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Effect of Cervical Wiping with Sterile Cotton on the Quality of Pap-smear

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Abstract

***Background*:** There are conflicting reports about the effect of wiping cervix with cotton on Pap-smear results. Therefore, we aimed to do a research about this subject.
***Materials and Methods*:** 234 eligible women attended to have Pap-smear at an educational hospital in Rasht, Iran, from July to September 2011, were allocated by block randomization into two groups. In the intervention group, we cleaned cervix with a sterile cotton rotating 360 degrees and obtained samples using spatula for exocervix and cytobrush for endocervix. This method was performed without cleaning the cervix on the control group. Data collection, vulvovaginal examination, laboratory assay were done by investigators masked to the group allocation. Participants were also blind. The data were analyzed using logistic regression in SPSS-13.
***Results*:** Rate of sufficient endocervical cell of the slides in the intervention group was significantly higher than in the control group (70.3% vs. 57.8%, p=0.03). In the intervention group 42.4% of the slides were satisfactory and 57.6% had limited quality for interpretation. These figures in the control group were 37.1% and 62.9%, respectively. This difference was not statistically significant. Also, there was no significant difference between the groups on rate of slides with inadequacy of squamous cells and obscuring 75% or more of the slides with inflammatory exudate or blood (p>0.05).
***Conclusion*:** There were no significant differences between the groups on some quality indicators of the smears. However, frequency of smears with sufficient endocervical cells was higher in the group with cervical wipping. Therefore, it is recommended to clean cervix before obtaining the smears.

Introduction

Cervical cancer is the second most common cancer among women worldwide and is an important health problem for women in developing countries [1, 2]. Its reported global incidence and mortality was 15.3 and 7.8 per 100,000, respectively, in 2008 [3]. More than 80-85% of the cases occur in developing countries [3, 4]. Its exact incidence and mortality rate are unknown in Iran. However, 643 [2] to 1118 [1] recognized cases and 286 [2] to 581 [1] deaths per year due to cervical cancer have been reported in Iran.

This cancer can be prevented because of the long pre-invasive period [5]. The Papanicolaou (Pap) smear is one of the best screening tests for cervical cancer [6-8]. Its reported false negative rate is between 1.5% and 55%. This difference could be due to different sampling methods and interpretation errors [7].

Inadequate cervical smears need re-sampling. This repeat causes distress and inconvenience for women and also imposes additional costs on health systems [7]. Common causes of inadequate smear is masking of epithelial cell detail by inflammation and mucosa and/or inadequate epithelial cells [9-11]. Therefore, efforts to improve the quality of this smear have a very important role in the cancer diagnosis. Better quality smears reduce false negative and inadequate smear rates [12].

Use of cytobrush and spatula has been recommended to enhance quality of Pap-smear [7]. Also, liquid based Pap-smears have been brought up to eliminate factors such as obscuring elements and poor fixation. However, this method has high cost [9] and some studies have not shown its any advantage over conventional Pap-smears for detection of cancerous lesions [13-17].

Some have recommended that removing cervical mucus before collecting the sample and using appropriate sampling device has similar sensitivity and specimen adequacy as liquid-based technique [18]. Use of the swab before taking Pap-smear is not recommended in the European guidelines [18], while it is recommended by the British Columbia Cancer Agency [8].

There are inadequate studies in this field that whether cleaning the cervix prior obtaining Pap-smear improves its quality [9]. This strategy is recommended in some articles [19, 20], while others did not find any improvement in the quality of Pap-smear using it [21-24]. Therefore, we aimed to determine effect of cervical wiping with cotton on quality of Pap-smear.

Materials and Methods

This randomized controlled study was carried out at the Al-Zahra educational hospital, Rasht, Iran, from July to September 2011. All married women in reproductive age requesting Pap-smear were candidates for inclusion in the study. They were not enrolled into the study in case of current pregnancy; delivery in the past 6 weeks; menopause; vaginal bleeding; endocervical polyp; a history of the intraepithelial disease or cervical cancer, radiation or hysterectomy; having sexual intercourse, douching, use of spermicidal jelly, vaginal cream or lubricant, colposcopy with acetic acid within 24 hours; or having any cervical surgery in the past 3 months. Reason for these exclusion criteria was their possible interference with the Pap-smear [19, 25].

We used STATA-9.2 software to calculate the sample size. Sample size was determined based on primary information obtained from the study by Kotaska et al. [20]. For an expected absolute difference of 0.15 between intervention and control groups in quality of the smears (p_1=0.74, p_2=0.89) and considering α=0.05 and a power of 80%, the sample size was computed as 117 for each study group.

The randomization sequence was determined using a computer random number generator. We used block randomization with block sizes 4 and 6 to allocate the enrolled subjects into the two groups. To hide the sequence, we used sealed opaque consecutively numbered envelopes prepared by a person not involved in the recruitment, data collection and analysis.

The first part of questionnaire used for data collection was completed by interview before examination. It included demographic and reproductive characteristics (i.e, age, age of marriage, level of education, job, income, gravid and parity, contraception method used, last menstrual period (LMP), time of last Pap-smear).

The second part of the questionnaire contained questions about the appearance of cervix in terms of its erythema, the amount of mucosa on the cervix, inflammation of the lining of the vagina, strawberry cervix, cervicitis. It was completed by observation after placement of women in lithotomy position and inserting a speculum. Then, the participant's group was determined by opening the envelopes.

For Pap-smear preparation in the intervention group, we cleaned cervix with a sterile dry cotton rotating 360 degrees until no mucosa was observed and obtained samples from exocervix with spatula and from endocervix with cytobrush, and transferred them to a one glass slide. This method was performed without cleaning the cervix on the control group, regardless of the amount of mucosa or discharge present on the cervix. A meta-analysis by Hirsch et al. showed that combination of spatula and cytobrush is the best combination [7]. Conventional method recommended by the European guideline used for smear preparation [18]. The slides were fixed immediately by fixation spray. The slides with coded questionnaires were sent to the hospital pathology lab.

It was also recorded whether or not the patient was bleeding while taking the Pap-smear. The third part of questionnaire included questions about quality of Pap-smear (satisfactory, limited quality for interpretation, unsatisfactory), whether a repeat Pap-smear was required, whether sufficient squamous cells were in smear, whether sufficient endocervical cells were in smear, and whether over 75% of the smear was covered by inflammatory cells. It was completed by a pathologist based on his interpretation of the slides. The pathologist was blinded to the group assignment and clinical presentation of the participants.

Interpretation of Pap-smear was reported according to the 2001 Bethesda system [25]. The slides were reported "unsatisfactory", when more than 75% of the epithelial cells on slide were obscured with blood or inflammation exudates [25] or cells in the specimen were not enough for interpretation [26]. Slides were deemed to be of "limited quality for interpretation" when there were adequate squamous cells with no endocervical or metaplastic cells (showing not taking the specimen from the transitional area) or smears were covered with partially obscuring blood or inflammation exudates (50-75% of the slide surface) [25, 26]. The slides were reported "satisfactory" at the presence of an estimated minimum of 8,000-12,000 well-preserved and well-visualized squamous epithelial cells and presence of at least 10 well preserved endocervical or squamous metaplastic cells [26-28].

All interviews, clinical examinations, and samplings were performed by one person trained in this field (a MSc midwifery student from the research team).

Content validity of the questionnaire was determined using comments of 8 midwives, 2 gynecologists and 2 pathologists. To determine the reliability of Pap-smear interpretations, we sent 20 Pap-smear samples (10 from the control group and 10 from the intervention group) to two different pathologists. Correlation coefficient was 1 in terms of sufficient number of squamous cells, obscuring more than 75% of slide surface, and the need for re-sampling, and 0.7 in terms of satisfactory slides and a sufficient number of endocervical cells. We analysed data using SPSS-13. Logistic regression test was used to compare the two groups in terms of the quality components of Pap smear. Informed consent was obtained from all participants after explaining the purpose and methods of the study. The study was approved by the Ethics Committee at Tabriz University of Medical Sciences.

Results

During the course of the study, 246 patients were consecutively approached to take part in the study, of which 10 were not eligible and 2 patients refused to participate. The 234 eligible individuals were randomly allocated into the groups (i.e., 118 in the swab group and 116 in the no swab group).There were no statistically significant difference between the groups in terms of most baseline characteristics, except age (p=0.04).

The withdrawal was the most common contraception method in the both groups. At the time of Pap-smear, about one third of the women in the both groups were in their 10th to 18th day of menstrual period (the best period for the sampling [28]). A slightly more than one third (37.6%) of the women reported having had a Pap-smear within three years (Table 1). There were no significant statistically difference between the groups in terms of any of the characteristics, except age. There was no significant difference between the two groups in terms of the redness of the cervix, vulva and vagina; the amount of mucosa on the cervix; inflammation of the lining of the vagina; strawberry cervix and cervicitis (Table 2).

Table 1. Baseline characteristics of the participants

Characteristics	Intervention N=118	Control N=116
Age (years), Mean±SD	33.8 ± 8.7	36.7 ± 8.4
Age at the time of marriage (years)		
Mean±SD	19.9 ± 4.1	20.0 ± 5.1
Employed N(%)	11 (9.3)	14 (12.1)
Educational level		
Illiterate N(%)	17 (14.4)	21 (18.1)
1-5 years N(%)	24 (20.3)	24 (20.7)
6-8 years N(%)	22 (18.6)	27 (23.3)
9 years or higher N(%)	55 (46.6)	44 (37.9)
Parity		
0-1 N(%)	63 (53.4)	50 (43.1)
2-3 N(%)	44 (37.3)	53 (45.7)
≥4 N(%)	11 (9.3)	13 (11.2)
Mean ±SD	1.7 ± 1.5	2.0 ± 1.5
Last menstrual period		
4-9 days ago N(%)	17 (14.4)	9 (7.8)
10-18 days ago N(%)	37 (31.4)	41 (35.3)
≥19 days ago N(%)	34 (28.8)	23 (27.6)
Don't know N(%)	30 (25.4)	34 (29.3)
Contraception method used		
Hormonal methods N(%)	16 (13.6)	21 (18.1)
Condom N(%)	8 (6.8)	17 (14.7)
IUD N(%)	5 (4.2)	3 (2.6)
Male or female sterilization N(%)	14 (11.9)	18 (15.5)
Withdrawal N(%)	65 (55.1)	46 (39.7)
Others N(%)	10 (8.5)	11 (9.5)
Reason for referring to clinic		
Menstrual problems N(%)	13 (11.0)	25 (21.6)
Abdominal pain N(%)	15 (12.7)	16 (13.8)
Vaginal infection N(%)	52 (44.1)	41(35.3)
Others N(%)	19 (16.1)	14 (12.1)
Time of prior Pap smear		
1-3 years ago N(%)	45 (38.2)	43 (37.1)
≥4 years ago N(%)	11 (9.3)	11 (9.5)
Never N(%)	62 (52.5)	62 (53.4)

Table 2. Frequency of signs according to the clinical examination

Signs	Intervention N(%)	Control N(%)
Redness of cervix	18(15.3)	21(18.1)
Amount of mucosa		
No mucosa	33(28.0)	35(30.2)
Light mucosa	59(50.0)	57(49.1)
Heavy mucosa	26(22.0)	24(20.7)
Inflammation of the lining of the vagina	36(30.5)	34(29.3)
Strawberry cervix	6(5.1)	6(5.2)
Cervicitis	9(7.6)	7(6.0)

Cervical bleeding was occurred in 12% of control group and 15% of the intervention group at the time of Pap-smear sampling. There was no statistically significant difference between the groups in terms of frequency of the signs.

Results of the slide interpretation are reported in table 3. There was no report of need for re-sampling in any of the groups. In the intervention group, 42.4% of the slides were satisfactory and 57.6% had limited quality for interpretation. These figures in the control group were 37.1% and 62.9%, respectively. This difference was not statistically significant. The rate of sufficient endocervical cell in the intervention group was significantly higher than that in the control group (70.3% vs. 57.8%, p=0.03). There was no significant difference between the groups on adequacy of squamous cells and obscuring slide surface with inflammatory or blood cells.

Discussion

In this study, frequency of slides with sufficient number of endocervical cells in the intervention group was significantly higher than that in the control group. However, there was no significant difference between the groups in terms of satisfactory slides, adequacy of squamous cells, need for repeat Pap-smear, and obscuring smear with inflammatory exudate.

Probable reason for higher frequency of smears with sufficient endocervical cells is that cleaning the cervix can reduce the amount of mucosa picked up by the cytobrush and thus cytobrush could more effectively gather cells from the endocervical canal and deposit them on the Pap-smear slide. These findings are consistent with those of another study in Canada that found an association between cleaning with an oversized cotton swab and a lower frequency bof smears with inadequate endocervical cells [20]. In another study, Obwegeser and Brack reported a similarly low proportion of smears with no endocervical cells (3.6%) in a large series in which most smears were obtained after cervical cleaning using conventional and liquid-based methods [17].

Table 3. Comparison of Pap-smear adequacy among subjects with and without cervical cleaning prior to Pap-smear performance

	Intervention N(%)	Control N(%)	OR (95%CI)*	p-Value*
Satisfactory smear	50 (42.4)	43 (37.1)	1.37 (0.80-2.36)	0.24
Sufficient number of squamous cells	116 (99.2)	115 (99.1)	0.70 (0.04-11.94)	0.80
Sufficient number of endocervical cells	83 (70.3)	67 (57.8)	1.84 (1.06-3.20)	0.03
At least 75% of the slide not being covered with inflammatory cells	79 (66.9)	78 (67.2)	0.93 (0.53-1.63)	0.81
No repeat Pap-smear required	118 (100)	116 (100)		

The data are given as N (%) unless otherwise is specified. OR (95%CI) =odds ratio (95% confidence interval); *: Results of logistic regression adjusted for age of the participants.

Our findings differ from Hild-mosley et al. study [22] that reported no association between adequacy of endocervical cells and cervical cleaning before the Pap-smear. They did not report devices used for taking smear, the results of cervix observation and amount of cervical mucosa before taking Pap-smear.

Also, Hans et al. [23] in a similar study in Canada reported no statistically signifcant difference in the quality of the Pap-smear, using adequacy of endocervical cells as the quality index, when using cotton to collect endocervical secretions before taking Pap-smears.

In the present study, frequency of satisfactory slides in group with cervical wiping was higher than in the control group, but this difference was not statistically significant. Hild-mosley et al. study in their study was also found that the removal of cervical secretions with a dry cotton swab before Pap-smear did not affect satisfactory slides [22]. Hildesheim et al. [21] also reported that using a Weck-cel sponge for 20 to 30 seconds to collect endocervical secretions before preparing Pap smears did not affect the quality of Pap-smear.

The present study did show no difference between the two groups on covering the slides by inflammatory cells. This was similar to results of Hildesheim et al. study. On the contrary, the results of Kotaska et al. [20] and Hild-Mosley et al. [22] were against our results. The reason for the difference with Kotaska et al. study can be related to difference in their methodology. They used the past Pap-smear slides (taken from 1990 to 2003) of each subject as their own control. They may have been treated because of vaginitis, cervicitis or other diseases. Therefore, it could have affected the study results. Also Hild-Mosley et al. [22] did not report the amount of cervical mucosa before taking Pap-smear which may have been different in the two groups at the sampling time and affected the study result in the end. In our study no repeat Pap-smear was required in any of the groups. It was similar to the result of Hans et al. study [23].

In this study, allocation concealment and blinding the participants, the interviewer, the examiner and the pathologist at the time of completing different parts of the questionnaire could prevent the possible biases. Meanwhile, it was not possible to blind provider during taking the sample, which might have affected her sampling method.

These study findings may only applicable to conventional Pap-smears and cannot be generalized to those obtained using liquid-based cytology. Furthermore, only the quality of the samples was examined in this study and the sensitivity and specificity of two methods was not determined. Therefore, we recommend other studies comparing the quality of Pap-smear, sensitivity and specificity of two conventional Pap-smear and liquid-based cytology after cervical wiping with cotton.

Based on results of this study we can conclude that although there were no significant differences between the groups on some quality indicators of the smears, frequency of smears with sufficient endocervical cells was higher in the group with cervical wiping. Therefore, it is recommended to clean cervix before obtaining the smears.

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Authors' Contributions

Mahin Kamalifard, Sakineh Mohammad-Alizadeh-Charandabi, Sedighe Rezaie-Chamani had equal role in design, work, statistical analysis and manuscript writing. S. Alireza Mesbah helped in design, did laboratory work, and read and confirmed manuscript.

Conflict of Interest

The authors declare no conflict of interest.

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