# Özgün Araştırma

## **Original Article**

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## The Interobserver Agreement of The Hysteroscopy in Evaluation of Uterine Cavity

Uterin Kavitenin Değerlendirilmesinde Histeroskopinin Gözlemciler Arası Tutarlılığı Selçuk SELÇUK, Şebnem TÜRKYILMAZ, Şeyma İÇÖZ, Masum KAYAPINAR, Mehmet KÜÇÜKBAŞ, Çetin ÇAM, Ateş KARATEKE

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#### **ABSTRACT**

Aim: To evaluate the inter-observer agreement of hysteroscopy procedures in the assessment of uterine cavity of patients with benign uterine disease.

Material and Methods: Patients that underwent hysteroscopy procedures for benign uterine disease at our gynecology department were included into this prospective study. Three expert gynecologists evaluated the digitalized images of each patient. Kappa statistics were performed to assess the inter-observer agreement. The equivalent of the overall weighted Kappa ( $\kappa$ ) values and the intra-class correlation coefficients (ICC) were applied to calculate the mean  $\kappa$  values.

Results: Fifty-seven patients who underwent a hysteroscopy proceduredue to benign uterine pathology were enrolled. Reproducibility of the hysteroscopy procedure showed poor to moderate agreement for detection of normal uterine cavity, endometrial polyp, submucous myoma, uterus subseptus with ICCs values of 0.59, 0.60, 0.41, 0.32, respectively. The reproducibility of hysteroscopy was moderate for uterine cavity abnormalities. There was good agreement for the diagnosis of endometrial polyps, whereas this was poor for the diagnosis of uterus subseptus.

Conclusion: Inter-observer agreement of hysteroscopy for the diagnosis of benign uterine conditions was generally moderate in our setting.

Keywords: Hysteroscopy, inter-observer agreement, uterine pathology

### ÖZ

Giriş: Benign uterin hastalık ön tanısı olan olguların uterin kavitelerinin değerlendirilmesinde histeroskopinin gözlemciler arası tutarlılığının araştırılması

Gereç ve Yöntemler: Çalışmamıza benign uterin hastalık ön tanısı nedeniyle histeroskopi yapılan olgular dahil edildi. Üç jinekolog tarafından histeroskopi işlemi sırasında elde edilen dijital görüntüler değerlendirdi. Gözlemciler arası tutarlılık Kappa istatistiği ile değerlendirildi. Toplu olarak eşitlenmiş kappa değeri olan sınıf içi korelasyon katsayısı, ortalama kappa değerlerinin hesaplanması için kullanıldı.

Bulgular: Toplam 57 olgu çalışmaya dahil edildi. Histeroskopi işleminin gözlemciler arası tutarlılığı normal uterin kavite, endometrial polip, submüköz myom ve uterin subseptum tanısında zayıf ile orta derece arasında tutarlılık gösterdi ve sınıf içi korelasyon katsayısı sırasıyla 0.59, 0.60, 0.41, 0.32 olarak tespit edildi. Gözlemciler arası tutarlılık; anormal uterin kavite için orta tutarlılık düzeyinde ve endometrial polip tanısı için iyi tutarlılık düzeyinde, uterin subseptum için zayıf tutarlılık düzeyinde saptandı.

Sonuç: Benignuterin hastalıkların tanısında, histeroskopinin gözlemciler arası tutarlılığı çalışmanın yapıldığı ortamda orta derecede saptanmıştır.

Anahtar Kelimeler: Histeroskopi, gözlemciler arası tutarlılık, uterin patoloji

### Introduction

Hysteroscopy is a safe and well-tolerated procedure in the assessment of patients with abnormal uterine bleeding, subfertility or habitual abortion. The higher diagnostic accuracy performance of the hysteroscopy in evaluation of uterine cavity was emphasized, and hysteroscopy was accepted as gold standard for the evaluation of the uterine cavity with its advantages of direct visualization. Besides, it provides the chance of diagnosis and treatment of the uterine abnormality at the same time (1-4).

The level of agreement is an essential issue for the diagnostic tools assessing

the uterine cavity such as transvaginal ultrasonography, saline infusion sonohysterography, and hysteroscopy. Inter observer or intra observer agreement of a diagnostic tool should be at a sufficient level to make an essential contribution to the management of patients with uterine benign disease.

Interestingly, there are only few studies that investigated the reproducibility of hysteroscopy in the diagnosis of intrauterine pathology. Conflicting resultswere reported considering reproducibility of hysteroscopy for the diagnosis of uterine pathology (5-7).

There fore, we aimed to evaluate the inter observer agreement of hysteroscopy

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GelişTarihi/ Received: 04/02/2016 Kabul Tarihi/ Accepted: 09/02/2016 procedures in the assessment of uterine cavity of patients with benign uterine disease.

#### **Material and Methods**

#### Study population

Patients who underwent hysteroscopy procedures for benign uterine disease at our gynecology department were included in to this prospective study. The protocol of present study was approved by the ethics committee of ourinstitute. Signed and written informed consent form was obtained from all patients before surgery.

Hysteroscopy was performed during the early mid follicular phase of the cycle. The distension of the uterine cavity was established with normal saline solution. During the procedure, serial digitalized images were recorded by a research assistant blinded to the clinical characteristics of the patients. The capturing of the digitalized images was started with insertion of hysteroscope into the cervix and finalized when the device left the external os of the cervix.

#### **Observers**

Three expert gynecologists whose experiences in endoscopy ranged from 5-15 years evaluated the digitalized images of each patient. All gynecologists who evaluated the digitalized images were blinded to the clinical management of the patients. Patients with poor quality digitalized images of the hysteroscopy procedure were excluded. The observers evaluated the uterine cavity in terms of its anatomy (normal, arcuate or septate)and presence of abnormal intrauterine pathology (endometrial polyps, submucos myoma, and subseptus).

#### Statistical Analyses

Statistical analyses were performed using SPSS11.5 software. Kappa statistics were performed to assess the inter observer agreement. Inter observer agreement was expressed as kappa ( $\kappa$ ) coefficients.  $\kappa$  is a measure of the difference between observed and expected agreement.  $\kappa=$  (observedagreement–agreement by chance)/(1 –agreement by chance). A  $\kappa$ -value of <0.40 denotes poor agreement, 0.40 - 0.59 moderate agreement, 0.60 and 0.80 good agreement, and  $\geq$ 0.75 indicates excellent agreement (8).The equivalent of the overall weighted  $\kappa$ , the intra-class correlation coefficient (ICC), was applied to calculate the mean  $\kappa$  values (9).The level of significance was set at  $\rho$ <0.05.

### Result

Fifty-seven patients who underwent hysteroscopy due to an uterine benign pathology were enrolled into the study. The mean ( $\pm$  SD) age of the patients was 36.0  $\pm$  10.39 years,and the mean of the body mass index was 26.92  $\pm$  4.85 kg/m². About 30% of the patients had normal uterine cavity, 53% had endometrial polyp, 9% had submucous myoma, and 9% had uterus subseptus (Table 1).

Table 1: Characteristics of the included patients

	Values
Age (y)	36.0 ± 10.4
Body-mass index(kg/m²)	$26.9 \pm 4.8$
Uterine cavity	
Normal	17 (29.8)
Endometrial polyp	30 (52.6)
Submucous myoma	5 (8.8)
Uterus subseptus	5 (8.8)

Data are expressed as mean  $\pm$  SD or n(%)

The ICCs (equivalent of the mean  $\kappa$ ) of inter observer agreement of three gynecologists calculated for the diagnosis of normal uterine cavity, endometrial polyp, submucous myoma, uterus subseptus was 0.59, 0.60, 0.41, and 0.32, respectively (Table 2). The inter observer agreements were moderate for the diagnosis of any abnormality of uterine cavity, good for endometrial polyp, but poor for the uterus subseptus.

**Table 2:** Inter observer agreement and  $\kappa$  coefficients for the assessment of abnormality of the uterine cavity (a), presence of endometrial polyp (b), submucous myoma (c) and uterus subseptus (d)

#### a. Diagnosis of uterine cavity abnormality

	Gynecologist (1)	Gynecologist (2)	
Gynecologist (1)			
Kappa value			
Agreement			
Gynecologist (2)			
Kappa value	0.657		
Agreement	84.2%		
Gynecologist (3)			
Kappa value	0.533	0.568	
Agreement	77.2%	78.9%	
ICC (%95 CI)	0.589 (0.447 - 0.714	0.589 (0.447 - 0.714)	

#### b. Diagnosis of the endometrial polyp

	Gynecologist (1)	Gynecologist (2)
Gynecologist (1)		
Kappa value		
Agreement		
Gynecologist (2)		
Kappa value	0.681	
Agreement	84.2%	
Gynecologist (3)		
Kappa value	0.497	0.607
Agreement	75.4%	80.7%
ICC (%95 CI)	0.600 (0.458- 0.723)	

#### c. Diagnosis of submucous myoma

	Gynecologist (1)	Gynecologist (2)
Gynecologist (1)		
Kappa value		
Agreement		
Gynecologist (2)		
Kappa value	0.516	
Agreement	85.9%	
Gynecologist (3)		
Kappa value	0.378	0.309
Agreement	84.2%	80.7%
ICC (%95 CI)	0.407 (0.245 - 0.567)	

#### d.Diagnosis of uterus subseptus

	Gynecologist (1)	Gynecologist (2)
Gynecologist (1)		
Kappa value		
Agreement		
Gynecologist (2)		
Kappa value	0.397	
Agreement	91.2%	
Gynecologist (3)		
Kappa value	0.301	0.257
Agreement	87.7%	85.9%
ICC (%95 CI)	0.316 (0.152 - 0.486)	

ICC, intraclass correlation coefficient (equivalent of the overall weighted k).

Concerning the analysis of inter-observer agreement of pairwise comparison of the gynecologists for the diagnosis of the uterine cavity as normal or abnormal, the  $\kappa$  value ranged between 0.53 and 0.66. The  $\kappa$  value ranged between 0.50 to 0.68 for the detection of an endometrial polyp, 0.31 to 0.52 for the detection of the submucous myoma, and 0.40 to 0.26 for the detection of the uterus subseptus (Table 2).

#### **Discussion**

In this study, the reproducibility of the hysteroscopy procedure using prerecorded images showed poor to moderate agreement for the detection of normal uterine cavity, endometrial polyp, submucous myoma, and uterus subseptus. The reproducibility of hysteroscopy revealed moderate agreement for any abnormality of the uterine cavity and good agreement for the diagnosis of endometrial polyp, whereas poor agreement was found for the diagnosis of uterus subseptus.

In a study by González-Becerra et al. in 2015, inter observer agreement for diagnosis of uterine abnormality by using digitalized images of hysteroscopic procedures was investigated among gynecological endoscopy residents. The reported kappa values for inter-observer agreement were 0.81, 0.71, 0.71, 0.84, 0.76, 0.87 for the diagnosis of normal uterine cavity, endometrial polyp, submucous myoma, intrauterine synechia, uterine septum, and endometrial hyperplasia/possible endometrial cancer, respectively. The reproducibility of hysteroscopy ranged between substantial to perfect concerning inter-observer agreement for diagnosing various endometrial abnormalities (7).

Inter observer variations for the assessment of endometrial pattern recognition with hysteroscopy, transvaginal sonography, and gel infusion sonography in 122 patients with diagnosis of postmenopausal bleeding were evaluated in a study by Dueholm et al. The  $\kappa$  value of inter observer agreement of hysteroscopy for detection of normal endometrium was reported as 0.74, whereas this was 0.56 for the diagnosis of malignancy. Reproducibility of hysteroscopy and transvaginal sonography was reported as reliable for the diagnosis of a normal endometrium. However; reproducibility of hysteroscopy, transvaginal sonography, and particularly gel infusion sonography were poor for the diagnosis of cancer. The authors emphasized that the presence of concomitant endometrial polyps reduced agreement on hysteroscopy among women with hyperplasia or cancer (10).

Another study evaluated the inter observer agreement of hysteroscopy in patients that underwent hysteroscopy before hysterectomy for benign uterine pathology through the assessment of video recordings of the hysteroscopy procedure by two different gynecologists. The inter observer agreement of hysteroscopy for diagnosis of normal or abnormal uterine cavity was good (0.63). In addition, the reproducibility of hysteroscopy was assessed for anuterine pathology and was found as intermediate and moderate for diagnosing submucous myoma and polyp, respectively (6).

Kasius et al evaluated the inter-observer and intra observer agreement for the assessment of uterine cavity, using videos recorded during hysteroscopy for asymptomatic patients before infertility treatment. The intra observer agreement for the predefined uterine cavity pathology was found as substantial ( $\kappa = 0.707$ ), while the inter-observer agreement was found as moderate ( $\kappa = 0.491$ ) (5).

In our study, the reproducibility of hysteroscopy procedure for normal or abnormal uterine cavity and different uterine pathologies (endometrial polyp, submucous myoma, uterus subseptus) was consistent with the literature. One of the most important limitations of our study for assessing reproducibility of hysteroscopy was that the findings of video recording were mostly related with the surgical skills of the first performer. Small sample size of our study was a drawback for the outcomes regarding interpretation of the digitalized images of hysteroscopy by different gynecologists. Particularly low numbers of submucous myoma and uterus subseptus might effect the inter observer agreement.

In conclusion; despite the moderate inter observer agreement of hysteroscopy, it is still an essential clinical tool for gynecologists in evaluation of the uterine cavity with its advantages of direct visualization and providing the chance of diagnosis and treatment of the uterine abnormality at the same time.

#### References

- Bettocchi S, Nappi L, Ceci O, Selvaggi L. Office hysteroscopy. Obstet Gynecol Clin North Am 2004;31:641–654.
- Grimbizis GF, Tsolakidis D, Mikos T, Anagnostou E, Asimakopoulos E, Stamatopoulos P, et al.. A prospective comparison of transvaginal ultrasound, saline infusion sonohysterography, and diagnostic hysteroscopy in the evaluation of endometrial pathology. Fertil Steril 2010;942720-5.
- Van DongenH, de Kroon CD, Jacobi CE, Trimbos JB, Jansen FW.Diagnostic hysteroscopy in abnormal uterine bleeding: a systematic review and meta-analysis.BJOG 2007;114:664-75.

- Gimpelson RJ, Whalen TR. Hysteroscopy as gold standard for evaluation of abnormal uterine bleeding. Am J Obstet Gynecol 1995;173:1637-8.
- Kasius JC, Broekmans FJ, Veersema S, Eijkemans MJ, van Santbrink EJ, Devroey P et al. Observer agreement in the evaluation of the uterine cavity by hysteroscopy prior to in vitro fertilization. Hum Reprod 2011;26:801-7.
- Dueholm M, Lundorf E, Olesen F. Imaging techniques for evaluation of theuterine cavity and endometrium in premenopausal patients beforeminimally invasive surgery. Obstet Gynecol Surv 2002;57:388–403.
- González-Becerra JE, Moreno-García JD, Leroy-López L, Gallardo LE.Interobserver diagnostic agreement on digital images of hysteroscopicstudies.Gynecol Obstet Mex 2015;83:414-21.
- Fleis, J.L. Statistical Methods for Rates and Proportions.1981; Wiley, New York.
- Fleiss JL, Cohen J. The equivalence of weighted kappa and the intraclasscorrelation coefficient as measures of reliability. Educ Psychol Meas 1973;33:613–619.
- Dueholm M, Hjorth IM, Secher P, Jørgensen A, Ørtoft G.Reproducibility
  of endometrial pathologic findings obtained on hysteroscopy, transvaginal sonography, and gel infusion sonography in women with postmenopausal bleeding. J Minim Invasive Gynecol 2015;22:1036-44.