Transvaginal Hysterosalpingo-Contrast Sonography (HyCoSy) Compared with Chromolaparoscopy : A Preliminary Report

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Abstract

Fifteen infertile women who required tubal passage evaluation by chromolaparoscopy were recruited. Those who had lower genital tract infection or abnormal uterine bleeding were excluded from the study. Transvaginal HyCoSy was performed during the first half of the menstrual cycle at least 24 hours prior to chromolaparoscopy. The results from both transvaginal HyCoSy and chromolaparoscopy were compared in assessing tubal patency and uterine pathology.

A high correlation was noted regarding uterine examination using transvaginal HyCoSy compared with chromolaparoscopy (sensitivity, specificity, PPV and NPV were 91.7%, 33.3%, 84.6% and 50%, respectively). The correlation of the outcome between the two procedures in assessing tubal patency, when combining both tubes, was also high (sensitivity, specificity, PPV and NPV were 100%, 55.6%, 80% and 100%, respectively). The most common adverse event was only mild pelvic pain which did not necessitate any treatment.

These preliminary results reveal the potential value of transvaginal HyCoSy as an alternative in infertility investigations. It seems to be as effective but less invasive than conventional chromolaparoscopy. The adverse events reported in this study relate more to the procedure (catheter insertion) rather than the trial substance.

Evaluation of the female genital anatomy is an essential part of an investigation of infertility or recurrent pregnancy wastage. Tubal factors are involved in 25 per cent to 50 per cent of infertile couples(1). The main tools in the diagnosis of tubal disorders so far have been hysterosalpingography (HSG) and chromolaparoscopy. Both procedures have a number of disadvantages and limitations that point to a potential role for an alternative technique.

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Transvaginal ultrasound is now established as an important investigative tool for many aspects of gynaecology. The first report of ultrasound used in infertility was published in 1972 by Kratochwil[2]. Since then, ultrasound has been widely used in many infertility investigations and procedures, such as monitoring of growing follicles, oocytes retrieval, etc[3-5]. Compared with HSG and chromolaparoscopy, ultrasound does not pose any risk, but it is unable to provide any information about tubal patency.

Earlier experience has shown that intrauterine findings are easier to establish when the uterus is filled with fluid, i.e. in hematometra or serometra[6]. Thus, a process of contrast-enhanced visualization of uteri and fallopian tubes combined with transvaginal ultrasound was introduced into this sterility diagnosis programme, known as Hysterosalpingo-Contrast Sonography (HyCoSy). Several studies have been published using an echo-free fluid such as saline with varying degrees of success[7-10]. The echogenic properties of new echocontrast agents such as Echovist^{R}-200 have also been employed in HyCoSy and have allowed consistent visualization of the fallopian tubes using transvaginal ultrasound[11].

The purpose of this study is to compare HyCoSy using positive echocontrast agents with conventional chromolaparoscopy in the assessment of tubal patency.

MATERIAL AND METHOD

From May to August 1997, following the approval by the Ethical Committee of our institute, 15 women visiting the infertility clinic, Chulalongkorn Hospital were included into the study. All women were informed of the nature of the comparative study and informed consent was obtained before commencing the study. Exclusion criteria included age less than 18 years old, galactosemia, pregnancy, abnormal uterine bleeding, poor general medical condition, and pelvic inflammatory disease (PID).

The diagnostic procedure was performed during the first half of the menstrual cycle (proliferative phase). Each patient was placed in the lithotomy position and transvaginal ultrasonography was carried out to evaluate the pelvic organs using of ALOKA SSD 2000-Multiview with a 5-mHz vaginal probe. Then, vulva and vagina were prepared with 10 per cent povidone iodine solution and a bivalve speculum was then inserted into the

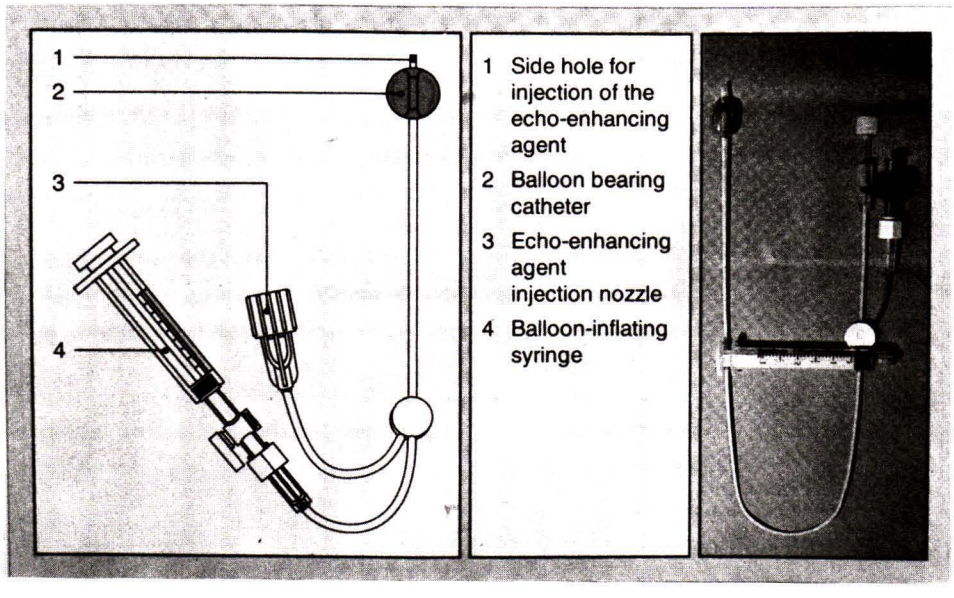

Fig. 1. Transcervical balloon catheter.

vagina to expose the portio. The transcervical balloon catheter (Fig. 1) was inserted gently through the cervix using a pair of forceps, and the balloon was inflated with room air to fix it in position. If the first attempt to insert the balloon catheter is unsuccessful, a 2 mm Hegar's dilator might be used to probe the cervical canal.

Once the balloon was correctly positioned above the internal os, the speculum was removed. The vaginal probe was disinfected, covered with a condom and inserted into the upper part of the vagina. In the meanwhile, the SH U 454 echocontrast agent (Echovist^{R}-200, Schering AG, Germany) was prepared. The galactose solution was aspirated with a 20 ml disposable syringe and transferred to the vial with the galactose microparticles using the minispike supplied. The vial was then shaken vigorously for about 5 seconds to mix the contents well, after which the suspension was drawn up into a 20 ml syringe ready for use (Fig. 2).

The suspension was injected slowly into the uterus via the catheter. The outline of the uterus and the portions of the tubes were evaluated as the echocontrast agent flowed-up and through them. The uterus was scanned in the longitudinal projection, and then in the transverse projection. Then the echogenic flow through different sections of the tubes was observed in the transvaginal scan while the echocontrast agent SH U 454 was injected intermittently (Fig. 3 A, B). Additional colour or pulse-wave Doppler was applied in case tubal patency could not be clearly demonstrated.

Chromolaparoscopy was performed in all women at least 24 hours after performing the HyCoSy, under Meperidine 75 mg and Midazolam 5 mg intravenously combined with local infiltration of 1 per cent Lidocaine solution 20 ml.

The results of the study were compared in assessing tubal and uterine factors of infertility using sensitivity, specificity, positive and negative predictive values, using 2x2 table.

RESULTS

The mean age of the studied population was 32.0 ± 4.6 years (range 25-41). The indications for investigation were primary infertility in 9 cases and secondary infertility in 6 cases. The mean time taken for HyCoSy was 18.7 ± 5.6 minutes (range 12-30) and mean volumes of contrast used was 14.7 ± 3.9 ml (range 10-20). The majority of the women had a normal medical history (12 out of 15). Those with an abnormal medical history included women with gastritis, renal stones and a thyroid nodule.

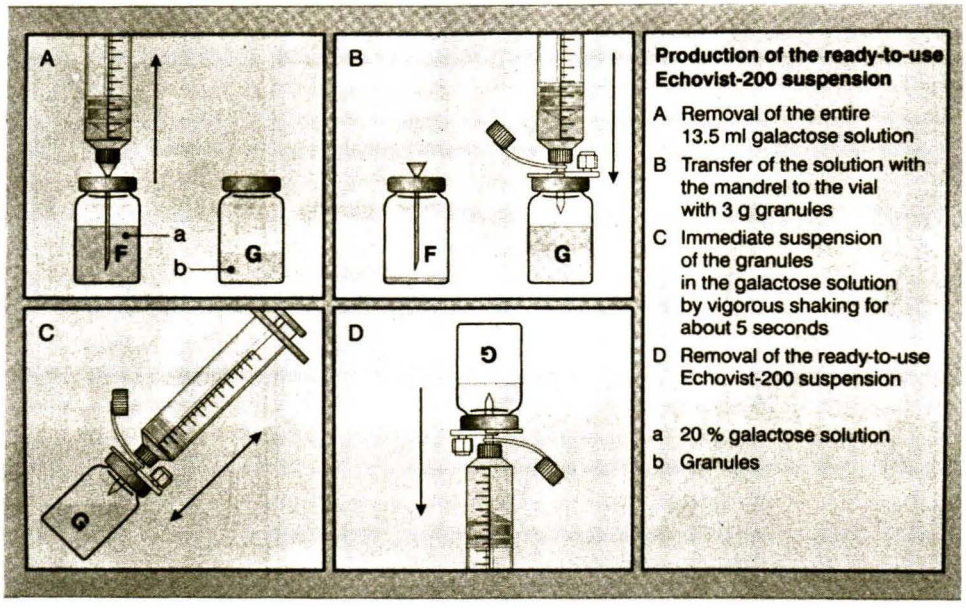

Fig. 2. Preparation of the ready-to-use suspension of Echovist^{R}-200.

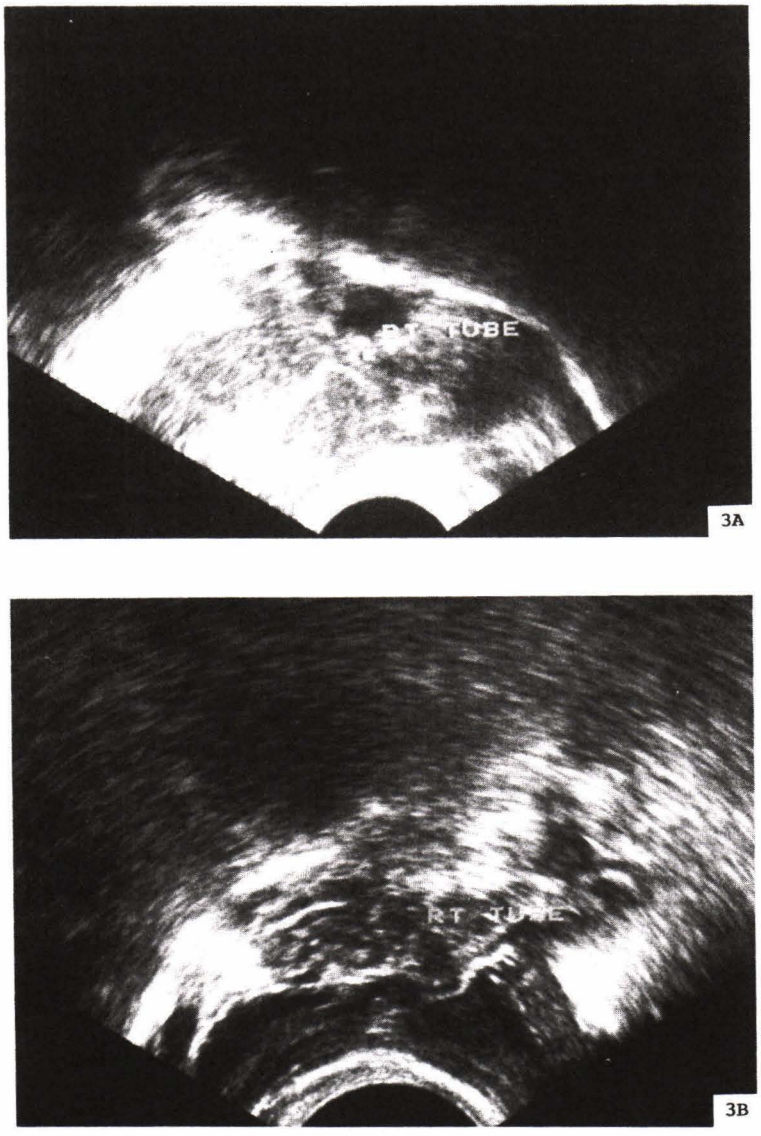

Fig. 3. Intrauterine cavity with the cornual (A) and ampular (B) parts of the right Fallopian tube as visualised on HyCoSy.

The tubal findings demonstrated by HyCoSy and chromolaparoscopy are shown in Table 1. One case of severe pelvic endometriosis with obliterated cul-de-sac was excluded. Only 25 out of 28 fallopian tubes were compared because three occluded fallopian tubes which had different findings of sactosalpinx between two procedures were also excluded. The results showed that

Table 1. Comparison between the outcomes of HyCoSy and Chromolaparoscopy regarding fallopian tube findings

HyCoSy \ Chromolaparoscopy	Patent	Occluded
Patent	16	4
Occluded	0	5

HyCoSy was able to detect tubal patency with a sensitivity of 100 per cent, specificity of 55.6 per cent, positive predictive value of 80 per cent and negative predictive value of 100 per cent.

Regarding uterine examination, there was a high correlation as shown in Table 2. Twelve of 15 cases yielded the same results. Chromolaparoscopy revealed small myoma in two cases which could not be detected by HyCoSy. One case of endometrial polyp was diagnosed by HyCoSy (Fig. 4), but could not be seen from chromolaparoscopy. The sensitivity and specificity of HyCoSy compared with chromolaparoscopy was 91.7 and 33.3 per cent. The positive predictive value was 84.6 per cent while the negative predictive value was 50 per cent.

Table 2. Comparison between the outcomes of HyCoSy and Chromolaparoscopy regarding uterine findings.

HyCoSy \ Chromolaparoscopy	Normal	Pathological
Normal	11	2
Pathological	1	1

A total of 10 adverse events were reported from 9 patients. Eight of the 10 adverse reactions were pelvic pain, the majority of which were mild and did not necessitate any form of therapy. Only one case of severe pelvic pain which recurred after the procedure lasted for another 4 hours. Fifty mg of Meperidine was administered to relieve the pain. There was one case of vaginal bleeding which occurred due to technical problems in catheter insertion. Another case involved mild nausea which again did not necessitate any treatment.

DISCUSSION

Chromolaparoscopy is the investigation of choice in assessment of tubal patency and pelvic pathology in most infertility clinics. However, it is not without surgical and anaesthetic morbidity, particularly in less experienced hands. It has been reported that nearly 50 per cent of patients undergoing diagnostic laparoscopy require post-operative analgesia prior to discharge, and pain can persist for up to 48 hours after surgery[12,13]. In the present study, we used contrast-enhanced sonography to determine tubal patency and the findings obtained were compared with those yielded by conventional chromolaparoscopy.

Deichert et al, compared HyCoSy with the conventional tubal diagnostics and found that

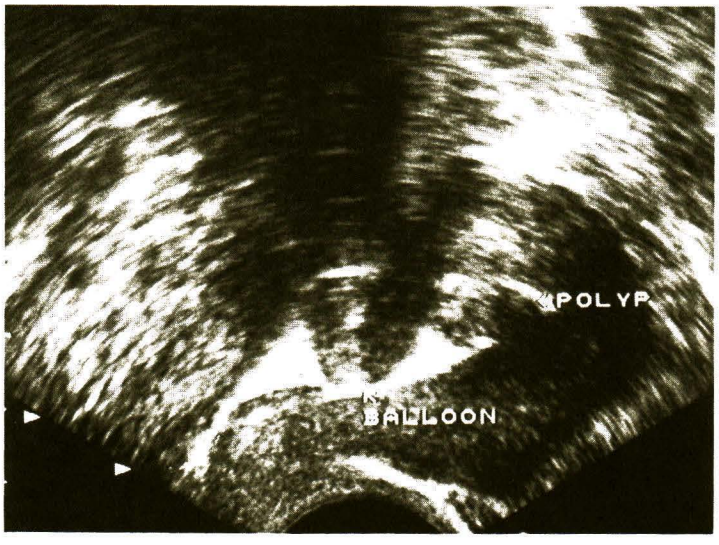

Fig. 4. Endometrial polyp as visualised on HyCoSy.

HyCoSy could serve as an adequate tubal screening method in sterility diagnostics. They also concluded in their later study that the additional use of pulsed wave Doppler in HyCoSy was recommended as a supplement to gray scale imaging in cases of suspected tubal occlusion and in the event of intratubal flow demonstrable only over a short distance(14).

In this study, the results of HyCoSy agreed very well with those of chromolaparoscopy with respect to tubal patency. There was 80 per cent of cases in which tubal patency was similarly diagnosed by both methods. The results of HyCoSy with respect to a diagnosis of tubal occlusion were all confirmed by chromolaparoscopy. The occurrence of false positive findings with HyCoSy (i.e. tubes incorrectly classified as patent, 20%) can result if the observation time of intratubal flow of the echo-enhancing agent in one segment of the tube is too short, so that distal occlusions is overlooked. Another rare possibility might be the presence of a tubal fistula where free tubal passage can be simulated by a flow observed distally of the fistula. Or on the contrary, it may be due to tubal spasm on the patent tubes during injection of dye in chromolaparoscopy.

Regarding uterine examination, the low specificity may be due to the small number of pathological conditions (only 3 cases). One patient who had endometrial polyp could be diagnosed by observing hypointense spherical structure surrounded down to its base by the echocontrast agent. This is one of the advantages of HyCoSy in detection of uterine pathology.

Although there were 8 patients who experienced pelvic pain, the majority of which were mild and it was most often experienced at the time of catheter insertion or injection of the media. Other minor adverse events were short-lived and no medication was required for these cases.

The above preliminary results indicate the potential usefulness of HyCoSy as a less invasive alternative to other diagnostic procedures in infertility. High degrees of correlation between this method and the conventional chromolaparoscopy in terms of results show promise in this ultrasound procedure using contrast material. The use of the echocontrast agent SH U 454 in this study seems to be effective and safe. The adverse events reported in this study relate more to the procedure of HyCoSy (catheter insertion) rather than the trial substance.

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เปรียบเทียบการประเมินภาวะของมดลูกและท่อนำไข่โดยการใช้เครื่องตรวจคลื่นเสียงความถี่สูงทางช่องคลอดร่วมกับสารสะท้อนคลื่นเสียง (HyCoSy) และการตรวจส่องกล้องทางหน้าท้องร่วมกับการฉีดสี : การรายงานเบื้องต้น

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สตรีที่มีภาวะมีบุตรยากซึ่งได้รับการพิจารณาให้รับการตรวจส่องกล้องทางหน้าท้องร่วมกับการฉีดสีจำนวน 15 ราย ได้รับการให้คำปรึกษาและเข้าร่วมโครงการ โดยคัดสตรีที่มีภาวะอักเสบในอุ้งเชิงกรานและเลือดออกจากช่องคลอดผิดปกติออก สตรีทุกรายได้รับการตรวจ HyCoSy ในช่วงครึ่งแรกของรอบเดือนและก่อนได้รับการตรวจส่องกล้องทางหน้าท้องร่วมกับการฉีดสีอย่างน้อย 24 ชั่วโมง ผลการเปรียบเทียบการประเมินภาวะของมดลูกโดยวิธีทั้งสองค่อนข้างดี โดยมีความไว 91.7% ความจำเพาะ 33.3% Positive predictive value 84.6% และ Negative predictive value 50% การเปรียบเทียบการประเมินภาวะของท่อนำไข่โดยวิธีทั้งสองก็พบมีความสัมพันธ์กันสูง โดยมีความไว 100% ความจำเพาะ 55.6% Positive predictive value 80% และ Negative predictive value 100% ภาวะแทรกซ้อนที่พบในการศึกษานี้ ส่วนมากเป็นอาการปวดท้องน้อยที่ไม่รุนแรงและไม่ต้องรับการบำบัดรักษา

จากรายงานเบื้องต้นนี้พบว่า การตรวจ HyCoSy เป็นวิธีประเมินภาวะของมดลูกและท่อนำไข่ในสตรีที่มีภาวะมีบุตรยากที่ได้ผลดีและปลอดภัยกว่าการตรวจส่องกล้องทางหน้าท้องร่วมกับการฉีดสี ภาวะแทรกซ้อนที่เกิดขึ้นมีสาเหตุมาจากหัตถการ (การสอดสายสวนผ่านทางปากมดลูก) มากกว่าเกิดจากสารที่ใช้

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