Hysterosalpingo contrast sonography (HyCoSy) with SH U 454 (Echovist®) for the assessment of tubal patency

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A total of 88 Fallopian tubes from 44 patients was examined with hysterosalpingo contrast sonography (HyCoSy), hysterosalpingography (HSG), and laparoscopic chromotubation (LC) in order to assess their relative accuracy for measuring tubal patency. HyCoSy was done by transvaginal ultrasound and the contrast was SH U 454 (Echovist®). The flow of multiple fractions of the contrast medium through each Fallopian tube was observed in real time in appropriate imaging planes by means of a transvaginal probe. Compared with laparoscopic results, we found a sensitivity of 85.2%, a specificity of 85.2%, a positive predictive value (PPV) of 71.9%, a negative predictive value (NPV) of 92.9% and concordance (HyCoSy/LC) of 85.2%, while the corresponding values for HSG were sensitivity = 85.2%, specificity = 83.6%, PPV = 69.7%, NPV = 92.7% and concordance (HSG/LC) of 84.1%. Compared with HSG results, HyCoSy obtained a co-positivity of 66.7%, a co-negativity of 81.8% and a concordance of 76.1%. In conclusion, HyCoSy with SH U 454 proved to be a reliable and safe modality for evaluating tubal patency; it is suitable as an outpatient diagnostic procedure to be used before more invasive procedures.

Key words: Fallopian tube patency/HyCoSy/infertility/transvaginal ultrasound

Introduction

Between 8 and 20% of couples of reproductive age are infertile, according to various epidemiological studies (Barad, 1991; WHO, 1993). The main causes of infertility are male factor, ovulatory and tubal disorders. Tubal disorder is the most frequent female factor, occurring in up to 35% of infertile women (Cates et al., 1991). It is a consequence of pelvic inflammatory disease, endometriosis, pelvic surgery, ectopic pregnancy, appendicitis with peritonitis and septic abortion. Traditionally, hysterosalpingography (HSG) and laparoscopy and dye have been used to assess tubal function. Hysterosalpingo contrast sonography (HyCoSy) with contrast medium has been used for such a purpose (Deichert et al., 1989; Schlief and Deichert, 1991). It consists of endovaginal ultrasonography with concomitant instillation of an ecogenic contrast medium into the uterine cavity, using a catheter inserted in the uterine cavity through the cervical os. It has been demonstrated that HSG and HyCoSy have the same accuracy at detecting tubal patency (Campbell et al., 1994; Heikkimen et al., 1995). HyCoSy, however, offers a number of benefits over HSG as a diagnostic test: the uterine cavity is better evaluated by HyCoSy; there is no risk of anaphylaxis since there is no iodide contrast; it is a less expensive test and causes less pain; there is no radiation exposure; and it can be conducted by the reproduction specialist themselves, at their office, allowing a dynamic study of the patient’s pelvis (Schlief and Deichert, 1991; Deichert et al., 1992; Campbell et al., 1994).

The main purpose of this study was to evaluate the accuracy of HyCoSy in the assessment of tubal patency with regards to HSG and laparoscopy and dye (gold standard).

Materials and methods

Patients

After our preliminary experience with hysterosonography (Reis et al., 1997), we examined a total of 88 Fallopian tubes from 44 patients with HyCoSy. Samples came from a consecutive series of patients who presented with inability to conceive after 2 years of intercourse without contraception and whose male partners had not shown severe impaired sperm parameters. Altogether, 88 Fallopian tubes were examined with HyCoSy, HSG, and laparoscopy and dye (LC). The study was performed according to the Helsinki guidelines and after approval by the Ethic Committee of Hospital das C linicas of the Universidade Federal de Minas Gerais (UFMG). Written informed consent was obtained from all patients.

Conditions

Exclusion criteria included active pelvic inflammatory disease, galactosaemia, pregnancy, age <18 years and women whose male partners had had oligospermia (sperm count <3×10⁹). Clinical findings and laboratory parameters confirmed the criteria. The diagnostic procedures (HyCoSy and HSG) were performed in the first half of the cycle without anaesthesia and laparoscopy and dye was carried out under general anaesthesia.

HyCoSy

A standard transvaginal ultrasound examination was followed by transvaginal HyCoSy with SH U 454 (Echovist®; Schering AG, Berlin, Germany), a galactose microparticle/air microbubble suspension. After the uterine cavity had been filled with Ringer’s solution via the ZUI (Zinnanti Uterine Injector, Chatsworth, CA, USA) catheter, the contour of the uterus was evaluated for the presence or absence of leiomyoma, polyp, malformations or synechiae. After that, the Echovist suspension was injected in 1–2 ml boluses whilst scanning continuously. The flow of multiple fractions of the contrast
medium (SH U 454) through each Fallopian tube was observed in real time in appropriate imaging planes by means of a transvaginal probe (Figure 1).

If drainage into the tube was unimpeded, the echogenic fluid formed a narrow white line within the tube and flow was seen on real-time. No echogenic fluid was seen within occluded segments of the tube, while a hydrosalpinx was seen as a collection of echogenic fluid in the lateral portion of the tube. Each tube was examined as far as the infundibulum as well as in the region around the ovary, to demonstrate echogenic fluid spilling into the peritoneum. In patients with bilateral tubal occlusion, distension of the uterine cavity was seen without demonstration of echogenic fluid in the tubes; this phenomenon is not usually seen in cases of unilateral tubal occlusion because the fluid drains via the patent side. Antibiotic therapy was given for patients who presented pathological findings at HyCoSy procedure.

**Sample size**

Hulley (Hulley and Cummings, 1988) considers the studies with diagnostic procedures such as descriptive study, suggesting the following formula for sample size:

\[ n = \frac{4 \times Z_{\alpha/2} \times P \times (1 - P)}{W^2} \]

\( n \) = sample size; \( Z_{\alpha} \) = \((1 - \alpha) = (1 - 0.05) = 1.96; P = \) expected proportion; \( W \) = total width confidence interval.

Selecting the confidence level for the 95% interval, the sample size varies according to sensitivity and specificity of the test and total width of confidence interval desired for the test (Hulley and Cummings, 1988). In our pilot study, we obtained a sensitivity of 100% and specificity of 91.7% and in published studies (Schlief and Deichert, 1991; Campbell et al., 1994), the HyCoSy also showed a sensitivity ranging from 90 to 100% and specificity ranging from 86 to 100%. Thus, we have used the lower parameter of sensitivity (90%) for calculating sample size.

Studies on tubal patency (Schlief and Deichert, 1991; Campbell et al., 1994) have considered each patient with two sample unity, since each tube is independent. Therefore, we consider in our study each tube as a sample unit, obtaining a sample size that ranged for 65 (width 15%) to 140 tubes (width 10%).

**Results**

The mean age of the patients was 30.48 ± 4.63 (ranged from 19 to 40), with infertility length of 6.8 ± 0.6 years. The lowest length of infertility was 2 years and the highest was 17 years. The most common length of infertility was 8 years, but 25% of patients did not know the length of their infertility precisely. Primary infertility was reported in 54.5% of cases and secondary infertility in 45.5%. No patients had a history of cardiac problems, galactosaemia or salpingectomy. Pelvic surgery was reported by 22.7% of patients. Previous pelvic inflammation disease (PID) was reported for one patient (2.3%) and two patients did not know to report any previous episodes of PID.

HyCoSy, when compared with laparoscopy and dye, showed a sensitivity of 85.2% (65.4; 95.1), a specificity of 85.2% (73.3; 92.6), a positive predictive value of 71.9% (53.0; 85.6), negative predictive value of 92.9% (81.9; 97.7) and a concordance rate of 85.2% (75.7; 91.6) (Table 1). The results from this series of patients indicate that HyCoSy is capable of providing an accurate picture of whether or not the Fallopian tubes are potentially involved in the patient’s infertility.

**Figure 1.** HyCoSy technique showing ultrasound scanning in (top) cross-sectional plane; (middle) longitudinal plane; (bottom) fluid being transferred from the uterine cavity through the Fallopian tubes.
HSG and HyCoSy
laparoscopy and dye and hysterosalpingography (HSG) 

When the right tube and left tube were compared separately, we found that the concordance for the right tube between HyCoSy and laparoscopy and dye was 86.4% and for the left tube was 81.8%. The concordance between HSG and laparoscopy and dye for the right tube was 86.4% and for the left tube was 93.2%. The concordance between HSG and laparoscopy and dye was 77.3% and for the right tube and left tube was 81.8%.

Considering independently analysis for right and left tubes, we observed that the right tube was occluded for HyCoSy evaluation in 43.2%, for HSG in 38.6% and for laparoscopy and dye in 34.1% (Table IV).

**Discussion**

The data presented from 88 Fallopian tubes show that this new diagnosis procedure has a completely satisfactory accuracy comparable with the current techniques (HSG and laparoscopy and dye). A similar accuracy was found in a number of studies of HyCoSy using Echovist® (Campbell et al., 1994; Degenhardt et al., 1996; Ayida et al., 1997; Kleinkauf-Haucker et al., 1997; Tekay et al., 1997), supporting the view that HyCoSy has the potential to be employed as a reliable and well-

Although HyCoSy has shown similar accuracy in detecting

### Table I. Fallopian tubes classified as either not patent or patent comparing laparoscopy and dye and hysterosalpingo contrast sonography (HyCoSy)

<table>
<thead>
<tr>
<th>HyCoSy</th>
<th>Laparoscopy and dye</th>
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<tbody>
<tr>
<td></td>
<td>Not patent</td>
</tr>
<tr>
<td>Not patent</td>
<td>23</td>
</tr>
<tr>
<td>Patent</td>
<td>4</td>
</tr>
<tr>
<td>Total</td>
<td>27</td>
</tr>
</tbody>
</table>

Sensitivity 85.2% (65.4; 95.1), Specificity 85.2% (73.3; 92.6), Positive predictive value 71.9% (53.0; 85.6), Negative predictive value 92.9% (81.9; 97.7), Concordance rate 85.3% (75.7; 91.6).

### Table II. Fallopian tubes classified as either not patent or patent comparing laparoscopy and dye and hysterosalpingography (HSG)

<table>
<thead>
<tr>
<th>HSG</th>
<th>Laparoscopy and dye</th>
</tr>
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<tbody>
<tr>
<td></td>
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</tr>
<tr>
<td>Not patent</td>
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<tr>
<td>Patent</td>
<td>4</td>
</tr>
<tr>
<td>Total</td>
<td>27</td>
</tr>
</tbody>
</table>

Sensitivity 85.2% (65.4; 95.1), Specificity 83.2% (71.5; 91.4), Positive predictive value 69.7% (51.1; 83.8), Negative predictive value 92.7% (81.6; 97.6), Concordance rate 84.1% (74.4; 90.7).

### Table III. Fallopian tubes classified as either not patent or patent comparing HSG and HyCoSy

<table>
<thead>
<tr>
<th>HyCoSy</th>
<th>HSG</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<tr>
<td>Patent</td>
<td>11</td>
</tr>
<tr>
<td>Total</td>
<td>33</td>
</tr>
</tbody>
</table>

Co-positivity 66.7%. Co-negativity 81.8%. Concordance rate 76.1%.

HSG, when compared with laparoscopy and dye, showed a sensitivity of 85.2% (65.4; 95.1), a specificity of 83.6% (71.5; 91.4), a positive predictive value of 69.7% (51.1; 83.8), negative predictive value of 92.7% (81.6; 97.6) and a concordance rate of 84.1% (74.4; 90.7) (Table II).

In this study, three procedures were studied for assessment of Fallopian tube patency (HyCoSy, HSG, laparoscopy and dye), allowing comparison of HyCoSy with HSG. The concordance rate between HSG and HyCoSy was 76.1%, co-positivity 66.7% and co-negativity 81.8% (Table III).

When the right tube and left tube were compared separately, we found that the concordance for the right tube between HyCoSy and laparoscopy and dye was 77.3% and for the left tube was 93.2%. The concordance between HSG and laparoscopy and dye for the right tube was 86.4% and for the left tube was 81.8%.

Considering independently analysis for right and left tubes, we observed that the right tube was occluded for HyCoSy evaluation in 43.2%, for HSG in 38.6% and for laparoscopy and dye in 34.1% (Table IV).

### Table IV. Independent analysis of patency for right and left tube in HyCoSy, HSG and Laparoscopy and dye

<table>
<thead>
<tr>
<th></th>
<th>HyCoSy (%)</th>
<th>HSG (%)</th>
<th>Laparoscopy and dye (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Right tube</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not patent</td>
<td>43.2*</td>
<td>38.6</td>
<td>34.1</td>
</tr>
<tr>
<td>Patent</td>
<td>56.8</td>
<td>61.4</td>
<td>65.9</td>
</tr>
<tr>
<td>Left tube</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not patent</td>
<td>29.5*</td>
<td>36.4</td>
<td>27.3</td>
</tr>
<tr>
<td>Patent</td>
<td>70.5</td>
<td>63.6</td>
<td>72.7</td>
</tr>
</tbody>
</table>

*χ² McNemar = 1.23 (P = 0.2678).

**HyCoSy for assessment of tubal patency**
the tubal patency of HSG, this new procedure offers a number of benefits over HSG as a diagnostic examination, as was also confirmed in previous studies (Deichert et al., 1992; Campbell et al., 1994; Degenhardt et al., 1996; Ayida et al., 1997; Kleinkauf-Haucker et al., 1997): the uterine cavity is better evaluated by HyCoSy when Ringer’s solution is utilized in the initial evaluation (Deichert et al., 1996; Kleinkauf-Houcken et al., 1997; Reis et al., 1997); there is no risk of anaphylaxis, since there is no iodide contrast medium (Campbell et al., 1994; Degenhardt et al., 1996); it is a less expensive test (Campbell et al., 1994; Degenhardt et al., 1996); it causes less pain and does not require general anaesthesia (Campbell et al., 1994; Ayida et al., 1996; Degenhardt et al., 1996); there is no radiation exposure (Campbell et al., 1994; Degenhardt et al., 1996; Ayida et al., 1997); and it can be performed as an outpatient procedure (Campbell et al., 1994; Degenhardt et al., 1996; Kleinkauf-Houckeir et al., 1997).

As a procedure that can be carried out during early outpatient conduction, HyCoSy appears to be a rapid and inexpensive method of tubal evaluation that might allow the patient to be assigned to the appropriate treatment at an earlier stage.

In conclusion, HyCoSy with SH U 454 (Echovist®) proved to be reliable and safe for evaluating tubal patency; it is suitable as an outpatient diagnostic procedure to be used before more invasive procedures.

Acknowledgements

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References


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