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Comparative Evaluation of Hysterosalpingo Contrast Sonography with Laparoscopy for Tubal Factor in Infertility

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Authors' contributions

This work was carried out in collaboration between both authors. Author SRA designed the study, performed the statistical analysis, wrote the protocol and wrote the first draft of the manuscript. Author GA managed the analysis of the study and managed the literature searches. Both authors read and approved the final manuscript.

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ABSTRACT

Tubal pathology accounts for 25-35% of cases of infertility. Rubin`s test, hysterosalpingography, saline infusion sonography, hysterosalpingo contrast sonography and laparoscopic chromotubation are the tests done for tubal evaluation. Laparoscopic chromotubation is the gold standard test and the results of all other tests are compared with laparoscopic findings for its specificity and sensitivity. Hysterosalpingo contrast sonography (HyCoSy) is done by injecting an echo contrast drug containing microbubbles, into the uterine cavity and studying the tubal patency ultrasonographically. The study aimed at establishing the validity of HyCoSy as a reliable method of tubal patency and to compare its efficacy with larascopic chromotubation. The present study was done in an infertility centre in south India. Eighty four women underwent HyCoSy with Sono Vue by 2D B mode trans abdominal sonography. The results were compared with the results of laparoscopic chromotubation on the same women. In identifying unilateral or bilateral tubal patency

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or tubal block yCoSy results were with 87.5% sensitivity; 92.31% specificity; 87.5% positive predictive value and 92.31 negative predictive value and the diagnostic value is 90.48%. The study concludes that HyCoSy is a reliable method for diagnosing tubal patency.

Keywords: Tubal infertility; hysterosalpingography; saline infusion sonography; hysterosalpingo contrast sonography; laparoscopy.

1. INTRODUCTION

In sub-fertile couples, 25-35% has tubal pathology as a cause of their infertility. Primary infertility is inability to conceive within one year of unprotected regular intercourse. Secondary infertility is inability to conceive after one conception, irrespective of the result of pregnancy [1]. Tubal factor in infertility is the commonest indication for IVF. Fallopian tube is not only an anatomic passage, but have a functional role of tubal peristalsis, ovum pick up, transport of ovum and zygote [2]. The functional integrity of the tube is difficult to assess, but the patency of the tubes can be established by some tests.

To assess tubal patency—clinically Rubin`s tubal insufflation test; X ray based hysterosalpingography; ultrasonography based saline infusion sonography; combining the advantages of these two- Hysterosalpingo Contrast Sonogrphy (HyCoSy); and direct visualisation of the tube by laparoscopy—are used. In addition to tubal patency, these tests can identify endometrial cavity diseases, tubal adhesions, ovarian abnormalities, tubo-ovarian relationship.

Hysterosalpingography (HSG) is used for many years, relatively simple, can assess tubal patency and block in the tubes and to some extent intra uterine pathology; but it can`t identify pelvic organ diseases [3]. Tubal patency correlates well with laparoscopy findings, but tubal block diagnosed in HSG can be confirmed in laparoscopy in 38% only.

Trans cervical instillation of normal saline and viewing the flow of saline through the tubes, spill of saline into the Doulas pouch by means of ultrasound is called Saline Infusion Sonosalpingography (SIS). This can give an idea of tubal patency, but may not identify the site of the block [4].

Hysterosalpingo contrast sonography combines the advantages HSG and SIS. Echo enhancing contrast agents, when injected into the uterus, can visualise the tubular lumen ultrasonographically [5,6]. Sono Vue is one such contrast agent, containing sodium hexafluoride in micro particles in normal saline, which on vigorous shaking gives micro bubbles. B mode 2D scan can visualise tube and spill of the dye into the pelvic cavity [3]. Colour coded 3D Power Doppler Imaging (3D PDI) is superior to conventional HyCoSy. The results obtained by 3D PDI are on par with the results obtained by laparoscopy [7,8].

In our study, an attempt was made to evaluate the tubal pathology by 2D HyCoSy and compare the results with those obtained by laparoscopy.

2. MATERIALS AND METHODS

Women who attended the outpatient department of Obstetrics and Gynaecology of Vinayaka Mission`s Medical College and Hospital, Karaikal, Pondicherry were the subjects of study. The study was undertaken during August 2017 to March 2019.

All the women with history of primary or secondary subfertility with no assessment of tubal factor for infertility earlier were included in the study. Wives of the men who have azoospermia or severe degree of male infertility with no improvement after treatment; who are not willing for assisted reproductive technologies were not included in the study. Women with infection in the genital tract were treated with appropriate antibiotics and then were taken for study. Women with suspicion of pelvic tuberculosis clinically or by investigations were excluded from the study temporarily.

Thorough clinical examination and relevant investigations and ultrasonography was done. The procedure was done two days after stoppage of menses and in ten days of last menstrual period.

HyCoSy⊗Foley`s catheter 8 fr was inserted into cervical canal and inflated with one ml of normal saline solution. The position of the Foley`s bulb in the cavity was ascertained by trans vaginal

sonography. The procedure of HyCoSy was done trans abdominally after distention of the bladder. Injection Buscopan 1 cc given IV. In apprehensive women, injection Diazepam 5 mg IV was given.

Sono Vue; Bracco Imaging Geneva, Switzerland was used. The dye was reconstituted and shaken vigorously. The trans abdominal ultrasonic probe was positioned to have a clear view of Foley`s bulb, uterine cavity and both cornual ends in the same view. One ml of the dye was mixed with 9 ml of normal saline to make 10 ml. The diluted Sono Vue was injected rapidly through foley`s catheter. B mode trans abdminal probe with 2D settings was used.

The passage of the drug from the uterine cavity through cornual junction, Fallopian tube, leakage of the dye through fimbrial end into the peritoneal cavity on either side was observed ultrasonographically. Occasionally, the passage of the drug through a tortuous tube may not be visualised clearly. Then spillage of the dye into the peritoneal cavity on that side was taken as indicative of patency. If there is no clarity about patency of the tube, another dose of the drug one ml diluted in 5-7 ml of normal saline was given.

In case of bilateral tubal block, reverse pressure in the syringe was felt by the operator and a sharp uterine pain was felt by the patient. In case of unilateral or bilateral tubal block – entry of the drug beyond cornual junction; entry of the drug into a proximal part of the tube; entry of the drug through whole length of the tube with distended distal tube without peritoneal spill was noted. The contour and filling of the uterine cavity was observed and any abnormality was reviewed with special interest. The findings were recorded immediately by text and graphic description.

Hystero laparoscopy and chromotubation were done in the proliferative phase under general anaesthesia. At hysteroscopy with prior knowledge of any uterine abnormality gained by HyCoSy, the findings were ascertained. At laparoscopy, in addition to the routine viewing of the peritoneal cavity, special emphasis was laid on the uterus, fallopian tubes, structure of the tube, distention, distortion of the tube, fimbrial ends, ovary, tubo ovarian relationship and ovary pelvic cavity relationship. 10 ml of 1% methylene blue dye was injected into the uterine cavity trans cervically. Peritoneal spill of the dye through the fimbrial end was observed. If there is no spillage of the dye on one or both sides, another dose of 10 ml was injected to verify. In case of non spillage of the dye on one or both sides, the length of bluish discolouration of the serous coat of the tube was noted, to be taken as the point of obstruction.

The findings of the HyCoSy and hysteron laparoscopy were tabulated. The findings of the uterine cavity, right tube, left tube, spillage in the two procedures was matched and compared. Taking the findings of the hystero laparoscopy as gold standard, the findings of HyCoSy were assessed for their sensitivity, specificity, positive predictive value, negative predictive value. 2#2 frequency tables and Cohen`s K co efficient were used. Kappa is a chance adjusted measure of agreement between two rates- observed agreement, chance agreement, potential agreement beyond chance.

3. RESULTS

A total of 100 HyCoSy were done and 84 of these women underwent laparoscopy also. Hence assessment of 100 women for tubal patency by HyCoSy and comparison of 84 women for tubal status by HyCoSy and laparoscopy was done.

Comparison of HyCoSy findings with lapatoscopy findings

Left tube: total 84

A). Laparoscopy findings abnormal 34

HyCoSy findings abnormal. 26
HyCoSy findings normal. 08

B). Laparoscopy findings normal. 50

HyCoSy findings normal. 42
HyCoSy findings abnormal. 08

Right tube: total: 83 (one previous ectopic with salpingectomy)

A). Laparoscopy findings abnormal. 31

HyCoSy findings abnormal 27
HyCoSy findings normal. 04

B). Laparoscopy findings normal. 52

HyCoSy normal 48
HyCoSy abnormal 04

Table 1. Number of respondents with different age group

Age	Number
19-25 years	20
26-30 years	36
31-35 years	39
36-40 years and above	5
Primary infertility	74
Secondary infertility	26

Table 2. Number of respondents with different associated disease

Associated diseases	Number
Hypertension	3
Diabetes	4
Tuberculosis	6
Other potential causes of infertility	**Number**
Previous ectopic	2
Endometriosis	3
Fibroid uterus	8
PCOS	17
Hypothyroidism	12

4. DISCUSSION

Out of 84 subjects, five subjects who were diagnosed by HyCoSy to be having a bilateral tubal block, during laparoscopic chromotubation, these blocked tubes were found to be open, may be due to release of spasm at general anaesthesia. Six subjects who were found to have patent tubes by HyCoSy, two were identified as bilateral tubal block and four were identified as unilateral tubal block on laparoscopic chromotubation. This may be due to dilated tubal ends or hydrosalpinx, mistaken for the dye spill. The tubal block observed at HyCoSy can be a tubal spasm or a transient debris collection at the test.

In our study, as the sensitivity and specificity to diagnose tubal block in subjects had come out to be very good when either unilateral or bilateral tubal block was taken as abnormal finding and false negative and false positive results were only 6-7%-- in women with severe tubal pathology identified by HyCoSy can be directly taken for IVF without laparoscopy.

In our study we had 31 subjects who complained of pain. 10 women had severe pain, six women had vomiting which was relieved by symptomatic treatment. None went into vasovagal shock. No post procedure fever or infection.

There was no significant difference in the clinical pregnancy rate in the PCOS women diagnosed as tubal patency by HyCosy and Laparoscopic chromotubation.

In the study group, three women are hypertensive, four women are diabetic, which don`t have any bearing in the results. Tuberculosis in pelvic organs is almost always associated with tubal involvement, and is one of the known reasons of tubal infertility. Previous ectopic pregnancy may be the result of partial tubal block and in one woman unilateral salpingectomy was done, in another case, tube was conserved by salpingostomy. Endometriosis can cause tubal block by kinking the tube and pelvic adhesions, Cornual fibroid may cause corneal or interstitial tubal block.

Table 3. Parameters showing estimate and Lower-Upper 95% Cis

Parameter	Estimate	Lower-Upper 95% Cis
Sensitivity	87.5%	63.98, 96.5
Specificity	92.31%	75.86, 97.86
Diagnostic accuracy	90.48%	

Table 4. Comparison of 2D HyCoSy Vs Laparoscopy in studying tubal status (considering individual tubes as study unit) in different studies [9,10,11,12]

Author	N=	Sensitivity	Specificity	PPV	NPV	Concordance
Hamilton et al	185 Subjects	90.4%	70.3%	91.2%	68.2%	85.8%
Marcos M Reis	44 subjects	85.2%	85.2%	71.9%	92.9%	85.2%
Strandell et al	85 tubes	27%	90%	75%	88%	80%
Radic V et al	68 subjects	100%	77%	70%	100%	
Scolov V	95 subjects	81.39%	87.69%	67.3%	97.9%	
Present study	167 tubes in 84 subjects	67.50%	85.71%	79.41%	76.36%	78.41%

The technical difficulties encountered in visualising and interpreting the sonographic picture after contrast injection were mostly in women with increased body mass index; acutely retroverted uterus; gross deviation of uterus to one side; ovaries situated close to the uterus or adherent to the uterus or over the pelvic wall; multiple bowel loops or gaseous shadows anterior to uterus. Intravasation of SonoVue is a technical difficulty in [13]. In cases with tortuosity of the fallopian tube, only the proximal portion of the tube is visualised and the spill of the drug at the fimbrial end is difficult to visualise, resulting in wrong results. Occasionally it is difficult to distinguish the white echoes of the tube from the bowel as shadows, thereby lowering the sensitivity of the test. The sensitivity, specificity and diagnostic value of Hycosy when compared with laparoscopic chromotubation obtained in this study was comparable to those obtained by is comparable with that of APA Wood et al. [14].

5. CONCLUSION

HyCoSy is a simple, sensitive and relatively inexpensive preliminary screening procedure in diagnosing tubal patency, tubal blocks with good concordance with laparoscopic findings. The sensitivity , specificity, positive predictive value, negative predictive value of HyCoSy in identifying tubal patency is very good and in identifying tubal block is good when compared with laparoscopic chromotubation.

CONSENT AND ETHICAL APPROVAL

Local ethical committee approval and informed consent of the women were obtained.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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