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New Screening Method For Cervical Cancer- Polar Probe

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Abstract

Objective: Although extensive screening methods had been developed, cervical cancer remains to be an essential health problem. Early detection and administration of appropriate therapy is still a lifesaving procedure, especially for cervical cancer. The most common screening method for cervical cancer is still the cervical cytology (Pap-test). We aim to find out the advantages and disadvantages of a recently developed method, which is called as Polar Probe.

Methods: Two different approaches had been used (conventional Pap test and Polar Probe), and 1438 patients were included in the study. Of these, 819 had been screened with Polar Probe. All eligible patients were firstly screened using Polar Probe and then using the Pap test. Each patient with an abnormal Polar Probe result was referred to colposcopy room, where she was re-evaluated using colposcopy.

Results: The rate of abnormal smear result was 1.04%, and the corresponding percentage was calculated as 0.62% in LSIL, 0.34% in ASCUS, and 0.069% in HSIL. A total of 819 patients underwent Polar Probe, and the results were abnormal in 261 patients and normal in 558 patients. Abnormality rate was 1% in Pap test and 31.9% in Polar Probe. Although the positive predictive value was 27% for Polar Probe test and 16% for Pap test, as the colposcopy was indicated only for the patients with abnormal results in Polar Probe. The need for colposcopy dramatically increased with the use of Polar Probe.

Conclusion: Use of Polar Probe alone was not found to be cost effective. Combination with other methods of screening would decrease the cost of the process.

Keywords: Polar Probe, Pap test, pre-invasive cervical lesion.

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Servikal Kanser İçin Yeni Tarama Metodu- Polar Probe

Öz

Amaç: Kapsamlı tarama yöntemleri geliştirilmiş olmasına rağmen, rahim ağzı kanseri temel bir sağlık sorunu olmaya devam etmektedir. Uygun tedavinin erken tespiti ve uygulanması, özellikle serviks kanseri için hala hayat kurtarıcı bir prosedürdür. Serviks kanseri için en yaygın tarama yöntemi servikal sitolojidir (Pap-testi). Bu çalışmada Polar Probe adı verilen ve yeni geliştirilen bir tarama yöntemin etkinliğini test ettik.

Yöntemler: İki farklı yaklaşım kullanıldı (geleneksel Pap testi ve Polar Probe) ve çalışmaya 1438 hasta dahil edildi. Bu hastalardan 819 tanesi Polar Probe ile de tarandı. Tüm uygun hastalar önce Polar Probe ve ardından Pap testi kullanılarak tarandı. Anormal bir Polar Probe sonucu olan her hasta kolposkopi odasına yönlendirildi ve burada kolposkopi cihazı kullanılarak hastalar yeniden değerlendirildi.

Bulgular: Anormal smear sonucunun oranı %1,04 idi ve ilgili yüzde LSIL'de %0,62, ASCUS'ta %0,34 ve HSIL'de %0,069 olarak hesaplandı. Toplam 819 hastaya Polar Probe uygulandı ve sonuçlar 261 hastada anormal ve 558 hastada normaldi. Anormallik oranı Pap testinde %1 ve Polar Probe %31,9 idi. Pozitif prediktif değer Polar Probe testi için %27 ve Pap testi için %16'idi. Kolposkopi sadece Polar Probe'da anormal sonuçları olan hastalarında yapıldı. Bu çalışmada Polar Probe kullanımıyla kolposkopi ihtiyacı önemli ölçüde artmıştır.

Sonuç: Sadece Polar Probe kullanımını kolposkopi gerekliliği nedeniyle maliyeti artırmaktadır. Diğer tarama yöntemleri ile kombinasyon, işlemin maliyetini düşürebilir.

Anahtar kelimeler: Polar Probe, Pap testi, pre-invaziv servikal lezyon.

INTRODUCTION

Cervical cancer is one of the leading causes of cancer-related deaths in women worldwide. In the 1930s, cervical cancer was the leading cause of cancer-related deaths in the USA. Although cytological screening decreased these deaths by 70%, cervical cancer remains to be among the first three leading cause of cancer-related deaths in women worldwide. Based on Globocan 2018 data, cervical cancer is the 3rd prominent women's cancer in worldwide, and 569.847 new cases annually occurs, and within the same year, 311.365 cases die. This number is mostly due to the cases occurring in developing countries[1]. In our country, the incidence in women is 4.3/100.000 and the mortality rate is 1.7/100.000[2].

Although the mean age at the diagnosis of cervical cancer is 52 years, its incidence peaks between the ages of 35 and 39 years and between the ages of 60 and 64 years. Cervical carcinoma in situ (CIS) is seen 10 years earlier, which corresponds to the ages of 35-40 years, than cervical cancer. Low-grade cervical lesions are detected approximately between the ages of 26-30 years, which corresponding to detection at an earlier age compared to CIS[3]. Dysplasias are the precursor lesions of cervical cancer and, if left untreated, some of them will progress to cancer[4]. It is observed that, annually, half of the patients diagnosed with cervical cancer had not had an early diagnosis due to either low coverage of the Pap smear test or the low diagnostic capacity of Pap smear test. Therefore, alternative methods for cervical cancer screening come up.

For the conventional Pap test, a wide sensitivity range was given in high-grade lesions (30%-87%) American College of and Gynecologists[5]. Also, a false negativity rate ranging between 14% and 33% was given[6]. For these reasons, screening utilizing elective strategies came up. TruScreen (Polarntechnics Limited, Sydney, Australia), which is one of the devices produced for this purpose, has been firstly accredited in 2003. The response that the tissues are giving according to low-dose electrical pulsation was digitalized and is express as "normal" or

"abnormal" upon the comparison done with the results of various cervical tissues previously memorized in the device. The device uses a combination of biosensors, including directly reflected light, backscattered light, and electrical decay curves. The tissue is illuminated at four discrete wavelengths in the visible and infrared regions of the spectrum. The information is filtered, sampled, and processed by a microcomputer within a portable console to extract the parameters of the highest value for tissue discrimination[7].

Fricke and Morse firstly suggested that the hypothesis that the resistance of the tissues against the electrical current was different in 1926 with a study for breast cancer. After that, in 1949, Langman and Burr discovered that cancerous and noncancerous cervical tissues had different electrical parameters. Indeed, the performance of the test in vivo was not possible in that period, because the equipment was not appropriate. However, over the last decades, technological advances made this technology more applicable.

In this study, we investigated the efficacy of the screening using Polar Probe (TruScreen) in our patient population.

METHOD

Patient selection

After the approval of Baskent University Hospital, Ethics Board (project number KA09/159), three contiguous districts with similar characteristics were considered to be eligible for this screening (Anamur, Bozyazi, and Aydincik). These three districts are both economically and socially identical. In some parts of all three regions, there were difficulties of health services access due to low socioeconomic status. Each admitting patient was enrolled in the study if fulfilling the inclusion criteria.

Criteria for Pap test are as follow

• Having turned 20 years old or at least 3 years after the first sexual intercourse.

• The absence of a previous hysterectomy due to the benign reason (The patients who were not known to have a benign reason or who reported to have never had Pap test underwent a Pap test but were not included in the study.)

• Absence of a Pap test within the last year.

Polar Probe (TruScreen) criteria

• Signed informed consent,

• Age between 18 and 70-years-old

• Absence of a Pap smear within the last 6 weeks

• Absence of heavy bleeding during the procedure

• Absence of pregnancy or having passed more than 4 months since the last delivery

• Absence of the previous hysterectomy

• Absence of cervical surgery within the last three months

• Absence of a known photosensitive disease

• Absence of prior radiotherapy on the pelvic area

• Chemotherapy-naïve or absence of chemotherapy within the previous five weeks

• Eligible for Pap test

Each patient was examined in the rooms designed for TruScreen and Pap test and colposcopy and small surgical interventions. In each room, TruScreen device was used by a physician, nurse, or technician, whereas the physicians applied colposcopy.

All eligible patients were firstly screened using TruScreen and then using the Pap test. Each patient with an abnormal TruScreen result was referred to colposcopy room, where she was re-evaluated using colposcopy.

Evaluation Using TruScreen

A speculum of appropriate size was inserted and positioned to leave the cervix in the midline. In the patients with very thick mucus, the mucus was removed using a ring forceps and gauze without touching the cervix. TruScreen device was calibrated using a specially designed optical test plug after ensuring that the device was open and that the printer had enough paper. After the calibration, a single use sensor (SUS) was connected to the device. The sensor of the equipment was moved across appropriate points on the cervical transformation zone. At the end of the screening, a print-out was taken automatically by the device or by pushing to a button. Patient information and TruScreen result were registered in the patient registration form and, if the result was abnormal, the patient was sent to colposcopy room.

Smear Sample Collection

Conventional Pap test and two different smear brushes were used. In the patients in whom the endocervical canal cannot be visualized, the smear sample was collected using endocervical smear brush.

Colposcopic Evaluation

Each patient with an abnormal TruScreen result underwent colposcopy. For colposcopy, two different devices were used at different time points. In the district of Anamur, digital colposcopy (Centrel S1 Grimed) device was used. In the regions of Bozyazi and Aydincik, classic colposcopy (colposcopy F1 Grimed) device was used. Following the preparation of the patient, acetic acid 3% and iodine solution were administered to the cervix, and biopsy specimens were collected from the areas with abnormal appearance using biopsy forceps.

Evaluation Of Pap Test And Biopsy

Pap test and biopsy results were evaluated in 2 different centers. Mersin KETEM evaluated pap-test slides. Biopsy specimens were evaluated by Onay Laboratory of Pathology and Cytology (Ankara). Each center evaluated the samples without knowing the result of the other center.

Statistical Analysis

Study data were analyzed using SPSS version 17.0 statistical package software) (Statistical Package for the Social Sciences, version 17.0, SPSS Inc, Chicago, III, USA). Comparative data were analyzed using a Chi-Square test. Statistical significance level was considered to be $p<0.05$.

RESULTS

In a total of 3 districts, 1438 patients were screened, and 819 patients underwent TruScreen. Statistical analysis was performed on 819 patients (cytological abnormality rate was expressed based on the total number of patients). The demografic characteristics of the regions were given in Table 1.

Table I: The demographic characteristics of the regions

	Anamur	Bozyazi	Aydincik	Total
Age	42,5±8,7	43,7 ± 9,8	41,3 ± 8,4	42,5 ±9,04
Premenopausal	263 (72%)	160 (70%)	177 (76%)	600 (73%)
Vaginal discharge	153 (42%)	132 (58%)	180 (77%)	465 (56%)
Postcoital bleeding	38 (10%)	16 (7%)	7 (3%)	61 (7.5%)
Previously existing pap test	42 (11%)	22 (9%)	9 (3.8%)	73 (8.9%)
Pap-test applied	697	374	367	1438
Truscreen applied	361	225	232	818
Colposcopy applied	125	75	64	264
Biopsy was taken	87	59	51	197

A total of 1438 patients had a Pap test. In all three districts, a total number of abnormal Pap test results was 15 and, of these, 5 were defined as ASCUS, 9 as LSIL and 1 as HSIL. The rate of abnormal smear result was 1.04%, and the corresponding percentage was calculated as 0.62% in LSIL, 0.34% in ASCUS, and 0.069% in

HSIL. ASC-H and AGC cell was not reported for any of the three districts.

A total of 819 patients underwent TruScreen, and the results were abnormal in 261 patients and normal in 558 patients. All of the patients with abnormal TruScreen result underwent colposcopy. Six patients with normal TruScreen results additionally underwent a colposcopy, one due to smear result showing ASCUS and 5 dues to the presence of clinical suspicion of the low-grade lesion. A total of 267 patients underwent colposcopy. Of these patients, 197 underwent biopsy concomitantly to colposcopy. A total of 242 biopsy sample were collected and evaluated. Seventy-one patients underwent colposcopy alone and did not undergo biopsy because of the absence of a pathological appearance.

Biopsy results of a total of 197 patients are given in Table 2. Three patients had a high-grade lesion, and 7 patients had a low-grade lesion. However, when condyloma and koilocytic changes were considered to be abnormal, the total number of histologic abnormalities was 55 (55/197; 27.9%). Most commonly observed histopathologic result was chronic cervicitis (122/197; 61.9%).

Table II: Cervical biopsy results of participants

Histopathological results	Number
High-grade lesion	3
Low-grade lesion	7
Condyloma (flat and verrucous)	25
Koilocytic change	20
Immature squamous metaplasia	1
Chronic cervicitis	122
Normal epithelial	11
Nabothian cyst	8

Of 15 patients with cytological abnormalities, 8 underwent TruScreen, and its results are given in Table 3. As 4 patients with cytological abnormality showed normal TruScreen results, they did not undergo colposcopy at that moment. However, Patient 3 was called for the next screening and re-evaluated. Patient 5 admitted to our clinic by herself and was taken to close monitoring. Colposcopy and biopsy that we performed in our clinic resulted in the high-grade lesion. The patients with a biopsy result equal to or greater than CIN1 are listed in Table 3. Biopsy result and smear result were correlated in none of the patients, except in Patient 8 (Ş.D.).

Table III: Cytology Results compare with Truscreen and biopsy

Patients number	Cytology Results	TruScreen results	Biopsy results
1 T.E.	ASCUS	Normal	No biopsy
2 Ü.Y.	ASCUS	Abnormal	Chronic cervicitis
3 H.K.	ASCUS	Normal	Chronic cervicitis
4 K.B.	LSIL	Normal	No biopsy
5 A.G.	LSIL	Normal	HSIL
6 S.G.	LSIL	Abnormal	Chronic cervicitis
7 A.S	LSIL	Abnormal	Chronic cervicitis
8 Ş.D.	HSIL	Abnormal	HSIL
9 H.D.	Normal*	Abnormal	HSIL
10 F.B.	Normal*	Abnormal	LSIL
11 H.Y.	Normal*	Abnormal	LSIL
12 H.K.	Normal*	Abnormal	LSIL
13 A.Ç.	Normal*	Abnormal	LSIL
14 M.G.	Normal*	Abnormal	LSIL
15 A.Ö.	Normal*	Abnormal	LSIL
16 A.Ş.	Normal*	Abnormal	LSIL

** Malignancy and intraepithelial lesions were not observed*

Abnormality rate was 1% in Pap test and 31.9% in TruScreen (table 4). When these patients were evaluated using colposcopy, half of the patients showed eventual low-grade or high-grade lesions. However, when these patients were assessed using biopsy, only 28% showed abnormal histology.

Table IV: Abnormality Rates

	Normal (%)	Abnormal	Total
Pap-Test	802 (97.9%)	8 (1%)	819*/**
TruScreen	557 (68%)	261 (31.9)	819
Colposcopy	126 (47%)	138 (53%)	264
Cervical biopsy	142 (72%)	55 (28%)	197

**9 patients' pap-test were result as degenerate*

*** 1 patient has insufficient pap-test results*

As seen in Table 5, only 4 of the patients who showed abnormal results with TruScreen were found to have epithelial cell abnormality using the Pap test. On the other hand, 254 of 258 patients who were found to be abnormal based on TruScreen test were reported to be normal using the Pap test. Compare results of TruScreen, colposcopy and Pap test with biopsy results were given at Table 6.

Table V: Compare the results of Truscreen and pap-test

	Truscreen		total(n)
Pap Test	Abnormal(n)	Normal(n)	
Abnormal **(n)**	4	4	8
Normal **(n)**	254	547	809
Total (n)	258	551	809

Table VI: Compare results of TruScreen, colposcopy and Pap test with biopsy results

	Abnormal histology	
	Positive (n)	Negative (n)
TruScreen (n)		
Positive	53	137
Negative	1	5
Colposcopy (n)		
Positive	47	91
Negative	8	51
Pap Test (n)		
Positive	2	4
Negative	52	136

Although the positive predictive value was 27% for TruScreen test and 16% for Pap test, as the colposcopy was indicated only for the patients with abnormal results in TruScreen in our group, the sensitivity and specificity of this test would not be accurate. For colposcopy, the sensitivity was 85%, and the specificity was 35%. The positive predictive value was 35% in the patients who underwent colposcopy.

Among the patients who were screened using TruScreen, 35 had minor bleeding, 1 had significant bleeding, and 1 had minor discomfort. There is no statistical significance between TruScreen operator and the complication (p=.112), but abnormal TruScreen rates were significantly lower if TruScreen operator was a doctor (p .001). However, no statistical significance was found between the number of spots examined and the abnormal result (p= .598).

DISCUSSION

For the screening for cervical cancer, the use of a less demanding test with a higher accuracy rate has always been needed. Upon the introduction of the conventional Pap test in 1941 and the efficient use of colposcopy in the 1960s, the incidence and the mortality of cervical cancer showed a substantial drop. In our study abnormality rate was 1% in Pap test and 31.9% in TruScreen. The positive predictive value was 27% for TruScreen test and 16% for Pap test. The need for colposcopy dramatically increased with the use of TruScreen.

Given that the efficacy of the cervical cytology screening varied by laboratory conditions, it is indispensable that alternatives of this inert program always appear. The coming up of alternative TruScreen test is the result of these reasons.

Potential advantages of the screening with TruScreen are as follows: TruScreen test is the first objective, that is not required to be interpreted. The results are expressed as "normal" or "abnormal" and each patient with an abnormal result proceeds to the next test. Another advantage of the test is that the

declaration of the result does not require additional time. Therefore, patient satisfaction is maximal. Although the population to be screened is invited in advance in the community-based screening strategy, based on opportunistic approach, this is on own initiative of the patients. The patients who immediately learn the result will have higher satisfaction, increasing the rate of participation in the screening program. In the study performed by Mould T AJ et al.[8], the questionnaire done by 152 patients revealed that the patients experienced less anxiety (2/10 vs. 4.5/10), less pain (3% vs. 33%) and less bleeding and discomfort (5% vs. 12%) with Polarprobe. As a result, the majority of the women preferred Polarprobe to smear test (82% vs. 2%). In our study, the complication rate was 4.6%, and all but one of these complications was minor bleeding or minor discomfort.

The disadvantages of TruScreen include being affected by any tissue abnormality. Chronic cervicitis is a quite common pathology, and despite its benign nature, it is misinterpreted by TruScreen, giving an abnormal result. Another disadvantage of TruScreen is regarding its safety. A device that is not well-prepared will give an abnormal result. Its reasons include the calibration of the equipment, the cleanliness of the probe end, and whether the disposable end used is broken. There is no method to analyze whether the abnormally reported result is due to the perception of the tissue as “abnormal” or due to the device. Therefore, the safety range of the device is quite narrow.

Although the ability to detect the abnormal tissue using electrical current has been discovered in the 1990s, this method has not been introduced in the routine practice, and there is a limited number on literature concerning it, leading to biggest handicaps of this method.

Based on the literature (Table 7)[4,7,9-13], the first study for Polarprobe was published by M. Coppleson et al. in 1994[9]. This study was conducted on 183 patients, and the results obtained with Polarprobe and colposcopy/histology were given. In this study, the accuracy rate was detected to be 85% in the patients who were known to be histologically low-grade, 90% in high-grade lesions, and 99% in invasive cancers. However, the first patient-to-patient clinical study was performed by Singer A et al. in 1997[10]. In this study, the patients were classified into two groups. While Group 1 included 41 patients with cervical carcinoma at various stages with the symptomatic and visible lesion, Group 2 included 45 patients who had not undergone cervical surgery within the last 12 months and who had negative results of both Pap test and colposcopy. In the patients with histologically confirmed cervical carcinoma, Polarprobe method was found to have a sensitivity of 98% and a specificity of 91%. In the study of Singer, A et al., which was conducted on a total of 651 patients from 10 centers and published in 2003,[7] the researchers reported the sensitivity of TruScreen, Pap Test and the combination of these two tests. Two different categories of patients were enrolled in the study. The first group included only the volunteers (n=485) and the second group included the patients who admitted to a colposcopy clinic for a previously known abnormal result. The prevalence rates of CIN1 and CIN2-3 were 1% and 0.6% in the first group and 14% and 31% in the second group, respectively. In this study, the sensitivity of TruScreen for CIN2/3 and CIN3 was calculated as 70% and 67%, respectively, and the specificity as 81%. In this study, for Pap test and combined test (TruScreen + Pap Test), the sensitivity was reported to be 69% and 93% for CIN2/3 and 45% and 87% for CIN1, respectively. The specificity was calculated to be 95% for Pap test and 80% for the combined test.

Table VII: Studies from literature about the polar probe

	sensitivity	specificity
M. Coppleso et al. 1994[9]	85% CIN1-atypia 90% CIN2-CIN3 99% Invasive cancer	86-97%
Singer A et al. * 1997[10]	98%	91%
Singer A et al. 2003[7]	67% (CIN1) 70% (CIN2-3)	81%
Abdul S et al. 2006 [11]	74%(CIN2/3)	53%
Pruski D et al. 2008[12]	53% CIN (1-2) 80% CIN3	84%
He Xiu-kui et al 2010 [13]	32.2%	96.7%
Long S et al. 2013 [4]	67.4%	68.1%

** Values for invasive cancer*

In our study, as all patients included in the screening group did not have a histological diagnosis, the sensitivity and the specificity could not be calculated. Only the patients with an abnormal result of TruScreen were referred to colposcopy and gave biopsy specimens. PPV was 27% for TruScreen test, 16% for Pap test and 33% for colposcopy. In our study, there were 8 patients with abnormal cytological results, who underwent TruScreen test. When we compared these results, we observed that TruScreen gave a false negative result in 1 patient with HSIL. One patient with ASCUS and 1 patient with LSIL had not to biopsy result due to previously normal TruScreen result. However, despite the observation of abnormal cytological results obtained with TruScreen in 7 patients with biologically confirmed LSIL and 1 patient with biologically confirmed HSIL, the cytological analysis gave a false negative result in these patients. In two tests, different patient groups were diagnosed, and it is clearly observed that the combination of two tests will increase the accuracy rate of the screening.

Ultimately, the positivity rate of TruScreen was 31.9%, and 27% of these patients would have histological HPV effect and other dysplasias. Seventy-three percent of the patients, who had abnormal results, would have undergone unnecessary colposcopy. In our study, the rate of chronic cervicitis was quite high (62.2%). This may be explained by the fact that we enrolled all the patients in whom the transformation zone was visualized and who were found to be eligible for TruScreen to the screening.

When we evaluated TruScreen based on the tests performed in the literature, we found that it was at least as effective as the Pap test. Thus, a good sensitivity rate is important for diseases with low prevalence. As our study had a limited number of colposcopy facilities, and the test gave positive results at a rate of 1/3, in this study, colposcopy was performed only in the patients with positive TruScreen result. As also seen in our study, histologic abnormality capturing is better with TruScreen compared to the Pap test. In 1438 patients, the prevalence of cytological abnormality detected with Pap test was 1.04% (15 patients), similarly to the prevalence published by Turkish Cervical Cancer and Cervical Cytology Study Group in 2009. In this study, Overall, the prevalence of cervical cytological abnormalities was 1.8%; the prevalence of ASCUS, ASC-H, LSIL, HSIL, and AGC was 1.07%, 0.07%, 0.3%, 0.17%, and 0.08%, respectively[14]. However, this rate was given as 6.9% (ASCUS, 4.5%; LSIL, 1.6%; HSIL, 0.5%; AGC, 0.3%) in an American study that contained laboratory data obtained in 2000[15]. In our study, the patients who were screened using TruScreen showed a rate of histologic abnormality of 6.5% (54/819). In our study, based on the patients with histological diagnoses, Pap test gave a false negative result in 1 patient with a high-grade lesion (50%; ½ patient) and in 7 patients with LSIL (0/7). TruScreen omitted high-grade lesion in 1 patient. However, as the number of the patients with normal TruScreen results in whom we performed colposcopy and biopsy is limited, it

would not be right to compare TruScreen and Pap test in this point.

CONCLUSION

In our study, TruScreen was found to have a higher cervical dysplasia capturing rate compared to the Pap test. However, in the screening performed using TruScreen, the rate of colposcopy substantially increases, affecting the cost of the screening. Use of TruScreen alone is not a cost-effective method. Its combination with other tests would decrease the excessively high rate of colposcopy use and allow its use as a more efficient screening method. Conducting the studies for the use of TruScreen test combined with other tests rather than for its use alone seems to be more promising for the future.

Ethics Committee Approval: Baskent University Hospital, Ethics Board (project number KA09/159)

Declaration of Conflicting Interests: The authors declare that they have no conflict of interest.

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