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Original Article

Hysteroscopic Evaluation of Tubal Patency Using Bubble Sign in Comparison to Diagnostic Laparoscopy

Emad Abdelmahdy Mabrouk Ismaeil [*1], Walaa Mohammed El-Bassioune [2], Alaa Eldin Mahmoud Megahed [2]

[1] Department of Obstetrics and Gynecology, Kafr-Saad Central Hospital, Ministry of Health, Damietta, Egypt
[2] Department of Obstetrics and Gynecology, Damietta Faculty of Medicine, Al-Azhar University, Damietta, Egypt

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*Corresponding author
Email: emadmohdy93@gmail.com

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ABSTRACT

Background: Tubal patency assessment is vital in infertility evaluation. The bubble sign observed during hysteroscopy has emerged as a potential indicator of tubal patency, offering a less invasive alternative to diagnostic laparoscopy.

Aim of the work: This study aimed to compare the efficacy of hysteroscopy utilizing the bubble sign with diagnostic laparoscopy in evaluating tubal patency.

Patients and Methods: A prospective study was conducted on 100 patients undergoing infertility evaluation. Hysteroscopy with the observation of the bubble sign and diagnostic laparoscopy were performed to assess tubal patency. Sensitivity, specificity, positive predictive value [PPV], and negative predictive value [NPV] of the bubble sign in comparison to laparoscopy were calculated.

Results: Positive predictive value of hysteroscopy was estimated to be 94.2% [87.6%-99.9%] and negative predictive value was estimated to be 87.5% [81.4%-92.8%]. When the laparoscopic method was used as a standard, the accuracy of the hysteroscopic method was 91.5% [85.1%-97%] overall.

Conclusion: Hysteroscopic evaluation using the bubble sign proved to be a reliable method for assessing tubal patency, comparable to diagnostic laparoscopy. The non-invasive nature of hysteroscopy and its accuracy in determining tubal patency make it a promising tool in infertility investigations, potentially reducing the need for more invasive procedures.

Keywords: Fallopian Tube Patency Tests; Hysteroscopy; Laparoscopes.

INTRODUCTION

The advancement of medical fiber optics has enhanced diagnostic tools for gynecologic endoscopy. This improvement extends to intraperitoneal imaging through laparoscopy and culdoscopy, as well as visualization of the interior of the uterus and the tubal ostia. Hysteroscopy allows for observation of the cervix and uterine interior. It is estimated that 12-33% of couples experiencing infertility may have issues with their fallopian tubes [1].

The function and diameter of the Fallopian tubes can be assessed both within and outside the hospital setting. Tests such as hysterosalpingography X-rays, hystero-contrast-sonography ultrasounds, or saline injection sonography can be conducted in an outpatient setting [2].

The gold standard for a test to see if the tubes are open is laparoscopic chromohydrotubation. This is the most exact test, but it costs a lot to do because it needs an operating room, a staff, and a hospital stay [3].

Transvaginal hydro-laparoscopy [TVHL] offers similar advantages to laparoscopy and can be performed outside of a hospital setting, resulting in cost savings related to operating room and hospital expenses [4]. Nonetheless, novel outpatient techniques for assessing tubal patency exhibit high negative predictive values and are recommended as the primary approach to determine the cause of female infertility [3].

During hysteroscopy, the uterine cavity can be visualized while distension media are utilized to expand it. By introducing air into the fluid, air bubbles can be observed on a hysteroscopic monitor. Observing the movement of these bubbles allows for tracking them to and through the tubal ostia. The emergence of bubbles from the ostium is commonly considered a possible indicator of tubal patency, although it is not unequivocally conclusive. Research studies have been conducted to investigate this phenomenon and ascertain the accuracy of the bubble sign [5].

The presence of a discernible "flow" of air bubbles in the fallopian tubes during hysteroscopy served as a reliable indicator of tubal patency, exhibiting a satisfactory sensitivity and specificity rate [3].

Therefore, the primary objective of this study is to examine the predictive utility of the visible air bubble sign in determining actual tubal patency during hysteroscopic procedures.

PATIENTS AND METHODS

This cross-sectional study was conducted at the Department of Obstetrics and Gynecology, Al-Azhar University hospitals within 6 months starting from June 2021 to November 2020. The study included 100 infertile women who met the conditions for a diagnostic laparoscopy and hysteroscopy done together. We followed the declarations of Helsinki. Ethical approval and informed written consent were obtained.

The inclusion criteria were: 1] Age 20 to 40 years. 2] Primary or secondary infertility. 3] Between the fifth and tenth days of the cycle. 4] Must have a uterus, and 5] Negative testing for gonorrhea and chlamydia.

Exclusion Criteria were: 1] Pregnancy. 2] Any hysteroscopic contraindication like Pelvic Inflammatory Disease [PID].

Once a patient had been selected for hysteroscopy, a Papanicolaou smear, cervical/vaginal smear, and cultures were used to rule out any active infection.

Complete medical and gynecological history, physical and gynecological examinations, and routine laboratory and radiological examinations were done for each case during enrollment.

Air bubbles [usually 1–2 mL] are infused into the uterine cavity and monitored to see if they pass through the ostia and into the Fallopian tubes. The hysteroscopic suction test for bubbles was thought to be positive if the ostium on the patient's side was suctioned and an air bubble was seen within one minute. Neither adding air nor raising the pressure happened during this time. When the air bubbles didn't pop, the tester waited one minute more. Again, the test was considered negative if no air was taken.

Laparoscopy was performed while the patient was under general anesthesia through two 5 mm trocars in the lower abdomen and a 10 mm scope manufactured by Karl Storz in Tuttlingen, Germany. A Hegar 8 was used to access the cervix, and a Cooper Surgical Rumi was implanted into the uterus. A tube containing 20 ml of saline with a blue dye was connected to the uterine manipulator.

Abnormalities such as endometriosis, fibroids, and adhesions were noted after a thorough examination of the uterus, tubes, ovaries, and neighboring organs. Methylene blue dye was injected by the assistant, and its passage via the fallopian tubes was observed. To remove the methylene blue dye from the abdominal

cavity, a cannula for suction and irrigation was inserted into the suprapubic port. The uterine cannula was then removed and the peritoneal cavity was drained of gas before the incisions were closed.

Statistical analysis: SPSS Inc., Chicago, Illinois, USA] was used to conduct statistical analyses on the collected data. Quantitative data were presented as means and standard deviations [SD]. The qualitative information was presented as a set of percentages and frequencies. The proportions of different qualitative criteria were compared using a Chi-square test. Comparison of laparoscopy and hysteroscopy for the diagnosis of patent and occluded uteri using the kappa statistic. A P value of 0.05 was considered significant.

RESULTS

The mean age of the studied population was 31.52 ± 5.5 years, as indicated in Table 1. The mean body mass index was 27.5 ± 3.6 kg/m^2.

In Table 2, the causes of infertility were categorized as Primary [57.0%] and Secondary [40.0%].

Diagnostic hysteroscopy revealed that 60% of the tubes were patent, while 40% were obstructed. Similarly, diagnostic laparoscopy showed that 38.5% of the tubes were occluded, and 61.5% were patent. All cases identified as patent by hysteroscopy were confirmed to be patent by laparoscopy. However, three cases diagnosed as patent by hysteroscopy were identified as occluded by laparoscopy [Table 3].

Upon comparing the results of hysteroscopy to those of laparoscopy, sensitivity, specificity, positive predictive value [PPV], negative predictive value [NPV], and accuracy were calculated at 91.9%, 90.9%, 94.2%, 87.5%, and 91.5%, respectively [Table 4].

Table [1]: Distribution of women according to their age and BMI demographic data

Demographic data	Total [n=100]
Age [years]	31.52 [5.5]
Body mass index [Kg/m^2]	27.5 [3.6]

Table [2]: Distribution of women according to their cause of infertility

Infertility	Total [n=100]
Primary infertility	57 [57]
Secondary infertility	43 [43]

Table [3]: Comparison between the hysteroscopy and laparoscopy for assessment of tubal patency

		Laparoscopy [n=200]		P value
		Patent	Occluded	
Hysteroscopy [n=200]	Patent	120 [60%]	0 [0 %]	0.001* [a]
	Occluded	3 [1.5%]	77 [38.5%]	

a: Chi-square test. *: Significant

Table [4]: Diagnostic performance of hysteroscopy for assessment of tubal patency

	Percentage
Sensitivity	91.9%
Specificity	90.9%
Positive predictive value	94.2%
Negative predictive value	87.5%
Accuracy	91.5%

DISCUSSION

In a study, the effects of three methods were compared in a group of women with infertility. Transvaginal sonography [TVS] was more effective in detecting myometrial disease, hysterosalpingography [HSG] was superior in assessing tubal patency, and hysteroscopy [HSC] was more capable in identifying endometrial polyps compared to both HSG and TVS. None of the methods accurately detected all the different diseases. Since each method provides distinct information, women struggling with infertility can utilize all of them in their evaluation. However, considering that each imaging test has its own strengths in detecting specific diseases, a combination of HSG, HSC, and TVS may be recommended for individualized care in gynecology patients based on their clinical presentation [6]. Hystero-contrast sonography [HyCoSy], a novel method, was

statistically comparable to HSG and aligned with it when combined with dye laparoscopy. HyCoSy is well-tolerated and may serve as a viable option for a hospital-based procedure. HyCoSy with a contrast agent appears to be more effective than a saline solution in detecting tubal blockages [7].

The obstruction of the Fallopian tubes is the most prevalent cause of infertility. Assessing tubal patency is the initial step in fertility evaluation; thus, the appearance of air bubbles during hysteroscopy serves as a secondary indicator of tubal patency [3].

In this study, the mean age was 31.52 years with a standard deviation of 5.5 years, and the mean BMI was 27.5 kg/m2 with a standard deviation of 3.6. Our findings were consistent with those of **Lörincz et al.** [3], where sixty-one patients participated with a mean age of 32.0 ± 4.36 years and an average BMI of 22.7 ± 4.19 kg/m2.

Our study demonstrated primary infertility [57.0%] and secondary infertility [43.0%], with the mean duration of infertility being 4.35 years [SD 1.59]. These results align with the findings of **Darwish *et al.*** [8], who reported primary and secondary infertility in 51 and 27 cases, respectively. Additionally, **Ahmed *et al.*** [9] included 100 women, where 74 had primary infertility and 26 had secondary infertility. The duration of infertility was categorized as < 5 years [48%], ≥ 5 - < 10 years [48%], and ≥ 10 years [4%], with a mean duration of 4.9 ± 2.51 years. Furthermore, **Allam *et al.*** [10] demonstrated that 46 of the women [72%] experienced primary infertility, while 18 of the women [28%] had secondary infertility.

Gynecologists worldwide face challenges in distinguishing between functional and organic causes of infertility. Laboratory tests can aid in identifying the underlying issue and its mechanism. Various imaging techniques and minimally invasive procedures are available to investigate organic causes. The assessment of tubal patency remains a topic of ongoing biological discussion. Both outpatient and inpatient methods can be employed to assess the functionality and patency of the Fallopian tubes. Hospitalization is not necessary for procedures such as X-rays, ultrasounds, or hysterosalpingography using a saline infusion sonogram [11].

During hysteroscopy, the uterine area can be visualized while distension media are employed to expand it. A hysteroscopic monitor can display air bubbles when this fluid is aerated. By observing the movement of these bubbles, they can be traced to and through the tubal ostia. Although the emergence of bubbles from the ostium is commonly regarded as an indication of tubal patency, it is not a definitive sign. Research studies have been conducted to investigate the accuracy of the bubble sign. Utilizing ultra-sonography to detect fluid in the Cul-de-sac post-hysteroscopy adds a layer of reliability to the process. Recent outpatient methods for evaluating tubal patency have demonstrated high negative predictive values and are advocated as the initial approach for investigating infertility. While these outpatient techniques may not match the precision of TVHL and the gold standard laparoscopy performed in a hospital setting, they offer a more cost-effective, less burdensome, and minimally invasive alternative [4].

In our study, results indicated 60% patency and 40% occlusion on diagnostic hysteroscopy. Consistent with our findings, **Ahmed *et al.*** [9] reported on utilizing a bubble test for determining tubal patency. Their study demonstrated bilateral tubal patency at 71%, unilateral tubal blockage at 11%, and bilateral tubal blockage at 18%. In the research by **Lörincz *et al.*** [3], occlusions were detected in 36 right tubes [29.5%] and 33 left tubes [27%] out of a total of 122 tubes using the bubble method, and 57 tubes [46.7%] using the reference method.

The present study revealed that 61.5% of cases were patent and 38.5% were blocked on diagnostic laparoscopy, findings consistent with **Ott *et al.*** [12]'s results. Additionally, **Ahmed *et al.*** [9] reported that as a secondary outcome, surgical findings for tubal patency indicated that 75% had both tubes open, 13% had only one tube open, and 12% had both tubes blocked.

The study demonstrated a strong agreement between laparoscopy and hysteroscopy in identifying open tubes, with a significant p-value < 0.001. Positive predictive values were 94.2% [CI: 87.6%-99.9%], and negative predictive values were 87.5% [CI: 81.4%-92.8%]. Hysteroscopy showed an overall accuracy of 91.5% [CI: 85.1%-97%] compared to laparoscopy. Consistent with our findings, **Hefny *et al.*** [13] also reported a high level of agreement between the two methods of tube detection.

The comparison between laparoscopy and hysteroscopy for determining tubal patency yielded

a weighted Kappa value of 0.822 [p < 0.001]. Both methods identified 113 patent tubes but differed in detecting tube blockages. Laparoscopy and hysteroscopy findings were concordant in 70 cases of blocked tubes. Discrepancies between the methods were noted in 17 cases. Specificity was 90.9%, sensitivity 91.9%, positive predictive value 94.2%, and negative predictive value 87.5%. Hysteroscopy demonstrated an overall accuracy of 91.5% when compared to laparoscopy. **Ott *et al.*** [12] corroborated our results, highlighting the accuracy of hysteroscopic assessment in predicting fallopian tube patency [p < .001], with a sensitivity of 85.3% and a specificity of 66.1%.

Lörincz *et al.* [3] identified varying performance metrics for the bubble sign in determining tubal patency; sensitivity 73.2%, specificity 70%, PPV 83.3%, and NPV 56% for any tubal patency; on the left tube, sensitivity was 65.6%, specificity 75.9%, PPV 75%, NPV 66.7%; and on the right tube, sensitivity 48.5%, specificity 67.9%, PPV 64%, NPV 52.8%. Additionally, **Allam *et al.*** [10] discovered that in 95% of cases, laparoscopy and hysteroscopy agreed with each other. In 12.5% of cases, laparoscopy indicated bilateral tubal block [BTB] without HSC shedding, while in 82.5% of cases, both laparoscopy and HSC shedding confirmed open tubes. This resulted in a sensitivity of 94.6%, specificity of 100%, PPV of 100%, and NPV of 72.7%.

Conclusion: Diagnostic hysteroscopy is a quick, accurate, and minimally invasive way to check the tubal patency.

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