Impact of Bimanual Vaginal Examination on Pap Smear Test Results

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ABSTRACT

OBJECTIVE: The aim of the study is to evaluate the possible effects of the various conditions especially bimanual examination on the adequacy of pap smear test.

STUDY DESIGN: Presented here is a prospective controlled clinical trial carried out at Ankara Atatürk Training and Research Hospital between November 2013 and March 2014. Total of 1771 patients seen at the gynecology outpatient clinic were included in the study. The technique described by the American Society of Cytopathology Criteria 2000 for the preparation of the specimen was followed. Updated Bethesda system 2014 was used for reporting the results.

RESULTS: Number of subjects in smear before examination group was 1194 and in the smear after examination group was 577. Two percent (n=36 subjects) of the cervicovaginal report was inadequate. When other clinical conditions were not taken into consideration, the likelihood ratio for inadequate smear in the smear after examination group was 2.64 compared to smear before examination group (p=0,004).

CONCLUSIONS: In some conditions cervicovaginal smear sampling may be carried out after bimanual vaginal examination instead of missing the chance to screen the women. However, the patients have to be informed that cervicovaginal smear result might be inadequate so that a repeat test has to be carried out.

Keywords: Pap smear, Cytological technique, Pelvic examination

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Introduction

Papanicolaou test is a widely used effective screening test for cervical pathologies. During the last 50 years, the mortality rate from cervical carcinoma has decreased 80% due to Papanicolaou screening test (1,2). Therefore, it is utmost important to routinely screen sexually active women at regularly defined intervals and do not miss any opportunity for screening.

Even though the test is widely used, inadequate sampling is still an important problem (3). Physicians should be aware of the reasons for inadequate sampling. The drawbacks of such reports are the need for repeat testing that will take time, cost extra labor and money. Meanwhile, patients might be lost from follow-up such that cervical pathologies might be missed. The reasons for inadequate smear are inappropriate sampling (preparation), inadequate cell number due to blood cells or mucous overlying the cells and interpretation mistakes (4). Inadequate cell number is the most common and not to overcome reason as now (5). Even though there are no studies about the timing of doing the Pap Smear test during a gynecological examination, the widespread approach in practice is to take the sample before doing the bimanual examination. However, there are various situations that are actually not so infrequent when the chance for carrying out the procedure is missed such that the physician might forget to ask before the examination when the patient had her last smear test, the information the patient gives turns out to be wrong or since the cervix might not be visualized with a speculum, bimanual examination has to be carried out first.

The primary aim of the study is to evaluate the possible effects of the various conditions especially bimanual examina-

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tion on the adequacy of pap smear test. The secondary aim is to evaluate for possible factors that would affect presence of endocervical/transformation zone component.

Material and Method

Presented here is a prospective controlled clinical trial carried out at Ankara Ataturk Training and Research Hospital between November 2014 and March 2015. Total of 1771 patients seen at the gynecology outpatient clinic were included in the study. Ethics committee approval was taken before the study. And written informed consents were taken all of the participants.

Exclusion criteria were refusing to have a bimanual examination, history of hysterectomy, radiation therapy or chemotherapy, conditions previously shown to affect the adequacy of the smear test like sexual intercourse or vaginal douching during the last 24 hours and use of vaginal medication during the last seven days.

Information about age of the patient, obstetrical history, presence of vaginal delivery, history of any cervical operation (loop electrosurgical excision procedure, conization, cauterization, cryotherapy, etc.), presence of intrauterine device (IUD), menopausal status and date of cycle at the time of examination were all recorded. Patients were allocated in two groups: smear before and smear after the bimanual examination. All the examinations were carried out by the same physician. The sample for the smear test was taken using a plastic speculum without application of any gel by Cervix Brush /smear brush SMF 41. The technique described by the American Society of Cytopathology Criteria 2000 for the preparation of the specimen was followed (6). All the samples were taken to the pathology laboratory in half an hour and evaluated by the same pathologist who was blind to the group number. Updated Bethesda system 2014 was used for reporting the results (7). For conventional smear, number of squamous cells good preserved and visible to the naked eye less than 10000, and blood, inflammation or other processes covering more than 75 % of the slide area is considered as inadequate sample for evaluation (8).

Statistical analysis was carried out using IBM SPSS Statistics 21.0 (IBM Corp. Released 2012. IBM SPSS Statistics for Windows, Version 21.0. Armonk, NY: IBM Corp.) and MS-Excel 2007 program. Comparison of adequacy for different variables was performed with chi-squared test, a univariate analysis was performed for possible factors that would affect inadequacy of cytological examination and presence of endocervical/transformation zone component. Multivariate analyses were performed for possible factors that would affect presence of endocervical/transformation as open zone component. A power was performed by using computer based calculator kit based on the rates of smear adequacy before and after examination. Power of this study was 93.5% with an Alpha of 5% corresponds to a 95% Confidence Interval.

Results

Total of 1771 patients were recruited into study. Number of subjects in smear before examination group was 1194 and in smear after examination group was 577. In smear before examination group the median (minimum; maximum) age, gravidity, parity, number of cycle day and menopause period were respectively 41(18;79) years, 2 (0;13), 2 (0;13), 15 (1-240) and 6 (1-30). In smear after examination group the median (minimum-maximum) value of these variables were respectively 43 (17;84), 3 (0;15), 2 (0;12), 15 (3;210), 7 (0;41). There are significant differences between age and gravida number (P values of these variables are respectively p=0.002; <0.001). There are no significant differences between parity, cycle day, menopause duration (p values are respectively (p=0.92;0.52;0.395).226 (21.4%) of the patients whose smears were taken before examination were nulliparous and 99 (20.3%) of the patients whose smears were taken after examination were nulliparous. 168 (14.1%) of the patients whose smears were taken before examination and 63 (10.9%) of the patients whose smears were taken after examination have IUD. 237 (19.8%) of the patients whose smears were taken before examination and 193 (33.4%) of the patients whose smears were taken after examination are postmenopausal womens.13 (1.1%) of the patients whose smears were taken before examination and 10 (1.7%) of the patients whose smears were taken after examination have cervical operation history. There was significant difference between menopause situation and smear sampling time (p<0.001) but statistically significant difference wasn't detected between smear sampling time and cervix situation, presence of IUD, cervical operation history.

Endocervical/transformation zone wasn't detected 318 (26.6%) of the patients whose smears were taken before examination and 135 (23.4%) of the patients whose smears were taken after examination. Distribution of the smear specimens' pathological evaluation results according to the smear sampling time was given at table 1. There were no significant differences between smears taken before examination and taken after examination in terms of presence of endocervical/transformation zone, intraepithelial lesion/malignancy, inflammatory cellular changes and specific microorganism (P values are respectively; p=0.143;0.926;0.053;0.966). Atrophic vaginitis ratio of the smears taken after examination is 13% and there were significant differences between atrophic vaginitis ratio of the smears taken before examination (8%) and taken after examination (p=0.002). Distribution of categorical variables according to adequacy of the smear was given in table 2.

Sixteen (2%) of the patients whose smears were taken before examination and 20 (4%) of the patients whose smears

were taken after examination were evaluated as inadequate. Cytological result was adequate in 98.1% of patients who had vaginal deliveries and in 99.1% of those who did not have history of vaginal delivery. In 97.4 % of subjects with IUD and in 98.1% of subjects without IUD, cytology report was adequate. Among menopausal subjects, the incidence of cytological adequacy was 98.4% whereas non-menopausal subjects had 97.8% adequate cytology. Patients with and without cervical operation history had respectively 95.7% and 98.0% adequate cytology. Comparing of the variables defined at the patients whose smears were inadequate with the smear sampling time was given in table 3.

Table 1: Distribution of the smear specimens' pathological evaluation results according to the smear sampling time

	Before examination n (%)	After examination n (%)		Before examination n (%)	After examination n (%)
Presence of endocervical/ transformation zone			Inflammatory cellular changes		
Absent	318 (26)	135 (23)	Absent	515 (43)	277 (48)
Present	876 (74)	442 (77)	Present	679 (57)	300 (52)
Presence of intraepithelial lesion			Presence of specific microorganism		
Absent	1173 (98)	566 (98)	Absent	1116 (93.5)	539 (93.4)
Present	22 (2)	11 (2)	Present	78 (6.5)	38 (6.6)
Variety of intraepithelial lesion			Variety of specific microorganism		
ASCUS	13 (1)	6 (1)	Bacterial vaginosis	51 (4)	32 (5)
L-SIL	6 (0.5)	1 (0.1)	Candida	24 (2)	6 (1)
H-SIL	1 (0.5)	4 (0.6)	Actinomyces	2 (0.1)	1 (0.1)
AGUS	1 (0.5)	0 (0.0)			
			Atrophic vaginitis		
			Absent	1089 (92)	488 (87)
			Present	99 (8)	74 (13)

Table 2: Distribution of categorical variables according to adequacy of the smear

Variables (n=1771)	**Adequacy of smear specimen**	
	Adequate	**Inadequate**
Smear sampling time		
Before examination	1178 (98)	16 (2)
After examination	557 (96)	20 (4)
History of vaginal birth		
Absent	322 (99.1)	3 (0.9)
Present	1195 (98.1)	23 (1.9)
Presence of intrauterine device		
Absent	1510 (98.1)	30 (1.9)
Present	225 (97.4)	6 (2.6)
Menopause situation		
Absent	1312 (97.8)	29 (2.2)
Present	423 (98.4)	7 (1.6)
History of cervical operation		
Absent	1713 (98.0)	35 (2.0)
Present	22 (95.7)	1 (4.3)

Table 3: Comparing of the variables defined at the patients whose smears were inadequate with the smear sampling time

Variables	Smear sampling time		p*
	Before examination n (%)	After examination n (%)	
Cervix situation			
Nulliparous	1 (33.3)	2 (66.7)	1.000
Multiparous	12 (52.2)	11 (47.8)	
Presence of IUD device			
Absent	11 (36.7)	19 (63.3)	0.069
Present	5 (83.3)	1 (16.7)	
Menopause situation			
Absent	14 (48.3)	15 (51.7)	0.426
Present	2 (28.6)	5 (71.4)	
History of cervical operation			
Absent	16 (45.7)	19 (54.3)	1.000
Present	0 (0.0)	1 (100.0)	

When other clinical conditions were not taken into consideration, the likelihood ratio for inadequate smear in the smear after examination group was 2.64 compared to smear before examination group (p=0.004). Age, gravidity, parity, presence of IUD, menopausal status and history of cervical operation had no statistically significant effect on adequacy of smear.

In univariate analyses, timing of smear sampling, situation of cervix (nulliparous/multiparous), presence of IUD and cycle day had statistically significant effect on presence of endocervical/transformation zone. In multivariate analyses just presence of IUD had statistically significant effect on presence of endocervical/transformation zone (p=0,047; OR=1,5).

Discussion

This study showed that the adequacy of smear test was significantly lower when specimen was taken after compared to before bimanual examination. Even though non powdered gloves were used and no lubricant was applied, still the result was the same. This might be due to deformation of cells and minimal bleeding after bimanual examination.

Gilson et al. studied the effect of gel application during pap smear test. They found that it had no negative effect on the cytological evaluation of cervicovaginal smear, and that stated that it might be used for the comfort of the patient if she chooses (9). Moreover, it was proposed that bimanual examination could be carried out by using gel if the cervix was not visible with a speculum (9). However, this suggestion is not evidence based. In this present study, even though non powdered gloves were used and no lubricant gel was applied, adequacy of smear test was significantly lower when specimen was taken after compared to before bimanual examination. This finding is not in accordance with the suggestion of Gilson's study.

There are various reports in the literature about clinical parameters known to affect cervicovaginal smear adequacy (5). Kosus et al. found lower incidence of inadequate smear report in menopausal women, but was not statistically significant (10). In accordance with this, this present study did not found any difference between groups with respect to effect of menopausal status on adequacy of smear (p=0.496). Cause of the significant difference between atrophic vaginitis ratio of the smears taken before examination and after examination is menopause situation of the patients whose smears were taken after examination is significantly higher than of the patients whose smears were taken before examination.

NTCC (New Technologies in Cervical Cancer Screening) is a randomized clinical study carried out in Italy among women of 25-60 years of age comparing HPV DNA test and new techniques of Liquid base cytology (LBC) with Conventional Papanicolaou test (CP) NETHCON (Netherlands Thin Prep versus Conventional Cytology) is another randomized clinical trial comparing LBC and CP among women aged 30 to 60 years with histologically proven cervical intraepithelial lesions. The incidence of inadequate smear results decreased minimally in CP group in NTCC whereas increased in NETHCON as age increased. Other studies also found a relationship between age and inadequacy of smears (5,11). However, our study contradicted this by finding no increase in incidence of adequate reports as age increased (p=0.852).

Some reports showed inadequacy when smear was taken during the first days of cycle (11). In contrast, no significant relationship was found between adequacy and timing of sampling with regard to days of menstrual cycle (p=0.268) in this present study. The only clinical condition that influenced the incidence of adequate smear result was the condition of being taken before or after the bimanual examination. The incidence

of inadequate smear was lower than in other reports (5,12,13). This observed lower inadequacy ratio is might be due to good application of the technique, having the same physician, and exclusion of clinical conditions that adversely affect the performance of the test.

Absence of endocervical component was 24.3 % (n=421) in this study. Presence of IUD ability to increase the rate of presence of the endocervical/transformation zone because of kept of the cervical os (p=0,047; OR=1,5). Some reports showed increased incidence of abnormal epithelial changes when endocervical cells were not present in the smear specimen (14,15) whereas others contradicted this finding (16,17,18). Absence of endocervical component should not be the only criteria to repeat the test earlier than routine (19,20). Previous smear results and clinical findings should also be taken into consideration.

Management of inadequate smear results is to repeat the test in two to four months (21). Many reports showed an association with high incidence of invasive carcinoma and intraepithelial lesion with inadequate smear (22-24). In the study presented here, for inadequate results in postmenopausal women, the test was repeated after local estrogen therapy, and in patients with cervicovaginal infection, it was repeated after appropriate infection therapy. However, many of these patients were lost to follow up and only eight out of 36 patients came back for repeat testing. In those, the repeated smear test results were adequate. This showed how important it was to treat the conditions like atrophy or infection that caused inadequate results before performing the smear test.

This study might be designed as taking the smear before and after the bimanual examination from the same patient. However, knowing that since smear test relies on the amount of shedding of cervicovaginal cells, it was thought that a second test in the same time from the same patient might lead to too few cells to be examined for the second test. Previous reports evaluating the clinical conditions that might lead to inadequate smear results were all retrospective (5,11). In these studies, in addition to univariate analyses multivariate analyses was performed for possible factors that would affect inadequacy of cytological examination. The strength of this study presented here is that it is prospective, the exclusion criteria was well defined to exclude many clinical conditions that might hinder adequacy, the sampling technique is followed meticulously, the same physician took all the samples. As a result, only in 2 % (n=36) patients the results were inadequate. Since this number was too small for multivariate analysis, this is the main limitation of the study.

As much as we know, this is the first prospective study evaluating if pap smear test taken after bimanual vaginal examination is adequate for evaluation. There are some clinical situations such as the physician might forget to ask before the examination when the patient had her last smear test, the information the patient gives turns out to be wrong or since the cervix might not be visualized with a speculum, bimanual examination has to be carried out first when instead of missing the chance to take smear test, it could be taken after the examination. However, the patients have to informed that cervicovaginal smear result might be inadequate so that a repeat test has to be carried out. In addition, in such cases, meticulous attention should be paid to stick to the proper technique and medical equipment.

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