

# Is color doppler necessary in the evaluation of tubal patency by hysterosalpingo-contrast sonography

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## Summary

**Background:** To evaluate the diagnostic efficacy of hysterosalpingo-contrast sonography (HyCoSy) and to establish whether, in doubtful cases, the additional use of transvaginal Color Doppler can improve the tubal diagnosis reached with gray scale imaging alone.

**Study design:** Ninety-six cases of unknown tubal function with infertility complaints were included. Within four weeks after sonographic hydrotubation, hysterosalpingography was performed. The diagnostic efficacy of gray scale and Color Doppler were compared with each other and against HSG.

**Results:** We calculated a sensitivity value of 82.9% and a specificity value of 86.1% for both tubes. The concordance value was of 83.5%. The total number of Color Doppler examinations compared with those of HSG showed a sensitivity of 91% for the right tube and 93% for the left tube and a specificity of 100% for both tubes.

**Conclusions:** HyCoSy provides reproducible findings for the evaluation of uterine abnormalities and tubal patency. The additional use of Color Doppler is recommended as a supplement to gray scale imaging in cases of suspected tubal occlusion.

**Key words:** Color doppler; Tubal patency; Hysterosalpingosonography; Infertility; Hysterosalpingography.

## Introduction

Tubal occlusion is responsible for infertility in 20-30% of cases. Since the decision as to which treatment to offer is largely dependent on whether at least one fallopian tube is patent, assessment should ideally be conducted early in the diagnostic work-up. Because of the known risks and expense of current methods for establishing tubal patency – chromolaparoscopy and hysterosalpingography (HSG) – these procedures tend not to be employed until towards the end of the diagnostic work-up [1, 2]. A rapid, well-tolerated technique that can be conducted on an outpatient basis is needed. The results of clinical trials suggest that Hysterosalpingo Contrast Sonography (HyCoSy) is just such a technique. HyCoSy, when used as an early examination procedure within the diagnostic work-up of infertility, thus has the potential to reduce the rate of more invasive diagnostic procedures and radiation exposure, saving both time and money [3, 4].

The aim of the present study was to demonstrate the diagnostic efficacy of hysterosalpingo-contrast sonography to establish whether, in doubtful cases, the additional use of transvaginal Color Doppler can improve the tubal diagnosis reached with gray scale imaging alone and to assess acceptability and tolerance of HyCoSy as an outpatient procedure in comparison to HSG.

## Materials and Methods

Ninety-six cases of unknown tubal function were included and evaluated in this study group between May 1993 and February 1996 (average age, 29 years; range, 20-38 years). A basic screening program for infertility, including medical history, basal body temperature, hormone status, spermogram and

gynaecological examination, was performed prior to HyCoSy to rule out causes other than mechanical obstruction in the uterus or fallopian tubes. Both HyCoSy and HSG were performed between the eighth and thirteenth day of the menstrual cycle, and because the cervix was dilated at this time it allowed easier positioning of the intrauterine catheter. The patients were advised to have a diagnostic laparoscopy if abnormal findings were detected by either procedure. Passage through the tubes at laparoscopy was examined with flushing of methylene blue.

Exclusion criteria included galactosemia (since galactose is the basic substance of the echo enhancing agent), pregnancy, age <18 years, poor general clinical condition and pelvic inflammatory disease. Particular caution was exercised in women with autonomic lability or unstable blood pressure, since there is a possible risk of short-lasting hypotension.

The applied contrast agent was SHU 454 (Echovist). The echoenhancement of Echovist-200 (Schering AG, Berlin, Germany) is based on air microbubbles stabilised by galactose microparticles. When the microparticle-microbubble suspension is administered into the uterine cavity for assessing tubal patency, the microparticles dissolve completely after warming up to body temperature within a few seconds. The galactose solution and the small amount of air originating from the microbubbles are released into the abdominal cavity after passing through the tubes. They are absorbed predominantly by the peritoneum [5, 6].

A standard transvaginal ultrasound examination was performed with a model machine Toshiba ECO CEE SSA-340A with a 3.5 MHz vaginal transducer. A transvaginal color flow imaging system was integrated in the vaginal transducer to provide additional information on flow. In cases of patency, and audible, initially spitting, drawn out Doppler signal was obtained. The absence of this acoustic signal and of visual demonstration was interpreted as occlusion.

The method of HyCoSy was the following: A transcervical balloon catheter was inserted gently through the cervix using a

pair of forceps, and the balloon was inflated with room air to fix it in position. Then, the vaginal probe was inserted into the upper part of the vagina. Echovist-200, was injected slowly into the uterus via the catheter. The uterus was first scanned in the longitudinal projection, and then in the transverse projection. The tubes were scanned in transverse and oblique projections. Observation of either forward flow of the contrast agent for a least five seconds between pars intramuralis and isthmus tubae without interruption and hydrosalpinx formation and/or the fimbrial turbulence to cul-de-sac were considered as the presence of tubal patency. Because Echovist was remained in the tube in cases of ampullar occlusion, an antibiotic was given for three days to prevent inflammation of the tubal epithelium due to the additional tubal dilation.

The results of transvaginal hysterosalpingo-sonography by gray scale imagin and the Doppler recordings were compared with those of subsequent HSG that was performed four weeks later. X-ray HSG required the presence of a gynecologist, radiographer and radiologist. Iopamidol, a new generation, water-soluble, non-ionic contrast medium was injected slowly through the cervix under direct fluoroscopic guidance using the image intensifier. Hard copies of selected image were kept for review.

Statistical analysis was performed using student t-test for paired and unpaired data. The  $\chi^2$  test was used to determine whether the frequency of pain or need for analgesia for both procedures was statistically significant.

## Results

The mean times taken for HyCoSy and HSG were  $11.9 \pm 5.1$  (range 4-18) and  $10.1 \pm 4.5$  (range 4-19) min, respectively, and mean volume of contrast used were  $9.5 \pm 4.8$  (range 3-21) and  $11.6 \pm 6.2$  (range 4-30) ml, respectively.

The radiological and ultrasound findings are shown in Table 1. Uterine pathology was detected with both HyCoSy and HSG, but ovarian pathology was only detected when the HyCoSy technique was used (Table 2). The accuracy of HyCoSy compared to the reference method in assessing tubal patency is summarised in terms of sensitivity, specificity and predictive values and concordance in Table 3.

We have compared the results of the total number of Color Doppler examination ( $n=96$ ) with those of HSG. We found a sensitivity of 91% for the right tube and 93% for the left tube and a specificity of 100% for both tubes. The positive predictive value was found to be 1.0, while the negative predictive value was 0.6 for the right tube and 0.8 for the left tube.

The most common side-effect reported during or following both procedures was pelvic pain in 62/96 (65%) women. The pain was sufficient to warrant the use of simple non-steroidal analgesia in the 48 hours following the procedure in 14/96 (14.6%) women. There were no statistically significant differences in the incidence, timing or duration of pain, or analgesia requirements in the two groups (Table 4). The number of patients reporting pain at various steps of the examination with HyCoSy are shown in Figure 1. Other minor side-effects were short-lived and there were no serious adverse effects in either group (Table 5).

## Discussion

The prospects of success and the efficacy of infertility treatment are very much dependent on the preceding dia-

Table 1. — Findings with HyCoSy and HSG

	Patent tubes	Non-patent tubes	Non-assessable tubes
HyCoSy (n=49)	55/94 (58.5%)	22/94 (23.4%) hydrosalpinx (n=2)	17/94 (18.08%)
HSG (n=46)	67/93 (72.04%)	10/93 (10.75%) hydrosalpinx (n=3)	7/93 (7.5%)

Table 2. — Details of abnormal findings with HyCoSy and HSG

	Uterus	Ovaries
HyCoSy (n=49)	5/94 (5.3%) endometrial polyp (n=2) fibroids (n=2) uterine septum (n=1)	21/94 (22.3%) endometrioma (n=8) dermoid cyst (n=4) polycystic ovaries (n=9)
HSG (n=47)	3/93 (3.2%) endometrial polyp (n=1) submucosal fibroid (n=1) uterine septum (n=1)	

Table 3. — Comparison of the different methods (in %) HyCoSy versus HSG

Sensitivity	82.9
Specificity	86.1
Positive predictive value	94.0
Negative predictive value	63.6
Concordance	83.5

The second method is used as the reference

Table 4. — Pelvic pain associated with HyCoSy and HSG

	HyCoSy (n=49)		HSG (n=47)		p-value
	n	%	n	%	
Pain with procedure	22	45	24	51	0.83 (NS)
Pain occurring at 0-2h	18	37	14	30	0.47 (NS)
Pain occurring at 2-24h	15	31	15	32	1.00 (NS)
Moderate pain lasting >1h	6	12	8	17	0.43 (NS)
Severe pain lasting >5 min	1	2	4	8.5	0.37 (NS)
Analgesia required	9	18	5	10.6	0.40 (NS)

NS, not significant.

Table 5. — Side-effects associated with HyCoSy and HSG

Side-effect	maximum duration	HyCoSy (n=49)		HSG (n=47)	
		n	%	n	%
Hyperventilation	6 h	1	2	0	0
Hypotension	24h	2	4	1	2
Light vaginal bleeding	36 h	3	6	5	10.6
Feeling faint	35 min	1	2	4	8.5
Feeling bloated	24h	1	2	1	2
Panic attack	12 min	1	2	0	0

gnostic work-up, and yet the investigation of tubal patency is seldom, if ever, one of the first steps in determining the cause of infertility. A non-invasive, low-risk, procedure which could be carried out on an out-patient basis is obviously desirable as an early assessment method to determine the tubal and uterine situation and to indicate the direction that further diagnosis and treatment should take.

Diagnostic laparoscopy and dye insufflation with or without hysteroscopy is the investigation of choice for tubal patency and pelvic assessment in most fertility clinics. In the present study, we have shown that HyCoSy and HSG are both simple, well-tolerated outpatient procedures. Deichert *et al.* found complete agreement between

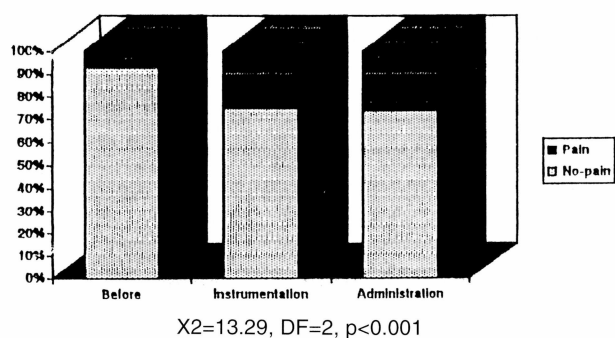


Fig. 1. — Local pain sensation at different steps of the HyCoSy examination.

the results obtained with HyCoSy and those obtained with either HSG or lap and dye in 22 of 34 cases (65%) and partial agreement in 11 cases (32%) [7]. A comparison of the results of HyCoSy and HSG revealed a sensitivity of 82.9% and a specificity of 86.1%. There was again good agreement with the reference method with respect to tubal patency (agreement in 94% of cases), but less agreement with respect to a diagnosis of tubal occlusion (63.7% of cases).

There are several possible reasons for a false negative finding for tubal patency (i.e. the diagnosis of an occluded tube in the presence of an anatomically patent tube), including tubal spasm, differing resistance between the two tubes causing the echo-enhancing agent to run mainly via the free tube, injection of too small amounts of the echo-enhancing agent, and poor positioning of the catheter. A false negative finding in comparison to a reference method may be due to spontaneous tubal recanalization, salpingostomy after the method being assessed but before the reference method, or tubal occlusion after performance of the reference method but before the procedure being assessed. Likewise, there are several possible reasons for a false positive finding for tubal patency, including extravasation of the echo-enhancing agent, tubal fistula or misinterpretation of partial patency in the proximal segment of the tube.

The diagnosis of tubal occlusion is therefore made as an

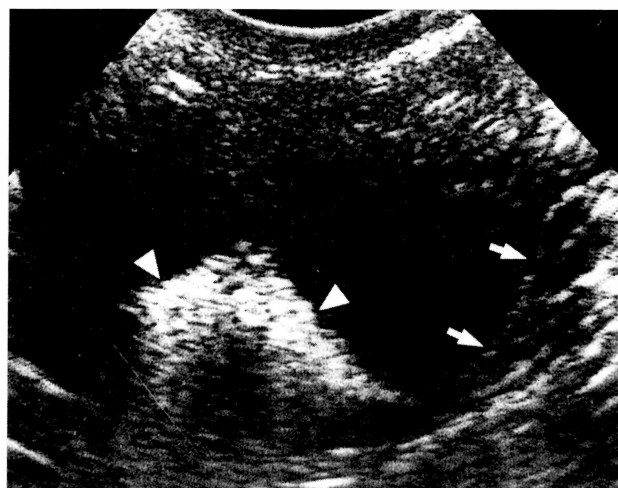


Fig. 2. — Transverse projection of the uterine cavity (➤) with the intramural and isthmic parts of the left fallopian tube (➡) as visualized on HyCoSy.

exclusion diagnosis based on the fact of nonvisualization of the tubal flow in gray scale imaging. However, confirmation of at least one patent fallopian tube would be achieved if an increased amount of fluid were to be detected in the cul-de-sac (Fig. 2). The use of Color Doppler offers advantages here because it permits a more sensitive detection of the echogenic contrast flow even in borderline sized areas of interest.

In a study by Schlieff *et al.* Doppler examinations were performed in 27 patients with resultant sensitivities of 92% and 91% for the right and left tubes, respectively, and a specificity of 100% for both sides in comparison with HSG or lap and dye [8]. Deichert *et al.* went on to report on comparative examinations in 67 patients in whom 13 were additionally examined by Color Doppler. This time complete agreement with the reference techniques was found in 72% cases [9].

This study has demonstrated that HyCoSy is as well-tolerated as modern HSG and is thus a suitable alternative outpatient procedure. It has been shown to be accurate in the diagnosis to tubal patency and allows scanning of the uterine corpus and ovaries at the same time. The additional use of Color Doppler is recommended in the following situations: 1) for checking the non-patent tube in the gray scale image and 2) to confirm the patency in those cases with flow demonstrable over only a short stretch. However, we do not consider it necessary to perform Color Doppler as a routine check in every hysterosalpingo-contrast sonography because demonstration of intratubal flow in the image over a longish section of the tube and for approximately ten seconds is a highly specific, diagnostically adequate finding.

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