Evaluation of Efficacy of Transvaginal Sonography with Hysteroscopy for Assessment of Tubal Patency in Infertile Women Regarding Diagnostic Laparoscopy

Abstract

Background: Infertility, as one of the most common gynecological disorders, affects many people worldwide. To choose the clinical treatment, correct assessment of tubal patency can provide an important clue; therefore, it is considered as one of the major steps in workup examinations of infertile women. In this study, we aimed to compare the results of transvaginal ultrasonography (TVS) after hysteroscopy (HSC) with laparoscopy, as a gold standard, for assessing the fallopian tubal patency in infertile women. Materials and Methods: This is a cross-sectional study which included 49 infertile women referred to Shahid Beheshti Hospital affiliated with Isfahan University of Medical Sciences during the years 2015 and 2016. At first, patients who met the inclusion criteria were examined through HSC in by a specialist in gynecology and obstetrics in operating room because laparoscopy was performed after TVS with HSC, but HSC was performed without anesthesia. TVS was performed before and after of HSC to observe fluid in the pouch of Douglas. The findings of TVS with HSC and laparoscopy were compared. Results: There was a strong agreement between TVS after HSC and laparoscopy (kappa coefficient = 0.935, 95% confidence interval [CI]: 0.81, 1.00). The sensitivity of TVS after HSC was 100% (95% CI: 66.37, 100) and specificity was 97.50% (95% CI: 86.84, 99.94) with a positive predictive value of 90% (95% CI: 55.50, 99.75) and negative predictive value of 100% (95% CI: 90.97, 100). Conclusion: TVS after HSC is an accurate diagnostic tool for examination of fallopian tubal patency in infertile women.

Keywords: Fallopian tubal patency, hysteroscopy, infertility, laparoscopy, transvaginal sonography

Introduction

Worldwide, millions of couples estimated as infertile. Infrertility, as one of the most common gynecological disorders, affects many people worldwide. To choose the clinical treatment, correct assessment of tubal patency can provide an important clue; therefore, it is considered as one of the major steps in workup examinations of infertile women. The tubal patency evaluation usually consisted of a combination of hysterosalpingography (HSG), hysteroscopy (HSC), transvaginal ultrasonography (TVS), and laparoscopy. The gold standard, but invasive and expensive, test for diagnosing tubal patency is laparoscopy. HSG is widely used as a first-line approach in the routine infertility workup, for assessing the patency of fallopian tubes and investigating uterine anomalies. Contrast reaction and X-ray radiation exposure during HSG may induce abdominal pain and allergic reactions. Moreover, to rule out the presence of endometriosis and peritubal adhesions, which could be missed with HSG, laparoscopy is a forced step after diagnosing tubal patency by HSG. However, although diagnostic laparoscopy offers the possibility of surgical treatment, it expose the patient to operative and anesthesia risk. Diagnostic HSC is superior to other method for assessing the uterine cavity.

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HSC in combination with sonography is also applicable to examine infertile women for tubal patency. It is the first and best practice to evaluate the uterine cavity, the functional problem of uterine, such as polyps, and myoma development. [9] Accurate and precise diagnosis of intrauterine conditions is provided by HSC due to its ability to make available panoramic vision of the uterine cavity and direct biopsy of lesions. There is about 30% disagreement between HSG and HSC. [11] Nevertheless, HSC does not help to examine fallopian tubal patency except when it is followed by ultrasonography. [9, 12, 14]

Although a number of studies [3, 8] found that HSC had better diagnostic value in combination with TSV than other modalities, in this study, we aimed to compare the results of TSV after HSC with laparoscopy, as a gold standard, for assessing the fallopian tubal patency in infertile women referred to Shahid Beheshti Hospital affiliated with Isfahan University of Medical Sciences (IUMS).

Materials and Methods

This is a cross-sectional study which included 49 infertile women referred to Shahid Beheshti hospital affiliated with IUMS during the years 2015 and 2016. The Ethics Committee of IUMS approved the study. After an explanation of the aims of the study, informed written consent was taken from the participants. Women with proven infertility (failure to conceive after 12 months unprotected intercourse) that filled informed consent were included in the study. Patients with abnormal uterine bleeding, pelvic infections, urinary tract infection, male factor infertility, and pelvic inflammatory disease were excluded from the study. All procedures were carried out between the 7th and 9th day of follicular phase the menstrual cycle. At first, patients who met the inclusion criteria, baseline TVS examination of the pelvis was performed using GE Voluson E6, Japan. The presence of free fluid in the cul-de-sac in the sagittal plane of the pelvic area was recorded before HSC to calculate prehysteroscopic free fluid. Immediately, after the performance of TVS, the vagina and the cervix were cleaned with an iodine solution. HSC was performed in operating room but without anesthesia. A hysteroscope with 30 optic and 3/5mm external sheet was employed (Karl Storz GmbH and Co., Tuttingen, Germany). Normal Saline was used as the distension media throughout the procedure, the intrauterine pressure was maintained at 80–100 mmHg. The uterine cavity, endometrial thickness, proximal tube orifices, fundus contour, and cervical canal were assessed. The hysteroscope was then withdrawn, and TVS probe was reinserted into the posterior fornix of the vagina to measure the abdominal fluid of the cul-de-sac in the sagittal plane. TVS was performed with 15 min of finishing HSC to observe fluid in the pouch of Douglas. The presence of the fluid was considered positive for unilateral or bilateral tubal patency. Patients underwent the laparoscopy under general anesthesia during the follicular phase of the menstrual cycle; after making a pneumoperitoneum, a thorough inspection of the pelvis, internal genitalia, and liver region was performed, followed by testing for fallopian tube patency using methylene blue. Chromopertubation was done by injecting a dilute solution of methylene blue through the cervix. Passage of the dye was observed through the fimbrial ends. The presence of any adhesions, structural anomaly of the uterus, endometriosis, and fallopian tube occlusion was recorded. On completion of the procedure, the incision was repaired; analgesic and antibiotic were given for 24 h. During laparoscopy, if needed, reproductive surgery such as excision and ablation of endometriosis and adhesiolysis was performed. Results of TVS after HSC were compared with those of laparoscopy.

Quantitative and qualitative variables were described by mean ± standard deviation (SD) and frequency (percent), respectively. The sensitivity, specificity, positive predictive value, and negative predictive value of TVS after HSC were calculated by comparing the results with those obtained by laparoscopy. The kappa coefficient was employed to assess the agreement between TVS after HSC and laparoscopy. The following cutoff points were used for the interpretation of kappa: <0.20, very poor; 0.21–0.40, poor; 0.41–0.60, moderate; 0.61–0.80, good; and ≥0.81, very good. [13] Chi-square and Mann–Whitney tests were used to compare qualitative and quantitative variables among the groups, respectively. All of the statistical analysis was performed using MedCalc software version 15 (MedCalc Software, Broekstraat 52, B-9030 Mariakerke, Belgium). *P < 0.05* was considered significant.

Results

HSC was normal in 29 (59%) of the 49 cases. Endometrial myoma was most common finding (seven cases) among women with abnormal results. The other findings were submucous myoma (four cases) and uterine septum (two cases). Ultrasound examination indicated the presence of fluid in the pouch of Douglas in 39 cases [Figure 1]. In 39 of these cases, tubal patency was confirmed by laparoscopic chromopertubation. In 10 cases with fluid in the pouch of Douglas, unilateral tubal occlusion was confirmed by laparoscopy. Of the 10 negative cases (without fluid in the pouch of Douglas), bilateral tubal occlusion was confirmed in 9 cases by laparoscopic chromopertubation. In one of the negative cases, patent tubes were confirmed by laparoscopic chromopertubation. In a further one negative cases, bilateral hydrosalpinx was confirmed by laparoscopy. Mean ± SD age of the participants was 30.91 ± 3.52 ranged from 25 to 38 years. Out of 49 participants included in the study, 34 (69.4%) were cases of primary infertility and 15 (30.6%) were cases of secondary infertility.

Other laparoscopic findings were myoma (7 cases out of 49), endometriosis Grade III (3 cases), and 2 patients with endometriosis Grade I.
Table 1 shows the results of TVS after HSC and laparoscopy. Of 49 patients examined by laparoscopy, 30 (61.2%) were patent, 10 (20.4%) unilateral tubal block, and 9 (18.4%) bilateral tubal block, respectively.

There was a very good agreement between TVS after HSC and laparoscopy (kappa coefficient = 0.935, 95% confidence interval [CI]: 0.81, 1.00). The sensitivity of TVS after HSC was 100% (95% CI: 66.37, 100) and specificity was 97.50% (95% CI: 86.84, 99.94) with a positive predictive value of 90% (95% CI: 55.50, 99.75) and negative predictive value of 100% (95% CI: 90.97, 100).

Graph 1 shows percentage of the findings detected by TVS with HSC or laparoscopy. The three most frequent findings among the patients were myoma (7 cases out of 49), polyp (6 cases out of 49), and endometriosis Grade III (3 cases out of 49). Furthermore, 2 patients with uterine septum and 2 patients with endometriosis Grade I were diagnosed. Twenty-nine out of 49 patients had no findings.

**Discussion**

Infertility, as one of the most common gynecological disorders, affects many people worldwide. An accurate tubal patency examination is important to diagnose and correct choice for the treatment of infertility. Till now, expensive and invasive gold standard for tubal patency evaluation is laparoscopy that provides a direct diagnosis.

In this study, we utilized TVS after HSC to examine tubal patency and compared the outcomes to those acquired by laparoscopy. In our study, HSC was performed without anesthesia, and during laparoscopy, therapeutic reproductive surgery, such as coagulation of Grade 1 or 2 endometriosis and adhesiolysis, was performed when required.

In our study, TVS after HSC for testing fallopian tubal patency showed a very good concordance with the findings from laparoscopy rather than other study. We correctly identified 100% and 97.50% of the patent tubes and blocked tubes by TVS, respectively. Therefore, the diagnostic value of TVS after HSC was high. These results are in line with other researches.

Habibaj *et al.* concluded that TVS after HSC could provide extra useful information about tubal patency. Luciano *et al.* and Allam *et al.* proposed HSC in combination with TVS as an appropriate alternative to HSG and laparoscopy. In contrast to these researches, Youssef *et al.* demonstrated TVS after HSC is a good outpatient diagnostic tool for detecting at least one patent tube; although, they reported low negative predictive value but high positive predictive value. Although most of the studies verified the high diagnostic value of TVS after HSC, the low number of cases studied in the sparse researches is the limitation of concluding a general rule about it.

At present, the most accurate diagnostic tool to evaluate tubal patency in infertile women is laparoscopy that would be an invasive examination in combination with some necessary items, such as an equipped operating room, general anesthesia, laboratory test and trained staff, make laparoscopy an expensive and complex gold standard. HSG is less invasive and widely used tool:

**Table 1: Examination results of 49 infertile women**

| Variables                        | Laparoscopy | P     |
|----------------------------------|-------------|-------|
| TVS after HSC, n (%)             |             |       |
| No fluid in the pouch of Douglas | 9 (90)      | 1 (10) 0.001 |
| Fluid in the pouch of Douglas    | 0 (0)       | 39 (100) |
| Infertility type, n (%)          |             |       |
| Primary                          | 5 (14.7)    | 29 (85.3) 0.550 |
| Secondary                        | 4 (26.7)    | 11 (73.3) |
| Infertility duration (year)      | 3.89±0.93   | 3.15±0.98 0.043 |
| Age (year)                       | 32.22±3.42  | 30.63±3.51 0.223 |

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to detect fallopian tubal patency.\cite{14,18} It used radiation and is associated with some complications such as allergic reactions.\cite{7,18} Our results with confirmation of the other researches\cite{3,9,12} could propose TVS after HSC as an accurate, uncomplicated, quick with low-cost outpatient diagnostic test for detecting fallopian tubal patency. Further studies in large scale are required to assess reliability and precision of TVS after HSC. To complete the finding of the present study, taking three-dimensional sonography for accurate diagnosis is suggested.

**Conclusion**

In comparison with laparoscopy, as an invasive with the high-cost test, TVS after HSC is an accurate, rapid, easy, and outpatient diagnostic procedure for examination of fallopian tubal patency in infertile women.

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**Conflicts of interest**

There are no conflicts of interest.

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