



# Does “no-touch” technique hysteroscopy increase the risk of infection?

## “No-touch” teknik histeroskopi enfeksiyon riskini artırır mı?

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### Abstract

**Objective:** Today, thanks to its many advantages, hysteroscopy with a vaginoscopic approach (no-touch) is increasingly being used more in outpatient diagnoses and treatments. However, there are concerns that the “no-touch” technique increases ascending genital tract infections since a speculum is not inserted, and disinfection of the cervix cannot achieve.

**Materials and Methods:** Between 2011 and 2017, 302 patients who underwent office hysteroscopy with the vaginoscopic approach (group 1) and 254 patients who underwent hysteroscopy with the standard method under anesthesia in the operating room (group 2) were compared in terms of early complications (within two weeks postoperatively). The primary outcome was early postoperative infection, and the secondary outcome was other early complications, such as bleeding and rupture.

**Results:** In this study, the success rate of hysteroscopy with the vaginoscopic approach was 96.4%. According to the visual analog scale scoring system, 88.7% of the patients described mild-to-moderate pain. When group 1 and 2 were compared in terms of postoperative infection (3% and 2.4%, respectively) and other early complication rates (0% and 0.8%, respectively), no statistically significant difference was found ( $p>0.05$ ).

**Conclusion:** Hysteroscopy with a vaginoscopic approach continues to be the gold standard method that is safe and well-tolerated by patients.

**Keywords:** Hysteroscopy, vaginoscopy, office hysteroscopy, complication, infection

### Öz

**Amaç:** Günümüzde pek çok avantajı nedeniyle, vajinoskopik (no-touch) yaklaşımla histeroskopi, ayaktan tanı ve tedavilerde, giderek daha fazla kullanılmaktadır. Ancak spekulum yerleştirilmediği ve serviksin dezenfeksiyonu sağlanamadığı için “no-touch” tekniğinin asendan genital sistem enfeksiyonlarını artırdığına dair endişeler mevcuttur.

**Gereç ve Yöntemler:** 2011-2017 yılları arasında vajinoskopik yaklaşımla ofis histeroskopisi yapılan 302 hasta (grup 1) ile ameliyathanede, anestezi altında standart yöntemle histeroskopi yapılan 254 hasta (grup 2) erken (postoperatif 2 hafta içindeki) komplikasyonlar açısından karşılaştırıldı. Birincil sonuç erken postoperatif enfeksiyondu, ikincil sonuç ise kanama ve rüptür gibi diğer erken komplikasyonlardı.

**Bulgular:** Bu çalışmada vajinoskopik yaklaşımla histeroskopinin başarı oranı %96,4 olarak bulundu. Görsel analog skala skorlama sistemine göre hastaların %88,7'si hafif ve orta şiddette ağrı tanımladı. Grup 1 ve grup 2, postoperatif enfeksiyon (sırasıyla %3 ve %2,4) ve diğer erken komplikasyon oranları (sırasıyla %0 ve %0,8) açısından karşılaştırıldığında aralarında istatistiksel olarak anlamlı fark bulunmadı ( $p>0,05$ ).

**Sonuç:** Vajinoskopik yaklaşımla histeroskopi, güvenli ve hastalar tarafından iyi tolere edilen, altın standart yöntem olmaya devam etmektedir.

**Anahtar Kelimeler:** Histeroskopi, vajinoskopi, ofis histeroskopisi, komplikasyon, enfeksiyon

**PRECIS:** In this study, we evaluated whether the risk of infection increases in no-touch vaginoscopic hysteroscopy compared to the standard method.

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## Introduction

Hysteroscopy is accepted as the gold standard and minimally invasive method in the diagnosis and treatment of intrauterine pathologies<sup>(1)</sup>. Inserting a speculum, cleaning the cervix, applying a tenaculum to the cervix, and initiating cervical dilatation in traditional hysteroscopy are painful procedures and are performed in the operating room, under local or general anesthesia<sup>(2)</sup>. Since 1990, office hysteroscopy (outpatient hysteroscopy) has been increasingly used by clinicians with the concept of "see and treat" intrauterine pathologies in the same session<sup>(3)</sup>. Over time, the vaginoscopic "no-touch" technique<sup>(4)</sup> has proven to be better tolerated than the traditional technique in the office setting, without the use of anesthesia or analgesia<sup>(5)</sup>. With small-diameter, continuous-flow hysteroscopes manufactured with the latest technological advances, office hysteroscopy has become safe, efficient, inexpensive, less invasive, and less painful without the risk of anesthesia<sup>(6)</sup>. However, there are also concerns that the vaginoscopic approach is more likely to result in postoperative genital tract infections because the cervix is not cleaned before the hysteroscope being inserted into the uterine cavity<sup>(5)</sup>. In this study, we evaluated whether office hysteroscopic procedures with the vaginoscopic approach, which are increasingly used, are associated with an increase in infections and any other early complications (such as bleeding, uterine perforation and fluid overload) compared with the traditional method.

## Materials and Methods

This study was conducted retrospectively at a tertiary referral university hospital. Ethical approval was obtained from the institutional ethics committee (approval number: 2020.07.2.07.108). By examining patient records, 302 women who underwent office hysteroscopy with the vaginoscopic approach between 2011 and 2017 were considered group 1. In the same data range, 254 women who underwent hysteroscopy with the standard method under local or general anesthesia in the operating room were designated as group 2. Diagnostic or operative hysteroscopy was planned for the patients with various indications, such as abnormal uterine bleeding, submucosal fibroids, increased endometrial thickness, uterine anomalies, and intrauterine devices that cannot be removed. Diagnostic or operative hysteroscopy was also planned for those with recurrent pregnancy loss, unexplained infertility, endometrial and cervical polyps. Office hysteroscopy with the vaginoscopic approach was first offered to patients who were prescribed diagnostic or short-term hysteroscopic procedures. Hysteroscopy under direct general or local anesthesia was planned for women with intracavitary fibroids or polyps larger than 2 cm, for those who preferred the procedure under anesthesia, and for those who had a history of severe cervical stenosis or vaginismus. Informed consent of the patients was obtained for the procedure. Suspected pregnancy, heavy uterine bleeding, ongoing vaginal infections, pelvic

inflammatory disease, and a history of cervical or endometrial premalignant lesions were the exclusion criteria. All procedures were performed in the early proliferative phase of the menstrual cycle in the premenopausal patients. There were no restrictions regarding the day of the procedure in the postmenopausal patients. All the women were informed that menstrual-type cramping may occur during or after the procedure. They were assured that the hysteroscopy could be terminated at any time upon their request. All office hysteroscopy procedures were performed using the vaginoscopic approach by three experienced gynecologists following aseptic rules, in the gynecological position, without analgesia or anesthesia, without vaginal disinfection, without the use of a vaginal speculum and tenaculum<sup>(4)</sup>. A 2.9 mm diameter, 30° lens system, 5 mm outer diameter continuous flow Bettocchi® hysteroscope was used for outpatient procedures (Karl Storz SE&Co. KG, Germany). For the diagnostic and surgical procedures performed under anesthesia in the operating room, a 4 mm diameter, 12° lens system continuous flow Hopkins® hysteroscope with an 8.7 mm resectoscope sheath was used (Karl Storz SE&Co. KG, Germany). The uterine cavity was inflated with 0.9% normal saline solution at a pressure below 60 mm Hg, controlled by an electronic irrigation pump (Endomat, Karl Storz SE & Co. KG, Germany). Illumination was provided by a high-intensity cold light source provided by a fiber optic lead.

The hysteroscope was inserted into the lower vagina, then inflated with the distention medium for vaginoscopy. Fornixes and vaginal walls were examined. After the external cervical ostium was identified, the instrument was inserted into the cervical canal and directed towards the uterine cavity. The cervix, cervical canal, uterine cavity, tubal ostia and endometrium were examined. The patient was in communication with the surgeon and, could report any discomfort or pain during the office hysteroscopy. Patients were also encouraged to watch images of the procedure on the monitor. When the pain became unbearable for the patient, office hysteroscopy was stopped and postponed to be performed under anesthesia in the operating room at a later time. Pain was assessed on a 10 cm visual analog scale (VAS) (0 for no pain and 10 for the worst imaginable pain). Since the procedures are short and simple in office hysteroscopy, fluid deficit was not calculated. After the procedure, the patients were observed for any side effects for at least one hour and then discharged.

Every patient in group 2 was placed under anesthesia after standard aseptic preoperative conditions were provided. Once anesthetized, the speculum was inserted. The vagina and cervix were disinfected with a betadyn sponge. The cervix was grasped with a tenaculum. Adequate cervical dilatation was provided with dilators according to the necessity of the procedure. The VAS scoring system was not applied to the patients in group 2. The fluid deficit was carefully studied during the operative hysteroscopic procedures. The patients were discharged after being observed in the hospital for 24 hours.

Pharmacological cervical preparation, urinary catheter and antibiotics were not used in any patient in either group. Patients who required antibiotic treatment due to urinary tract infection, vaginal discharge, fever, pelvic pain and fever above 38 °C within two weeks after the procedure were recorded. The primary study outcome was defined as infection due by office hysteroscopy with the vaginoscopic approach. The secondary study outcome was defined as other procedure-related complications.

### Statistical Analysis

Mean standard deviation, median, and interquartile range were given for descriptive statistics for continuous data, and number and percentage values were given for discrete data. The Shapiro-Wilk test was used to examine the conformity of continuous data to a normal distribution. The Mann-Whitney U test was used for comparisons between groups of continuous variables. The chi-square test was used for comparisons of categorical variables between groups. The IBM SPSS Statistics 20.0 program was used in the evaluations and  $p < 0.05$  was accepted as the statistical significance limit.

### Results

A total of 556 patients between the ages of 19 and 80 (mean  $38.17 \pm 11.24$ ) participated in the study. For their diagnoses, endometrial sampling and, where possible, therapeutic hysteroscopy without anesthesia with the vaginoscopic approach (group 1) in the office setting were performed on 302 of the patients. The hysteroscopy on every patient in group 1 was completed in approximately 15 minutes. There were 254 patients who did not accept the diagnostic office hysteroscopy procedure without anesthesia or if the operative hysteroscopy procedure was complicated enough to require cervical dilation

and would take a long time were performed under regional or general anesthesia in operating room conditions (group 2). The main characteristics of each patient are shown in Table 1. The distributions of the patients diagnoses are shown in Table 2. A comparison between group 1 and group 2 shows that the group 1 patients were statistically younger ( $p < 0.001$ ), parity and the number of children was lower ( $p < 0.05$ ), and the nulliparity rate was higher ( $p < 0.05$ ) because the pathologies that will require operative hysteroscopy will be encountered more frequently as age progresses, and the mean age of group 2 was higher due to the atrophic cervixes of the menopausal patients.

Most patients (57.9%) in the office hysteroscopy group (group 1) reported moderate pain ( $4 \leq$  VAS score  $< 7$ ), 30.8% mild (VAS score  $< 4$ ) and 11.3% severe (VAS score  $\geq 7$ ) (Table 3). Additionally, when the VAS scores of the patients in the reproductive period who underwent office hysteroscopy were compared with the patients in menopause, no statistically significant difference was found between the median values ( $p < 0.05$ ) (Table 4). The completion of the procedure was defined as complete hysteroscopy with an acceptable pain level for the patient without intraoperative complications. The procedure was completed in 96.4% ( $n = 291$ ) of the patients who underwent hysteroscopy without anesthesia with the vaginoscopic approach (group 1). An incomplete hysteroscopy was defined as the inability to enter the uterine cavity through the cervical canal in a sufficient time, failure to perform a full systematic examination of the uterine cavity, or the planned procedure. Since vasovagal reactions were observed in six patients (2%) in group 1, the procedure could not be completed and they recovered completely after bed rest and hydration. In group 1, five patients could not complete the procedure due to pain, anxiety and poor imaging. There was no morbidity

**Table 1.** Comparison of main characteristics of the 556 patients

	Total (n=556)	Group 1 (n=302)	Group 2 (n=254)	p-value
<b>Age (year)</b> Mean $\pm$ SD Median (Min-Max)	38.17 $\pm$ 11.24 36 (19-80)	36.34 $\pm$ 9.53 35 (19-80)	40.33 $\pm$ 12.27 37 (20-80)	<b>&lt;0.001*</b>
<b>Gravida</b> Median (Min-Max)	2 (0-9)	2 (0-9)	2 (0-9)	0.912*
<b>Parity</b> Median (Min-Max)	1 (0-8)	1 (0-8)	2 (0-8)	<b>0.012*</b>
<b>Number of children</b>	1 (0-7)	1 (0-5)	1 (0-7)	<b>0.013*</b>
<b>Period n (%)</b>				
<b>Premenopausal</b>	464 (83.5)	270 (89.4)	194 (76.4)	<b>&lt;0.001**</b>
<b>Postmenopausal</b>	92 (16.5)	32 (10.6)	60 (23.6)	
<b>Type of delivery n (%)</b>				
<b>Nulliparity</b>	170 (30.9)	106 (35.5)	64 (25.5)	<b>0.034**</b>
<b>Vaginal delivery</b>	258 (46.9)	134 (44.8)	124 (49.4)	
<b>Cesarean section</b>	122 (22.2)	59 (19.7)	63 (25.1)	

\*Mann-Whitney U test, \*\*chi-square test, SD: Standard deviation, Min: Minimum, Max: Maximum

**Table 2.** Distribution of patients' indications of hysteroscopy

	Total n (%)	Group 1 n (%)	Group 2 n (%)
<b>INDICATIONS</b>	556	302	254
Increased endometrial thickness	109 (19.6)	87 (28.8)	22 (8.7)
Recurrent pregnancy loss	104 (18.7)	86 (28.5)	18 (7.1)
Abnormal uterine bleeding	102 (18.4)	36 (11.9)	66 (26)
Endometrial polyp	80 (14.4)	27 (8.9)	53 (20.9)
Unexplained infertility	48 (8.6)	32 (10.6)	16 (6.3)
Submucous myoma	30 (5.4)	4 (1.3)	26 (10.2)
Postmenopausal bleeding	26 (4.7)	3 (1.0)	23 (9.1)
Removal of intrauterin device	20 (3.6)	10 (3.3)	10 (3.5)
Asherman syndrome	16 (2.9)	8 (2.6)	8 (3.1)
Uterine anomaly	13 (2.4)	4 (1.3)	9 (3.6)
Niche	5 (0.9)	2 (0.7)	3 (1.2)
Recurrent in vitro fertilization failure	2 (0.4)	2 (0.7)	0
Rectovaginal fistula	1 (0.2)	1 (0.3)	0

**Table 3.** VAS distributions of patients who underwent office hysteroscopy

VAS	n (%)
<4	93 (30.8)
≤4-<7	175 (57.9)
≥7	34 (11.3)

VAS: Visual analog scale

**Table 4.** Comparison of VAS scores of patients who underwent office hysteroscopy with those in the reproductive period and those in the menopause period

	Reproductive n (270)	Menopause n (32)	p-value
<b>VAS Median (Min-Max)</b>	4 (1-9)	4 (2-9)	0.846*

\*Mann-Whitney U test, VAS: Visual analog scale, Min: Minimum, Max: Maximum

requiring hospitalization due to any complication in group 1. In group 2, uterine rupture developed during synechiolysis in two patients with diagnoses of Asherman's syndrome. Since the bleeding was self-limiting and did not develop sufficiently to require surgical intervention, the patients were discharged after two days of hospitalization with full recovery. Nine patients in group 1 (three urinary tract infections, five increased vaginal discharges, one fever and pelvic pain) and six patients in group 2 (one urinary tract infection, three vaginal discharge, two fever and pelvic pain) were followed up within two weeks after the procedure with diagnoses of infection presumed to be due to the procedure. Three patients with fever and pelvic pain

were hospitalized and the others recovered completely with outpatient antibiotic treatment. However, when the two groups were compared in terms of infection and complication rates, no statistical difference was found ( $p>0.05$ ) (Table 5).

## Discussion

The results of our study showed that the incidence of infection, uterine rupture, or bleeding did not increase in office hysteroscopy performed with the vaginoscopic approach. In our department, we perform hysteroscopic procedures with a vaginoscopic approach, without analgesia and anesthesia in office settings for most patients who apply to the gynecology outpatient clinic and require intracavitary imaging and intervention. In numerous retrospective and randomized studies to date, the vaginoscopic “no-touch” technique during an office hysteroscopy procedure is successful, less painful and faster compared with traditional techniques using a vaginal speculum and cervical grasped<sup>(7,8)</sup>. Moreover, those who have not had sexual intercourse, who are nulliparous, and who have genital tract atrophy or vaginismus benefit most from the vaginoscopic approach.

The probability of complications after hysteroscopy is 1-2.7%<sup>(9-11)</sup>. Although some studies have shown that there are fewer surgical complications in vaginoscopy than in standard hysteroscopy<sup>(7)</sup>, it has been shown that there is no statistical difference in terms of surgical complications in others<sup>(12)</sup>. Serious complications, such as uterine perforation or bleeding are rare in the office setting, but vasovagal reactions occur in 2.3 and 9.0%<sup>(7,13)</sup>. In this study, we observed a 2% vasovagal reaction in the group that underwent hysteroscopy with the vaginoscopic approach, consistent with these findings.

Routine antibiotic prophylaxis is not recommended because the ascending infections (endometritis and urinary tract infections) do not increase since the cervix can be sterilized by inserting a speculum in standard hysteroscopy<sup>(14)</sup>. There are few studies reporting that the rate of infectious complications after hysteroscopic surgery is 0.18-1.5%<sup>(13)</sup>. After retrospective operative hysteroscopy, consisting of 21,676 procedures, the infection rate was reported as 0.01%<sup>(9)</sup>. However, in a prospective study of 2,116 cases (endometritis 0.9%, urinary tract infection 0.6%), it was found to be 1.42%<sup>(15)</sup>. The risk of endometritis ranges between 0.85% and 2.7% in the literature<sup>(16)</sup>. However, there are concerns about the risk of ascending genital tract infection since adequate disinfection cannot be performed before hysteroscopy with the vaginoscopic approach. In a randomized controlled study by Smith et al.<sup>(7)</sup> in 1,597 women in 2019, vaginoscopic hysteroscopy without disinfection was compared with standard hysteroscopy showing that the rate of genital tract infection did not increase in the vaginoscopy group. Tien et al.<sup>(12)</sup> disinfected the vagina and cervix with betadine-soaked cotton swabs before vaginoscopy and found that there was no significant difference in the genital tract infection rate between the vaginoscopy and standard hysteroscopy groups.

The probability of bleeding requiring intervention after hysteroscopic procedures were found to be quite low (0-0.61%) in various studies<sup>(9-11,17)</sup>. One of the most common complications of hysteroscopy (0.12%) is uterine perforation, while the most common bleeding cause is uterine perforation. Depending on the type of operation, the perforation may be partial or complete. Even vital organ damage may develop due to blunt or electrosurgical damage<sup>(9-11)</sup>. Uterine perforation is most commonly seen in Asherman's syndrome cases (4.5%)<sup>(10)</sup>.

In this study, uterine rupture developed in only two patients with a diagnosis of Asherman's syndrome (0.4%), which was consistent with the literature. No uterine ruptures developed in the office hysteroscopy group. All these findings are compatible with the literature.

The reasons for not completing the hysteroscopic procedure with the vaginoscopic approach include pain, anxiety, cervical stenosis, excessive flexion of the cervix, vasovagal reaction, a retroverted uterus and adhesions<sup>(5,7,18)</sup>. Between 83% and 98% of diagnostic procedures can be successfully performed with office hysteroscopy<sup>(7,8,13,19,20)</sup>. However, there are studies reported that the success of outpatient hysteroscopy varies between 44% and 99.5%<sup>(21-23)</sup>. In this study, the failure rate for all outpatient hysteroscopy procedures was 3.6%, which is lower than 10% reported in the previously<sup>(24)</sup>. The reason for such a good result may be that the procedures included in our study were performed by gynecologists highly experienced in hysteroscopy. In the study of Campo et al.<sup>(21)</sup>, it was shown that the procedures performed by experienced surgeons are less painful.

Most studies till date have compared the pain scores and success rates of the vaginoscopic approach and standard hysteroscopy. In most of these studies, it has been shown that the vaginoscopic approach causes a lower VAS score than standard hysteroscopy<sup>(7,25-27)</sup>. However, Sharma et al.<sup>(28)</sup> showed no difference in pain scores between vaginoscopy and standard hysteroscopy. In our department, we do not perform hysteroscopy in the outpatient setting for patients who require direct standard hysteroscopy or who cannot tolerate the vaginoscopic approach. In the outpatient clinic, we only perform hysteroscopy with the vaginoscopic approach. Therefore, we could not compare the pain scores between the two groups. In

**Table 5.** Comparison of the groups in terms of success and complications

	Total n (%)	Group 1 n (%)	Group 2 n (%)	p-value
<b>Process completion</b>				
Yes	540 (97.1)	291 (96.4)	249 (98)	0.240**
No	16 (2.9)	11 (3.6)	5 (2.0)	
<b>Vasovagal reaction</b>				
No		296 (98)		-
Yes		6 (2.0)		
<b>Infection</b>				
No	541 (97.3)	293 (97)	248 (97.6)	0.654
Yes	15 (2.7)	9 (3.0)	6 (2.4)	
<b>Uterine rupture or bleeding</b>				
No	554 (99.6)	302 (100)	252 (99.2)	0.208
Yes	2 (0.4)	0	2 (0.8)	

\*\*chi-square/Fisher's Exact test

fact, 88.7% of the patients in this study defined the pain scores of office hysteroscopy with the vaginoscopic approach as mild-moderate. Additionally, it was determined that the patients' being in the reproductive period or menopause did not change their pain scores.

Fluid overload, another early but rare complication (<5%) of operative hysteroscopy, did not develop in any patient in this study<sup>(9-11)</sup>. No severe complications, such as infectious shock<sup>(29)</sup> or pelvic abscesses<sup>(30)</sup> were noted in our study.

It appears that hysteroscopy with the vaginoscopic approach does not show a statistically significant increase in the risk of complications, including the worrisome risk of infection. However, after rare cases of septic shock have been reported, we now prefer to perform vaginoscopy after cleaning the vaginal entrance with betadyn swabs.

The strengths of our study are the large number of patients from different age groups, the fact that all procedures were performed using the same devices and by a small group of surgeons. However, pain assessment was only possible in patients in the vaginoscopy group. The limitation of the study was that it was retrospective and only patients with registered infections were considered positive. Patients who could not be reached were considered negative for infection. Unfortunately, our groups were not similar in terms of diagnosis and patient characteristics as we did not perform the standard hysteroscopy that would require us to hold and dilate the cervix in the office.

## Conclusion

Office hysteroscopy with a vaginoscopic approach is increasingly used in daily practice as technological developments and surgical experience increases. Although our results do not indicate that there would be an increased risk of infection and complications compared with standard hysteroscopy, care should be taken in terms of the risk of serious infection considering the rare cases in the literature. Vaginoscopy should be a routine method for outpatient hysteroscopy. In this way, the number of procedures performed under anesthesia will decrease, the duration of hospital stays will be shortened and the cost will decrease. Therefore, clinicians accustomed to standard hysteroscopy will also require training to become proficient in this technique. Women should be informed that there is a low risk of genital tract infections, which may necessitate antibiotic treatment within two weeks following the procedure. We believe that more accurate data can be obtained on this subject with well-planned, prospective studies with more cases in the future.

## Ethics

**Ethics Committee Approval:** This study was conducted retrospectively at a tertiary referral university hospital. Ethical approval was obtained from the institutional ethics committee (approval number: 2020.07.2.07.108).

**Informed Consent:** Informed consent of the patients was obtained for the procedure.

**Peer-review:** Externally peer-reviewed.

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