Original article

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A COMPARATIVE STUDY OF TRANSVAGINAL SONOHYSTERO-SALPINGOGRAPHY (TV-SH) AND HYSTERO-SALPINGOGRAPHY (HSG) FOR ASSESSMENT OF TUBAL PATENCY IN INFERTILITY PATIENTS

Nirmala Jaget Lakkawar[1], Manash Bora[2] and Thirupurasundari Rangaswamy[1]

There has been a significant increase in cases of infertility and sterility in the last decade. Approximately, 10-15% of couples in reproductive age are affected by the inability to conceive and bear a child. Amongst all causes, anatomical defect linked to the fallopian pathological conditions contributes considerably to female infertility. The evaluation of tubal patency is traditionally considered fundamental in the study of cases of infertility and it represents one third of the total cost in the management of infertility. Tubal patency is routinely assessed by hysterosalpingograpgy (HSG) and/or laparoscopy. However, other techniques are nowadays being investigated to obtain high efficacy, with low cost and risk, and also can be used as office procedures at an outpatient infertility clinic. Transvaginal sonohysterosalpingography (Tv-Sh) is one of such promising procedure which can be simultaneously performed in place of HSG at the time of conventional ultrasonogram in the initial workup of infertile patients. It also provides additional information regarding intracavitary and intramyomentrial components of submucous myomas as well as information about adnexae. The present study encompasses the comparative diagnostic accuracy of Tv-Sh and HSG in evaluating uterine cavity and tubal patency in women of reproductive age group. The compatibility between Tv-Sh and HSG was found to be 87% and efficacy in diagnosis of hydrosalpinx by both procedures was the same. There was also no significant difference in the diagnosis of congenital malformations of uterus or intracavity adhesions. The study concludes that Tv-Sh can be used as a "first choice" screening procedure without any risk of ionizing radiation. *Acta Medica Medianae 2011; 50(4):29-34.*

Key words: *infertility, tubal patency assessment, hysterosalpingography (HSG), transvaginal sonohystero-salpingography (Tv-Sh)*

Department of Obstetrics & Gynaecology, Aarupadai Veedu Medical College & Hospital, Kirumampakkam, Puducherry, India[1]
Department of Radiology & Imaging, Aarupadai Veedu Medical College & Hospital, Kirumampakkam, Puducherry, India[2]

Contact: Nirmala Jaget Lakkawar
Ishwaryam Appartments, Plot No 71, 72,
II Main road, Moogambigai Nagar
Nainarmandapam, Pondicherry- 605004, India
E-mail: drnirmalajaget@yahoo.com

Introduction

Infertility is defined as inability to conceive after one year of unprotected sexual intercourse. The overall prevalence for this condition is about 10-15% in couples of reproductive age. Female factor attributes in about 40-45% of cases and male factor is reported in about 25-40% cases, whereas 10% cases can have unexplained infertility. The important factors for pregnancy to occur involve normal functional ovaries, fallopian tubes, uterus, presence of normal sperms, fertilization followed by implantation of embryo. Amongst all, tubal factors accounts for 30-40% cases of infertility in females (1). Frequent organic causes of sterility and infertility are linked to the tubal pathology. Tubal patency is routinely assessed by hysterosalpingography (HSG) and laparoscopy. However, relatively high costs and associated side effects of these procedures as a first line diagnostic tests are stressed. Therefore, other techniques to evaluate tubal patency are being searched. Transvaginal sonohystero-salpingography (Tv-Sh) is a cost-effective procedure and can be performed at the outpatient basis without any anaesthetic and radiation hazards. Tv-Sh can be done simultaneously at the initial ultrasound evaluation, wherein saline with air bubbles are infused into the uterine cavity through the cervix during transvaginal sonography to determine tubal patency. This method can also diagnose/ locate endometrial polyps, submucosal fibroids, intrauterine adhesions, bicornuate and septate uterus, ovarian architecture and its pathological conditions and help in follicular study. Considering the above merits, Tv-Sh can be the preferred "first choice" investigation, which can later be followed by more complex or invasive procedures. Employing this technique can therefore lower the cost and risk so as to achieve a high diagnostic accuracy with non-invasive good compliance methodology.

The aim of the current study was to evaluate the role of Tv-Sh in the assessment of tubal patency and to compare the results obtained

with those of HSG findings among the infertility patients.

Materials and methods

A prospective study was conducted in the Department of Obstetrics & Gynaecology in collaboration with department of Radiology and Imaging at Aarupadai Veedu Medical College & Hospital, Pondicherry, India during the period between January to December, 2010. The study was carried out on 50 infertility patients. Patients were divided into two groups. Group I consisted of primary infertility patients (29 cases) and group II involved secondary infertility patients (21 cases). Patients in both groups were aged between 25–35 years.

Tv-Sh was performed by the obstetricians and HSG was done by the radiologists. The HSG was carried out between 5-8 days of menstrual cycle and the Tv-Sh was performed between 9-12 days in the same or next cycle. The observers were kept blind about the results of both procedures for further comparison. The results obtained by the Tv-Sh were compared with those of HSG for efficacy of the procedure. The exclusion criteria were the patients with recent or ongoing pelvic infection, delayed menses with suspected pregnancy and technical difficulties during any of the procedures. The informed consent was obtained from all the studied patients.

Procedure for HSG:

Hysterosalpingography is radiographic evaluation of the uterus and fallopian tubes after injecting radiographic dye. In this procedure, the patient was put in lithotomy position, cervix was cleansed with povidone iodine and anterior lip of cervix was held with tenaculum for stabilization. Leech-Wilkinson's cannula was inserted through endocervix. Sodium di-trizoate (Urograffin 76%) 10 ml was instilled through the cannula. Radiographic images were obtained intermittently to document filling of the uterine cavity and fallopian tubes. Patency of the tubes was checked by observing the spillage of the contrast into the peritoneal cavity.

Procedure for Tv-Sh:

Detailed sonographic examination was carried out using Sonoscape SS - 4000 machine using transvaginal probe with a frequency range of 5–7.5 mHz. Scanning was done in longitudinal and transverse planes and any uterine, fallopian tubes and ovarian abnormalities noted. During Tv-Sh procedure, a Sim's speculum was placed in vagina, cervix was cleansed with povidone iodine and anterior lip of cervix was held with tenaculum. A Foley's catheter (size 8-10) was introduced through the endocervix and balloon inflated with 5-7 cc of saline to prevent leakage. Transvaginal probe was reinserted after removal of speculum and tenaculum. Saline with air bubbles (by shaking the syringe) instilled through the catheter into the cavity. During the procedure endometrial cavity was evaluated for contoure, regularity of endometrium, presence of any polypoid mass, submucous fibroid, adhesions, septations as well as tubal patency by noticing the movement/oscillations of fluid through the tube and its spillage into the peritoneal cavity. Colour Doppler was also used for better diagnostic accuracy. Prophylactic antibiotics, Doxycyclline (200mg stat) and antispasmodic, Dicyclomine (10 mg) were given 30 minutes before each procedure.

The obtained results were analysed by Chi-square, the primary statistical test for studying the relationship between variables, the sensitivity, specificity, and diagnostic accuracy of HSG and Tv-Sh was compared accordingly.

Results

The study comprised 50 infertility cases divided into two groups. Group I had 29 patients diagnosed with primary infertility and group II involved 21 patients belonged to secondary infertility. The mean age for patients with primary infertility was 26.4±2.3 years and for secondary infertility 29.6±4.2 years. The mean duration of infertility was 3.6±1.2 years for primary infertility group and 5.4±2.2 years for secondary infertility group.

Results summerised in Table 1 show that Tv-Sh procedure was longer, it lasted 12-15 minutes as compared to HSG which took 10 minutes because of the detailed scanning of the uterus and adnexae done before the instillation of normal saline. The time difference was statistically insignificant for both procedures. The perception of pain during both procedures was statistically significant. During HSG, 30 (60%) cases experienced pain as compared to 12 (24%) cases who experienced pain during Tv Sh. Twenty-four (48%) cases needed analgesics after HSG procedure whereas only 6 (12%) patients needed analgesics after Tv-Sh for management of pain. This difference was statistically significant (p value). There were no reported complications following both procedures.

The results of detection of tubal patency/ blockage by HSG and Tv-Sh procedures are presented in Table 2. HSG could detect unilateral blockage in 12(24%) cases of primary infertility and 6(12%) cases of secondary infertility. Tv-Sh could detect unilateral block in 10(20%) cases of primary infertility and 8(16%) cases with secondary infertility. Compatibility between the procedures was found to be 83.3% and incompatibility was observed in 12.7% of cases. The incompatibility between the procedures was found to be statistically insignificant. Bilateral tubal blockage was detected in 6(12%) of cases in primary infertility in both procedures and these results

were 100% compatible. In secondary infertility group, bilateral block was detected in 8(16%) cases as compared to 6(12%) cases by Tv-Sh. The compatibility between the techniques was found to be 83.3% and incompatibility noted in 12.7% of cases was found to be statistically insignificant. Bilateral tubal patency was noted in 12 (24%) cases of primary infertility and 8(16%) cases of secondary infertility by HSG whereas 13(26%) cases of primary infertility and 9(18%) cases of secondary infertility were detected by using Tv-Sh. Here the compatibility between the tests in both groups (primary and secondary infertility) was 92% and incompatibility was observed in 8% of the cases. The difference observed was statistically insignificant.

The additional findings which were observed by employing both procedures are presented in Table 3. Midsegmental block was detected in 12(24%) of cases and Fimbrial block was seen in 6 (12%) cases by HSG. The Tv-Sh could diagnose tubal blockage in these cases, however, the actual site of blockage could not be appreciated. Hydrosalpinx was correctly detected by both procedures in two cases. Ovaries and their different pathological conditions like enlarged ovaries, cysts, polycystic ovaries could be visualized only by Tv-Sh procedure. Endometrial polyp was detected in 2(4%) cases by Tv-Sh, but the HSG findings were normal in both patients. Submucosal myoma was detected in 2(4%) cases by Tv-Sh whereas HSG showed only one case. In addition, intramural mayoma was detected in 4(8%) cases only by Tv-Sh. HSG detected septate uterus in 1 (2%) case, but the uterus was normal on Tv-Sh study. Bicornuate uterus was detected correctly in both procedures in 1 (2%) case. The observed filling defect suggestive of intrauterine adhesions was found in 1(2%) case, but Tv-Sh study showed a normal uterine cavity. This finding was later confirmed by hysteroscopy, which also showed normal uterine cavity.

Table 1. Comparison of pain perception in HSG and Tv-Sh

Diagnosis	Procedure	Unilateral block	Bilateral block	Bilateral tubal patency
Primary infertility	HSG	12 (24%)	6 (12%)	12 (24%)
	Tv-Sh	10 (20%)	6 (12%)	13 (26%)
	Compatibility	83.3%	100%	92%
	P value	NS	NS	NS
Secondary infertility	HSG	6 (12%)	8 (16%)	8 (16%)
	Tv-Sh	8 (16%)	6 (12%)	9 (18%)
	Compatibility	83.3%	83.3%	92%
	P value	NS	NS	NS

Table 2. Comparison of Tubal Patency by HSG and Tv-Sh

Diagnosis	Procedure	Unilateral block	Bilateral block	Bilateral tubal patency
Primary infertility	HSG	12 (24%)	6 (12%)	12 (24%)
	Tv-Sh	10 (20%)	6 (12%)	13 (26%)
	Compatibility	83.3%	100%	92%
	P value	NS	NS	NS
Secondary infertility	HSG	6 (12%)	8 (16%)	8 (16%)
	Tv-Sh	8 (16%)	6 (12%)	9 (18%)
	Compatibility	83.3%	83.3%	92%
	P value	NS	NS	NS

Table 3. Additional findings on HSG & Tv-Sh

Findings	HSG	TV-Sh
Mid segmental block	12 (24%)	-
Fimbrial block	6 (12%)	-
Hydrosalpinx	2 (4%)	2 (4%0
Ovaries visualization & its Pathological conditions	-	50 (100%)
Endometrial polyps	-	2 (4%)
Submucus myoma	1 (2%)	2 (4%)
Intra-mural myoma	-	4 (8%)
Septate uterus	1 (2%)	Normal
Bicornuate uterus	1 (2%)	1 (2%)
Intrauterine adhesions	1 (2%)	Normal

Discussion

The evaluation of tubal patency is traditionally considered fundamental in the study of causes of infertility. It represents one third of the total cost in the management of the infertile couple (2). Laparoscopy with chromopertubation is widely accepted as the "Gold standard" method for evaluating tubal patency. At present, this procedure is considered the most accurate test available for assessing tube related sub-fertility. The advantages of this procedure include an ability to simultaneously evaluate the abdominal cavity in addition to other pelvic structures and also allows for therapeutic excision of endometriotic lesions as well as restoration of abnormal pelvic findings (3). Although laparoscopy has higher diagnostic merits, however, it additionally incurs high operative cost, operative and anaesthesia related risks and requires a period of postoperative recovery. Therefore, a low cost and risk methodological approach should be addressed as a "first choice" investigation, which can be later followed by more complex or invasive procedure whenever needed (4). Tubal patency is routinely assessed by hysterosalpingography (HSG), but it involves radiation exposure (5,6). Sonohysterosalpingography (Tv-Sh) appears to be inexpensive, quick and well-tolerable first line diagnostic method for determining the tubal status and uterine cavity and can be performed at the time of conventional ultrasound scan in place of HSG and laparoscopy(5). The concept of intrauterine saline infusion during concomitant ultrasonography was described by Nanini et al (7, 8). This instillation of fluid allows for differentiation of intrauterine, endometrial and submucosal abnormalities without the use of potentially harmful contrast medium or ionizing radiation (3). Tv-Sh can differentiate myoma from polyp and can also demonstrate the full intramural component of submucus myoma. In addition, this technique can also provide additional information regarding ovarian architecture and its pathological conditions (6, 9) as well as tubal status.

In the present study, there was no significant difference in the mean time taken by each of the procedures. Tv-Sh required approximately 13.1 minute for completion of the test, while HSG had taken approximately 10 minutes. The earlier reported mean procedural time for Tv-Sh was 12.1 min. and for HSG was 9.5 min (3).

In our study, 60% of cases complained significant pain and discomfort during HSG procedure in comparison to 24% of the cases during the Tv-Sh. In addition, higher percentage of patients had reported persistent pain and required analgesics to alleviate pain even after 24 hours following HSG in comparison to Tv-Sh procedures. The earlier study indicated that 72% of the cases reported significant pain during HSG procedure as compared to 56% after Tv-Sh, however, the pain perception after 24 hours following both procedures was almost the same, 41% after Tv-Sh and 47% following the HSG procedure (3).

In our study, for the diagnosis of tubal patency (unilateral blockage, bilateral blockage or bilateral tubal patency), the compatibility between Tv-Sh and HSG was found to be 87%. In similar studies conducted earlier on compatibility between Tv-Sh and HSG, Holz et. al (10), Campbell et, al (8), Strandell et. al (11) had reported 83%, 84-91% and 85.8%, respectively. In the similar studies conducted earlier, the reported compatibility between the two tests' results ranged from 84% to 89.6% (12-14).

Mid segmental tubal block was observed in 12 (24%) cases and fimbrial block in 6 (12%) cases by HSG but site specific block could not be appreciated by Tv-Sh. All these cases were reported as having blocked tube by Tv-Sh. Similar studies conducted earlier revealed that midsegmental block can be diagnosed by Tv-Sh procedure (15). In our study, 100% compatibility was observed between the two techniques for diagnosis of hydrosalpinx. In similar studies conducted earlier, Tabbakh and Slamka (15) and Saunders et al. (3) reported a sensitivity of 72.7% and 86%, respectively for detecting hyderosalpinx by employing Tv-Sh procedure. Ovarian architecture and its other pathological conditions like PCO, enlarged and cystic ovaries could be visualized during Tv-Sh but the same could not be possible by HSG. Similar observations have been reported earlier (15, 16). There was no significant difference noted in detection of endometrial polyps, submucus myomas, uterine malformations and intrauterine adhesions by the two procedures and the findings are in agreement with the earlier observations (16). Our findings on Tv-Sh for delineating the intramyometrial extension of submucus myomas and clear visualization of intramural myoma are in corroboration to the earlier report (16). There are conflicting reports on the merits and demerits of the diagnostic procedures in terms of sensitivity and specificity. According to Tabbakh and Slamka (15) and Saunders et al. (3) TV-Sh could be added to the usual conventional procedure to assess tubal patency as a new, easy and safe method. However, Balen et al (16) and Bonilla-Musoles et al (17) opined that sonohysterosalpingography can not be considered as a substitute for hysterosalpingography for tubal assessment.

Conclusion

The most advantageous screening infertility protocol necessitate methods that are diagnostically accurate, timely, cost-effective, reliable and minimally invasive. The transvaginal sonohysterosalpingography procedure is cost-effective,

safe, easy to perform in an outpatient infertility clinic and is without any radiation hazards. It enables providers to simultaneously evaluate ovarian structure and its reserve, uterine cavity's contour, myometrial structure as well as tubal architecture and patency which will be helpful in the preoperative assessment and decision making in these infertile patients. Therefore, it can be used as a 'first choice' investigation at the initial workup of infertility patients.

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KOMPARATIVNA STUDIJA O TRANSVAGINALNOJ SONOHISTERO-SALPINGOGRAFIJI (TV-SH) I HISTERO-SALPINGOGRAFIJI (HSG) ZA PROCENU PROHODNOSTI JAJOVODA KOD NEPLODNIH PACIJENTKINJA

Nirmala Jaget Lakkawar, Manash Bora i Thirupurasundari Rangaswamy

U poslednjoj dekadi beleži se značajan porast stope neplodnosti. Otprilike, 10-15% parova u reproduktivnom periodu ima probleme sa začećem. Od svih razloga, anatomski defekti vezani za patološka stanja jajovoda značajno doprinose problemu ženske neplodnosti. Procena prohodnosti jajovoda se tradicionalno smatra osnovom u proučavanju neplodnosti i čini trećinu troškova u njenom lečenju. Prohodnost jajovoda se rutinski procenjuje histerosalpingografijom (HSG) i/ili laparoskopijom. Međutim, danas se izučavaju i druge tehnike kako bi se omogućila bolja efikasnost, uz malu cenu i rizik, a takođe se mogu primenjivati i kao ostale procedure na klinikama za lečenje steriliteta. Transvaginalana sonohisterosalpingografija (Tv-Sh) je jedna takva potencijalno dobra procedura, koja se umesto HSG-a može istovremeno primenjivati sa konvencionalnim ultrasonogramom za pripremu pacijentkinja koje se leče od neplodnosti. Takođe, ova procedura pruža dodatne informacije u pogledu intrakavitarnih i intramiometrijalnih komponenti submukoznog mioma, kao i podatke o adneksama. Ova studija prikazuje komparativnu dijagnostičku tačnost Tv-Sh i HSG-a u proceni kaviteta materice i prohodnosti jajovoda u grupi žena u reproduktivnom periodu. Utvrđeno je da je kompatibilnost između Tv-Sh i HSG-a 87%, dok je efikasnost u dijagnozi hidrosalpinksa uz primenjivanje obe procedure bila ista. Takođe, nije bilo značajne razlike u dijagnozi kongenitalnih malformacija uterusa ili intrakavitarih adhezija. Dolazimo do zaključka da se Tv-Sh može primeniti kao skrining procedura prvog izbora bez ikakvog rizika od jonizujućeg zračenja. *Acta Medica Medianae 2011;50(4):29-34.*

***Ključne reči**: neplodnost, procena prohodnosti jajovoda, histerosalpingografija (HSG), transvaginalna sonohistero-salpingogrfaija (Tv-Sh)*