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CLINICAL ARTICLE

Gynecology

The clinical importance of polyp size measurement through two-dimensional saline infusion sonohysterography prior to hysteroscopic resection in predicting premalignant and malignant endometrial lesions

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Abstract

Objective: To evaluate the clinical importance of endometrial polyp size measured using saline infusion sonohysterography (SIS) before performing a hysteroscopic resection in predicting premalignant/malignant lesions.

Methods: A retrospective observational study analysis was conducted of 365 patients, who underwent SIS, in a reference hospital. The longest plane of the polyp size was taken as base. Polyps were classified as benign, premalignant, or malignant.

Results: The rates of premalignant and malignant lesions were 7.4% and 0.9%, respectively. The mean polyp size was 17.7 ± 0.5 mm in benign patients and 23.7 ± 1.8 mm in premalignant/malignant individuals ($P < 0.001$). In the group of polyps that were 0–10, 10–20, 20–30, and >30 mm, premalignancy/malignancy rates were 0.0%, 4.8%, 13.3%, and 18.8%, respectively. The cut-off value for polyp size to be able to predict lesions was calculated as 22.5 mm (sensitivity: 63%, specificity: 80%) on receiver operating characteristics curve analysis ($P = 0.001$, area under the curve 0.732). The power of the study was calculated as 90.86%.

Conclusion: During the female reproductive years, endometrial polyps smaller than 10 mm, as measured in SIS, can be followed. However, when the polyp size is 22.5 mm or more, especially in postmenopausal women, treatment should be planned.

KEYWORDS
endometrial polyp, hysteroscopy, polyp size, saline infusion sonohysterography

1 | INTRODUCTION

Endometrial polyps are focal hyperplasic areas of the basal layer and do not shed during progesterone withdrawal bleeding.[1] They can range in size from a few millimeters to a few centimeters and there may be more than one. Most endometrial polyps are benign, but they can show a malignant transformation. Because of this risk, the diagnosis and treatment of polyps are critical.

Hysteroscopy is the reference standard method because the size and localization of endometrial polyps can be identified and the polyps can be treated in the same session.[2] However, a few insertions of the hysteroscopic device can be necessary to resect endometrial polyps.[3,4] Frequent insertions of devices may cause

worse visibility of the polyp and uterine cavity. As a result, the polyp size cannot be measured because it is resected in a few moves. Saline infusion sonohysterography (SIS) simultaneously performs ultrasonographic imaging of the endometrial surface while providing distension of the uterine cavity with a sterile fluid.[5] Although it is a less invasive procedure compared with hysteroscopy, it has been reported that it can reach a diagnostic accuracy as high as hysteroscopy.[6] Even though the importance of polyp size for the endometrial hyperplasia or malignancy that may develop on the polyp base remains unclear, measuring the polyp size using SIS can allow us to make a clearer identification and a more accurate analysis.

The aim of this study was to analyze the clinical (demographic) factors and determine the diagnostic value of the endometrial polyp size measured in SIS before hysteroscopy resection in terms of distinguishing benign and premalignant/malignant lesions.

2 | MATERIALS AND METHODS

The present study was conducted in the Department of Obstetrics and Gynecology at Ümraniye Training and Research Hospital, Istanbul from March 2011, to March 2016. It was a retrospective observational single-center study involving 365 patients who underwent hysteroscopy after a pre-diagnosis endometrial polyp on SIS. The patients' ages, obstetric histories (i.e. gravidity, parity, and abortions), bleeding symptoms, use of hormonal therapy, preoperative hemoglobin and hematocrit (day before operation), number of polyps, polyp size, and post-resection final histopathology results were obtained from hospitalization files and computer records. As a result of the retrospective nature of the study, local institute ethical approval was not required. Written and verbal informed consent to use patient documents was obtained from the patient during hospitalization.

Patients with abnormal bleeding symptoms in the reproductive period were questioned and categorized as menorrhagia, metrorrhagia, or menometrorrhagia. Any uterine bleeding in the postmenopausal period was defined as postmenopausal bleeding. No patient described polymenorrhea. Patients who did not describe deviations from normal menstrual bleeding were classified as asymptomatic. Asymptomatic participants consisted of patients who applied for routine gynecologic examination or were referred for consultation. Patients with oligomenorrhea were included in the asymptomatic group. If uterine cavity abnormality was suspected or noted on transvaginal ultrasonography as an endometrial polyp, SIS was performed before hysteroscopy in all patients as a routine clinical practice. During the SIS procedure, an 8-fr infant aspiration catheter was used. Subsequently, the speculum and tenaculum were carefully removed without dislodging the catheter, and a transvaginal ultrasound probe (General Electric Logiq S6; GE Healthcare, Chicago, IL, USA) was inserted. The endometrium was examined simultaneously with the sterile saline infusion. Approximately 15 ml of sterile saline solution was instilled using a 60-cm^3 syringe into the uterine cavity slowly until sufficient distension was provided. The measurement for the longest plane of the polyps during SIS was used as the basis for classification. SIS was performed by scheduling the appointment to time with the follicular phase in an outpatient setting under the observation of GK and AG. Hysteroscopy was planned by the same authors again for patients who were thought to have endometrial polyps as a prediagnosis during SIS. The first author (SA) was responsible for recording the findings and measurements during the SIS and for the follow up of the hysteroscopy final reports.

Hormonal drug use, any bleeding symptoms, and the last menstrual period dates were questioned again on the day before hysteroscopy. The patients' status as reproductive or menopausal was determined. Their menopausal status was described as not having undergone menstruation for more than 1 year or having a follicle-stimulating hormone of over 30 mIU/ml. The patient files were filled in, and written and verbal informed consents were obtained from all patients. Hemoglobin, hematocrit, coagulation parameters, and pregnancy tests—if the patients were of reproductive age—were studied and interpreted. All patients received misoprostol (400 μg) vaginally 6 h before hysteroscopy. In the operation room, cefazolin (2 g) was administered intravenously before induction of anesthesia. Almost all hysteroscopies were performed in the dorsolithotomy position following appropriate site cleaning and sterile dressing under general anesthesia with laryngeal mask airway. The distension of the cavity was achieved with a 5% mannitol solution. After the exploration of the endometrial cavity, the resected material was sent for pathology in a 10% formaldehyde solution. All of the histopathologies were reported by expert pathologists. The reports were classified as benign (polyps), premalignant, or malignant (hyperplasia or carcinoma developed on the basis of polyps). Patients who received hormonal treatment (e.g. tamoxifen) did not undergo SIS, had multiple monitored polyps, did not show polyps in diagnostic hysteroscopy after SIS, or were found to have lesions other than endometrial polyps (e.g. submucous myoma) on their final histopathologic reports were excluded from the study. The flow diagram is given in Figure 1.

IBM SPSS Statistics for Windows, version 25 (IBM Corp., Armonk, NY, USA) was used for statistical analysis. Descriptive statistics were used to define continuous variables. The Shapiro-Wilk normality test results or skewness/kurtosis values were assessed to check whether the variables were normally distributed.[7] Student's *t* test was used to compare two independent and normally distributed continuous variables. The comparison of two variables that were independent and incompatible with normal distribution was performed using the Mann-Whitney *U* test. To examine the relationship between categorical variables, Pearson's χ^2test was used (or Fisher's exact test where appropriate). The statistical significance level was set at 0.05. The power analysis was measured by using the Open Source Epidemiologic Statistics for Public Health's (OpenEpi) open-source calculator, Power for Comparing Two Means, available

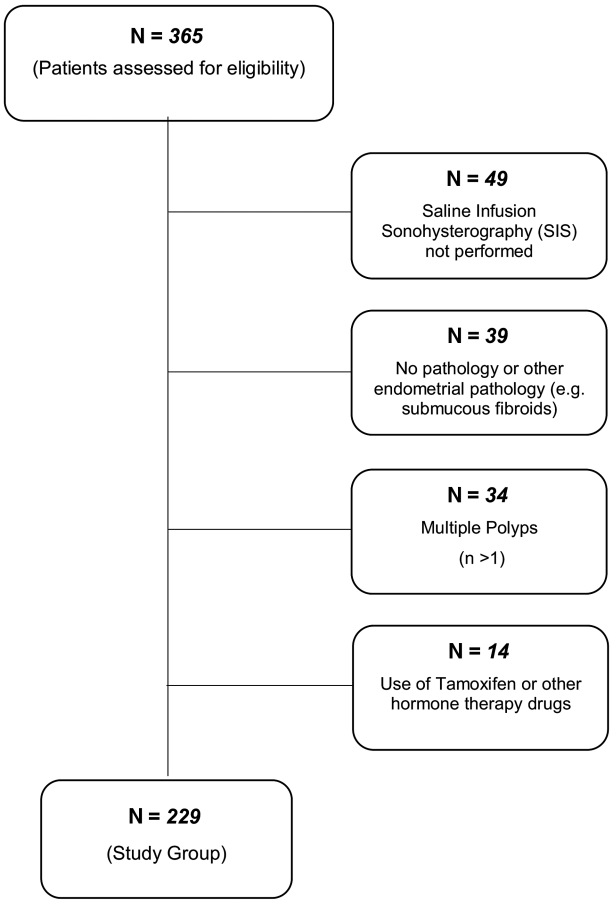

FIGURE 1 Flow diagram of the study

at http://www.openepi.com.[8] The receiver operating characteristic (ROC) curve analysis was used to determine the cut-off values and diagnostic qualifications of the variables.

3 | RESULTS

A total of 229 patients between the ages of 19 and 83 years who underwent SIS and hysteroscopy resection were included in the study. The mean age of the patients (mean ± standard error) was 42.3 ± 0.7 years, and the gravida and parity values were 3.1 ± 0.1 and 2.6 ± 0.1, respectively. There were 194 (84.7%) patients who were of reproductive age and 35 (15.3%) patients who were in the menopausal period. At least one chronic disease was present in 101 (44.1%) patients. Hemoglobin and hematocrit mean values (minimum–maximum) were 11.6 g/dl (6.7–16.2 g/dl) and 35.5% (23.2%–48.7%), respectively.

In total, 43 (18.8%) patients were asymptomatic. The most common complaint in the symptomatic group was menorrhagia with a rate of 57.0%. Polyp sizes of 10–20 mm (55.0%) and 20–30 mm (32.8%) were the most common. The average operation time was 24.9 min (range 5–90 min). When the histopathology results were analyzed, the rates of premalignancy (endometrial hyperplasia) and malignancy were 7.4% and 0.9%, respectively.

TABLE 1 Clinical data and patient-related characteristics (N = 229)[a]

Characteristics		
Chronic disease		
Yes	101	(44.1)
Diabetes	14	
Hypertension	27	
Hypothyroidism	21	
Other or combination	11	
No chronic disease	128	(55.9)
Ovarian function		
Reproductive age	194	(84.7)
Menopausal age	35	(15.3)
Bleeding symptoms		
Asymptomatic	43	(18.8)
Symptomatic	186	(81.2)
Menorrhagia	106	
Metrorrhagia	11	
Menometrorrhagia	44	
Postmenopausal bleeding	25	
Polyp size, mm[a]		
<10	12	(5.2)
≤10 × <20	126	(55.0)
≤20 × <30	75	(32.8)
≤30 × <40	14	(6.1)
≤40	2	(0.9)
Pathology results		
Polyp (benign)	210	(91.7)
Hyperplasia (premalignant)	17	(7.4)
Non-atypical	13	
Atypical	4	
Malignancy	2	(0.9)

[a]Values are presented as number (percentage).
[b]Measured by saline infusion sonohysterography.

All the detailed demographic and pathologic data are available in Table 1.

The mean values for age (P = 0.114), hemoglobin (P = 0.506), and hematocrit (P = 0.690) of the benign and premalignant/malignant groups were similar. The distribution of hypertensive (P = 0.745), diabetic (P = 0.701), and symptomatic (P = 0.366) patients also did not differ between these groups. However, symptomatic patients showed significantly lower rates compared with asymptomatic patients, in terms of hemoglobin value (11.5 ± 0.1 g/dl versus 12.0 ± 0.3 g/dl, respectively; P = 0.044). Similarly, symptomatic patients (35.2% ± 0.3%) showed significantly lower rates compared with asymptomatic patients (36.8% ± 0.7%) in terms of hematocrit value (P = 0.019). Although the polyp size was larger in the symptomatic group (18.4 ± 0.5 mm) compared with the asymptomatic group (17.4 ± 1.1 mm), the sizes were not significantly different

($P = 0.427$). We also failed to find a significant relationship between symptomatology and polyp diameter in women of reproductive age ($P = 0.500$) and menopausal women ($P = 0.336$) women. The mean polyp size in SIS was 17.7 ± 0.5 mm in benign patients and 23.7 ± 1.8 mm in premalignant/malignant patients ($P < 0.001$). No premalignant or malignant lesions were detected in the 0- to 10-mm group. In the groups with polyp sizes of 10–20, 20–30, and >30 mm, the premalignancy/malignancy rates were 4.8%, 13.3%, and 18.8%, respectively. The statistical analysis results and evaluation methods are given in Table 2.

The cut-off value of the polyp size for predicting premalignant and malignant disease was determined as 22.5 mm (sensitivity: 63%; specificity: 80%). The ROC curve analysis was statistically significant ($P = 0.001$), and the area under the curve was measured as 0.732 (Figure 2). When the polyp size during SIS was classified as less than 22.5 mm and 22.5 mm or more, the premalignant and malignant lesions were 4.0% (7/175) and 22.2% (12/54), respectively. In addition, the probability of premalignant or malignant disease in postmenopausal patients whose polyp size was greater than 22.5 mm was calculated as 31.3% (5/16). The power of the study was calculated as 90.86%.

In subgroup analysis, we found that the polyp size measured in SIS in the reproductive period, was significantly ($P < 0.001$) higher in the premalignant/malignant group (23.8 ± 2.6 mm) compared with the benign group (17.2 ± 0.4 mm) (Table 3). In contrast, in postmenopausal patients, the polyp size did not differ between the groups ($P = 0.135$). In the reproductive period, the percentage of premalignant/malignant lesions in endometrial polyps did not differ between the asymptomatic and symptomatic groups (Fisher's exact test; $P > 0.99$). Therefore, the reproductive and symptomatic subgroup who had the largest sample size ($n = 162$) was examined in further analysis to avoid the possible confounding factors. Similarly, the polyp size measured in SIS was analyzed to be significantly larger in premalignant/malignant lesions ($P = 0.002$). In ROC analysis (area under the curve 0.726, $P = 0.013$), the threshold value was determined as 23.5 mm in the reproductive and symptomatic subgroup (sensitivity: 55%; specificity: 86%).

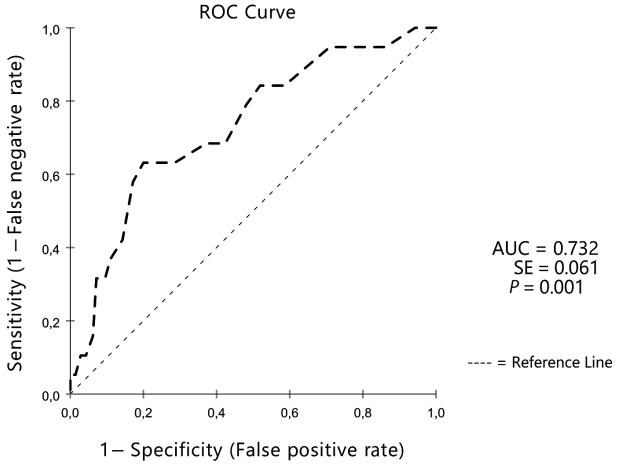

FIGURE 2 Receiver-operating characteristics curve for polyp size, measured by saline infusion sonohysterography, for premalignant or malignant lesions in endometrial polyps ($n = 229$; 19 with pre-malignant or malignant lesions in polyp, 210 with benign endometrial polyp). AUC, area under the curve; SE, standard error

TABLE 2 Analyzing factors according to benign and premalignant/malignant status[a]

Factor	Benign	Premalignant / malignant	*P* value
Age, y	42.0 ± 0.7	45.8 ± 2.7	0.114[b]
Patient status			*0.050*[c]
Reproductive	181 (93.3)	13 (6.7)	
Menopausal	29 (82.9)	6 (17.1)	
Hemoglobin, g/dl	11.7 ± 0.1	11.3 ± 0.5	0.506[b]
Hematocrit	35.5 ± 0.3	35.0 ± 1.2	0.690[b]
Symptom			0.366[c]
Asymptomatic	38 (18.1)	5 (26.3)	
Symptomatic	172 (81.9)	14 (73.7)	
Polyp size, mm[d]	17.7 ± 0.5	23.7 ± 1.8	*<0.001*[b]

[a]Values are presented as mean ± standard error or as number (percentage).

[b]Obtained by Student's *t* test (mean ± standard error values were specified).

[c]Obtained by Pearson's χ^2 test (number [percentage] values were specified).

[d]Measured by saline infusion sonohysterography.

4 | DISCUSSION

Advances in medical technology offer reassuring approaches to the pre-diagnosis of endometrial polyps, even in outpatient settings.[9] We showed that polyp size, which was measured using SIS before hysteroscopy, could predict premalignant or malignant lesions. The cut-off polyp size was determined as 22.5 mm.

The prevalence of endometrial polyps was shown to be 10%–24% in the histopathology reports of endometrial biopsies or hysterectomies.[10] Endometrial polyps can be asymptomatic and are one of the most common causes of abnormal uterine bleeding. Over 70% of patients with endometrial polyps complain of menorrhagia or metrorrhagia.[11] Polyps are more common in premenopausal patients and are also more common in menopausal symptomatic patients than in asymptomatic patients. The possibility of detecting polyps especially increases in symptomatic menopausal patients.[12] Hemoglobin and hematocrit values were found to be statistically significantly lower in the symptomatic group compared with the asymptomatic group, in support of this view. It is also stated that the risk of malignancy increases when patients are symptomatic. In a meta-analysis, Lee et al.[1] showed that the risk of malignancy increased in the menopausal period and in symptomatic women. In the present study, during the menopausal period, the malignancy rate was 5.7%, and one

TABLE 3 Detailed subgroup analysis of polyp size measured by saline infusion sonohysterography according to benign and premalignant/malignant status[a]

Subgroups	Benign	Premalignant/malignant	*P* value[b]
Symptomatic (*n* = 186)	172 (92.5)	14 (7.5)	0.002
Asymptomatic (*n* = 43)	38 (88.4)	5 (11.6)	0.025
Reproductive (*n* = 194)	181 (93.3)	13 (6.7)	<0.001
Menopausal (*n* = 35)	29 (82.9)	6 (17.1)	0.103

[a]Values are presented as number (percentage).

[b]Statistical analysis was obtained by Student's *t* test (mean ± standard error values were specified).

of our two malignant cases was in the symptomatic group. This rate is consistent with the malignancy rate (4.9%) in other studies conducted in postmenopausal women regardless of whether they are symptomatic.[13] Antunes et al.[14] reported that the rate of endometrial carcinoma based on polyps was 2.7%. This rate was reported as being between 1.5% and 3.4% in different studies.[1,14–16] Gregoriou et al.[17] reported the rates of premalignant and malignant lesions as 1.2% and 1.9%, respectively, in a study of 516 cases. In a study conducted on 957 infertile patients, the rate of premalignant and malignant lesions was reported as 1.9.[18] In the present study, the premalignant and malignant rates were calculated as 7.4% and 0.9%, respectively. The ages of our malignant cases were 57 and 58 years. Hileeto et al. reported that age was the most important risk factor in malignancy developing from polyps and that this risk especially increased after the age of 65 years. Although this rate was 32% in patients aged 65 and over, they cited the rate as 7.2% in patients aged 25–64 years.[19] These differences can depend on the percentages of premalignant and total cases as well as the observational variability between pathologists. However, we did not include patients who used tamoxifen or were examined with probe curettage or hysterectomy materials without SIS before hysteroscopy.

Long-term and high-dose stimulation of the endometrium by estrogen is one of the greatest determining factors in the development of endometrioid-type adenocarcinoma. It has further been reported that hypertension and the use of tamoxifen increase the risk of malignancy.[20] It may contribute to the development of adenocarcinoma by triggering certain mechanisms through excessive estrogenic stimuli, such as the use of tamoxifen. So we excluded patients using tamoxifen. We investigated the relationship between premalignant/malignant lesions with diseases, such as hypertension, diabetes mellitus, and hypothyroidism. We found no significant difference, which was consistent with the study conducted by Desteli et al.[21] Tohma et al.[18] stated that premalignant/malignant lesions were not related to polyp size or number, hypertension, or diabetes. Namazov et al. also indicated that premalignant/malignant lesion risk was not associated with polyp size in a population with a 2.3% lesion risk ratio.[22] We showed the statistical significance of polyp size in this study. The difference may exist as the result of a transformation involving hormonal drugs that do not change the polyp size. An evaluation of multiple polyps may not have a straightforward rationale as its basis. In the present study, multiple polyps had been excluded. We did not find a significant relationship between symptomatology and polyp diameter in reproductive or menopausal status. The polyps measured 0–10 mm during SIS, constituting 5.2% of the cases. No premalignant or malignant cases were found in this group.

Subgroup analysis was performed to detail the results and reduce the possible confounding factors. In postmenopausal patients, we showed that the polyp size did not differed with final pathology results. It should be kept in mind that the size of the polyp in postmenopausal patients may not contribute any advantages. This may be due to the relatively small number of menopausal patients. Also, we interpreted the results obtained from the further analysis of patients in the reproductive period. We found that whether a patient is symptomatic was not related to their final pathology results. The threshold value was similar to the value of all patients. So, we would like to emphasize the requirement of routine gynecologic examination. Even patients who do not have any complaints should be evaluated in terms of endometrial pathology.

When hysterectomy was performed in patients with atypical hyperplasia in endometrial sampling, it was reported that endometrial carcinoma accompanied it at a rate of 25%.[23] The progression from premalignant lesions to malignant lesions depends on the presence and severity of cytologic atypia.[24] In the present study, endometrial hyperplasia, also known as premalignant lesions, was detected in 17 (7.4%) of 229 patients. Of these 17 patients, 13 had endometrial hyperplasia without atypia, and four had endometrial hyperplasia with atypia. Additionally, one of the four women with endometrial hyperplasia with atypia continued to be treated in another medical center. For the remaining three patients, an intraoperative frozen section was planned and finally, one patient was diagnosed with well-differentiated endometrioid-type adenocarcinoma. However, simultaneous endometrial sampling was not performed in this patient during the hysteroscopy and the data were not included in the total malignancy rate, because it could not be proved that it had developed on the base of polyp.

In many studies, the effect of body mass index (calculated as weight in kilograms divided by the square of height in meters) has been investigated and controversial results have been revealed. The data that we have cannot reveal the relation between body mass index and pathology results. This issue must be discussed with a prospective follow-up study. The limitation of the present study is that it is retrospective. However, the strengths are that it included

a large number of patients and that multiple polyps were excluded. Hormone use being an exclusion criterion added significant value to the present study. We simultaneously think that these factors play a major role in the determination of polyp size. There is no answer or method that can give us an idea about histopathology from the appearance of endometrial polyps.[25] Unlike previous studies, we emphasized the importance of polyp size in this study. Polyp size measured through SIS in the preoperative period is an ideal method to provide guidance about premalignant or malignant circumstances.

In the reproductive period, endometrial polyps smaller than 10 mm during SIS can be followed, but it should not be forgotten that malignant lesions have been reported beforehand. However, when the size of the polyp is 22.5 mm or more, especially in postmenopausal women, a more careful evaluation should be made and treatment should be planned.

CONFLICTS OF INTEREST

The authors have no conflicts of interest.

AUTHOR CONTRIBUTIONS

The literature review was performed by SA. Data were acquired by SA, and interpreted by SA, GK, and AG. The conception of the study was contributed to by SA, GK, and AG. All authors contributed to drafting the manuscript, revising it critically for intellectual content, and also approved the final version of the manuscript to be published.

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