	Feasibility and Efficacy of Office Hysteroscopic Fallopian Tube Functional Tests
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ABSTRACT

Objectives: To assess how feasible and effective current hysteroscopic fallopian tube (FT) functional tests, namely bubble test, flow test, and proximal tubal peristalsis test, are in predicting FT status in apparently normal FT.

Methods: A prospective bicentric cohort study done at the Endoscopy Units of tertiary university hospitals that included women with bilaterally apparently normal and patent FT on a previous diagnostic laparoscopy (DL) with successful tubal chromopertubation test, or hysterosalpingography (HSG) planned for office hysteroscopy (OH) for a variety of indications. They were subjected to vaginoscopic OH to access the cornual ends of the FT with observation of proximal FT bubble and flow patency tests and peristalsis on both sides. Main Outcome Measures were estimating the percentage of the success of hysteroscopic FT function tests in already proved patent FTs.

Result(s): In 141 cases (98.6%), successful uterine cavity access was possible. In 134 cases (95%), access to Darwish Triad (DT) for the evaluation of various hysteroscopic tubal functional tests was feasible. A successful test was considered successful for prediction of proximal FT status. In terms of right and left FT, the bubble test was successful in 118 (88.1%) and 122 (91%) cases, and the flow test was successful in 68 (50.7%) and 67 (50%) cases, respectively. The peristalsis test was successful in 106 (79.1%) FT on both sides. There was an insignificant difference between successful hysteroscopic FT function tests in patients with prior patent FT diagnosed by DL or HSG.

Conclusion(s): Vaginoscopic office hysteroscopy is a simple and effective tool for provisional assessment of proximal FT functions. Hysteroscopic FT patency and peristalsis testing are good indicators of anatomic and physiologic functions of the proximal FT. Both are superior to flow test. Proximal FT function testing would be a valuable addition to hysteroscopic examinations of infertile patients.

Key Words: Abortion, bubble test, flow test, hysteroscopy, infertility, peristalsis.

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INTRODUCTION

Access to the fallopian tubes (FT) from the uterine cavity is one of the additional benefits of diagnostic hysteroscopy. It facilitates excision of osteal polyps, tubal cannulation, or tubal occlusion in cases of hydrosalpinges not accessible by laparoscopic approach^[11]. There is a growing interest in hysteroscopic assessment of FT functions and describing what's behind tubal ostia. An important anatomic FT landmark describing what's seen behind the ostia has been published^[2]. It is composed of a triad of a cone-shaped part of the FT; its base is the ostium, its wall is the converging intramural part, while its summit is the dark spot representing the narrowest part of the FT. Office hysteroscopy (OH) has been used as a predictor test of anatomical tubal patency by observing the passage of air bubbles through tubal ostia (bubble test) in women with unexplained infertility^[3]. Hysteroscopic documentation of proximal FT peristalsis was an additional advantage described in that study. By this way, hysteroscopy succeeded in illustrating two important functions of the proximal FT, namely, anatomic patency and physiologic peristalsis. Subsequently, other studies demonstrated high sensitivity of the hysteroscopic bubble test for assessing tubal patency in infertility evaluation^[4,5]. However, these studies failed to differentiate between normal FTs and damaged or narrowed but still patent FTs^[6]. Others described passage of endometrial shreds, debris, or blood clots via tubal ostia as an alternative test of patency and called it a hysteroscopic flow test^[7]. Recently, tubal peristalsis was used as a physiologic tubal patency

test^[8]. Moreover, diagnostic accuracy improved after its combination with the anatomic bubble test in a study that compared normal and pathologic hydrosalpingeal FT^[8]. Currently, there is no universal agreement on the reliable tests of tubal function assessment to be added to the routine diagnostic hysteroscopic examination in infertile women. The purpose of this study was to assess how feasible and effective current hysteroscopic FT functional tests, namely bubble test, flow test, and proximal tubal peristalsis test in predicting FT status in apparently normal FT.

METHODS

Study Oversight

This prospective bicentric study was approved by the Institutional Review Boards (IRBs) at the Assiut and Mansoura Medical Faculties (#17300725 and R.21.09.1464) and was carried out at the outpatient hysteroscopy units of Women's Health University Hospital, Assiut, and Mansoura University Hospital, Mansoura, Egypt, between September 1st, 2021, and September 22nd, 2022. The study was registered at ClinicalTrials.gov (identifier is NCT04825041). It was not funded, receiving no financial support from grants or industry. All authors contributed to this study and agreed to its submission for publication. Dr. Darwish AM supervised adherence to the study protocol, accuracy of the data, and validity of the analysis. Study Population: The study included reproductive age (18-35 years) women who underwent office hysteroscopy (OH) for a variety of indications. Only women with bilaterally apparently normal and patent FT on a previous diagnostic laparoscopy (DL) with successful tubal chromopertubation test or hysterosalpingography (HSG) were enrolled. At our institutions, diagnostic laparoscopy was indicated for cases of unexplained infertility despite continuous marital life for at least three years as recommended by ASRM[9], particularly for relatively old women or traveling husbands for a long period to work abroad, which is a common situation in our country. Performing operative laparoscopy, an intrauterine or open pelvic surgery, or a history of pelvic inflammatory disease (PID) after normal DL or HSG were exclusion criteria. Cases with unilateral tubal patency were not included in the study. Pre-procedure counseling and the acquisition of informed written consent were requirements for all cases. None of the participants were receiving estrogens or progestogens. For every case, comprehensive clinical and transvaginal ultrasonographic (TVS) assessments as well as a preoperative history were obtained.

Procedure

Every procedure was carried out during the follicular phase. Using a 30-degree 2.9 mm telescope and a 3.2 mm outer sheath, office hysteroscopy (OH) was carried out without the need for any kind of anesthesia or the use of a vaginal speculum or cervical tenaculum (vaginoscopic OH) as previously described^[10]. The distending medium was 0.9% saline infused via a manual pump. The manual pump pressure was kept constant after appropriate visualization was attained. Assessment of the isthmus and cervical canal was initially done. Hysteroscopic cervical negotiation, as previously described, was used to resolve any cervical kinking or difficulties, particularly in nulliparous women^[11]. After entering the uterine cavity and giving it some time to cleanse and distend, a comment on the clarity of visualization was made. It was essential to notice and report any intrauterine pathology, including polyps, submucous myomas, adhesions, and Mullerian duct anomalies. The telescope was pointed at the cornual ends one after the other. The first step of this study was to evaluate the patency of the FT, and to do so, the hysteroscopist had to appropriately access and view the Darwish triad (DT), which is a conical portion of the FT visible by hysteroscopy2. Its summit is a dark area that symbolizes the narrowest portion of FT, its base is the ostium; and its wall is the convergent intramural portion (Figure 1). If a hysteroscopist observed the passage of air bubbles via DT, this was considered a successful bubble test (Figure 2). If no bubble passage was seen, injection of a few CCs of air in the side channels was made. If bubbles didn't enter DT, the hysteroscopist waited for 1 minute without increasing intrauterine pressure. If there was still no bubble entry to DT, the bubble test was considered failed. In the meantime, observation of passage of any tiny endometrial shreds, debris, or blood clots, if any, via DT was reported (Figure 3). If it was seen passing, a successful flow test was recorded. If it didn't pass, the flow test was considered failed without increasing intrauterine pressure. The successful bubble and/or flow tests meant success to confirm FT patency, while failed bubble and flow tests meant failure to confirm FT patency. The third step was to report on any simultaneous rhythmic contractions and relaxation of the ostium (peristalsis). During osteal contraction, the converging intramural part and the dark spot were not seen, while the reverse occurred during relaxation. If well seen within one minute, a successful peristalsis test was reported, but if not seen, the test was considered failed. The same steps were observed on the other FT after tilting the telescope towards the contralateral cornual end. In all cases, intrauterine pressure was maintained throughout testing. The primary outcome of this study is estimating the percentage of the success of hysteroscopic FT function tests in detection of patency in already proved patent FTs. Statistical Analysis The Statistics Package for Social Sciences (SPSS) (IBM, Armonk, NY, USA) Version 25 for statistical analysis was used. After performing normality tests (Kolmogorov-Smirnov and Shapiro-Wilk tests), it was found that the age, BMI, and menstrual day data were not normally distributed. Frequency and percentage were used to describe qualitative data. The median and interquartile range (IQR), which represented the distribution of the data, were used to express continuous quantitative data. IQR is defined as the difference between the 75th and 25th percentiles of the data.



Fig. 1: Darwish hysteroscopic triad (DT).



Fig. 2: Bubble test (notice air bubbles at DT.



Fig. 3: Flow test (notice blood clots approaching DT.

RESULTS

This study included 143 women with a report of patent both FT by DL or HSG and were planned for OH for clinical indications. Infertility was encountered in 109 cases (76.2%) as OH was indicated for unexplained infertility, IVF/ICSI preparation according to institutional protocols, previous failed IVF/ICSI, or preovulatory thin endometrium (7 mm or less). A history of early recurrent pregnancy loss (RPL) was encountered in 34 cases (23.8%). (Table 1) shows demographic and clinical OB/GYN data of studied patients without significant risk factors of patients or infertility etiologies/histories. HSG was done for 61 cases (42.7%), while laparoscopy was done for the rest of 82 cases (57.3%). (Table 2) shows details of prior laparoscopic findings of both fallopian tubes. A detailed description of hysteroscopic findings in all cases is shown in (Table3). Successful endometrial cavity access was feasible in 141 cases (98.6%) except 2 cases due to excessive bleeding. Access to DT to assess different hysteroscopic tubal functional tests was successful in only 134 cases (95%). In the remaining 7 cases, it was inaccessible due to excessive endometrial shreds or blood. (Table 4) shows the success of different hysteroscopic functional tests in all studied cases without significant difference between DL and HSG cases. A 5 mm-outer sheath operative hysteroscopy was done under local paracervical block and IV sedation to treat endometrial pathologies in 17 (12.1%)and 4 (2.8%) of cases due to small endometrial polyps and filmy adhesions, respectively (Table 3). Otherwise, patients reported little discomfort during the procedure thanks to the use of a smart fine telescope of 2.6 mm, the skill of the hysteroscopists to negotiate the internal os, and simultaneous patient education on a concomitant screen to see what's inside the uterus and to deviate their attention till the end of the procedure. The average duration of diagnostic hysteroscopy was 4-8 minutes.

Table 1: Demographic and clinical characteristics of the study

population

Variab	Study population, (n = 143)			
	Median	26		
Age (years)	IQR	23 - 29		
	Median	27		
BMI	IQR	24 - 30		
Q	Rural n, (%)	44	30.8%	
Socioeconomic level	Urban n, (%)	99	69.2%	
Devites	Nullipara n, (%)	108	75.5%	
Parity	Parous n, (%)	35	24.5%	
Abortion	No n, (%)	109	76.2%	
Abortion	Yes n, (%)	34	23.8%	
L.f. (100)	Primary n, (%)	73	66.9%	
merunty (109 cases)	Secondary n, (%)	36	33.1%	
Mandmustion Dava	Median		8	
Mensuruation Days	IOR	6 - 10		

The data has been represented as N, %, IQR: Interquartile range

Table 2: Laparoscopic findings in 82 cases.

Variables		Right side $(n = 143)$		Left side $(n = 143)$	
	Done and normal caliber and successful chromopertubation test	82	57.3%	82	57.3%
Diagnostic Laparoscopy	Not done*	61	42.7%	61	42.7%
	Normal length and patent	75	91.5%	75	91.5%
Tubal Length	Shortened but patent	7	8.5%	7	8.5%
T 1 1 XV 14	Normal width and patent	74	90.2%	75	91.5%
Tubai Width	Distended or diverticulum but patent	8	9.8%	7	8.5%
Finchair	Normal	78	95.1%	72	87.8%
Fimoria	Abnormal but patent	4	4.9%	10	12.2%
Donitated adhesions	No	74	90.2%	78	95.1%
r cinubai aunesions	Yes	8	9.8%	4	4.9%

The data has been represented as N, %.

*Included based on patent and apparently normal FT by HSG.

Table 3: Hysteroscopic findings in all 143 studied cases.

Hysteroscopy		Studied patients $(n = 143)$		
	a 1	Accessible	135	94.4%
Cervical Canal		Kinking that required hysteroscopic negotiation	8	5.6%
T 01		Normal	126	88.1%
Isthm	18	Stenosis	17	11.9%
Endometrial cavity access		Accessible	141	98.6%
		Inaccessible due to excessive bleeding	2	1.4%
Endometrial Cavity Abnormality Total accessible Patients n= 141		No abnormality	120	85.1%
		Polyps	17	12.1%
		Fine adhesions	4	2.8%
Endometrial Thickness Total accessible Patients n= 141		Normal	111	78.7%
		Thick	24	17%
		Atrophic	6	4.3%
	Right side (n = 141)	Accessible	134	95%
		Inaccessible	7	5%
Access to Darwish Iriad	t Left side (n = 141)	Accessible	134	95%
		Inaccessible	7	5%

The data has been represented as N, %

Accessible patients in Darwish Triad Access (N=134) DL (N=80) HSG (N=54) Total (N=134) P-value Successful 69 86.3% 49 90.7% 118 88.1% RT bubble test 0.43 NS Failed 11 13.8% 5 9.3% 16 11.9% Successful 73 91.3% 49 90.7% 122 91% Lt bubble test 0.92 NS Failed 7 5 9.3% 12 9% 8.8% 42 52.5% 26 48.1% 50.7% Successful 68 RT Flow test 0.62 NS Failed 38 28 51.9% 49 3% 47 5% 66 Successful 40 50% 27 50% 67 50% LT Flow test 1 NSFailed 40 50% 27 50% 67 50% Successful 64 80% 42 77.8% 106 79.1% Rt peristalsis Test 0.76 NS Failed 16 20% 12 22.2% 28 20.9% Successful 63 78.8% 43 79.6% 106 79.1% LT peristalsis Test 0.9 NS Failed 17 21.3% 11 20.4% 28 20.9%

Table 4: Success rate of different hysteroscopic tubal patency tests in relation to prior tubal patency tests

The data has been represented as N, %. *P-value* is considered significant if (p<0.05)

DISCUSSION

Routine use of hysteroscopy for infertility assessment is not universally agreed on, even in patients with failed IVF/ICSI^[12]. The objections include being invasive, costly, potential pain-related patient dissatisfaction, inadequate evidence-based studies, and most importantly the fact that 2D or 3D TVS or saline-infusion sonography (SIS) offer great information regarding the uterine cavity and FT. On the other hand, to obtain a more accurate assessment of infertility, some researchers recommended incorporating hysteroscopy into the standard infertility work-up^[10] to look for any intrauterine causes of infertility or ART failure. In this study, tiny endometrial polyps and fine intrauterine adhesions were reported and concurrently treated in 17 (12.1%) and 4 (2.8%) of the cases, respectively, despite normal uterine cavities by HSG and 2D TVS. Patients scheduled for first or repeat IVF/ICSI trials were included in this study according to our institutional guidelines, as ART is costly, not covered by public or private health insurance, and many patients, whether urban or rural, have limited financial resources. Furthermore, university hospitals provide OH at a relatively cheap symbolic cost (50 EGP). Two major achievements have led to the safe widespread use of hysteroscopy and the reduction of its limitations: the use of a vaginoscopic approach without speculum or tenaculum and smart OH with a smaller caliber than a uterine sound that doesn't require cervical dilatation beforehand, even in young patients^[10]. By this way, OH offers a reasonable approach for evaluating the uterine cavity with minimal discomfort, lower cost, and sometimes the ability to surgically remove intrauterine lesions^[9]. Furthermore, OH is a quick procedure, especially in the follicular phase, as in this study, where proper endometrial cavity visualization was achieved in 141 cases (98.6%). The fallopian tube (FT) is not merely a simple passive conduit; rather, it is a highly specialized dynamic paired organ. It permits the oocyte to travel from the fimbria and the sperms to rise from the endometrial cavity to the site of oocyte fertilization. Anatomic patency, precise ciliary motions, and paradoxical bidirectional peristalsis towards the ampulla are necessary for this function. In order to fully evaluate the tubal factor, anatomic patency alone is insufficient; peristalsis must be included. Regarding tubal patency, there are many procedures; however, none of them is considered ideal because they all have shortcomings and difficulties. Essentially, one of two invasive methods, DL or HSG, is recommended. That's why, based on recent previous HSG or DL, infertile women with patent FT were included in the present study to ensure tubal patency. HSG has been the standard FT patency test^[13]. That's why patients with patent FT by prior HSG were included in this study. However, it usually causes discomfort and poses some hazards, such as an infection, fainting, spotting, iodine allergy, or exposure to ionizing radiation. The gold standard test is DL, as it gives an idea about the patency of the whole FT. Again, cases with patent FT by DL were included in this study. However, DL is associated with some surgical risks and is expensive and invasive^[14]. Nevertheless, in this study, DL was performed for women with unexplained infertility for more than 3 years as previously recommended^[9]. Trials to use less invasive tubal patency tests implemented 2D or 3D ultrasonography (US), which is free of radiation and includes saline-infusion sonography (SIS) or hysterosalpingo-foam sonography (HyFoSy) using either air-saline or microbubble US contrast material, respectively. Unfortunately, many gynecologists face some technical difficulties in performing US tests and analyzing the findings, especially in 3D. Furthermore, failure to localize unilateral or bilateral patency is a real problem^[15]. Due to the well-known benefits of OH and the paucity of published human studies, we have been interested in in vivo studies on the FT functions in humans utilizing OH for more than ten years, starting in February 2013^[3]. Since the only part of the FT accessible via hysteroscopy is the proximal part, hysteroscopic assessment of patency or peristalsis is just presumptive but not confirmatory of the whole FT functions. We conceived the reality that a successful bubble test with confirmed passage of bubbles doesn't guarantee patent whole FT simply because the rest of FT is not seen, as it may be distended and patent, pathologic, has a diverticulum or even blocked hydrosalpinx. In a previous study^[8], the bubble test was successful in 56 cases (50%) of blocked hydrosalpinx. This basic concept puts hysteroscopic FT function tests in their real size without over-enthusiasm, unlike others who later considered the hysteroscopic bubble test a predictor of the whole FT patency and was superior to "historic" HSG and US methods^[4,5]. Thereafter, nearly the same team performed studies utilizing pre- and postoperative TVS to detect any change in fluid volume in the pouch of Douglas after OH^[16,17]. Their results of failure to address the laterality of patency and may be misleading with high initial volumes supported our concept that the hysteroscopic patency test is just a presumptive test of only the proximal FT. The main drawbacks of their technique are converting OH from a fast, simple procedure into a more complex one to observe fluid by TVS and the need to infuse the distension medium with added pain and discomfort. Hysteroscopic assessment of anatomic tubal patency is an emerging approach that is performed through the direct observation of air bubble flow into the DT3. In contrast to DL or HSG, in this study, the omission of any increase in intrauterine pressure during FT function testing supports the concept that the passage of bubbles is aided by the peristalsis of the proximal part of FT, which mimics the suction mechanism rather than the pushing of fluid. This study reported successful bubble tests in 118 cases (88.1%) with already patent FT, which was more or less similar to our previous study^[3] that comprised 85 infertile patients scheduled for laparoscopy. The hysteroscopic bubble flow test was successful in 91% and 88.5% on the right and left FT, respectively. Subsequent imitative studies^[5,17] reported nearly similar findings. A meta-analysis of six Scopuspublished trials demonstrated that the utilization of hysteroscopy to predict tubal patency had a sensitivity of 88% and specificity of 85% if compared with laparoscopic chromopertubation^[18]. A major methodological error of this meta-analysis is missing the inclusion of 85 women in a study13 that fulfilled their inclusion criteria, which eventually weakened their results. In this study, the flow test was successful in 68 cases (50.7%), which is a lower percentage if compared to the bubble test. This can be explained by performing OH in the follicular phase, as the endometrium is thin without significant passage of endometrial shreds, debris, or blood clots via tubal ostia. Likewise, diagnostic indices were significantly lower in the flow test group when compared to the bubble flow group in a previous study^[19]. Since FT expresses two paradoxical peristaltic movements, it seems logical to use OH and DL to test proximal and distal FT peristalses, respectively. In a recent study^[20], DL detection of distal FT peristalsis was disappointing as it was seen in 5 (4.2%) and 5 (4.4%) in 59 cases of normal or 56 cases of hydrosalpingeal FT, respectively. After the exclusion of cases with unilateral

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patent FT from hydrosalpingeal FT, the percentage dropped to 3.2% (only 3 FT). In the same study, hysteroscopic detection of proximal tubal peristalsis was significantly higher in normal FT 80 (67.8%) vs. 40 (35.7%) in hydrosalpingeal FT. On the other hand, proximal FT peristalsis is easily observed via hysteroscopy^[3]. In this study, it was diagnosed in 106 (78.1%) of 134 accessible Darwish Triad 2 on both sides. These results agree with a previous study^[8] that reported successful proximal FT peristalsis in 67.8% of normal FT while it was successful in only 14% of hydrosalpinges. In this study, the high percentage of successful bubble test and proximal FT peristalsis in apparently normal FT supports the concept that hysteroscopy is an ideal tool for assessment of two important FT functions^[3]. A combination of successful bubble test and peristalsis test resulted in increased diagnostic indices in a previous study^[8]. Ideally, assessment of diagnostic accuracy of hyteroscopic FT function tests should be compared to the gold standard laparoscopic chromopertubation test as previously done by our team^[8]. This step was omitted in this study as the selected cases had already proved patent FT by recent HSG or DL. Moreover, there was an insignificant difference between successful FT function tests if compared to prior HSG or DL, which supports the selection criteria of this study to rely on either HSG or DL patency tests. The purpose of this study was not to answer the controversial question of using OH as a tubal patency test or not. Its message was clear: if OH is done for an infertile woman, the hysteroscopist should observe DT and offer the patient an additional few minutes to evaluate two vital FT functions, namely patency and peristalsis. In this way, hysteroscopy would contribute a significant benefit to the report by indicating the current state of the proximal portion of the FT. In the era of precision medicine, assuring hysteroscopic FT functions would postpone some invasive FT tools like SIS, HSG, or DL, especially for individuals who have experienced short periods of infertility and do not have a history of pelvic laparoscopic or open surgeries or PID. This study would expand the use of hysteroscopic examination and add advantages of simple assessment of FT patency and peristalsis since OH is frequently available in clinics. Collaborating to achieve optimal results is exemplified by conducting this study in two experienced academic institutions that are eager to learn more about FT functions utilizing hysteroscopy^[3,6,8]. The inclusion of 34 cases (23.8%) with RPL already subjected to OH endometrial cavity screening contributed to the increased sample size of this cohort. Limitations of this study include a relatively small sample size due to restricted selection of patients with confirmed normal and patent both FT by HSG or DL. Additionally, it did not evaluate the specificity or diagnostic accuracy of single or combination tests. This can be attributed to the selection of a group of patients with confirmed patent FT by DL or HSG based on a previous study^[8] that already demonstrated significantly successful findings in the normal FT when compared to pathologic FT. Lack of intraoperative surveillance for FT functional tests is another drawback of this study, as it relied on prior DL or HSG. The inability to detect distal tubal disease is an additional drawback of this study. From this study, it is concluded that vaginoscopic office hysteroscopy is a simple and effective tool for provisional assessment of proximal FT functions. Hysteroscopic FT patency and peristalsis testing are good indicators of anatomic and physiologic functions of the proximal FT. Both are superior to flow tests. Proximal FT function testing would be a valuable addition to hysteroscopic examinations of infertile patients.

AUTHORS'S CONTRIBUTION

Darwish AM is the principal investigator, who made most of the hysteroscopic procedures at Assuit University Woman's hospital and wrote the paper from A to Z. Shokeir T performed a hysteroscopic procedure at Mansura University Hospital and reviewed the paper. Darwish DA reviewed the data and the whole paper. Hindi II performed some hysteroscopic procedures and reviewed the paper. Borahay MA shared the idea and reviewed the paper.

CONFLICT OF INTERESTS

There are no conflicts of interest.

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