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ORIGINAL ARTICLE

Role of hysteroscopy in the evaluation of tubal patency in infertile women

Ihab Serag Allam [a,*], Ahmed M. Rashed [a], Khaled H. Sweedan [a], Gasser A. El Bishry [a], Walaa E. Ahmed [b]

[a] Obstetrics and Gynaecology Department, Ain Shams University, Cairo, Egypt
[b] Mataria Teaching Hospital, Egypt

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KEYWORDS

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Abstract *Study objective:* To evaluate the effectiveness of hysteroscopy as a method for the diagnosis of tubal patency using saline distention media.

Design: Prospective cohort study.

Setting: Infertility clinic of the Ain-shams University maternity hospital.

Materials & methods: Sixty-four infertile women underwent hysteroscopy (HSC) and hysterosalpingography (HSG) on two consecutive days. Transvaginal ultrasonography (TVS) was carried out before and after hysteroscopy in order to measure the fluid in the cul-de-sac. The difference between the two methods in the diagnosis of tubal patency was compared using laparoscopy/chromotubation as a gold standard.

Main outcome measures: Fluid volume measurements were used to determine a cut off value for tubal patency. Pain was recorded at the end of the process.

Results: According to the laparoscopy, the sensitivity and specificity of HSC and HSG in detecting tubal patency were 94.6% and 100% vs. 92.8% and 50%, respectively. The best cut off point of the fluid volume in the cul-de-sac at which both tubes are patent is 6 ml. All of the patients reported significantly less pain during hysteroscopy in response to HSG.

Conclusions: Office hysteroscopy combined with TVS may be used as an alternative to HSG, as an effective, easy, safe and minimal invasive office procedure that can be offered as a first line method for the evaluation of the uterine cavity along with the tubes in infertile women.

Abbreviations: BTB, bilateral tubal block; HSC, hysteroscopy; HSG, hysterosalpingography; HyCoSy, hysterosalpingoconstrastsonography; IQR, interquartile range; NPV, negative predictive value; PPI, present pain intensity; PPV, positive predictive value; ROC, receiver Operating Curve; SD, standard deviation; TVS, transvaginalsonography

* Corresponding author. Tel.: +20 1001401569.
E-mail address: ihabserag@hotmail.com (I.S. Allam).

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1. Introduction

Infertility is defined as failure to achieve a successful pregnancy after 12 months of regular unprotected intercourse (1). Tubal dysfunction is responsible for approximately 30% of infertility cases. Tests to determine if the tubes are open and undamaged are an important part of the infertility workup (2). Fallopian tube patency is diagnosed by hysterosalpingography (HSG), laparoscopy/chromotubation and Hysterosalpingo-constrast-sonography (HyCoSy). Mucosal appearance was achieved by Falloposcopy per vaginam and Salpingoscopy was performed at laparoscopy (3). The indication for routine hysteroscopy as part of an infertility work up is still a matter of controversy (4). HSG has been the most commonly used diagnostic technique. Lack of agreement occurs in 30% of cases when HSG and Hysteroscopy (HSC) are compared (5). Hysteroscopy permits panoramic visualization of the uterine cavity and direct biopsy of lesions, thus increasing precision and accuracy in the diagnosis of intrauterine conditions (6). Nevertheless; hysteroscopy is not a method to investigate fallopian patency or anatomy. Hysteroscopy; however, can be used in tubal patency evaluation if combined with ultrasonography (2). During the past few years, sonosalpingography has been suggested as the first line method to study tubal patency (7). Both, negative and positive contrasts were used for tubal patency assessment. The tube is considered patent when the turbulence of the contrast is visualized on the side or in the Douglas pouch (8).

The objective of the study is to clarify the diagnostic accuracy of combined office HSC with transvaginalsonography (TVS) findings about tubal patency in comparison with the HSG, taking laparoscopy as a gold standard. We are aiming to highlight that hysteroscopy may be used as an alternative to HSG for the diagnosis of intrauterine lesions as well as tubal patency with the same accuracy reached by laparoscopy.

2. Patients and methods

The population of this prospective cohort study consisted of infertile women planned for laparoscopy as a part of infertility workup at the Ain-Shams Maternity Hospital in the period from June 2009 to May 2010. The study was approved by the Ethics Committee of the Faculty of Medicine, Ain-Shams University. Explanation and notification of the procedure and its aim, were done for all patients and written consent was taken. Patients with abnormal bleeding, active pelvic infection or suspicion of uterine malignancy were excluded. At the initial visit of the patients, information on demographic characteristics and medical and reproductive history was recorded. General, abdominal and pelvic examination was done.

Baseline TVS examination of the female pelvis was performed using SHIMADZU SDU-350A, Japan with 5.5 MHz trans-vaginal transducer. The presence of free fluid in the cul-de-sac in the sagittal plane of the pelvic area was recorded prior to hysteroscopy to calculate pre-hysteroscopic free fluid. Immediately after the performance of TVS, the vagina and the cervix were cleaned with an iodine solution. Office Hysteroscopy was performed during the early follicular phase 1–2 days after cessation of menstruation, using a rigid 30° hysteroscope with a 2.7 mm telescope and 4 mm diameter diagnostic sheath with an operative channel (SOPRO COMEG, Germany). Using the non-touch vaginoscopic technique, uterine cavity was systematically explored. Normal saline was used for uterine distension. For each hysteroscopic procedure the total saline usage was 200 ml at a fluid delivery system pressure of 100 cm H_2O. This pressure was achieved when the saline bag was 1 m above the uterine cavity (9). The hysteroscope was withdrawn, TVS probe was reinserted to measure the free fluid in the cul-de-sac in the sagittal plane. The volume of free fluid in the cul-de-sac was calculated in milliliters with a volume calculation program using the ultrasound device. The result of the ultrasound finding (hysteroscopic shedding) was calculated as: post-hysteroscopic free fluid minus pre-hysteroscopic free fluid. An equilibration time of 2 min was used as in initial pilot experiments little to no change happened after this period. The three dimensions (length, height and depth) of the pocket were measured by transvaginal sonography. Each measurement was repeated three times with a 1-min interval and the mean of each set of measurements was applied for the final calculation of volume (10). The accuracy of the prediction of a peritoneal fluid volume, calculated from all measured volumes, had an overall coefficient of variation ((standard deviation/mean) × 100) of 15.3%. The next day, HSG was done. A speculum, tenaculum and Leech Wilkinson cannula were used. Urographin dye was used as contrast material. The results obtained by HSG and HSC regarding tubal patency were compared, taking laparoscopy that was done in the next cycle as a gold standard. Pain experienced during the procedures was assessed using the present pain intensity (PPI). The PPI derived from the McGill Pain Questionnaire was obtained by grading patients' description of the pain as: 0 = none, 1 = mild discomfort, 2 = moderate discomfort, 3 = distressing and 4 = horrible (11).

2.1. Sample size justification

It was estimated that a sample size of 63 women in each arm would have a power of 80% to detect an effect size (d) of 0.3. The test statistic used was the two-sample *t* test and significance was targeted at an α-error of 0.05. The sample size was increased by 10% to compensate for post randomization exclusions related to performing HSC or HSG in infertile women.

2.2. Statistical analysis

Statistical evaluation was performed using the SPSS software program Version 15 (SPSS Inc., Chicago, IL, USA). Quantitative variables were described as mean and standard deviation (SD) versus median and interquartile range (IQR) as appropriate. Qualitative variables were described as number and percentage. Comparison of qualitative data was done using the Chi-square test. Percentage of agreement was done using the Kappa statistic (κ). The κ value was interpreted as follow: <0.20 = Poor, 0.21–0.40 = Fair, 0.41–0.60 = Moderate, 0.61–0.80 = Good, and 0.81–1.00 = Very good. Sensitivity and specificity of the calculated fluid volume were calculated and a Receiver Operating Curve (ROC) was constructed. The area under the ROC curve was calculated. An area of 1 represents a perfect test; an area of 0.5 represents a worthless test in order to select the best cutoff value that combined the highest sensitivity and specificity. Comparison of paired pain scores was done using the Wilcoxon non-parametric test. A *P* value of 0.05 was chosen as the level of significance.

3. Results

A total of 80 women were recruited in the study. Sixteen patients did not complete the study due to cervical stenosis and adhesions preventing HSC to be done, inconclusive finding of HSC or HSG, severe pain from HSC or HSG leading to stoppage of the procedures, dense adhesions around tubes preventing tubal patency assessment during laparoscopy and interruption of laparoscopy due to intraoperative hypoxia. Thus, the study was completed for 64 women, throughout which no complications occurred (Fig.1). The mean age, duration of marriage and infertility of the study group were 27 ± 5 years, 4.8 ± 3 years and 4 ± 2.6 years, respectively. Primary infertility was shown in 46 women (72%) and secondary infertility in 18 women (28%).

Tables 1 and 2 show the comparisons between the tubal patency results of laparoscopy and HSC and HSG, respectively. As shown in Table 1, laparoscopy and HSC agreed together in 95% of cases, 12.5% of cases had bilateral tubal block (BTB) in laparoscopy and no HSC shedding and 82.5% of cases had patent tubes by laparoscopy and HSC shedding. This gave a sensitivity of 94.6%, specificity of 100%, positive predictive value (PPV) of 100%, negative predictive value (NPV) of 72.7%, Total validity of 95% and Kappa agreement of 0.815. On the other hand, Table 2 shows that laparoscopy and HSG agreed together in 87.5% of cases, 6.3% of cases had BTB in laparoscopy and HSG and 81.3% of cases had patent tubes by laparoscopy and HSG. This gave a sensitivity of 92.8%, specificity of 50%, PPV of 92.8%, NPV of 50%, Total validity of 87.5% and Kappa agreement of 0.43.

According to the laparoscopy results, the women were categorized into three groups. Group-1 showed bilaterally normal fallopian tubes, Group-2 showed unilateral occlusion, and Group-3 had a bilateral occlusion. The peritoneal fluid measurement was a mean of 10.6 ± 4.3 ml in Group-1 with a range of 16–0 ml. For Group-2 the mean fluid volume was 6 ± 1.5 ml with a range of 3.3–9 ml, while for Group-3 no fluid could be detected. Fig. 2 shows that the best cut off point of the fluid volume at which both tubes are patent is 6 ml with sensitivity of 93% and specificity of 66.7. The area under the curve is 0.899. Regarding pain occurred during hysteroscope or HSG, the median of pain in HSC = 0 (IQR, 0–3) and the median of pain in HSG = 2 (IQR, 0–4). Hysteroscopy is less painful than HSG which is statistically significant ($P < 0.001$).

4. Discussion

HSG, laparoscopy or both can be applied to demonstrate tubal patency. Owing to its noninvasive nature and low cost, HSG is widely used as a first-line approach to assess the patency of the fallopian tubes and uterine anomalies in the routine fertility workup (12). However, HSG has disadvantages, including exposure to X-rays, radio-contrast material and infection risk. Furthermore, it is an invasive procedure and is dependent on an experienced radiologist. Alternative methods to HSG have been developed for many years (2).

The idea of detecting fluid in the cul-de-sac as a test of tubal patency was presented by few studies. These studies were not identical with our study in the way of passing of the saline solution from the uterus to the peritoneal cavity apart from one study (2). In our study and one study, saline was applied via hysteroscopic procedure while the uterine cavity was investigated, whereas in the other studies saline was infused via a Foley or Nylaton catheter (2). Richman et al., reported ultrasound demonstrated bilateral occlusion with a sensitivity of 100%, and showed tubal patency with a specificity of 96% when results were compared with HSG (13). Randolph et al. reported that U/S was as accurate (sensitivity 100%, specificity 91%) as HSG (sensitivity 96%, specificity 94%) in demonstrating the presence of tubal patency in comparison with laparoscopy (14). Lower sensitivity showed in our study attributed to the presence of 3 cases that were found to have adhesions (2 pelvic adhesions detected by laparoscopy and 1 intrauterine adhesion detected by hysteroscopy) that could prevent the saline to be accumulated in the cul-de-sac. Also, while comparing these 2 studies with our study regarding specificity (where our results showed higher specificity), their use of transabdominal U/S, as detected from the published years and taking HSG as a reference standard should be considered. Yildizhan et al. in their study concluded that hysteroscopic shedding gave a sensitivity of 77%, specificity of 57%, PPV of 87% and NPV of 55% (2). Our study showed better values for sensitivity, specificity, PPV and NPV when compared with this study. It could be attributed to the use of laparoscopy as a reference standard and not HSG. Our study was deficient in demonstrating which side the fluid had passed through the fallopian tubes, unlike sonosalpingography does, thus unable to detect the side of tubal block. This lack of visualization of the turbulence in sonosalpingography was substituted in our study by calculating the volume of fluid in the cul-de-sac before and after hysteroscopy to estimate the hysteroscopic shedding. After which, we calculated the cutoff point at/above which we could consider that both tubes are patent. It was found that 6 ml was the best cut off point of the fluid volume at which both tubes are patent, being of the highest sensitivity (93%) and highest specificity (66.7%).

The ultrasound saline contrast method for the assessment of the tubal status in comparison to laparoscopic findings of chromotubations showed 100% sensitivity and NPV, but also a low specificity of 66% and a PPV of 57%. Examination of tubal patency by the Echovist yielded a better specificity (77%) and PPV (70%) (8). A meta-analysis authenticated that saline HyCoSy procedure had a sensitivity of 76.1% and a specificity of 79.4%, with a PPV of 71.4% and NPV of 83.1%. The finding of HyCoSy and laparoscopy and the dye test was the same for 89 tubes, for compatibility rate of 78.1% indicated that Echovist had a false positive rate of 10.3% for the diagnosis of tubal occlusion and a false negative rate of 6.7% (15,16). According to our data, false positive diagnosis of tubal occlusion was 4.7% and false negative diagnosis was 0%. This non-accordance with the meta-analysis was caused by the 3 cases with pelvic and uterine adhesions as mentioned before.

More recent, Török et al., performed selective pertubation with office hysteroscopy in 35 infertile patients before their scheduled laparoscopy and chromohydrotubation as part of infertility assessment. They compared the findings of the two methods. Hysteroscopic tubal assessment had 82.9% accuracy with the laparoscopic dye method taken as the reference, with a PPV of 87.5%, and a NPV of 76.7%. No complication or failure occurred. They concluded that, selective pertubation with office hysteroscopy is a useful method for the evaluation of tubal patency. As a minimal invasive office procedure it can

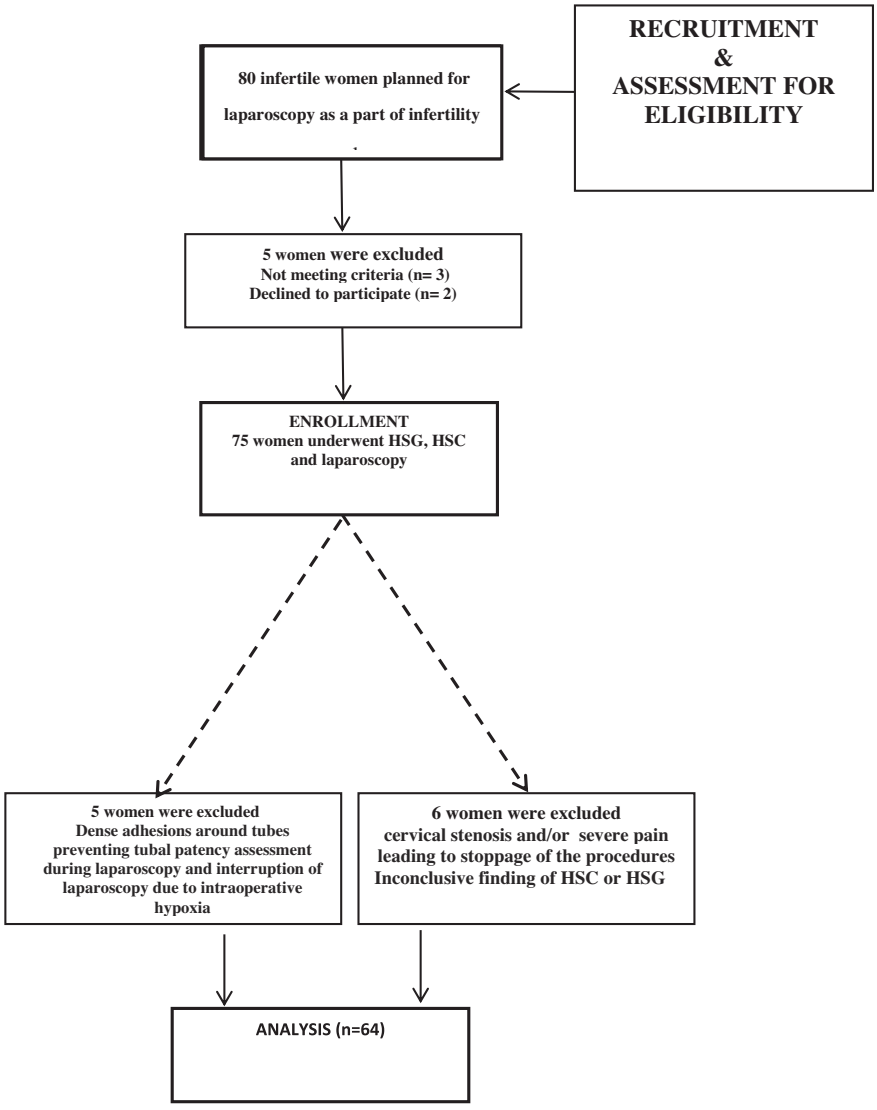

Figure 1 Participants' flow chart; HSC, hysteroscopy; HSG, hysterosalpingography.

Table 1 Results of hysteroscopy (HSC).

HSC shedding	Laparoscopy*		Total*
	BTB**	1 or 2 patent tube	
No	8(12.5%)	3(4.7%)	11(17.2%)
Yes	0(0%)	53(82.8%)	53(82.8%)
Total	8(12.5%)	56(87.5%)	64(100%)

* Values are given as number (percentage = % of Total (64)).
** Bilateral tubal block.

be conducted as a first line method for the assessment of the uterine cavity and the tubes in infertile women (17).

Another issue in the study was that hysteroscopy was well tolerated in most women, the median of pain in HSC was 0 (0–3). In contrast with HSG, the median of pain in HSG was 2 (0–4). Thus, hysteroscopy was less painful than HSG which is statistically significant ($P < 0.001$). This difference could be explained by the use of non-touch vaginoscopic technique, saline distention media, small diameter office HSC, and distraction of patient attention by screen viewing and experienced surgeon. Whereas in HSG, insertion of Cusco's speculum, penetration of the catheter, grasping the cervix with tenaculum and irritation of the peritoneal cavity with the dye used stimulated pain, resulting in low tolerance. Bettochi and Selvaggi reported their experience with more than 11,000 hysteroscopic procedures performed using the vaginoscopic technique (18). They found that as many as 99.1% of the patients reported no discomfort related to the procedure. Kremer et al. assessed the pain of hysteroscopy, without anesthesia, in outpatient setting in 554 women. 35.8% of the patients had no pain, 58.8% had mild pain, while 5.4% had moderate to severe pain (19). Pluchino et al., assessed the roles of instrument diameter (5.0- or 3.5-mm external sheath), uterine distention medium (CO_2 or saline solution), and hysteroscopist

Table 2 Results of hysterosalpingography (HSG).

HSG	Laparoscopy*		Total*
	BTB**	1 or 2 patent tube	
BTB	4(6.3%)	4(6.3%)	8(12.5%)
1 or 2 patent tube	4(6.3%)	52(81.3%)	56(87.5%)
Total	8(12.5%)	56(87.5%)	64(100%)

* Values are given as number (percentage = % of Total (64)).
** Bilateral tubal block.

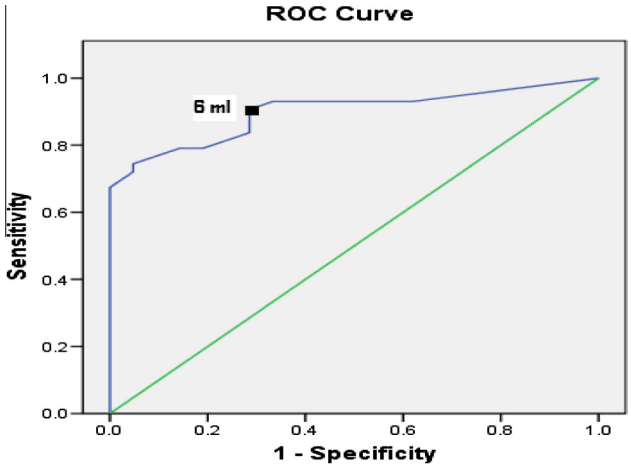

Figure 2 Cut off point of the fluid volume at which both tubes are patent.

experience as regarding pain (20). They concluded that instrument diameter and hysteroscopist's experience, but not the distention medium, seem to be the primary variables that affect the perception of discomfort during office hysteroscopy.

5. Conclusion

Office hysteroscopy combined with TVS may be used as an alternative to HSG, as an effective, easy, safe and minimal invasive office procedure that can be offered as a first line method for the evaluation of the uterine cavity along with the tubes in infertile women.

Conflict of interest

None.

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