Tolerability, side effects, and complications of hysterosalpingocontrast sonography (HyCoSy)

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Objective: To evaluate the tolerability, side effects and complications of hysterosalpingocontrast sonography (HyCoSy).
Design: Prospective study.
Setting: University hospital.
Patient(s): 669 infertile women.
Intervention(s): All patients were examined with HyCoSy and monitored for 30 minutes after the procedure. A telephone interview was subsequently carried out to record possible late side effects and postprocedural complications.
Main Outcome Measure(s): Tolerability to the procedure was evaluated by means of an 11-point (0 to 10) numeric rating scale of the pain experienced. Postprocedural fever, pelvic infections, peritonitis, hemorrhage were recorded.
Result(s): Of 660 patients who completed the examination, 483 (73.2%) completed the telephone follow-up after a period of 14.7 ± 9.9 months from the procedure. The mean patient age was 34.5 ± 4.3 years, and mean infertility duration was 28.1 ± 23.2 months. The mean numeric rating scale was 2.7 ± 2.5, and 10 patients (2.0%) required postprocedural drug treatment for pain relief. Mild vasovagal reactions were experienced in 20 cases (4.1%), and four patients (0.8%) had a severe vasovagal reaction. No late complications were reported. No patients required hospital admission after the procedure.
Conclusion(s): In our series, HyCoSy was a well-tolerated examination with a very low rate of side effects and no late complications that required no atropine or anti-inflammatory drugs. These data support the safety of HyCoSy when performed as described, but further work is needed to estimate the rate of late complications and side effects in other settings. (Fertil Steril® 2009;92:1481–6. ©2009 by American Society for Reproductive Medicine.)

Key Words: Infertility, diagnosis, tubal patency, hysterosalpingocontrast sonography, HyCoSy, transvaginal sonography, ultrasound

The diagnostic workup of infertile women is based on an accurate evaluation of tubal patency and uterine cavity morphologic characteristics. Tubal disease occurs in 30% to 50% of infertile patients (1–3), and approximately 25% of women with congenital or acquired structural uterine abnormalities experience delay in conception, accounting for up to 10% of infertility cases overall (2). Moreover, uterine abnormalities are found in 12.6% of women with recurrent pregnancy wastage (4).

Tubal damage can be a consequence of pelvic inflammatory disease, endometriosis, pelvic surgery, appendicitis, ectopic pregnancy, or septic abortion (5). The ideal technique for investigating tubal patency and the uterine cavity should be accurate, safe, easy to perform, inexpensive, and well-accepted by the patient (6). Traditionally, hysterosalpingography (HSG) has been used to evaluate tubal patency (5), but it has many disadvantages: it is invasive, painful (6–8), expensive (9), and carries the risk of tubal infection (10). Moreover, it requires the use of x-rays and the introduction of an iodinated contrast agent into the uterine cavity, which has been associated with allergic reactions (11). Also, it does not provide information about the ovaries or the external profile of the uterus (9, 12, 13).

Laparoscopy with chromopertubation and hysteroscopy are at present considered the gold-standard techniques for tubal (1, 14, 15), and endometrial cavity assessment (9, 15), respectively. Although considered accurate, these laparoscopic approaches are expensive, time-consuming, and are not devoid of surgical and anesthesiologic risks (16). Transvaginal sonography (TVS) can accurately diagnose the various pelvic conditions responsible for infertility, but it has no role in evaluating tubal status.

Hysterosalpingo contrast sonography (HyCoSy) is an ultrasound-based imaging modality that permits an accurate evaluation of tubal patency as well as the study of uterine and ovarian conditions (6, 9, 17, 18). It is based on the use of a sonographic contrast medium (e.g., Echovist, Albunex, Infoson, air and sterile saline solution) which, after injection into the uterine cavity, can be seen passing through the salpinges in the abdominal cavity at TVS. It has been shown to be a feasible and accurate first-line imaging modality

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(1, 14, 17–26). Moreover, HyCoSy is rather cheap (if performed with air and saline as contrast media) compared with HSG and laparoscopy, with an estimated cost around 30 to 55 Euros in Italy for the disposable material. Compared with HSG, HyCoSy is less invasive, avoids ovarian exposure to x-rays and the risk of allergic reactions, provides information on uterine cavity and ovarian morphology, and can be performed by the reproductive medicine specialist evaluating the infertile couple (5, 27–29). In addition, HyCoSy is better tolerated than HSG (8).

The main limits of such an examination are the scanty information provided about tubal morphology (6, 12) and the impossibility of ruling out distal tubal occlusion without sonographic signs suggestive of a hydrosalpinx (1). Many investigators have evaluated the diagnostic accuracy of HyCoSy and reported acceptable rates of sensitivity and specificity for the evaluation of tubal patency (1, 6, 12, 18, 27, 30). Unfortunately, only scant information is available about tolerability, side effects, and the complications of HyCoSy (17). In particular, vasovagal reactions, pelvic pain, pelvic inflammatory disease, fever, peritonitis, and hemorrhage have been reported, but the real incidence of such adverse events in a large population of women undergoing HyCoSy is unknown. Our prospective study evaluated the tolerability and the rate of side effects and late complications of HyCoSy in a large series of patients consecutively undergoing HyCoSy with a standardized technique at a tertiary level infertility clinic.

MATERIALS AND METHODS

Between January 2003 and June 2006, 669 infertile women underwent HyCoSy at the Reproductive Medicine Unit of S. Orsola-Malpighi Hospital in Bologna to evaluate tubal patency and uterine cavity morphology. Exclusion criteria for the procedure were: acute pelvic infections, vulvovaginal infections, an ongoing pregnancy, or a diagnosis of hydrosalpinx at TVS. Institutional review board approval was obtained before initiating the study, and all procedures were performed by three specialists in reproductive medicine (L. S., M. G., and G. V.) with good expertise in TVS using a standardized predefined technique. All patients gave their informed consent after reading precise information about the aims of the procedure and the possible side effects and complications of HyCoSy.

The examinations were scheduled in the proliferative phase of the menstrual cycle, immediately after menses. No antibiotic prophylaxis was given, no atropine or analgesia (before or after the procedure) was administered, and no cervical swabs were recommended before the examination. Before the examination, all patients were warned that distension of the uterine cavity by air and saline might cause mild pelvic discomfort and that they could stop the procedure at any time.

HyCoSy was performed as follows. The patients were examined in the lithotomy position. Transabdominal and transvaginal ultrasonographic scans were performed with a Sonoline Elegra (Siemens, Erlangen, the Netherlands) or a Hitachi Powervision (Hitachi, Tokyo, Japan) ultrasound machine equipped with a 5.0–8.0 MHz vaginal probe and 3.5–5.0 MHz abdominal probe to identify any uterine or adnexal pathology and to locate the interstitial part of the salpinges and the ovaries. The sonographic probe was then removed, and a disposable lubricated bivalve speculum was put into the vagina to visualize the cervix and disinfect it with iodized polyvidone (Poviderm 10%; Nuova Farmec, Settimo di Pescantina, Italy). Then, a Foley 6-Fr pediatric bladder drainage catheter (Rusch Brillant; Teleflex Medical, Varedo, Italy) was inserted into the cervix after the removal of its internal stylet. To fix the catheter and prevent saline backflow, a distal balloon was slowly filled with 1.5 mL of sterile saline solution.

If difficulty was encountered upon insertion through the cervix, the inner metallic stylet was maintained to improve the rigidity of the catheter and a speculum was used to straighten the cervical canal. Neither a Hegar dilatator nor a single-tooth tenaculum were ever required to insert the catheter into the cervical canal. The speculum was then removed, and a plastic 60-mL syringe containing 20 mL of air and 10 mL of sterile saline solution was attached to the catheter. The syringe could be tilted up or down to inject air or saline, respectively, into the uterine cavity. The vaginal probe was (re)inserted, and the correct position of the catheter was then confirmed.

The correct scanning method for evaluating tubal patency is the transverse view of the uterus at level of the fundus in a plane that identifies the interstitial part of the salpinges. Patency was investigated by injecting first air and then saline in small boluses of 1–2 mL each, up to an overall volume of 20 mL.

Based on previous reports (6, 31), a salpinx was considered patent if liberal flow of air bubbles was seen through its interstitial part for at least 8 to 10 seconds. Passage of air bubbles along the salpinx produces a line of hyperechogenic dots moving laterally from each interstitial portion toward the ovary (Fig. 1) (Video 1–HyCoSy right tube. Transvaginal scan of the right salpinx showing movement of air bubbles laterally from the interstitial part toward the ovary; available online); abdominal spillage can result in the disappearance of such line and the dispersion of white dots adjacent to the ovary.

After tubal examination, the uterine cavity was evaluated by injecting the smallest amount of saline solution that could separate the two endometrial layers to check for intracavitary pathologies (polyps, myomas, uterine congenital anomalies, synechiae), which could have been missed by simple TVS. In the vast majority of cases, the small quantity of air used, still remaining in the uterine cavity, did not disturb the visualization of the endometrial cavity profile.

At the end of the procedure, the balloon was deflated, and the catheter was removed.

Patients were monitored in the waiting room for 30 minutes after the examination to diagnose and treat potential late side effects such as vasovagal reactions, either mild