

# The efficacy, cost and patient satisfaction of classic versus office hysteroscopy in cases with suspected intrauterine space occupying lesions with 3-dimension ultrasound and abnormal uterine bleeding

*Üç boyutlu ultrasonografi ile intrauterin yer kaplayan lezyon şüphesi olan anormal uterus kanamalı olgularda ofis histeroskopi ile klasik histeroskopinin etkinlik, maliyet ve hasta memnuniyeti açısından karşılaştırılması*

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## Abstract

**Objective:** The aim of this study is to compare the diagnostic efficacy, treatment effectiveness and cost of office hysteroscopy procedure with classic hysteroscopy in women suspected of having an intrauterine space occupying lesion, after being examined for abnormal uterine bleeding.

**Material and Methods:** Among 544 cases admitted to our outpatient clinic due to abnormal uterine bleeding, 123 cases suspected of having an intrauterine space occupying lesion on 3D transvaginal ultrasound were included in the study. Patients were informed about classic and office hysteroscopy and asked to choose one of them. Fifty-seven cases preferred classic hysteroscopy and 66 cases preferred office hysteroscopy. The Visual analog scale was used to measure pain in office hysteroscopy cases while the Likert scale was used for patient satisfaction and cost was calculated in Turkish Lira.

**Results:** According to the histopathological examination, 65.9% of the cases (n=81) were diagnosed as polyp and 7.3% of the cases (n=9) were diagnosed as submucous leiomyoma. Mean operation time was 11±5.6 min. for office hysteroscopy and 42.6±18.4 min. for classic hysteroscopy (p<0.001). The level of pain before the operation was 0.3±0.1 (0-1), during the operation 2.8±2.5 (0-10) and after the operation 1.5±1.6 (0-8) in Office hysteroscopy cases. Among the Office hysteroscopy cases, 89.3% were very satisfied and 86.3% will advise other patients to have the procedure. Patients were evaluated at sixth month after the procedures and 92.4% of office hysteroscopy group and 96.4% of classic hysteroscopy group were symptom free. At sixth month of the office hysteroscopy procedure 83.3% of the cases were satisfied with the procedure and 81.8% would advice other patients to have the procedure. The mean cost of classic hysteroscopy was 3.6 times higher than the office procedure.

**Conclusion:** Office hysteroscopy is a safe and satisfactory procedure for the patient and provides a fast "see and treat" option at a low cost as an out patient procedure without need for general anesthesia. It should be utilized as a first line diagnosis and treatment option.

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**Key words:** Intrauterine pathology, office hysteroscopy, efficacy, patient satisfaction, cost

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## Özet

**Amaç:** Anormal uterin kanama yakınması ile başvuran, muayenesi sonrasında rutin yapılan transvajinal ultrasonografide endometriyal kavite içinde lezyon düşünülen hastaların, ofis histeroskopi ile ulaşılan tanı, tedavi sonuçlarını ve maliyeti klasik histeroskopik yaklaşımdan elde edilen sonuçlar ile karşılaştırmayı amaçladık.

**Gereç ve Yöntemler:** Çalışmaya anormal uterin kanama ile polikliniğe başvuran 544 olgu arasından 3D transvajinal ultrasonografide uterus içinde yer kaplayıcı lezyonu olan toplam 123 olgu alındı. Hastalara klasik ve ofis histeroskopi yöntemleri anlatılarak bir işlemi tercih etmesi istendi. Bu olguların 57 tanesi klasik histeroskopi ve 66 tanesi ofis histeroskopi ile tedaviyi tercih etti. Ofis histeroskopi olgularında görsel analog skala kullanılarak, tüm olgularda Likert skalası kullanılarak memnuniyet ve Türk Lirası olarak işlemin maliyeti hesaplandı.

**Bulgular:** Nihai patoloji sonuçlarına göre endometrial polip görülme sıklığı %65.9 (n=81), submuköz myom görülme sıklığı %7.3 (n=9) olarak bulundu. Ortalama işlem süresi ofis histeroskopi için 11.0±5.67, klasik histeroskopi için 42.6±18.4 dakika olarak bulundu (p<0.001). Ofis histeroskopisi yapılan hastalarda işlem öncesi ağrı ortalaması 0.3±0.1 (0-1), işlem sırasındaki ağrı ortalaması 2.8±2.5 (0-10), işlem sonrası ağrı ortalaması 1.5±1.6 (0-8) olarak bulundu. Ofis histeroskopi sonrası hastaların işlemde çok memnun kalma ve tavsiye edilir bulma oranları sırasıyla %89.3 ve %86.3 olarak tespit edildi. Ofis histeroskopi grubundaki 66 hastanın tedavi sonrası 6. ayda semptomsuz fayda görme oranı %92.4 ve klasik histeroskopi grubunda ise %96.4 olarak hesaplandı (p=0.3). Ofis histeroskopi sonrası 6 ayda ise hastaların işlemde memnun kalma ve tavsiye edilir bulma oranları sırasıyla %83.3 ve %81.8 olarak tespit edildi. Maliyet analizinde ofis histeroskopinin klasik yaklaşımdan 3.6 kat ucuz olduğu tespit edildi.

**Sonuç:** Ofis histeroskopisi, hızlı sonuç veren, genel anestezi gerektirmeyen, doğrudan görüntülemeyi ve tedaviyi sağlayan, ayaktan hastada yapılabilen, düşük maliyetli, hasta açısından güvenilir ve tatminkar bir yöntemdir. Anormal uterin kanamalı hastalarda intrakaviter lezyondan şüpheleniliyorsa ilk basamak tanı ve tedavi aracı olarak düşünülmelidir. (J Turkish-German Gynecol Assoc 2009; 10: 189-93)

**Anahtar kelimeler:** İntrauterin patoloji, ofis histeroskopi, etkinlik, hasta memnuniyeti, maliyet

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## Introduction

Abnormal uterine bleeding is a common cause of admission to the gynecology outpatient clinic and constitutes 15 - 30% of admissions (1, 2). In women with normal uterine size, 20% of the hysterectomies are due to abnormal uterine bleeding (2). In order to diagnose probable pathologies causing abnormal uterine bleeding, office hysteroscopy was proposed as an alternative to ultrasonography and saline infusion sonography as it serves both as a diagnostic and treatment tool (3). Due to its smaller diameter, office hysteroscopy can be applied on an outpatient basis without the need for cervical dilatation and general anesthesia. The procedure is a "see and treat" operation which can be expected to decrease cost and labour while increasing patient satisfaction (4). Despite these expectations, only a small percentage of gynecologists apply office hysteroscopy as an office procedure (2). The main reason for this is the anxiety of the care providers that the pain experienced by the patient without general anesthesia might cause ineffective visualization and incomplete operation.

The aim of this study is to compare the diagnostic efficacy, treatment effectiveness and cost of office hysteroscopy procedure with classic hysteroscopy in women suspected to have intrauterine space occupying lesion, following examination for abnormal uterine bleeding.

## Materials and Method

This prospective study was conducted between 01.01.2006 and 30.05.2008 after ethic committee approval in the Kocaeli University Obstetrics and Gynecology Clinic.

In 388 women who were admitted with abnormal uterine bleeding, 2D and real time 3D transvaginal ultrasonography scanning was performed (7.5 MHz vaginal probe, Voluson Pro 730, General Electric, USA). A total of 123 women constituted the study group providing they met all of the following inclusion criteria: 1) an intrauterine space occupying lesion was suspected on real time 3D transvaginal ultrasound scan, 2) gave written consent to be included in the study and accepted hysteroscopy. No other exclusion criteria was applied.

The women were informed about office hysteroscopy without anesthesia and classic hysteroscopy under general anesthesia. The operative technique was performed according to the patients' choice. Office hysteroscopy was preferred by 66 women. Office hysteroscopy was performed on the same day of the patients' admittance to the hospital, irrespective of the day of the menstrual cycle if there was no active bleeding. If the patient had active uterine bleeding they were asked to come back for office hysteroscopy when the bleeding ceased. A 2.7 mm in diameter telescope with a 30° angle was used within an office hysteroscopy of 5.5 mm in total diameter (RZMedizin-Technik, Germany). After speculum examination and cervicovaginal washing a teneculum was used to grasp the cervix from 11 and 1 o'clock positions. Hysteroscopy was applied without anesthesia and cervical dilatation. However, if the patient required analgesia during the operation, 5 ml of 2% prilocain HCl (Citanest® 2%, AstraZeneca, Sweden) was used for cervical

local analgesia. If the patient still felt pain, midazolam 1 mg/20 kg intravenous (Dormicum® 1 mg/ml, Roche, Germany) was given for sedation. If the cervix was tight and operation field restricted, the next attempt was performed two hours after the patient received 200 mcg misoprostol sublingually (Cytotec® 200 mcg, Aris, Turkey) for cervical ripening. All cases of endometrial polyps, submucous leiomyomas and intrauterine adhesions were removed with scissors. Saline in 200 ml bags was used for uterine distension. If no pathology was observed during office hysteroscopy then punch biopsy forceps were used to sample the endometrium from the anterior and posterior uterine walls. If the operation was not completed due to visualization problems, the patients were asked to come back a week later.

Classic hysteroscopy was performed in 57 women. The operation was conducted, under general anesthesia. Cervical dilatation was performed via Hegar dilators. A 4 mm diameter telescope with a 12° angle was used with an operative sheath 10 mm in total diameter (Storz, Germany). All patients received 200 mcg of misoprostol sublingually for cervical ripening 2 hours prior to the operation. For uterine distension 5% mannitol (Resectisol® 3000 ml, Eczacibasi-Baxter, Turkey) was used. In the postoperative period the patients received intramuscular 75 mg diclofenac sodium (Diclomec® 75 mg, Mecom, Turkey) whenever they report pain.

The operation time, complications and need for second operation were noted for all the patients. The Visual analogue scale (VAS) over 10 was used to evaluate the pain felt by the patients before the operation, during the operation after the uterus distended for ideal visualization and 30 minutes after the operation. The Likert scale was used to evaluate patient. Satisfaction after the operation was scaled as 1- very dissatisfied, 2- dissatisfied, 3- neither satisfied nor dissatisfied, 4- satisfied, 5- very satisfied. The patients were asked if they would recommend this office procedure to other patients as 1- strongly not recommend 2- not recommend 3- neither recommend nor not recommend 4- recommend 5- strongly recommend. The satisfaction and recommendation ranking was performed when the patient was alone and pain free after operation. The patients ranked these on a sheet of paper with no name given, and this was then put into a regular envelope and placed in a locked box.

All patients were re-evaluated six months after the operation for signs and symptoms of abnormal uterine bleeding. The data of the study was analyzed using SPSS 12.0 for windows (Statistical Package for Social Sciences, IL, USA). The results are presented as number and percentages or mean±standard deviation. Independent samples t-test was used to compare categorical variables between the office and classic hysteroscopy groups. Probability (p) value <0.05 was considered to be statistically significant.

## Results

The demographic variables of the patients are presented in Table 1. The mean age of the patients was 46±10.9 years in the office hysteroscopy group and 42±10.4 years in the classic hysteroscopy group (p=0.06). The percentage of menopausal, nulliparous, and primiparous women, the mean number of

previous pregnancies and the mean education in years were not statistically different in the two groups. Fourteen patients (21.2%) in the office hysteroscopy group and 12 patients (21%) in the classic hysteroscopy group had a systematic disease such as hypertension (n=10), diabetes (n=9) and chronic obstructive pulmonary disease (n=7).

The main complaints of the patients at the time of admission are presented in Table 2. Postmenopausal bleeding (n=20) was the most frequent complaint in the office hysteroscopy group, while menometrorrhagia (n=17) was the most common complaint in the classic hysteroscopy group. The distribution of the main complaints was not statistically different in the two groups. Fifty-nine (89.3%) patients in the office hysteroscopy group did not require or demand any anesthesia. Seven patients (10.6%) required paracervical infiltration with 2% prilocain and 3 (4.5%) patients required intravenous sedation with midazolam in addition to 2% prilocain infiltration due to severe pain. All 57 patients in the classic hysteroscopy group received general anesthesia.

Office hysteroscopy could not be performed in nine patients (13.6%) at the first attempt but was successful two hours after 200 mcg misoprostol sublingually. All patients in the classic hysteroscopy group received 200 mcg misoprostol sublingually 2 to 3 hours prior to the operation. In six patients, the office hysteroscopy operation was incomplete due to visualization problems in one patient, too much pain in two patients during myomectomy and the presence of more than one submucous leiomyoma. In all cases the office hysteroscopy was repeated in 2 to 4 days when the uterine bleeding stopped and the patient felt ready to undergo a second operation. The repeated office hysteroscopy was successfully accomplished in all patients. Leiomyomas were sliced and removed at the time of the operation in the classic hysteroscopy group. In the office hysteroscopy group the root of the leiomyomas were cut and they were left inside the uterus. The leiomyomas were expelled in a median of 12 days (7-22) and sent for pathological examination. All polyps were removed as a whole after their roots were cut or cauterized. No procedure related complications occurred in the two groups.

Three percent of the patients (n=2) had repeated pain before the office hysteroscopy procedure. The mean pain score evaluated via visual analogue scale (VAS) was 0.3±0.1 (0-1) prior to the operation, 2.8±2.5 (0-10) during the operation and 1.5±1.6 (0-8) after the operation. The distribution of pain scores reported by the patients is presented in Figure 1. When asked 30 minutes after the office hysteroscopy procedure, 89.3% of the patients of the patients were satisfied or very satisfied (Likert scale 4 and 5), 7.5% were neither satisfied nor dissatisfied (Likert scale 3) by the procedure. 86.3% of the patients would recommend or strongly recommend (Likert scale 4 and 5) the procedure to other patients while 6% would neither recommend nor not recommend the procedure (Likert scale 3).

There was no space occupying lesion in six patients of the office hysteroscopy group and five patients of the classic hysteroscopy group so only hysteroscopy guided endometrial sampling was performed. Surgically correctable pathologies such as polyp and leiomyoma were diagnosed in 49 (74.2%) and 41

(71.9%) of the office and classic hysteroscopy groups respectively. The pathological findings of the patients were presented in Table 3. The most common pathology in the two groups were endometrial polyps; 44 (66.7%) and 37 (64.9%) in the office and classic hysteroscopy groups respectively. The distribution of endometrial polyps, submucosal leiomyomas, secretory endometrium, proliferative endometrium, and simple and complex endometrial hyperplasia were similar among the two groups.

**Table 1. Demographic variables of the patients. Data is presented as number and percentages or mean ± standard deviation)**

Variable	Office hysteroscopy (n=66)	Classic hysteroscopy (n=57)	P
Age (years)	46±10.9	42±10.4	0.06
Postmenopausal (%)	19 (28.8)	15 (26.3)	0.76
Education (years)	6.09±2.6	6.2±2.7	0.8
Gravida	3.1±3.3	3.2±2.3	0.9
Nulliparity	21 (31.8)	11 (19.3)	0.11
Primiparity	3 (4.5)	5 (8.8)	0.34
Multiparity	42 (63)	41 (72)	0.32
Systemic diseases*	14 (21.2)	12 (21)	0.27

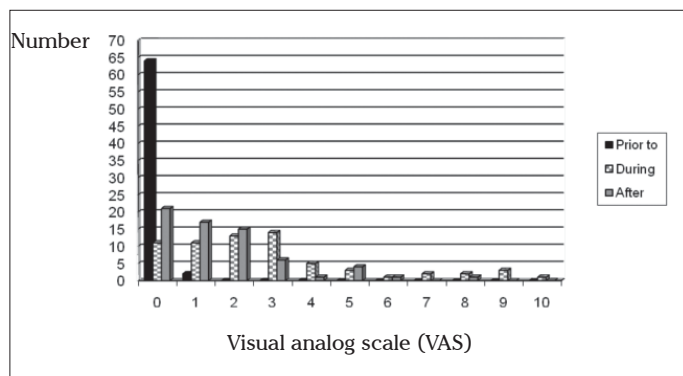
\*Systemic diseases include hypertension, diabetes and chronic obstructive pulmonary problems

**Table 2. Main complaints of the patients. Data is presented as numbers and percentages**

Variable	Office hysteroscopy (n=66) n (%)	Classic hysteroscopy (n=57) n (%)	P
Menorrhagia	12 (18.2)	10 (17.5)	0.91
Premenstrual spotting	18 (27.3)	15 (26.3)	0.90
Menometrorrhagia	16 (24.2)	17 (29.8)	0.48
Postmenopausal bleeding	19 (28.7)	15 (26.3)	0.76

**Table 3. Histopathology results of the patients. Data is presented as numbers and percentages**

Results	Office hysteroscopy (n=66) n (%)	Classic hysteroscopy (n=57) n (%)	P
Endometrial Polyp	44 (66.7)	37 (64.9)	0.83
Submucosal leiomyoma	5 (7.6)	4 (7)	0.89
Secretory endometrium	5 (7.6)	9 (15.7)	0.16
Proliferative endometrium	8 (12.1)	4 (7)	0.34
Simple hyperplasia without atypia	3 (4.5)	3 (3)	0.66
Complex hyperplasia without atypia	1 (1.5)	0	0.35



**Figure 1. Pain reported by the patients prior to, during and after office hysteroscopy According to Visual analog scale**

All postmenopausal women (n=34) were symptom and complaint free six months after the operation. Among the premenopausal patients, 8.5% (4/47) in the office hysteroscopy group and 7.1% (3/42) in the classic hysteroscopy group still had abnormal uterine bleeding six months after the first operation. All cases with persistent abnormal uterine bleeding were diagnosed to have endometrial hyperplasia so progesterone treatment was started in 3 patients and a Levonorgestrel containing intrauterine device was applied in one patient of the office hysteroscopy group. All three cases with persistent abnormal uterine bleeding and endometrial hyperplasia received progesterone treatment in the classic hysteroscopy group. The treatment efficacy of office hysteroscopy was 92.4% among 66 patients and 96.4% 57 patients of classic hysteroscopy. The patient satisfaction at the sixth month of treatment was 83.3% (Likert scale 4 and 5) in the office group and 81.8% of patients would recommend the procedure to other patients (Likert scale 4 and 5). The mean cost of the office hysteroscopy was 193 TL (152-203) while the mean cost of classic hysteroscopy was 696 TL (389-1277) (p<0.001).

## Discussion

Endometrial polyps and submucosal leiomyomas are frequent causes of abnormal uterine bleeding. These lesions constitute 40% of the causes of postmenopausal bleeding (5). The most commonly utilized diagnostic method is dilatation and curettage which can sample less than 50% of the endometrium with 65% sensitivity but can miss 30% of focal lesions (6). Dilatation and curettage might not diagnose 58% of endometrial polyps, 50% of hyperplasia and 11% cancer cases (7). Transvaginal ultrasonography has 54-85% of sensitivity and 84-90% of specificity for the diagnosis of intracavitary lesions (8, 9). The diagnostic efficacy of transvaginal ultrasound is increased by using real time 3D mode or intracavitary saline infusion during transvaginal ultrasonography with a sensitivity of 93.5-97.1% and specificity of 99.4%. Although diagnostic sensitivity of saline infusion sonohysterography is higher, up to 97.1%, it has a 6-15% false positive rate in premenopausal women with abnormal uterine bleeding (5, 10).

Apart from these factors, none of the diagnostic tools provide therapeutic opportunity at the time of diagnosis. Office hystero-

scopy is a cheap, easy to apply and safe method for the diagnosis and treatment of abnormal uterine bleeding with 98-100% sensitivity and 95% specificity (6, 11). Hysteroscopy in general is the current Gold Standard for evaluation of intrauterine pathologies and office hysteroscopy has been proposed as a first step tool for evaluating cases of abnormal uterine bleeding and rule out anatomic causes of bleeding (12).

Despite all its advantages, office hysteroscopy is still an underutilized method by the gynecologists. Pain is the main obstacle for widespread use of office hysteroscopy. The use of smaller diameter, rigid or flexible hysteroscopes and vaginoscopic entrance through the cervix did not increase acceptance of the technique (13). The cause of pain during office hysteroscopy is mainly due to cervical dilatation, distention of the uterine cavity and endometrial biopsy aggravated uterine contractions in addition to tenaculum application (14). The rates of severe pain have been reported to range from 2 to 14% in parallel with the diameter of the hysteroscope and were also reported to be 5% in another study (13, 15). Visual analogue scale (VAS) has been widely used to define the pain in a numeric system. A large series of studies reported that the mean VAS score of 4.7 in office hysteroscopy procedures was less than the endometrial biopsy mean VAS score of 5 (16, 17). Also, it was shown that the mean VAS score of thinner hysteroscopes such as 3.5 mm in diameter was  $1.8 \pm 0.1$ , which was significantly lower than for 5 mm hysteroscopes (VAS:  $3.4 \pm 0.2$ ) (18). We found that the mean VAS score of our patients was  $2.8 \pm 2.5$ , which was similar to the literature. Whether mild or severe, pain is a frequent problem in office hysteroscopy procedure but surprisingly, patient satisfaction was high in our study. Previous studies have reported that 73-79% of the patients found office hysteroscopy comfortable (18-19). In our study patient satisfaction was 89.3%, which was higher than the previous studies. As we allow the patients to choose the procedure, this might increase the patient satisfaction. Although not evaluated, women who have higher anxiety levels for the surgical procedure and women who have lower pain threshold might have chosen classic hysteroscopy under general anesthesia.

We applied a speculum to all patients but applied a tenaculum only when the vaginoscopic approach failed. As these tools might be quite disturbing it was advised that speculum and tenaculum application should be carried out only in selected patients (14, 20, 21). In order to overcome pain, Nagele and colleagues provided local anesthesia whenever the patients requested it and found that 29.8% of the patients who requested local anesthesia were mainly nulligravid, nulliparous and postmenopausal (22). In our study 10.6% of the patients needed local anesthesia and 4.5 % needed sedation. In our setting the office hysteroscopy procedure could not be completed in 9% of patients at first attempt which is higher than 0.4-4.6% reported in the literature (17, 23). This higher incidence might be due to multiple submucosal leiomyomas and higher frequency of nulliparous and postmenopausal women in our study group.

The mean operation time was reported to be 10 minutes for endometrial polyps and 22 minutes for submucosal leiomyomas (24, 25). The mean operation time was  $11 \pm 5.6$  minutes in our study although operative procedures constitute the major-

ity. Previous reports published that it was possible to resect endometrial polyps in 81% of the cases but in our study we resected all cases of polyps (4).

The efficacy of office hysteroscopy was evaluated and it was found that 75-100% of abnormal uterine bleedings cases were cured in a follow-up of 2-25 months (26). Betocchi et al. reproduced similar rates at 6 months after the office hysteroscopy, which was 92.4% in our study group (25). When compared to classic hysteroscopy, office hysteroscopy without local anesthesia had similar rates of postoperative analgesic use and patient satisfaction rates, which was also confirmed by our study (27). In addition office hysteroscopy procedure has lower cost, shorter hospital stay and no risks due to general anesthesia (28). The mean cost of office hysteroscopy was reported to be 62 USD (40 Euro) and the cost of classic hysteroscopy was 1799 USD (1187 Euro) (29). These costs were 193 Turkish Lira (91 Euro) and 679 Turkish Lira (323 Euro) for office and classic hysteroscopy respectively in our study. These costs are especially important as they represent the total cost of diagnosis and treatment in low resource settings.

We conclude that office hysteroscopy is a cheap, outpatient one step "see and treat" procedure. It causes low pain scores, high patient satisfaction and high cure rate at six months following the procedure.

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