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ORIGINAL ARTICLE

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

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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

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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.