



## SENSITIVITY OF SONOHYSTEROGRAPHY FOR THE DIAGNOSIS OF BENIGN UTERINE PATHOLOGY.

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### ABSTRACT

**Purpose:** For most of the pathologies that involve the female genital tract, pelvic sonography is an easily accessible, cost-effective tool and should be considered as the initial study of choice. However, its effectiveness depends on the operator ability and their experience demonstrated in its interpretation. A few studies exist that demonstrate the sensitivity of sonohysterography as a diagnostic method for specific uterine pathologies. With the above, our research question comes up: what is the sensitivity of sonohysterography for the diagnosis of benign uterine pathology? **Methods:** A prospective, cross-sectional, observational study of diagnostic sensitivity was carried out in patients who came to the office for abnormal uterine bleeding or fertility problems and who required imaging confirmation for this pathology. Sonohysterography and hysteroscopy with biopsy for histopathology were performed in all cases. **Results:** A total of 42 women were studied, with an average age of 36 years and a BMI of  $24 \pm 3$  kg / mt2, who's the most frequent reason for consultation was infertility (71%). The sensitivity of sonohysterography for the polyposis and uterine fibroids diagnosis was 93% and 85%, respectively. **Conclusion:** We propose the possibility that sonohysterography can be used as an alternative procedure to hysteroscopy, leaving the latter as a confirmatory method. This is a method that is easy to perform, less invasive, less costly, and is well-tolerated. Therefore, diagnostic hysteroscopy could be limited to an inconclusive Sono-HSG, raising the possibility of replacing 89% of outpatient diagnostic hysteroscopies.

**KEYWORDS :** Sonohysterography, Sensitivity, Specificity, Hysteroscopy, Uterine Pathology.

### INTRODUCTION

The uterus is a fundamental organ within the reproductive processes and takes part in key events, such as sperm transport, implantation and pregnancy itself, as well as fetal nutrition. Uterine fibroids, congenital anomalies, endometrial polyps, and uterine synechiae are the main uterine pathologies in women of reproductive and advance age, and can be the main cause of infertility, recurrent pregnancy loss, or premature delivery [1]. Most frequent reasons for gynecology consultation include: pelvic pain, menstrual cycle disorders or abnormal genital discharge. These are, in general, a manifestation of a female reproductive system disease [2]. By knowing the prevalence of the pathology and the patient's risk factors, as well as signs, symptoms and positive findings in the clinical examination, it is possible to define a clinical probability of the presence of pathology. In addition, given the possibility of diverse etiologies with different treatments, it will be also necessary to consider the use of complementary tests to limit this probability and define a specific therapy [3]. In this context, imaging studies support the gynecological diagnostic process. Hysteroscopy (H-Scope) is considered the gold standard for evaluation of the uterine cavity. However, the European Society for Human Reproduction and Embryology (ESHRE) indicates that H-Scope should only be used for confirmation and treatment of suspected uterine pathologies on ultrasound or hysterosalpingography (HSG), or after in vitro fertilization failures [4]. Sonohysterography (Sono-HSG) is a technique in which the uterine cavity is distended with saline solution, making it possible to evaluate both the cavity and the different layers of the uterus, and distinguish its focal and diffuse pathological conditions, with a sensitivity similar to HSG [5].

There are few studies that demonstrate the sensitivity of Sono-HSG as a diagnostic method for uterine pathology. Knowing these data is extremely valuable for those involved: the gynecologist and the patient to be evaluated. Having this type

of diagnostic support allows medical practitioners the timely detection of what are still considered public health problems. The objective of our study was to determine the sensitivity of Sono-HSG for the diagnosis of uterine pathology.

### MATERIAL AND METHODS

Cross-sectional, prospective, observational study of diagnostic sensitivity. After signing an informed consent form, patients who attended the gynecological consultation for problems of abnormal uterine bleeding or infertility, were recruited. The sample was calculated taking into account the formula for sensitivity / specificity studies, with a value = 0.05, an expected sensitivity of 99% and a variability of 0.05 for a one-tailed hypothesis, yielding a minimum value of 42 participants. They were scheduled by consecutive cases to perform the two types of study, firstly, Sono-HSG and then the H-Scope.

#### Technique For Performing Sonohysterography:

It was carried out between the 4th and 10th day of the menstrual cycle and in postmenopausal women without bleeding. In lithotomy position, after asepsis, the vaginal speculum was placed. A physiological sterile solution of 20 to 40 cc was instilled into the uterine cavity through a Cool Silicone Balloon HSG Catheter. A 7/9 MHz transvaginal transducer of a Philips iU22 ultrasound machine® was placed and moved to achieve a longitudinal, transversal and oblique view of the uterus and the separation of the endometrium is then observed.

#### Technique To Perform Hysteroscopy:

The procedure is performed under sedation and begins with aseptic and antiseptic techniques, followed by fixation of the surgical fields. This is done, while connecting the optics to the video camera, the fiber optic cable to the light source and this to the optics that have been previously assembled to the hysteroscope. The distension solution must be previously

"primed", since the bubbles will make it difficult for the gynecologist to see.

Once the hysteroscope has been prepared, previously primed and the camera fixed to the optics, the gynecologist traces the cervix with Pozzi tenaculum forceps. Afterwards, the hysteroscope was introduced through the endometrial canal, beginning to distend the uterine cavity, to later carry out the exploration. In case of difficulty accessing the uterine cavity, the endometrial cavity can be dilated with Hegar dilators, up to approximately number 5, to facilitate the entry of larger caliber instruments into the endometrial canal.

If polyps, fibroids or any other findings are seen, we proceed the extraction using different techniques: small curved Foerster forceps, microscissors, biotomes or even resectoscopy. For this, a non-electrolytic distension medium was prepared in 2 bags of 3 liters. Each one, which was incorporated through a double irrigation system, at a height of about 180 cm, to facilitate flow, since this distention would irrigate the cavity and distend it. At the same time, he would wash and aspirate the contents that remain after the resection, with the electrosurgical loop, of the fibroid, polyp or septa.

Once any of these procedures is completed, a uterine curettage of the cavity to remove the remains of tissue can be performed, if needed. Afterwards, a visual examination is made, through the hysteroscope or resectoscope, to ensure that the lesions had been completely resected and that no bleeding points remained. We pay special attention of the instilled and removed fluids throughout the procedure.

All the data collected were captured in a database for analysis in the statistical program SPSS see 25 in Spanish.

**COMPLIANCE WITH ETHICAL GUIDELINES**

All the procedures followed were in accordance with the ethical standards of the Human Experimentation Committee (institutional or national) and with the Declaration of Helsinki of 1975, revised in 2000. This work has the approval of the Research Committee and Research Ethics Committee of Hospital Ángeles del Pedregal with registration number HAP2594.

**RESULTS**

A total of 42 women were incorporated, with an average age of 36 ± 6 years and a body mass index of 24.3 ± 3 kg/m<sup>2</sup>, imaging tests were performed ensuring that the menstrual cycle was in the follicular phase (97.8%) (Table No.1). The most frequent reason for general consultation was infertility (71%), followed by abnormal uterine bleeding (9.5%). When analyzing these causes by age, we observe that in the 25 to 30-year-old group the most frequent cause is infertility, while in the 36 to 40-year-old group it is abnormal uterine bleeding (AUB) (Table 2).

AGE*	36 ± 6
BMI	24.3 ± 3
PHASE OF THE MENSTRUAL CYCLE	
FOLICULAR PHASE	97.80%
LUTEAL PHASE	2.40%
* Data represent mean and standard deviation	

	25 to 30 years n= 5	21 to 35 years n=15	36 to 40 years n=11	40 years or more n=11	p
RECURRENT PREGNANCY LOSS	0	0	18.2%	18.2%	0.821

INFERTILITY	40.0%	80.0%	72.8%	54.6%
ABNORMAL UTERINE BLEEDING	60.0%	20.0%	9.0%	27.2%

The difference between groups was calculated with the Chi square test

Regarding the uterine pathology identified, the most frequent was endometrial polyposis (73%), followed by uterine fibroids (33%). Histopathology added a wider range of information regarding such as the state of the endometrium (Table No.3).

	H-SCOPE	SONO-HSG	DHP*
POLYPOSIS	73.8%	71.4%	59.5%
FIBROIDS	33.3%	31.0%	31.0%
SYNECHIAE	4.8%	4.8%	
TUBAL OBSTRUCTION 2	4.8%	14.3%	
HYPERPLASIA E.1	2.4%		
ADENOMYOSIS			2.4%
PROLIFERATIVE ENDOMETRIUM			19%
* Histopathological Diagnosis, 1 Endometrial hyperplasia, 2p < 0.000			

A comparative exercise was performed to determine the sensitivity and specificity of hysteroscopy and sono-HSG, versus histopathological diagnosis for all diagnoses included as uterine pathology. Both tests yielded a sensitivity of 100% with a specificity of 50% (Table 4).

	H-SCOPE	Sono-HSG*
TRUE POSITIVES	32	32
TRUE NEGATIVES	5	5
FALSE POSITIVES	5	5
FALSE NEGATIVES	0	0
SENSIBILITY	100%	100%
SPECIFICITY	50%	50%
POSITIVE PREDICTIVE VALUE	86%	86%
NEGATIVE PREDICTIVE VALUE	100%	100%
* Sonohysterography, <sup>1</sup> (Includes diagnoses of: Polyposis, Fibroids, Synechiae, Septate Uterus, Adenomyosis)		

In order to identify the sensitivity of Sono-HGS for specific pathologies referring to H-Scope, a contingency table was developed. The exercise was performed, separating the two most frequent diagnoses: 1) Sensitivity and specificity to diagnose fibroids and 2) Sensitivity and specificity to diagnose polyposis (Table 5).

	UTERINE FIBROIDS	ENDOMETRIAL POLYPOSIS
TRUE POSITIVES	11	28
TRUE NEGATIVES	27	10
FALSE POSITIVES	2	2
FALSE NEGATIVES	2	2
SENSIBILITY	85%	93%
SPECIFICITY	93%	83%
POSITIVE PREDICTIVE VALUE	85%	93%
NEGATIVE PREDICTIVE VALUE	93%	83%

Finally, the correlation coefficient was determined by crossing each of the tests with each other, obtaining a similar coefficient between Sono-HSG and H-Scope contrasted against histopathology (0.529, 0.548, 0.552 and 0.552) all with a value of p < 0.001. On the other hand, when Sono-HSG is contrasted against hysteroscopy, we obtain a correlation coefficient of 0.714 for the diagnosis of fibroids and 0.767 for the diagnosis of polyposis, both with a value of p < 0.001 (Table 6).

**Table No.6 Coefficient Of Correlation Between Each Of The Diagnostic Tests For The Two Most Frequent Diagnostics N=42**

	UTERINE FIBROIDS DX*		
	Sono-HSG	H-SCOPE	PATHOLOGY
SONO-HSG	1	0.714	0.529
H-SCOPE	0.714	1	0.548
HISTOPATHOLOGY	0.529	0.548	1
	ENDOMETRIAL POLYPOSIS DX*		
	Sono-HSG	H-SCOPE	PATHOLOGY
SONO-HSG	1	0.767	0.552
H-SCOPE	0.767	1	0.552
HISTOPATHOLOGY	0.552	0.552	1

\*Sperman's Rho correlation coefficient was used; all correlations had a  $p < 0.001$

**DISCUSSION**

Acquired and congenital uterine anomalies are important causes of female infertility; therefore, investigation of the uterine cavity is a mandatory practice in the evaluation of infertile women, particularly before assisted reproductive technology (ART) cycles. H-Scope, being a more expensive method [6,7], is generally reserved for women who may also benefit for the evaluation or treatment of other pelvic pathology. This prospective study included 42 patients, with infertility problems, recurrent pregnancy loss and abnormal bleeding, they were checked by sono-HSG and H-Scope. Patients were  $36 \pm 6$  years of age and in a high percent of cases polyposis was found.

Dimitrijevic et al, developed a study with the objective of comparing the findings of Sono-HSG against H-Scope specifically in abnormal uterine bleeding [8]. In this context, they describe that for the diagnosis of submucosal fibroids, endometrial hyperplasia and endometrial polyps, Sono-HSG has proven to be a good detection method. By its use for diagnosing intracavitary uterine pathology, and thus also the pathology of bleeding in perimenopausal women, in many cases H-Scope can be avoided. A study which performed a comparison between H-scope and Sono-HSG in patients with abnormal bleeding found no significant difference for sensitivity and specificity between Sono-HSG and diagnostic with H-scope [9]. On the other hand, Akış S conducted a study with the aim of demonstrating the usefulness of Sono-HSG prior to performing therapeutic H-Scope specifically to determine the characteristics of polyps [10,11]. This study proposes Sono-HSG follow-up in women of childbearing age in polyps smaller than 10 mm, without the need for H-Scope, in polyps greater than 22.5 mm, especially in postmenopausal women, H-Scope should be performed to determine the therapeutic plan.

De Kroon CD et al., in a study conducted with the purpose of evaluating the usefulness of sonography as a replacement for H-Scope, they demonstrated a sensitivity of 100% with only 10% inconclusive results. With the above, they reported that diagnostic H-Scope can be used only after an inconclusive Sono-HSG and raising the possibility of replacing 84% of outpatient diagnostic hysteroscopies [12]. In our study, we can sustain that both the sensitivity (100%) and the specificity (50%) in the general diagnosis of uterine pathology, in the two tests challenged against histopathology, are similar. These data coincide with the results obtained in the study by Guven MA et al. [13] where they report a sensitivity of 90% and a specificity of 40% of H-Scope against histopathology. In the same way, the correlation coefficient for both tests is high and statistically significant, which supports the possibility of using the first-instance sono-HSG in the approach of the patient with problems of AUB or infertility. This approach supports the proposals of De Kroon CD et al. [12] as well as the later findings of Ahmadi F et al. [14]. This is expressed in cost savings and a reduction in the discomfort of the affected women, with the possibility of performing only H-Scope in

cases where the Sono-HSG has not provided us with clear or conclusive data.

An interesting finding in our study was the same false positive rate (5 cases) for H-Scope and Sono-HSG in the diagnosis of polyp or fibroid. On the other hand, Guven et al. [13] have reported a high false positive rate (22/61) 36% for Sono-HSG y in the diagnosis of polyps, of which (14/22) 64% was due to a thick secretory phase endometrium mimicking a polyp in Sono-HSG. We reduced this possibility by performing the majority of Sono-HSGs (90%) during the first phase of the menstrual cycle.

During the process of our study, no complications associated with the execution of either of the two techniques were reported. However, we consider that the use of the Sono-HSG represents a less uncomfortable procedure compared to H-Scope, where the patient must also meet special conditions to achieve adequate sedation.

**CONCLUSION**

From the foregoing, we can conclude that the sensitivity and specificity of both techniques (sono-HSG and H-Scope) are similar when challenged against histopathological reports. That when comparing sono-HSG against the gold standard (H-Scope) for specific pathologies, its sensitivity is 93% for the diagnosis of polyposis and 83% for the diagnosis of uterine fibroids. Compared to the gold standard (H-Scope), Sono-HSG turns out to be less invasive, easily accessible, and cheaper, making it a useful tool for use in a wider population.

We propose the possibility of being used as an alternative method to H-Scope, leaving the latter as a confirmatory and therapeutic method. Therefore, diagnostic H-Scope could be limited to an inconclusive Sono-HSG, raising the possibility of replacing 89% of outpatient diagnostic hysteroscopies.

**Author Contribution**

R Velázquez-Falconi: Protocol/Projecto development and data collection

JJ Stern-Colín y Nunes: Protocol/Project development

FM Caldera-Hernández: Data collection

QL Torres-Salazar Q: Manuscript writing and data analysis

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