

Can HyCoSy Replace Laparoscopy And Hysteroscopy As A Method To Assess Tubal Patency And Uterine Cavity Lesions?

Dr Disha Aggarwal

Abstract: Aim: A prospective observational study was conducted to evaluate and to compare Hysterosalpingo contrast sonography (HyCoSy) with diagnostic laparoscopy and hysteroscopy as a method to assess tubal patency and uterine cavity lesions in patients with infertility.

Methods: From September 2012 to March 2014, 45 infertile women of age 20 to 40 years were recruited in the study and all the patients underwent both techniques i.e. Hysterosalpingo contrast sonography and diagnostic laparoscopy and hysteroscopy and the results were compared in terms of sensitivity, specificity, positive predicted value, negative predicted value and kappa value.

Results: Forty five women were recruited in this study. The study showed that HyCoSy had sensitivity of 88%, specificity of 85%, PPV of 88% and NPV of 85% for diagnosing tubal factor infertility and a sensitivity of 75%, specificity of 100%, PPV of 100%, NPV of 95.6% for diagnosing uterine cavity lesions.

Conclusion: HyCoSy is a simple, safe, sensitive, less time consuming, non invasive and inexpensive preliminary screening procedure with good concordance in diagnosing uterine cavity lesions, tubal patency and tubal blocks when compared to diagnostic laparo-hysteroscopy.

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I. Introduction

Infertility is a condition that affects approximately 1 in every 6 couples. Diagnosis of infertility is made when a couple is unable to conceive over the course of one full year. Female infertility factors contribute to approximately 50% of all infertility cases and female infertility alone accounts for approximately one-third of all infertility cases.¹ The etiology of infertility is not always an isolated abnormality so, a battery of tests is necessary for infertility couples before decision on the most appropriate therapy is made. Tubal factor accounts for 14 to 26% of infertility.^{2,3}

As tubal factor is one of the most important causes of infertility so, fallopian tube patency needs to be established in all infertile women. What is needed is a screening test to identify those women with a high likelihood of tubal occlusion. The optimal initial infertility investigation protocol should be diagnostically accurate, expeditious, cost-effective, dependable, and minimally invasive.

The current established tests for tubal patency include various methods like laparoscopic chromopertubation, hysterosalpingography, saline infusion sonography and the newer techniques like hysterosalpingo contrast sonography (HyCoSy)^{4,5} but they all have their own advantages and disadvantages.

Laparoscopy with chromopertubation and hysteroscopy is viewed as the "gold standard" test for tubal and uterine cavity assessment but it is an invasive procedure mandating anaesthesia, intraoperative complications and operative costs. Moreover, its accuracy is subjected to provider expertise. The advantages are, the ability to evaluate the abdominal cavity and other pelvic structures for an enhanced diagnostic evaluation of other possible etiologies of subfertility and can be used for therapeutic purposes simultaneously.⁶ An alternative and widely accepted noninvasive procedure for the assessment of tubal patency and uterine cavity lesion is hysterosalpingography (HSG), but it gives no information regarding ovarian morphology and other pelvic abnormalities and also exposes the subjects to ionizing radiations and potentially allergenic contrast media.⁷

Saline infusion sonography (SIS) can help in identifying the intrauterine, endometrial and submucosal uterine lesions without the use of potentially harmful contrast agents or ionizing radiations but it also fails to show tubal lining and patency as qualitative ultrasound images are obtained which are difficult to interpret. Hence, it requires a supplemental study or procedure to determine tubal patency as the normal fallopian tube is a poor sonic reflector, devoid of the defined interfaces that produce clear organ outlines.^{8,9}

Hysterosalpingo Contrast Sonography (HyCoSy) has become an increasingly popular alternative, combining the principles of SIS with those of HSG. Rather than relying on the presence of post procedure cul-de-sac fluid, hyper contrast agents are used to obtain visualisation of actual contrast flow through each fallopian tube making them echogenic. HyCoSy is a simple, time efficient, well tolerated, safe and effective outpatient procedure that may add value to initial infertility evaluation. However, it was not used much in India, as the dye

Sonovue used for the procedure was not available here till the recent past. We have undertaken this study with the aim of evaluating Hysterosalpingo Contrast Sonography as a technique to diagnose uterine cavity lesions and tubal factor.

II. Materials and Methods

The present study is a prospective observational study done at IVF centre of Maulana Azad Medical College, New Delhi from September 2012 to March 2014 to evaluate tubal patency and uterine cavity lesions in infertile women by technique of hysterosalpingo contrast sonography and to compare the results with 'gold standard' i.e. diagnostic laparoscopy and hysteroscopy. Forty five women of age 20 to 40 years with primary or secondary infertility planned for tubal evaluation were included in the study. A detailed history was taken and systemic and local examination was performed. Patients with uncontrolled medical disorders, suspected pregnancy, history of allergy to any contrast media or any allergic disorder and any active pelvic infection were excluded from the study. Informed consent was taken from every patient about the procedure.

Hysterosalpingo contrast salpingography was carried out during proliferative phase of cycle by using a high resolution 4x9 MHz Transvaginal probe and 3x7 MHz Transabdominal probe (Medison SA 8000 EXEXP). Injection butylscopolamine bromide i.m. one ampoule was given half an hour prior to procedure. After bimanual pelvic examination baseline pelvic sonography using transvaginal sonography was performed and findings were noted. A foley catheter of 8-fr was introduced into cervical canal using a sponge holder and its bulb was inflated with 1 ml of saline and its position was confirmed by a transvaginal ultrasound. When bladder became full, a transabdominal USG on 2D settings with B-Mode was done visualising the bulb of the foley catheter and both the uterine cornua in a same plane. Then 1 ml of Sonovue as contrast media (sulphur hexafluoride microbubbles; by Bracco Imaging, Geneva, Switzerland) was reconstituted and mixed in 9 ml of saline to make a total of 10 ml and that was injected rapidly through foley catheter under ultrasound guidance. The cavity was well delineated by hyperechogenic contrast passing into the cavity and then passage of dye through both the cornua leading towards the distal end of tube was also noted. Flow of contrast in each fallopian tube making them echogenic and post procedure contrast in cul de sac were counted as positive findings. Once the test results were obtained the bulb of foley catheter was deflated and removed. All the patients were allowed to rest for 15 to 20 minutes to look for late side effects such as vasovagal reactions. They were then send home after prescribing tablet diclofenac 50 mg orally and tablet cefixime 200 mg twice a day for two days.

All the patients were posted for laparohysteroscopy and chromopertubation under general anaesthesia in same or subsequent cycle to confirm the findings of HyCoSy. None of the patient suffered from any significant side effects during either of the procedures.

With the help of a 2*2 table the sensitivity, specificity, positive predictive value and negative predictive value of hysterosalpingo contrast sonography in relation to laparoscopy and hysteroscopy was calculated. Chi square test was used to calculate the diagnostic accuracy of the test maintaining 80% power, with an alpha error of 0.05. The p value of < 0.05 was considered significant.

III. Results

Total women allocated in the study were 45 out of which 64.4% had primary infertility and 35.6% had secondary infertility. Mean age of the study group was 29.2 ± 3.72 years. Mean duration of cohabitation in the study group was 7.87 ± 3.56 years. Two women had undergone unilateral salpingectomy due to previous ectopic pregnancies.

HyCoSy, as compared to chromolaparoscopy, had sensitivity of 88%, specificity of 85%, PPV of 88%, NPV of 85% and Concordance or Accuracy rate of 86.67% (Table 1). Table 2 shows that there is 94.4% concordance in the site of blockage in proximal blocks, 72.72% in cases with mid-segmental block whereas only 58.33% was correctly depicted for distal tubal block.

Table 3 shows that there were total 6 uterine lesions diagnosed on HyCoSy among which all 6 were confirmed by hysteroscopy. These include 1 case of Ashermann's syndrome, 2 cases showing large fibroids, 1 case of adenomyosis, 1 case of septate uterus and 1 case of unicornuate uterus. Out of the 8 lesions found on Hysteroscopy, 6 corresponded to above mentioned findings of HyCoSy, where as two cases, one of bilateral pericornual fibrosis and another of focal fibrosis in cavity and at fundal region with pale endometrium were missed on HyCoSy. HyCoSy is 96% accurate for diagnosing uterine cavity lesion, with a sensitivity of 75%, specificity of 100%, positive predictive value of 100% and negative predictive value of 95%.

IV. Discussion

Most of the earlier studies on two-dimensional HyCoSy showed a sensitivity ranging from 70% to 90% for diagnosing tubal pathologies i.e. in a good overall agreement to laparoscopy.^{4,5,10,11} In the present study, the sensitivity of HyCoSy was 67.50% for blocked tube. The correspondence for tubal pathology status between two methods was more for proximal segment block than distal segment block. The possible explanation for this

may be due to the fact that it is difficult to see the distal end in tortuous tubes and therefore, spill from it. This is supported by other studies too.^{12,13} Moreover, in many cases the distal end of the tube was dilated leading to collection of dye there, which was misinterpreted as spill on HyCoSy as also described by Hamilton JA et al (1999).¹⁰

As per previous studies, HyCoSy is a good technique to diagnose uterine cavity lesions with sensitivity ranging from 72% to 100%, specificity of 90%, PPV of > 90% and NPV of >80%.^{4,5,14,15} However, in our study, sensitivity of the test was low (75%). The possible explanation is HyCoSy, being an ultrasound based procedure, fails to diagnose cavity fibrosis and endometrial lining defects as thickness of endometrial lining does not change till late stages of destruction disorders. Early changes can be appreciated only by direct visualisation of the cavity through a hysteroscope in form of pale endometrial lining, decreased vascularity, pin point deep seated ostia and pericornual fibrosis etc.

HyCoSy saves women with bilateral patent tubes from invasive procedures. As it has some false negative results, we suggest that those patients who do not conceive after 3-6 cycles of IUI, should directly be posted for laparoscopy and hysteroscopy. HyCoSy alongwith a thorough transvaginal ultrasound scan ensures that all women being investigated for infertility, have an assessment of tubal patency, uterine cavity, ovarian morphology and any pelvic abnormality. It also helps in early detection of cervical stenosis as, catheter is passed through the cervical canal.

There are some shortcomings of the procedure as well, like it has a long learning curve¹³, and there are some technical difficulties in interpreting the sonographic picture after contrast injection. These difficulties are more commonly encountered in women with increased body mass index (BMI), acutely retroverted or oblique uterine position, ovaries situated either in close proximity to the uterus (usually in the pouch of Douglas) or laterally in the pelvis (at the extremes of the penetration depth of the transvaginal probe) or in whom there are multiple loops of overlying, gaseous bowel.^{8,10,12} Various recent advances increase the diagnostic accuracy of HyCoSy i.e. color doppler duplex scan, contrast tuned imaging, 3D-Power Doppler HyCoSy and 4D-HyCoSy to overcome the shortcomings of conventional 2 D HyCoSy.

Laparoscopy and hysteroscopy remains the gold standard for diagnosing tubal patency, ovarian and pelvic pathology as it offers the advantage of direct visualisation omitting the chances of any artefact confusing with the appropriate diagnosis and has a therapeutic role to play simultaneously.

We found a very good sensitivity and specificity of HyCoSy, proving it to be a good screening method. Subjects who are diagnosed as having tubal pathology on HyCoSy, either bilateral and unilateral have a very high chance of having some tubal or peritoneal defect and should be posted as soon as possible for endoscopic evaluation and corrective surgeries and advanced ART techniques. It is a simple, sensitive and cost effective method to diagnose tubal patency, saves patient from radiation hazards, risks of anaesthesia, has good patient tolerability, help in managing long operative lists by sorting subjects who actually need endoscopic evaluation.^{14,10,16-21}

The advantages of this study are that it is a relatively newer modality tested in Indian perspective. Same patients undergo both investigative modalities and in the same cycle mostly. Same observer has done all the HyCoSy tests and laparo-hysteroscopies. Therefore, biases are minimized. The limitations of the study are that number of subjects was less.

V. Conclusion

HyCoSy is a simple, safe, sensitive and inexpensive preliminary screening procedure with good concordance in diagnosing uterine cavity lesions, tubal patency and tubal blocks. The correspondence for tubal pathology between HyCoSy and Laparoscopy was more for proximal segment block than distal segment block.

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