

# Comparison of Vaginoscopic No Touch Method with The Traditional Method of Outpatient Hysteroscopy

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## ÖZET

*Vajinoskopik no touch tekniği ile geleneksel ofis histeroskopinin karşılaştırılması*

**Amaç:** Anestezisiz, vajinoskopik no touch tekniğinin, intraservikal %2 prilokain enjeksiyonu uygulanan geleneksel ofis histeroskopi tekniğinin uygulanabilirlik ve ağrı duyumu açısından karşılaştırılması.

**Gereç ve Yöntem:** Tanısal laparoskopi uygulanacak 92 hasta randomize olarak iki gruba ayrıldı. Kırksekiz hastaya spekulum, tenakulum kullanılmadan ve anestezi uygulanmadan ofis histeroskopi uygulandı. Kırkdört hastaya 10 ml intraservikal %2 prilokain hidroklorür enjeksiyonunu (3:00 ve 9:00 noktalarına) takiben geleneksel histeroskopi uygulandı. Histeroskopi için rijid 3.7 mm histeroskop ve distansiyon medyumu olarak %0.9 salin kullanıldı. Alınan görüntüler ekran yardımı ile hastaya yansıtıldı. İşlem esnası ve sonrasında hissedilen ağrının ölçümünde 10 cm çizgiye sahip vizüel analog skorlaması kullanıldı. (Evre I: Geleneksel histeroskopide; spekulum yerleştirilmesi, tenakulum takılması, no touch tekniğinde ise histeroskopun vajene girerek vajinoskopi uygulaması, Evre II: histeroskopi internal servikal kanalın geçilmesi, Evre III: uterin kavitenin incelenmesi ve Evre IV: histeroskopi işlemi bittiminden 15 dk. sonrası).

**Bulgular:** No touch grubunda ortalama ağrı skoru ever I'de anlamlı olarak daha az tespit edildi ( $p<0.01$ ). No touch grubunda servikal stenoz nedeniyle beş hastada işlem tamamlanamadı (%10.4), Başarısızlık oranı iki grup için anlamsız bulundu ( $p>0.05$ ).

**Sonuç:** Vajinoskopik yöntem uygulanan hastalar vajinoskopi aşamasında geleneksel yöntemde uygulanan spekulum ve tenakulum ile intraservikal lokal anestezi uygulaması aşamalarına oranla daha az ağrı hissetmektedir. Her iki teknik için işlemin sonraki aşamalarında ve işlem sonrasında ağrı skorları benzer olup, başarısızlık oranı no touch tekniğinde geleneksel metotla karşılaştırılabilir yeterliliktedir. No touch tekniği kullanılabilir bir histeroskopi tekniğidir.

**Anahtar kelimeler:** Ofis histeroskopi, ağrı yönetimi

## ABSTRACT

*Comparison of vaginoscopic no touch method with the traditional method of outpatient hysteroscopy*

**Objective:** To compare the vaginoscopic "no touch" approach to diagnostic outpatient hysteroscopy without anesthesia with traditional diagnostic office hysteroscopy after intracervical injection of prilokaine hydrochloride 2% in terms of pain perception and feasibility.

**Material and Methods:** A total of 92 women undergoing diagnostic hysteroscopy were included in the study and were randomized, to one of two treatment groups. Forty-eight women underwent hysteroscopy without speculum, tenaculum, or anesthesia. Forty-four women received intracervical anesthesia with 10 mL of 2% prilocaine hydrochloride solution injected at two sites (3:00 and 9:00 positions) and underwent traditional hysteroscopy. Hysteroscopy was performed using a rigid 3.7-mm hysteroscope and a medium of 0.9% saline. The image was transmitted to a screen visible to the patient. A visual analog scale (VAS) consisting of a 10-cm line was used to assess the intensity of pain experienced during and after the procedure. Satisfaction was assessed by VAS at three different times during the procedure (Stage I: insertion of speculum, tenaculum placement, intracervical block for the traditional hysteroscopy group and insertion of hysteroscope into the vagina, vaginoscopy for the no touch method, Stage II: passage through internal cervical os, Stage III: observation of the uterine cavity and Stage IV: 15 minutes later, after hysteroscopy).

**Results:** The mean pain score was significantly lower at Stage I in the no touch group ( $p<0.01$ ). In five of the patients in no touch group (10.4%), hysteroscopy were unsuccessful because of cervical stenosis. Failure rate was not statistically significant in two groups ( $p>0.05$ ).

**Conclusion:** Patients reported significantly less pain with no touch method at the vaginoscopy compared with patients undergoing the traditional procedure with tenaculum placement and intracervical anesthesia. Both of the methods have had similar pain scores during the rest of the procedures and 15 minutes after the procedure with comparable failure rates. No touch method can therefore be considered as a useful hysteroscopic technique.

**Key words:** Outpatient hysteroscopy, pain management

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## INTRODUCTION

Optimal management of endometrial disease requires accurate and timely diagnosis followed by

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effective treatment. Modern outpatient hysteroscopy can be utilized as a first-line method for both a diagnostic and therapeutic procedure (1). Outpatient hysteroscopy have many advantages over inpatient hysteroscopy under general anesthesia, including reduced anesthetic risks, enhanced time, cost-effectiveness, and patient preference but the majority of women regard an outpatient hysteroscopy as acutely painful since it involves placement of a cervical tenaculum, traction on the cervix, and insertion of the

hysteroscope into the cervical canal and the uterine cavity (1). No touch technique have been introduced by, Bettocchi and Selvaggi used in attempt to make the procedure less painful (2). In the present prospective randomized study, we compared the traditional outpatient hysteroscopic technique using intracervical local anesthesia with the vaginoscopic no touch approach without anesthesia in terms of patient's pain perception in various stages of the procedures.

**MATERIAL AND METHODS**

A prospective, randomized, treatment-controlled study was conducted at the Bakirkoy Dr. Sadi Konuk Education and Research Hospital Obstetrics and Gynecology Outpatient Clinic, in Istanbul, Turkey. All participants received a detailed explanation about the study and signed an informed-consent form. Patients were encouraged to observe images of their procedure on the screen. Ninety-two consecutive women referred to our center were enrolled in the study. The patients were randomized into two groups.

The no-touch group included 48 women who underwent vaginoscopic hysteroscopy without analgesia or anesthesia. The patient was placed in dorsolithotomy position, and the vagina was cleansed with a noniodide disinfectant using a small swab positioned on a thin Collins forceps. The hysteroscope was then inserted into the vagina, while distending it by the flowing saline, obviating the need to assist the introduction of the scope into the cervix using a tenaculum. The anatomy could be followed by gentle movements of the hands that correctly drove the hysteroscope into the cervix and through the internal cervical os.

The control group consisted of 44 women who underwent the traditional hysteroscopic technique 2-3 minutes after an intracervical injection of 10 mL prilocaine %2 solution. The solution was injected with a 22-gauge spinal needle on two sites (at 3:00 and 9:00 positions). In

premenopausal women, all procedures were performed during the early proliferative phase of the menstrual cycle. All the procedures were performed with a rigid 3.7-mm hysteroscope in a medium of 0.9% saline, and the video image was transmitted to a screen visible to the patient.

A VAS score on a 10-cm line was used to assess the intensity of pain experienced at three stages during and 15 minutes after the procedure (0: no pain to 10: worst pain). Stage I: insertion of speculum, tenaculum placement, intracervical block for the traditional hysteroscopy group and insertion of hysteroscope into the vagina, vaginoscopy for the no touch method. Stage II: passage through the internal cervical os. Stage III: observation of the uterine cavity. Stage IV: 15 minutes later, after hysteroscopy.

Samples' size were calculated to provide 80% power to detect a true difference, by no touch group, of at least 40% in VAS, assuming a difference in VAS of 1±1.5, by no touch group, and a two-sided α of 0.05. Using these assumptions and a randomization ratio of 1, it was calculated that a total of 36 participants would provide adequate power. Analysis of data was carried out with NCSS 2007&PASS 2008 Statistical Software (Utah, USA). For continuous variables, descriptive statistics were calculated and are reported as mean±standard deviation. Distributions of continuous variables were tested for normality using the Kolmogorov-Smirnov test. Normally distributed continuous data were compared by group using the t test for independent samples. Variables with distributions differing significantly from normal were compared by using the Mann Whitney U. Chi-square test and Fisher's exact test were used to detect differences in categorical variables. All tests were considered significant at P<0.05.

**RESULTS**

Characteristics of study participants are described in Table 1. As can be seen, patients were similar by

**Table 1: Patient characteristics**

	No touch group N=48	Traditional group N=44	Significance
Age	41.68±10.14	40.43±10.87	P>0.05
Parity	1.52±1.20	1.54±1.22	P>0.05
Weight	68.45±14.85	69.32±15.34	P>0.05
Menopause	31.25%	31.81%	P>0.05
Failure	10.4%	0	P>0.05

Data are expressed as mean±standard deviation. Continuous variables were compared using the t test for independent samples; categorical variables (percentage menopausal patients and failure rate) were compared using the Chi-square test.

**Table 2: Indications for hysteroscopy**

	No touch group N=48	Traditional group N=44	Significance
Abnormal uterine bleeding	22 (45.8%)	20 (45.5%)	P>0.05
Infertility	11 (22.9%)	10 (22.7%)	P>0.05
Thick endometrium	8 (16.7%)	8 (18.2%)	P>0.05
Postmenopausal bleeding	7 (14.6%)	6 (13.6%)	P>0.05

Data are expressed as n (%). Groups were compared using the Chi-square test.

**Table 3: Pain Evaluation by Visual Analog Scale**

	No touch group N=48	Traditional group N=44	Significance
StageI	1.93±0.43	3.31±0.47	P<0.05
StageII	4.85±0.77	4.97±0.76	P>0.05
StageIII	6.37±0.57	6.11±0.72	P>0.05
StageIV	2.18±0.39	2.18±0.39	P>0.05

Data are expressed as mean±standard deviation. Visual analog scale scores were compared by the MannWhitney U test.

treatment assignment. The indications for hysteroscopy did not differ between the two groups (Table 2). No complications occurred in any of the patients in either group. Five procedures in the no touch group were unsuccessful because of cervical stenosis [abnormal uterine bleeding (n: 1), infertility (n: 2), thick endometrium (n: 1), postmenopausal bleeding (n: 1)] and were performed successfully using a traditional method. Nevertheless, these patients were analyzed in their originally assigned treatment group. Failure rate was not statistically significant between two groups  $p>0.05$ .

Visual analog scale scores are shown in Table 3. The mean pain score was significantly low only at stage I in the no touch group  $<0.01$ .

## DISCUSSION

Since the introduction of hysteroscopy, it has been proved to be a powerful diagnostic tool for visualizing the cervical canal and the uterine cavity (3-6). The main limitation to its widespread use is pain and low patient tolerance leading to perform the procedure under general anesthesia. Outpatient hysteroscopy reduces risks associated with general anesthesia. Using the "traditional technique" of diagnostic hysteroscopy, patients may experience pain during speculum insertion into the vagina, grasping and traction of the cervix by the tenaculum, passage of the hysteroscope through the cervical canal, and distention of the uterine cavity with the distention medium requiring local anesthesia. Various methods of local anesthesia have been tested to

reduce the discomfort of hysteroscopy with controversial results (7-18).

Bettocchi and Selvaggi, reported more than 11000 hysteroscopic procedures performed using the vaginoscopic no touch technique and found that as many as 99.1% of the patients reported no discomfort related to the procedure (19,20). Sagiv et al, in a randomized controlled trial; also reported significantly lower pain perception in patients undergoing office hysteroscopy with vaginoscopic method compared with the traditional method despite application of intracervical anesthesia (6). In our study, pain perception was statistically significantly lower in patients who underwent the office hysteroscopy with the no touch method than in those who underwent the traditional procedure with the local intracervical anesthesia in only first stage of the procedures. We have not found any significant difference in pain scores in the stages that hysteroscope has been introduced through the cervical canal, passing through the internal cervical os and examination of the uterine cavity. Patients also did not described different pain scores 15 minutes after the both procedures. In our study despite the application of local anesthesia we have not found any significant difference in pain scores between two methods. This may be due to the experienced gynecologist and use of low diameter office hysteroscope that causes low pain perception. Savig et al. did not examine the procedures in various stages and compared the procedures as during and after in their study. They also found similar satisfaction rates between the two procedures. In our

study patients had similar pain scores 15 minutes after the both procedures (6).

Limitation of our study is; none of the participating patients had prior experience with either vaginoscopy or the traditional approach, so it is unrealistic to presume that patients would be predisposed to report their experience of pain differently by treatment.

In our study failure rate was 10.4% in the no touch method and it was not statistically significant. Two of five patients were nulliparous with infertility and two of them were at menopause with cervical stenosis. Neither menopause nor infertility was not significant cofounders in the failure rate. Because of the low sample size, new studies with big sample size in specific patient subgroups are needed.

Inconsistent with observational studies and the randomized study by Sagiv et al. Sharma et al. failed to observe any advantage of no touch hysteroscopy, compared with traditional hysteroscopy (6,19,20,21). Small sample size and different diameters may also be the limitation of their study.

In summary, we have only found significantly less pain in the vaginoscopic stage of the no touch method compared with the traditional method including the insertion of the speculum, application of the tenaculum and the local anesthesia. This technique has the advantage of elimination of any type of premedication, analgesia, or anesthesia, making the procedure faster with acceptable failure rate. These findings support the use of vaginoscopy over the traditional method.

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