COMPREHENSIVE APPROACH TO FEMALE FERTILITY: INDIAN SCENARIOShailaja Prasad¹, P. Surekha², T. L. N. Praveen³**HOW TO CITE THIS ARTICLE:**

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ABSTRACT: The female factors responsible for infertility are ovulation disorders (25%), tubal disease (15%-35%) and endometriosis (10%) and the male factors contribute to infertility in approximately 25% of cases. Causes are unknown in a further 15% to 25% of the remaining cases.^{1,2} Laparoscopic chromo perturbation (LCP) is one of the investigations available to evaluate various tubal factors responsible for female infertility. Hysterosalpingography (HSG) is useful in assessing the tubal pathology. Both these modalities are effective and have their own benefits and limitations. Hysterosalpingo-contrast sonography (HyCoSy) is an effective alternative imaging modality providing a comprehensive approach to the investigations for female fertility. HyCoSy is performed as an out-patient procedure and is devoid of radiation exposure, anaphylaxis and anaesthesia. It provides information regarding uterine cavity, uterine abnormalities, tubal patency, ovaries and the pelvic cavity. In this paper, we have evaluated the efficacy of HyCoSy in comparison to laparoscopic dye perturbation, which is a gold standard in fertility workup. This prospective study has been taken up to establish this non-invasive, readily available, inexpensive, out-patient HyCoSy investigation to replace the invasive, sparsely available, expensive, operative LCP. This comprehensive approach is extremely essential in the management of infertile women in India.

KEYWORDS: Hysterosalpingo contrast sonography (HyCoSy), laparoscopic chromo perturbation (LCP), female fertility, Contrast enhanced ultrasonography (CEUS).

INTRODUCTION: Epidemiological studies indicate that 8 to 20% of couples in the reproductive age group are infertile. Main causes of infertility are male factor, ovulatory and tubal disorders. The tubal disorder accounts to 35% of infertile women and is the most frequent female factor. Hysterosalpingography (HSG) and laparoscopy and dye test have been used to assess tubal function.

Hysterosalpingo contrast sonography (HyCoSy) is an effective alternate imaging technique. HyCoSy is done by instilling ultrasound contrast media into the uterine cavity, using an 8F Foley's catheter inserted in the uterine cavity through the cervical os. Real time imaging of tubes is done by trans-vaginal ultrasound.

The main purpose of this study is to establish HyCoSy as an effective method on its own, in evaluation of female fertility, which gives us comprehensive information regarding various female factors that are essential in evaluating women with infertility in Indian Scenario. The technique provides clinically valuable information regarding tubal patency, ovarian and uterine abnormalities.³

MATERIALS & METHODS: Patient selection criteria included inability to conceive after 2 years of unprotected sexual intercourse and with normal semen analysis.

154 patients were subjected for LCP and HyCoSy. Written informed consent was obtained from all the patients.

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Exclusion Criteria: Included hyperprolactinaemia, pelvic inflammatory disease, pregnancy, age <18 years, women with oligospermia in male partners.

HyCoSy examinations were performed between days 7–10 following the menstrual cycle. Conventional trans-vaginal ultrasound examination of the pelvic organs was undertaken initially and was later followed by HyCoSy. The examination was performed using an Acuson S 2000 scanner with 6 MHz trans-vaginal transducer.

HyCoSy is performed with 2nd generation contrast medium, Sonovue. The micro bubbles are filled with sulfur hexafluoride and provide strong harmonic response at low acoustic pressure.

It consists of elastic microbubbles stabilized by a membrane of phospholipids.

The diameter of the micro-bubble is comparable to that of a red blood cell. Sonovue is packed in 25mg of pyrogen-free lyophilized powder in 11ml septum sealed glass vials, which is reconstituted with 5ml of saline solution. The solution is shaken well before use. 0.5ml of the solution is injected into the uterine cavity through a trans-cervical (8F) Foley's catheter. High resolution endo-vaginal probe is used to visualise the passage of the contrast.

Initial trans-vaginal ultrasound examination is performed to evaluate uterine abnormality, ovarian pathology and adnexal abnormalities. HyCoSy performed in real-time examination reveals passage of the contrast through the interstitial part of the tube, visualization of steady antegrade flow along the length of the fallopian tube, detection of contrast around the ovary (Peri-ovarian spill) and detection of contrast in the pouch of Douglas (Peritoneal spill).

Laparoscopic chromo perturbation (LCP) was performed under general anaesthesia. After bimanual examination, a uterine elevator was applied to the cervix to facilitate uterine manipulation. A sub-umbilical 10 mm incision was made and veere's needle was used to create pneumoperitoneum. 10 mm scope was introduced and pelvic cavity and abdomen inspected to confirm the findings. A second supra-pubic 5 mm incision was made to introduce second port, under vision. Methylene dye was used as a contrast instilled transcervically, to check tubal patency.

RESULTS: 154 cases were recruited for HyCoSy and LCP during 2010 to 2013. Mean age of the patients was 32.48, ranged from 19 to 49 years with mean infertility length of 6.8 years, ranging from 2 to 17 years. 54.5% were cases of primary infertility and 45.5% were secondary infertility.

In HyCoSy, the uterus and its cavity appeared normal in 132(85.7%) women. Uterine abnormalities in the remaining 22 women (14.2%) included structural abnormality (n=6), fibroids (n=12), endometrial polyps (n=3) and uterine synechiae (n=1). 308 fallopian tubes in 154 women were assessed: 244 tubes (79.2%) appeared patent (fig 1 and 2) and 46 appeared (14.9%) blocked. Out of the 46, 19 cases (38 tubes) showed bilateral tubal block diagnosed by distention of the uterine cavity with ultrasound contrast and absence of contrast in the tubes.

8 cases showed unilateral tubal block at the fimbrial end, which was confirmed by a normal uterine cavity with unilateral distention of tube. The remaining 18 tubes (5.8%) could not be assessed for various technical reasons, such as inability to introduce Foley's catheter due to cervical stenosis (n=1 case), marked retroversion of the uterus (n= 4 cases), overlying bowel gas (n=2 cases), transducer positioning (n=1 case), or cephalad displacement of the tubes beyond the depth of penetration of the vaginal probe (n=1 case). 7 women had polycystic ovaries, 1 had ovarian cyst and ectopic pregnancy was diagnosed in one patient. one patient had hydrosalpinx but tubes were patent (Fig 3 and 4). All these features were confirmed at laparoscopy.

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Out of the 19 cases (38 tubes) with bilateral tubal block on HyCoSy, LCP confirmed bilateral tubal patency in 14 cases (28 tubes) and bilateral tubal block in 5 cases (10 tubes). In 8 cases of unilateral blocks demonstrated on HyCoSy, LCP revealed 4 cases to have bilateral patent tubes and 4 cases had unilateral block. 18 tubes that were not assessable at HyCoSy, LCP revealed 8 cases (16 tubes) to be patent bilaterally and 1 case (2 tubes) were blocked.

No major adverse effects were noted with HyCoSy. Common adverse effects noted were nausea and mild to moderate pain, requiring simple analgesia, which confirmed HyCoSy as a simple and well tolerated outpatient procedure.

Tubes (n=308)	Uterus (n=154)	Ovaries & adnexa (n=308)
Patent - 244 (79.2%)	Normal - 132(85.7%)	Normal - 299(97%)
Blocked - 46 (14.9%) (Unilateral - 8)	Abnormal - 22 (14.2%)	Abnormal - 9 (3%)
Non-accessible - 18 (5.8%)	Fibroids - 12 Polyps - 3 Structural anomaly - 6 Synechiae - 1	Ectopic pregnancy - 1 Polycystic ovaries - 7 Ovarian cyst - 1
Table 1: HyCoSy findings in 154 women		

	HyCoSy	LCP
Patent tubes	244	292
Blocked tubes	46	16
Inaccessible tubes	18	0
Total	308	308
Table 2: Comparison of findings in women who had HyCoSy and LCP		

Prevalence	5.19
Sensitivity	100 (79-100)
Specificity	83.56 (78-87)
Positive Predictive Value	25 (15-37)
Negative Predictive Value	100(98-100)
Likelihood Ratio Positive Test	6.08(4.69-7.87)
Likelihood Ratio Negative Test	0 (0-NaN)
Table 3	

Note: (95% Confidence Interval calculated with Binomial Expansion)

DISCUSSION: HyCoCy is a well-accepted procedure and has the potential to reliably assess the tubal patency in infertile women. Similar reports have been published by various authors world over.^{3,4} Our study confirms that that the test has such a high sensitivity that if a HyCoSy result shows patent tubes, it can be accepted without further investigations. It is an ideal out-patient procedure and if the tubal patency is established by HyCoSy, the patient can be spared of other invasive investigation i.e.

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LCP. LCP is avoided in nearly 79% of the woman undergoing testing for tubal patency. However, if a HyCoSy shows blocked tubes or indeterminate, the patient would definitely need an LCP.

It is worth saying that HyCoSy is inconclusive because there is a 65% chance that the tubes are patent. Other benefits of HyCoSy includes diagnosis of uterine cavity abnormalities; no anaphylaxis, exposure to radiation, major adverse effects except mild to moderate pain requiring simple analgesia. This gives additional information regarding the pelvic viscera too.

CONCLUSION: LCP is a gold standard investigation in fertility workup. However, it is invasive, sparsely available and expensive. HyCoSy in contrast, is non-invasive, readily available, inexpensive out-patient investigation with very high sensitivity and negative predictive value and provides all the information provided by laparoscopy, with minimal patient morbidity. This procedure avoids surgical intervention in 4 in 5 women undergoing investigations for infertility work-up and should be highly recommended as a baseline investigation for tubal patency.

Fig. 1: HyCoSy – Patent tubes

Fig. 2: Patent tubes at laparoscopy

Fig. 3: HyCoSy Hydrosalpinx

Fig. 4: Hydrosalpinx at laparoscopy

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AUTHORS:

1. Shailaja Prasad
2. P. Surekha
3. T. L. N. Praveen

PARTICULARS OF CONTRIBUTORS:

1. Associate Professor, Department of Obstetrics and Gynaecology, Niloufer Hospital, Hyderabad.
2. Professor, Department of Radiology, Niloufer Hospital, Hyderabad.

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3. Consultant Radiologist, Department of Radiology, Abhishek Scan Centre, Hyderabad.

NAME ADDRESS EMAIL ID OF THE CORRESPONDING AUTHOR:

Dr. Shailaja Prasad,
Associate Professor,
Niloufer Hospital, Hyderabad,
Telangana State.
E-mail: mshailajaprasad@gmail.com

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