Comparison of Pap Smear Quality with Anatomical Spatula and Convenience (Spatula-CytoBrush) Methods: A Single Blind Clinical Trial

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Abstract

Objectives: The Papanicolaou smear is a standard test for cervical cancer screening; however, the most important challenge is high false negative results. Several factors contribute to this problem and one of the most important is inappropriate sampling. The aim of this study was to compare the quality of smears obtained by either an anatomical spatula or a spatula-cyto brush. Methods: One hundred married women participated in this single blind clinical trial. After all participants were interviewed, two samples were obtained from each: one with a spatula-cyto brush and another with an anatomical spatula. Slides were prepared and assessed by two pathologists for kappa coefficient analysis. Results: Cell adequacy was 96.1% in anatomical spatula method and 91.2% in spatula-cyto brush method (p=0.016). The rates for endocervical cells and metaplasia cells were 70.6% and 24.5%, respectively, with the anatomical spatula method and 69.6% and 24.5% using a spatula-cyto brush (p<0.001). No one reported pain and the amount of bleeding was 38.2% in both methods (p>0.05). In addition, there were no statistically significant differences regarding infection and inflammatory reactions (p>0.05). Conclusion: Based on the findings of this study, the results of sampling with anatomical spatula were more acceptable and better than those of spatula-cyto brush sampling.

Keywords: Pap smear - anatomical spatula - spatula-cyto brush - sampling

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Introduction

Sixty years ago, cervical cancer was a cause of death in women. Mortality has reduced by 50% since then, and this reduction has been credited to the development and use of a cytologic screening tool known as the Papanicolaou smear (Barbara & Bauman, 1993; George et al., 2004). Unfortunately, using traditional methods, false negative results are high (56% cases) due to the lack of enough endocervical cells. As a result of false negative reports, diseases are not diagnosed early and lead patients to advanced malignancy which eventually bring about the increase in the morbidity and mortality rates (Aghajani et al., 2006).

Several factors contribute to the incidence of false negative cases. These factors include sampling error (inappropriate and insufficient sample), the use of inappropriate tools for sampling, and error laboratory reports (Berek, 2007). Therefore, application of correct tool to prepare the Papanicolaou smear, reduce false negative results, and prevent insufficient sampling should be taken into account.

Since 1991, Szalay spatula was introduced to the world (Rammou-Kinia et al., 1991) with special advantages as follows: (a) reduce in the number of false negative results, because making enough sample from endocervix, exocervix and transitional zone is possible; (b) sampling with such device is very easy and sampling is done simultaneously from endo- and exo-cervix, instead of two stage sampling; (c) spreading samples on slides is very comfortable and can be done in one step, instead of pulling spatula twice on slides; (d) the transmission of the infection to women is less due to one step sampling; (e) anatomical spatula is similar to cervix canal and is easy to use in females with longer cervical canal; (f) because, it has slender tab; (g) reduce in cervical bleeding in women with fragile cervix tissue because of one step sampling; (h) the pathology report is more accurate because of less bloody samples and enough obtained cells on the slide spread on a thin layer (Negri et al., 2003).

Therefore, in this study, we determined to compare the quality of slides after sampling with both anatomical spatula and spatula-cyto brush. Anatomical spatula used in this study was the same as Szalay spatula that embodies the above-mentioned advantages. We hypothesized that this tool would be suitable for Papanicolaou smear, might have economical benefits and could help find hidden cases of cervical malignancy.

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Materials and Methods

The present study was a single blind clinical trial in which 100 women were recruited at the outpatient academic medical center in Zeynabiyeh Hospital in Shiraz-Iran, during the year 2009. The Medical Research Ethics Committee of Shiraz University of Medical Sciences approved the trial protocol prior to study initiation. Informed consent was obtained through the provision of an information leaflet coupled with verbal reassurance that participation was entirely voluntary. In addition all participants were assured of confidentiality and anonymity.

We used two different types of tools in order to take samples from cervix. The anatomica spatula is a wooden device whose length is 220 mm and its width is 5 mm. This spatula has a long narrow arm with a length of 1/7 cm for sampling from endocervix, a shoulder and a completely flat curve for exocervical sampling whose anatomic structure is more compatible with women cervix. The arm of the spatula is put into the canal whilst its shoulder is placed on the 3 o’clock position of the exocervix. With gentle pressure, the spatula is rotated in a clockwise direction through 360 degrees. Once the cells are spread on the slide, they are parallel to the slide edges and the slide is immediately fixed in a distance about 30 cm.

In the common method of sampling using cytobrush spatula, first the brush is put into the cervix and is rotated for 360 degrees in clockwise. Then, the upper slide is moved around on slides; so that, the brush is drawn on the glass. Then spatula wide head is put on exocervix and the 360 degrees rotation sample is taken from exocervix, pulled in the lower part of the slide and is fixed between 30 cm with a fixator.

Using convenience sampling, women aged 18 and older, attending regular cervical cancer screenings were enrolled in the study. Their demographic characteristics were gathered before taking cervical samples.

The following procedure was designed in order to take two cervical samples from each participant:

First, every participant lied down on a gynecology bed in lithotomy position and vaginal speculum was inserted. A sterile cotton swab was used to wipe excessive cervical discharge and mucosa. Then, cervical smears (from both endo- and exo-cervix) were taken by the two tools and the order of sampling in each subject was as follows: first, cytobrush spatula, then, anatomical spatula (for the first participant), first anatomical spatula, then cytobrush spatula (for the second participants). We followed this pattern alternately until all participants had two samples whose order was opposite, either cytobrush spatula-anatomical spatula or anatomical spatula-cytobrush spatula. The slides were coded by the researcher as 1a, 1b (for the first participant), 2a, 2b (for the second participant), 3a, 3b (for the third participant), etc.

The researcher was the only person who was in charge of taking samples and knew the codes. Next, 200 slides were sent out to laboratory and they were assessed by two pathologist who were not aware of the order of sampling and did not know which sample was related to which tool. The results were reported based on the Bethesda system.

Data analysis was carried out using SPSS version 15 for Windows. We used descriptive statistics in order to summarize demographic data. The kappa was used to compare the results of the two sampling tools.

Results

In this study, no cell sample was returned from laboratory, because all slides were satisfactory. The mean age of women was 30.58±8.4 years (rang, 16-55 years). In the current study, most prevalent contraceptives used by participants were OCP (29.4%), IUD (22.5%), Condom (20.8%), and Vasectomy (10%) and Tubectomy (10%).

Smears obtained by anatomical spatula had better cellular adequacy; although, there was no statistically significant difference between methods (96.1% in anatomical spatula method; 91.2% in spatula-cytobrush) (p = 0.16) (Table 1).

In Anatomical method the percentage of endocervical cells and metaplastic cells were similar to those of spatula-cytobrush, and their differences were not significant (p 0.06), Table 2.

The rates of discovered cellular infection and inflammation were similar in both methods (p>0.05 between methods). Almost 6% of participant were infected with Candida Albicans (p>0.05 between methods), and 38% of samples were diagnosed with inflammation in each method (p>0.05 between methods) (Table 3).

Although slides prepared with anatomical spatula had...
Table 1. Comparison of the Distribution and Adequacy of Cellular Anatomical Spatula and Spatula-Cytobrush

<table>
<thead>
<tr>
<th>p-value</th>
<th>Cytobrush spatula</th>
<th>Anatomical spatula</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Percent</td>
<td>Number</td>
<td>Percent</td>
</tr>
<tr>
<td>0.16</td>
<td>91.2</td>
<td>93</td>
<td>96.1</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>2</td>
<td>6.9</td>
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</table>

Table 2. Distribution of Endocervical Cells in the Two Methods of Sampling

<table>
<thead>
<tr>
<th></th>
<th>Anatomical spatula</th>
<th>Spatula-cytobrush</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Endocervical cells</td>
<td>Number</td>
<td>Percent</td>
<td>Number</td>
</tr>
<tr>
<td></td>
<td>72</td>
<td>70.6</td>
<td>71</td>
</tr>
<tr>
<td>Metaplastic cells</td>
<td>25</td>
<td>24.5</td>
<td>25</td>
</tr>
</tbody>
</table>

Table 3. Distribution of Cellular Infection and Inflammations in Both Methods of Sampling

<table>
<thead>
<tr>
<th>Cellular phenomenon</th>
<th>Anatomical spatula</th>
<th>Spatula-cytobrush</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>No infection</td>
<td>Number</td>
<td>Percent</td>
<td>Number</td>
</tr>
<tr>
<td></td>
<td>91</td>
<td>89.2</td>
<td>90</td>
</tr>
<tr>
<td>Infection</td>
<td>6</td>
<td>5.9</td>
<td>7</td>
</tr>
<tr>
<td>No inflammation</td>
<td>56</td>
<td>54.9</td>
<td>57</td>
</tr>
<tr>
<td>Inflammation</td>
<td>39</td>
<td>38.2</td>
<td>39</td>
</tr>
</tbody>
</table>

Figure 1. Resolution of Cells in Sampling with Anatomical Spatula

Figure 2. Resolution of Cells in Sampling with Spatula-cytobrush

Figure 3. The Slide Stained with Blood in Sampling with Anatomical Spatula

Figure 4. The Slide Stained with Blood in Sampling with Spatula-cytobrush

Discussion

Cervical cancer starts invading from cervical transitional zone. In order to take appropriate sample from the transitional zone cells, health care providers need appropriate sampling device. The results of the current study demonstrated that similar results can be obtained while sampling by anatomical spatula as well as spatula–cytobrush. It was shown that anatomical spatula enable physicians to take enough endocervix cylindrical cells, exocervix squamous cell, and transitional zone cell by using an easy one-step technique.

In a meta-analysis study, cytobrush in accompany with spatula was reported to be the most effective Pap smear device which is effective in creating high-quality smears and detecting cervical dysplasia (Barbara & Bauman, 1993). It has also been shown in previous studies that spatula-cytobrush can be known as the best tool to detect pre-cancerous cells is using (Valenzuela et al., 2001).

Another meta-analysis reported that using cytobrush alone could not be a suitable method of sampling from exocevical cells and it should be used along with sharp spatula (Szalay spatula) (Buntinx & Brouwers, 1996).

In the current trial, both anatomical spatula and spatula-cytobrush demonstrated similar results. We showed that anatomical spatula can be used alone in order to prepare...
cervical cell samples. Most studies have reported that smears, which lack endocervical cells, are more likely to carry false negative results. Therefore, in order to minimize the number of false negative results, the slides must contain enough squamous cells, transitional zone cells and endocervical cells (Lawrence et al., 1992; Taheri Panah et al., 2006). In the current study, 70.6% of smears obtained with Anatomical spatula contained endocervical cells and 69.6% of smear taken with spatula-cytobrush incorporated endocervical cells, which shows that the possibility of false negative results is less in sampling with anatomical spatula than that of spatula-cytobrush.

In their study, Canon et al. compared the results of two methods of sampling with either cervical brush or plastic Szalay spatula. They stated that the rates of endocervical cells were 90.7% and 98.5% in either method, respectively. Since smears containing endocervical cells are more likely to determine early stages of cervical cancers, Szalay spatula provided more endocervical cells and was more valuable in preparing better sample (Cannon & Blythe, 1993).

In addition, the study conducted by Rammou-Kinia et al. demonstrated that the rate of endocervical cells in slides prepared with Szalay spatula were higher and false negative results were less. Moreover, they mentioned that inflammatory lesions and cervical epithelial neoplasia within squamous metaplasia were more likely to be detected by means of this tool. The results of their research also showed that Szalay spatula was very easy to use and was able to take enough cells from endo- and exo-cervix. Furthermore, they demonstrated that the amount of bleeding was very low in this technique and cell adequacy was very high while using Szalay spatula (Rammou-Kinia et al., 1991).

In their study, George et al. stated that slides that had been fixed immediately after sampling, had less false negative results than those which had been exposed to the air and dried before fixation (George et al., 2004). In the present study, we were able to fix smears taken by anatomical spatula faster than those obtained by spatula-cytobrush; because, anatomical spatula was able to take both endo- and exo-cervical cells at the same time. After transferring cells to the slides, we did not have to take another sample and we could fix smears immediately. Therefore, there were less false negative results in smears taken by this device.

In another study, Noel explained that, in women with cervical stenosis, spatula-cytobrush was a suitable device in order to collect samples from endocervix. In that study, spatula-cytobrush was compared with sharp spatula and it was shown that in 64.8% of cases spatula-cytobrush was able to take cells endocervical (p<0.001 between the two methods) (Noel, 1989). The results of the present study showed that both anatomical spatula and spatula-cytobrush was able to take endocervical cells in 70.6% and 69.6% of cases, respectively (p>0.05). These results show that anatomical spatula is compatible with anatomy of women’s cervix and is able to take enough endocervical cells.

Regarding the results of the current study, anatomical spatula can be considered as a cheap and proper technique which can be used instead of spatula-cytobrush. We find it fair to conclude that our study had enough strength, because, we used both methods of sampling in each participants; nevertheless, we are not to generalize the results of our study to a large population. Further studies with larger sample size, different participants, and random sampling are needed to make definite decision on the usage of this device as the most proper tools for Pap smear.

In conclusion, based on the findings of this study, cytology results from sampling with both anatomical spatula and spatula-cytobrush were similar, although, anatomical spatula was easier to use. Anatomical spatula was also associated with less pain and bleeding and can be used instead of spatula-cytobrush.

Acknowledgments

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References


