, the difference was statistically significant ($P = 0.0082$). Positive pathology was seen in 11.11% of patients in the cytobrush group as compared to 6.45% in the cotton swab group. Although this difference is not statistically significant, there is almost a 5% increase in pick up rate with the cytobrush.

CONCLUSION(S): With cytobrush spatula there is an increase in the percentage of satisfactory smears. Inadequate smears in the form of absent endocervical cells occurred less frequently with cytobrush. The pick up rate of positive pathology was more with cytobrush.

Key words : cytobrush, cotton swab, Ayres spatula, smear quality, Papanicolou smear

Introduction

Cervical cancer is the third most common cancer in the world and the second most common cancer and leading cause of death from cancer in women in developing countries, where 80% of new cases occur. Every year cervical cancer affects 3,70,000 women worldwide and kills 1,90,000¹ with almost 1,25,000 new cases of cervical cancer in India alone². The regions of highest prevalence of invasive cervical cancer include developing countries in Latin America, Asia, Southeast Asia, Africa, and the Caribbean. Since the cost of screening women at 5-year intervals and the health services rendered after a risk factor is established, is lesser than that of treating or palliating

cancers, should we forgo screening²? The greatest limitation of the conventional Pap smear is the potential for sampling and preparation errors, which can occur when the cells on the slide are not representative of the condition of the cervix. Only a fraction of the epithelial cells collected on the sampling device are actually deposited on the slide. Few studies have reported that almost 90% of false negatives were attributed to sampling and preparation errors. Theoretically, endocervical elements should be excellent markers of accurate sampling of the squamo-columnar junction, resulting in increased sensitivity in screening for cervical carcinoma. Several studies also provide indirect support for the value of endocervical elements by decreased false negative rates for Pap smears taken from endocervical or ectocervical areas compared to those from vaginal pool aspirates. Cytobrush is being recently marketed in India, but no randomized clinical trial has been done to prove its effectiveness in our scenario.

This study was designed to test whether the use of cytobrush improves sample quality with subsequent better pick up rate

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of atypias than those with the use of cotton swab as is the routine practice in our institution.

Material and Methods

This randomized clinical trial was conducted from August 2002 to September 2003 at the district hospital in Belgaum and at our hospital after approval from the local Human Experimentation Ethics committee. All women above 18 years of age attending gynecological outpatient during the study period were eligible for the study. With the research hypothesis that by using cytobrush, pick up rate will increase by 10%, the power of the study being 80%, the sample size was calculated to 514 with 257 in each group. Women having active vaginal bleeding or menstruation, excessive vaginal discharge, insertion of vaginal cream / pessary within 24 hours, having undergone within one month hysterectomy or procedures like curettage, pregnancy termination, cervical biopsy, conization, or cryotherapy and women not willing or unable to give consent were excluded from the study. The 514 women were randomized into two groups of 257 each by envelope method; cytobrush group and cotton swab group.

The woman was put on the examination table in dorsal position and speculum was introduced into the vagina, exposing the cervix. Wooden Ayres spatula was used in both the groups. Blunt end of the Ayres spatula was introduced into the posterior fornix and the scraped material obtained was then spread on a slide. The pointed end of the Ayres spatula was introduced into the cervical os and rotated 360°, sampling the whole ectocervix. Materials obtained were then spread over the glass slide and fixed immediately with ethyl alcohol in the Koplins jar.

In the cytobrush group, a cytobrush was introduced into the cervical os till few bristles were seen outside the cervical os. The brush was rotated 180°, and then the brush was rolled over on a glass slide. Specimen was fixed immediately.

In the cotton swab group, a cotton swab was introduced into the cervical os, and rotated 360°. The swab was then smeared on a glass slide and the smear fixed.

After fixing the slides, they were sent to the Pathology Department, where they were stained with Pap stain. A single pathologist, who was blinded to the mode of collection, read all the slides following the Bethesda system (1991) of reporting, where smear adequacy was reported as satisfactory, satisfactory but limited by endocervical cells and unsatisfactory. General categorization of the diagnosis was made into benign changes associated with infection, benign reactive changes associated with inflammation or

atrophy, epithelial cell abnormalities like atypical squamous cells of undetermined significance (ASCUS), low grade squamous intraepithelial lesions (LSIL), high grade squamous intraepithelial lesions (HSIL), squamous cell carcinoma, and atypical glandular cells of undetermined significance (AGCUS).

The statistical analysis was done using 'Z' test and Chi-square test. The results were represented as mean and standard deviation, and in percentages.

Results

As shown in Table 1, both the groups were well balanced in demographic features. The groups were matched with respect to age, parity, age at menarche, years of married life and years after last delivery, ($P > 0.005$).

Table 1. Group characteristics

	Cytobrush (n=257)		Cotton swab (n=257)		P value
	(Mean)	(Range)	(Mean)	(Range)	
Age	37.86	(18-75)	37.44	(18-70)	0.6744
Parity	2.52	(0-7)	2.56	(0-7)	0.7718
Age at menarche	13.09	(11.15)	13.11	(0-16)	0.6825
Married life (years)	18.74	(0-55)	18.01	(1-50)	0.4412
Years after last delivery	10.92	(0-40)	10.56	(0-40)	0.6242

As shown in Table 2, there was a significant difference ($P = 0.0046$) in Papanicolaou smear quality between the two groups, 244 (94.94%) of 257 women had a satisfactory smear in the cytobrush group as compared to 226 (87.94%) in the cotton swab group. Inadequate smears in the form of absent endocervical cells occurred in 8 (3.12%) women of the cytobrush group as compared to 22 (8.56%) in the cotton swab group, this difference was also statistically significant ($P = 0.0082$). Thus in the cytobrush group, pick up rate of endocervical cells was more. There was no statistically significant difference between the groups in the number of slides that could not be read and needed repeat smears ($P = 0.2802$).

Table 2. Smear quality

	Cytobrush (n=257)		Cotton swab (n=257)		P value
	No.	Percent	No.	Percent	
Satisfactory	244	94.94	226	87.94	0.0046
Absent endocervical cells	8	3.12	22	8.56	0.0082
Repeat need for smear	5	1.95	9	3.50	0.2802

As shown in Table 3, 30.95% of the smears were within normal limits in the cytobrush group compared to 23.39% in the cotton swab group. Benign changes associated with infection accounted for 12.3% in the cytobrush group compared to 19.76% in the cotton swab group. Benign smears with reactive changes accounted for 45.63% in the cytobrush group compared to 50.40% in the cotton swab group. Epithelial changes in the form of atypical squamous cells of undetermined significance occurred in 1.19% of the cytobrush group compared to 0.4% in the cotton swab group. There was one (0.4%) smear that had atypical glandular cells of undetermined significance in the cytobrush group and none in the cotton swab group. LSIL were seen in 5.16% of smears in the cytobrush group compared to 4.03% in the cotton swab group. HSIL were seen in 4.36% of the smears in the cytobrush group compared to 2.02% in the cotton swab group.

Table 3. Cytologic diagnosis.

Benign changes	Cytobrush (n=252)		Cotton Swab (n=248)	
	No.	Percent	No.	Percent
Normal limit	78	30.95	58	23.39
Benign with infection	31	12.3	49	19.76
Benign with reactive changes	115	45.63	125	50.40
Epithelial changes				
ASCUS	3	1.19	1	0.4
AGCUS	1	0.4	0	0
LSIL	13	5.16	10	4.03
HSIL	11	4.36	5	2.02
Positive cytology	28 ^a	11.11	16 ^a	6.45

^a P = 0.065

Positive pathology was seen in 28 women (11.11%) in the cytobrush group as compared to 16 (6.45%) in the cotton swab group. Although this is not statistically significant (P = 0.065) there is almost 5% increase in the pick-up rate with the cytobrush.

Discussion

Numerous efforts have been made comparing different cell sampling devices in order to find a cell sampling device or

combination of two cell sampling devices that would yield optimal cytologic results.

In our comparative study we found statistically significantly more number of satisfactory smears (P = 0.0046) with cytobrush (94.94%) compared to those with cotton swab (87.94%) (Table 2). Koonings et al³ found 63% satisfactory smears with cytobrush compared to 57% with cotton swab. McCord et al⁴ also found 84.5% satisfactory smears with cytobrush compared to 83.5% with cotton swab; the difference was not statistically significant. Neinstein et al⁵ in their study comparing cytobrush with cotton swab found that 79% of the specimens with cytobrush showed good cellular yield compared to 50% with cotton swab⁵.

In our study inadequate smears in the form of absent endocervical cells occurred in 8 (3.12%) women of the cytobrush group as compared to 22 (8.56%) of the cotton swab group; this was statistically significant (P = 0.0082) (Table II). Koonings et al³ had 38% inadequate smears in cotton swab group and 28% in cytobrush group. Absence of endocervical cells were noted in 40% of these smears in cotton swab group compared to 20% in cytobrush group, which was statistically significant. They concluded that cytobrush - spatula is superior to the cotton swab - spatula in obtaining endocervical cells.

McCord et al⁴ comparing four sampling methods, found no statistical difference among the groups for non-pregnant patients. But for pregnant patients smear quality was improved with both cytobrush-spatula and Bayne Pap brush when compared to cotton swab-spatula. Cotton swab-spatula had fewer endocervical cells (16.5%) than the cytobrush-spatula (7.2%).

Neinstein et al⁵ found that 68% of the smears in cytobrush group had presence of endocervical cells compared to 56% in cotton swab group. Their study concluded that cytobrush has some impact on improving adequacy rates for Pap smears.

Pretorius et al⁶ concluded that the presence of endocervical cells increased the rate of detecting any pathology. In our study, positive pathology was seen in 28 (11.11%) women in the cytobrush group as compared to 16 (6.45%) in the cotton swab group.

Pretorius et al⁶ found that positive pathology accounted for 3.2% in the cytobrush group compared to 3% in the cotton swab group which was not statistically significant, but they found that the rate of positive pathology was significantly more in smears where endocervical cells were present.

Our study demonstrates that the cytobrush-spatula is more efficient in obtaining columnar endocervical cells than the cotton swab-spatula method, resulting in a higher pickup of positive pathology probably because of better sampling of transformation zone. Cytobrush is more expensive than cotton swab and the cost benefit ratio of cytobrush use for large screening programs needs evaluation.

Cytobrush is an easy instrument to use and is well tolerated by patients. It appears to be more effective than cotton swab in obtaining evaluable specimens and is far superior to the cotton swab in its ability to obtain endocervical cells. Another advantage of the cytobrush is its ability to collapse to 1mm, allowing it to be passed into a stenotic cervical os. This may suggest its preferential use in postmenopausal women³. The cost effectiveness has to be worked out in a larger trial before implementing it in screening programs.

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