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# Air-Contrast Sonohysterography as a First Step Assessment of Tubal Patency

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We assessed the use of air as a sonographic contrast agent in the investigation of tubal patency by sonohysterography. We examined 115 women assessed for infertility. After saline sonohysterography, small amounts of air were insufflated, and the tubal passage of bubbles was monitored. In five patients (excluded from the results), cervical stenosis prevented the procedure. Ninety-one tubes (right side) and 86 tubes (left side) were definitively patent; 5 and 7, respectively, were probably patent; and 12 and 16, respectively, were nonvisualized. Nine patients had polyps, 3 had synechiae, and 2 had

submucosal fibroids. None of the patients had infectious complications. Air-sonohysterography and laparoscopy with chromopertubation showed agreement in 79.4%. In 17.2% of patients, the tubes were considered nonvisualized by air-sonohysterography when they were patent. The sensitivity was 85.7% and specificity 77.2%. In conclusion, air-sonohysterography is a comfortable, simple, and inexpensive first line of tubal patency investigations yielding high accuracy. **KEY WORDS:** Tube, fallopian, patency; Air sonohysterography; Patency, tubal; Fallopian tube.

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**I**nvestigation of a couple for infertility includes several aspects, such as hormonal assessment, follicular monitoring, determination of tubal patency, and assessment of male factors. New techniques have recently been suggested to replace hys-

terosalingography as the procedure to assess tubal patency. Several new techniques have been proposed: sonohysterography with saline solution or contrast medium, radionuclide studies, MR imaging studies, and laparoscopy with chromopertubation or falloscopy.

The ideal procedure should have a high rate of success, be safe and easy to perform, be well accepted by the patient, and be inexpensive. This has led to the development of several procedures performed either ultrasonographically or under sonographic guidance. Several investigators, apparently frustrated by the cost of contrast medium, have independently attempted to use air as a contrast medium to assess fallopian tube patency.

We describe our experience using air-contrast sonohysterography technique in 115 patients.

## ABBREVIATIONS

PACS, Picture Archiving and Communication System; MR, Magnetic resonance; PPV, Positive predictive value; NPV, Negative predictive value

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## MATERIALS AND METHODS

One hundred and fifteen patients underwent air-contrast sonohysterography for tubal patency or infertility between January 1998 and September 1999.

The examination was performed during the first 5 days after completion of the menses. No antibiotic prophylaxis was recommended (none of the patients had valvular disorders or other risk factors). Six patients (early in the study) received premedication with ibuprofen (Advil or Motrin). The patients were informed that if at least one tube was patent it was likely that they would experience right shoulder pain. Consent for the procedure was obtained. The examination was recorded on videotape (to allow review of the examination and reduce the need for repeat air injection). A few representative frames also were captured in our PACS. All examinations were reviewed by the sonographers and physician (P.J.).

Conventional pelvic ultrasonography was performed before the air-sonohysterography, using Acuson 125 or Sequoia 512 (Acuson, Mountain View, CA) with 7-8 MHz transvaginal transducers. The range of the mechanical index was 0.7 to 1.2, and the thermal index was less than 1.9.

Air-sonohysterography is performed in much the same way as the usual sonohysterography, except that a balloon catheter<sup>1</sup> is used. The catheter is introduced into the uterine cavity, and the balloon filled with 1.5 ml air. As the balloon is filled, it can often be felt to "pop" from the isthmus into the uterine cavity. Five to 10 ml of saline solution is injected into the uterine cavity. This confirms that end of the catheter is not accidentally lodged in the endometrium (with a potential risk an air embolism<sup>2</sup>) and permits a preliminary assessment of the endometrial lining. The balloon is then gently withdrawn against the internal os to create a seal. The syringe is disconnected from the tubing and filled with 5 to 10 ml of air. The cornua of the uterus are then imaged successively. The passage of air is observed first at the level of the cornu, then further in the tubes as they become visible, sometimes even to the point of tracing the release of air in the peritoneal cavity.

The visibility of the tubes was graded according to the following criteria:

- 0 = nonvisualization. Nonvisualization of both tubes is associated with a much-increased resistance to pushing the piston of the syringe, something relatively striking when pushing air instead of saline solution.
- 1 = questionable. This includes bubbles seen moving in tubes or around ovary, without clear visualization of the bubbles at the level of the

cornu. Another finding is the peculiar appearance of free peritoneal air (Fig. 1). Finally, the presence of intense right shoulder pain, despite nonvisualization of the tube, was considered a possible indicator of tubal patency.

2 = small segments less than 3 cm.

3 = segment(s) greater than 3 cm (Fig. 2).

In general "visibility" implied several seconds during which the air bubbles were observed passing through several segments. However, we did the shortest sequences possible to reduce the amount of peritoneal air.

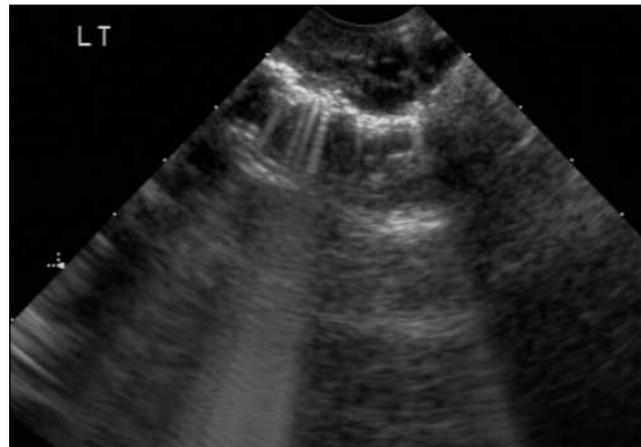
Occasionally one tube is clearly patent while the other is not. In these cases we rotated the patient from supine to the lateral decubitus position to elevate the nonvisualized side. This helped direct the bubbles in the cornu. A similar technique has been advocated for hysterosalpingography.<sup>3</sup>

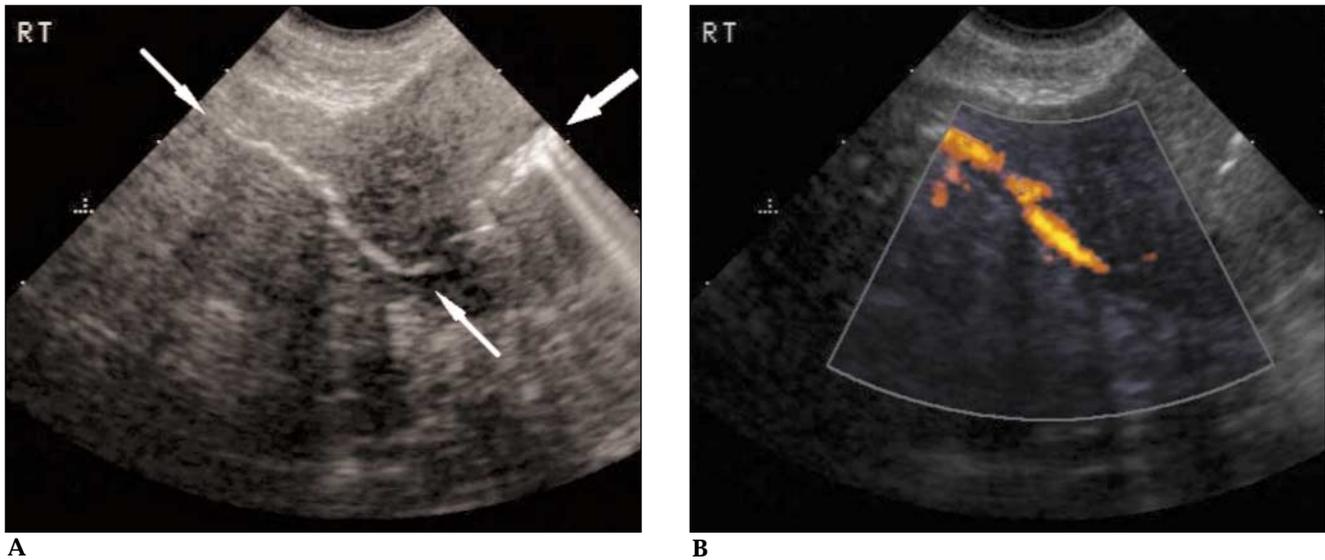
After both tubes have been assessed with air, the balloon is deflated and the cavity is studied with saline solution. This is useful to assess the presence of polyps, synechiae, or fibroids and, to a lesser extent, the presence of a uterus septus, uterus subseptus, or bicornuate uterus.

## RESULTS

In this study, 114 patients investigated for infertility with a primary question of tubal patency were included. An additional patient was investigated to confirm tubal blockage after tubal ligation. Five patients (4.3%) were excluded from the study because cervical stenosis prevented introduction of the catheter. The total population was thus 110 patients or 217 tubes (one left and two right tubes were known to have been surgically removed).

**Figure 1** Typical very fine-grained ring-down artifact that occurs when free peritoneal air is just collecting.





**Figure 2** A, Small bubbles of air highlight part of the uterine cavity on the right of the image (*thick short arrow*), the isthmic portion, and a relatively straight segment of the right tube (*between long thin arrows*). B, Power Doppler sonogram of the bubbles. In our experience, power Doppler sonography was not useful as it created so many flash artifacts that it masked the tube.

Follow-up evaluation after the procedure was between 2 weeks and 21 months. The patients' average age was 31.97 years (range, 18 to 47 years), and the average infertility period was 25.55 months (range, 6 to 144 months). The average duration of the examination was 5 min 22 s (range, 3 to 12 min) with between 2 and 3 min of insonation. The average volume of air injected to visualize the left tube was 11.8 ml (range, 3 to 40 ml; n = 70), and the average volume injected to visualize the right tube was 12.2 ml (range, 3 to 40 ml; n = 70). These volumes are indicative of the amount used and are not precise quantities, since air is not injected into one tube versus the other but is injected into the uterine cavity, and attention is paid to one or the other tube.

Twenty-seven patients (24.5%) became pregnant during the follow-up period and the exploration of their infertility was stopped.

The overall findings are displayed in Table 1 (by patients) and Table 2 (by tubes).

### Additional Investigations

Among the patients who did not conceive during the study period, 17 patients (20.5%) had further investigations, including 14 patients who had air-sonohysterography, hysteroscopy, and laparoscopy with chromopertubation (insertion via the cervix of blue dye with laparoscopic verification of its passage); 1 patient who had an air-sonohysterography with hysteroscopy, laparoscopy with chromopertubation, and

hysterosalpingography (early in our experience); and 2 patients who had both air-sonohysterography and hysterosalpingography (also early in our experience).

During laparoscopy one patient initially was found to have an obstructed tube, but under high pressure, the obstruction was released. The results of the comparison between air-sonohysterography and laparoscopy are provided in Table 3. Among the 15 patients who underwent a laparoscopy, 5 had bilateral patent tubes on air-sonohysterography but still underwent laparoscopy because, among other reasons, their infertility was longer (33.3 months versus 25 months) and they were seen earlier in our experience. As the study progressed, fewer patients had a laparoscopy.

Agreement was found between laparoscopy and air-sonohysterography in 17 patent tubes and 6 closed or nonvisualized tubes. The discrepancies included six tubes, with five tubes considered patent

**Table 1:** Results of Air-Sonohysterography by Patients (n = 110)

|   |                |
|---|----------------|
| Bilateral tubal patency                       | 68.1% (n = 75) |
| Bilateral nonvisualized tubes                 | 6.3% (n = 7)   |
| Probably bilateral tubal patency              | 0.9% (n = 1)   |
| One patent tube + one probably patent tube    | 8.1% (n = 9)   |
| One patent tube + one nonvisualized tube      | 12.7% (n = 14) |
| One probably patent + one nonvisualized tube  | 0.9% (n = 1)   |
| One patent tube + one surgically removed tube | 2.7% (n = 3)   |

**Table 2:** Results of Air-Sonohysterography by Tubes (n = 217)

|                       | Right tube (n =108) | Left tube (n =109) |
|-----------------------|---------------------|--------------------|
| Tubes patent          | 84.2% (n = 91)      | 78.8% (n = 86)     |
| Tubes probably patent | 4.6% (n = 5)        | 6.4% (n = 7)       |
| Tubes nonvisualized   | 11.1% (n = 12)      | 14.6% (n = 16)     |

at laparoscopy but nonvisualized at air-sonohysterography and one tube considered patent at air-sonohysterography but closed at laparoscopy. If the released tube is considered “closed,” the overall agreement is 24 of 29 tubes, with only 5 discordances. The results for open and closed tubes, respectively, are as follows: sensitivity, 85.7% and 87.5%; specificity, 77.2% and 80.9%; PPV, 54.5% and 63.6%; NPV, 94.4% and 94.4%; kappa, 0.53 and 0.61.

An additional three patients had a hysterosalpingography (including one who also had a laparoscopy). The numbers here are small, and agreement between the two procedures was achieved in only 50% (Table 4).

For the sole patient who had both a hysteroscopy and a hysterosalpingography, agreement occurred regarding the status of the left tube (obstructed on both examinations), but the right tube was considered obstructed and “partially” patent.

### Complications

Complications were generally uncommon (36.3%) and mild. They included cramping (26.3%) during the distention of the uterus with saline solution. Cramping was immediate, not a delayed complica-

tion. The air insufflations generally were not felt, but the presence of peritoneal air caused shoulder pain alone in 2.7%, and another 7.2% of patients experienced cramping and shoulder pain. In one case the shoulder pain was sufficient to cause a vasovagal reaction. This was a patient in whom the tubes were difficult to see and who needed a greater amount of air insufflated (about 70 ml). The shoulder pain allowed us to recognize that a tube was patent even if the sonographic image was not very clear (“probable”). Overall, cramping was such a mild problem that only six patients were premedicated. In bilaterally “nonvisualized” tubes the resistance to the syringe was notably increased, and the resulting intrauterine pressure was intensely painful. Those procedures were then rapidly discontinued. No patient had an infectious complication.

### Pregnancy After Air-Sonohysterography

Within the study period 27 patients (24.5% of the total population, 27% of those with at least one patent tube) had a confirmed pregnancy. The average time between the air-sonohysterography and the pregnancy was 25 weeks (range, 2 to 60 weeks). Twenty-two patients had both tubes open, two had one open and one “probably” open tube, another two had one open and one nonvisualized tube, and one had bilateral “probably patent” tubes (Table 5).

### Additional Findings

Aside from the findings related to the tubes, the procedure disclosed other information that might be of relevance to the infertility. Three patients had fibroids, including two in whom the fibroids were submucosal. Nine patients had one or more polyps

**Table 3:** Air-Sonohysterography Versus Laparoscopy with Chromopertubation (15 Patients, 29 Tubes)

|  | Released Tube, Considered Open* | Released Tube, Considered Closed* |
|--|---------------------------------|-----------------------------------|
| Patent tube  | 58.6% (n = 17)                  | [58.6% (n = 17)]                  |
| Nonvisualized tube   | 20.6% (n = 6)                   | [24.1% (n = 7)]                   |
| Error  | 20.6% (n = 6)                   | [17.2% (n = 5)]                   |
| Patent tube by laparoscopy with chromopertubation or nonvisualized air-sonohysterography | 17.2% (n = 5)                   | [13.8% (n = 4)]                   |
| Closed tube by laparoscopy with chromopertubation or patent air-sonohysterography        | 3.4% (n = 1)                    | [3.4% (n = 1)]                    |
| Sensitivity  | 85.7%                           | [87.5%]                           |
| Specificity  | 77.2%                           | [80.9%]                           |
| PPV  | 54.5%                           | [63.6%]                           |
| NPV  | 94.4%                           | [94.4%]                           |
| Kappa  | 0.53                            | [0.61]                            |

\*Results are presented with the “released tube” considered open in the left-sided results and with the “released tube” considered closed in the right-sided results (brackets).

**Table 4:** Air-Sonohysterography Versus Hysterosalpingography (3 Patients, 6 Tubes)

|  |   |
|--|---|
| Patent tube  | 2 |
| Nonvisualized tube   | 1 |
| Error  | 3 |
| Patent tube hysterosalpingography or nonvisualized air-sonohysterography | 2 |
| Nonvisualized tube hysterosalpingography or patent air-sonohysterography | 1 |

within the uterine cavity, and three patients had synechiae. All polyps and synechiae were removed.

Five patients had cervical stenosis preventing the procedure. We elected to be conservative for these patients since if we had to use cervical block or other analgesic procedures we thought that the patient would benefit more from a laparoscopy. In another patient, the cervix was patulous, and even with the balloon we were not able to establish a seal. This patient was considered to have nonvisualized tubes.

### DISCUSSION

Nonvisualization of both tubes is associated with a much-increased resistance to pushing the piston of the syringe, something rather striking when pushing air instead of saline solution. Attempts at quantifying the pressure difference with a manometer were unsuccessful owing to the clumsiness of the connections to the manometer. This increased pressure is intensely painful.<sup>4</sup> In hysterosalpingography, the pressure that is exerted on the fluid can distend a tube or force contrast agent into a hydrosalpinx. In air-sonohysterography, however, since air is less viscous than both saline solution and contrast medium, air simply refluxes around the balloon. This is easily demonstrated by placing the balloon in the field of view.

Other investigators have used a pediatric Foley urinary catheter instead of an expensive hysterosalpingography catheter.<sup>3,5-7</sup> We have not attempted this, since we only became aware of this idea late in our study.

Seven studies had combined Doppler interrogation with gray scale sonography to improve the demonstration of the tube in cases of nonvisualization.<sup>8-14</sup> We had great expectation that Doppler sonography and in particular power (energy) Doppler technique would be useful to assess the passage of air in the tubes. In practice, power Doppler sonography caused so many artifacts that identifica-

tion of the tubes was more difficult. In order to not extend the procedure and reduce the amount of air injected, we used it only a few times. Color Doppler sonography was less sensitive than power Doppler technique, but it still demonstrated too many flash artifacts, and it did not add to the gray scale image.

Nonvisualization of a tube may result from a spasm during the injection, peritubal adhesion, obstruction, or, more commonly, a difference in permeability between the tubes. Spasms also may occur with contrast sonohysterography, hysterosalpingography, and hysteroscopy.<sup>15-18</sup> If one tube is widely opened, air will go through this tube preferentially, sometimes even if the nonvisualized tube is placed in a superior position after turning the patient on the side contralateral to the obstruction. A similar phenomenon has been described with hysterosalpingography.<sup>3</sup> Therefore, we explained these other possibilities to the patient.

Compared to other procedures, air-sonohysterography causes a lesser degree of discomfort.<sup>19</sup> In at least one case the presence of shoulder pain was a sign of tubal patency. We inform the patient that this may occur so that they view this as a “happy” event more than as a complication. Pain usually subsides within a few hours.

We did not experience any major complications. We were not expecting many complications from the sonohysterography part, since we encountered few in the 798 saline sonohysterographies we had performed, but there was a theoretical risk of insufflation of bacteria with the room air that was used. That risk was considered small since air-sonohysterography is essentially a derivative procedure of the tubal insufflation test (Rubin test<sup>20,21</sup>), and other studies had not detected any infection (see Table 7).

According to the manufacturer’s data sheet the mechanical index for the 7-8 MHz frequencies used ranges between 0.7 and 1.2 (below the safety threshold of 2). The thermal index of soft tissue and the thermal index of bone are both less than 1.9 (below the safety threshold of 2).

**Table 5:** Pregnancies After Air-Sonohysterography (27 Patients)

|                                     | Number | Percent       |
|-------------------------------------|--------|---------------|
| Both tubes patent                   | 22     | 29% (n = 75)  |
| One patent + one probably patent    | 2      | 22.2% (n = 9) |
| Two tubes probably patent           | 1      | 100% (n = 1)  |
| One tube patent + one nonvisualized | 2      | 14% (n = 14)  |
| Both tubes nonvisualized            | 0      | 0             |

Air-sonohysterography allows identification of other uterine abnormalities that are relevant to the management of patient with infertility, including synechiae, polyps, and endoluminal fibroids. The air-sonohysterography is inexpensive, comfortable, and very fast (a few more minutes than a regular sonohysterography).

The disadvantage of the procedure is that it cannot provide information on the morphology of the tubes, whether they are visualized or nonvisualized (salpingitis isthmica nodosa, for instance). As the study progressed and our referring physicians became more comfortable with the results of the air-sonohysterography, there was a tendency to proceed to laparoscopy for patients with bilaterally nonvisualized tubes. Furthermore, air-sonohysterography does not provide any morphologic detail about the endoluminal appearance of the tubes, something that is possible with hysterosalpingography.

Several other techniques have been proposed to assess tubal patency. These include contrast agent sonohysterography (HySyGy),<sup>4,22-33</sup> hysterosalpingography,<sup>3,4,22,24,26,31,34-39</sup> hysteroscopy,<sup>40,41</sup> chromolaparoscopy,<sup>41</sup> nuclear medicine tests,<sup>42</sup> and MR imaging.<sup>43</sup>

Table 6 provides a comparison between the value of air-sonohysterography and other techniques to assess tubal patency.

Transvaginal sonography,<sup>32,33</sup> air-sonohysterography, contrast sonohysterography, and hysterosalpingography all allow detection of uterine and ovarian abnormalities. A few studies have compared the detection rates, and hysterosalpingography detected 6% of laparoscopy-confirmed anomalies whereas air-sonohysterography detected 85%.<sup>6</sup> Other studies compared contrast sonohysterography and hysterosalpingography versus laparoscopy.<sup>31,38</sup> Hysterosalpingography identified 65%,<sup>37</sup> 72.7%,<sup>39</sup> and 77.1%<sup>34</sup> of laparoscopic findings whereas contrast sonohysterography found 90.3%<sup>44</sup> of findings. Laparoscopy can differentiate between endometrial polyp and submucous leiomyomas,<sup>3</sup> can distinguish spasm or intraluminal debris,<sup>3</sup> and can be employed in performing biopsies.<sup>45-47</sup> Air-sonohysterography is a rapid procedure (lasting on average 5 min), compared to hysterosalpingography, laparoscopy, or hysteroscopy. The cost also is much lower since it does not require expensive contrast agent, equipment, or operating room.

Pelvic and shoulder pain occur as frequently with air-sonohysterography as with contrast sonohysterography.<sup>4,23,29-33</sup> Hysterosalpingography requires ionizing radiation and use of iodinated contrast agent and is responsible for pelvic pain,<sup>3,4,31</sup> infections (<1% to 1-2%<sup>48</sup>) and rare embolism of the dye.<sup>3,48</sup> Hysteroscopy combined with fallopscopy

also causes pelvic pain (3.9% of n = 800<sup>49</sup>), uterine perforation and distention, minor bleeding, and endomyometritis.<sup>40,41,50</sup> Laparoscopy causes minor complications (9.8% of n = 234, including infection, injury to blood vessels) and major complications (in 0.4% of n = 32,205<sup>51</sup> (overall rate of complication, 2.6%<sup>51</sup>).

Table 7 compares the results of this study with those of three other studies published in the literature. Two additional studies<sup>7,53</sup> used similar techniques but different patient populations and indications and were not included in Table 7. An additional study by Volpi and coworkers<sup>52</sup> in 1991 appeared to contain preliminary material for their study of 1996 (included in the table) and thus was not included in the comparison.

In conclusion, this study demonstrated excellent agreement with the gold standard (laparoscopy with chromopertubation) in 79.4% of the tubes. In 17% of patients air-sonohysterography could not demonstrate patency of a tube, which will lead to laparoscopy with chromopertubation. In only one tube did the air-sonohysterography overestimate the patency of the tubes.

These results confirm those of other studies in the literature. The combined studies all demonstrate that using air-sonohysterography is the most efficient, rapid, and accurate modality and the least painful method to assess tubal patency. These results suggest that air-sonohysterography may be the first-step procedure of choice in the assessment of tubal patency; and, that if it does not demonstrate patency, the next step may be chromopertubation.

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**Table 6:** Comparison of Air-Sonohysterography and Other Techniques in Assessment of Tubal Patency

|  | Air-Sonohysterography   | Sonohysterography with Contrast Agents  | Hysterosalpingography  | Hysteroscopy + Falloposcopy |
|--|---|---|--|-----------------------------|
| Sonohysterography with Contrast Agents | Not available   | Not available   |  |                             |
| Hysterosalpingography                  | 85% <sup>6</sup>  | Not available   | Sensitivity: 80.3% <sup>4</sup> –98% <sup>5</sup><br>Specificity: 70.1% <sup>4</sup> –15% <sup>5</sup><br>Agreement: Right 94% <sup>6</sup><br>Left 90.4% <sup>6</sup><br>Kappa: Right 0.52% <sup>6</sup><br>Left 0.51% <sup>6</sup><br>Discordance: 55.9% <sup>6,7</sup>                        |                             |
| Hysteroscopy + Falloposcopy            | Not available   | Not available   |  |                             |
| Laparoscopy and chromo-perturbation    | Sensitivity: 85% <sup>14</sup> –85.7%*–90.2% <sup>5</sup><br>Specificity: 77.2%*–83.3% <sup>5</sup> –91.6% <sup>14</sup><br>Agreement: 83.3% <sup>5,2</sup><br>Kappa: 0.53*<br>Discordance: 10% <sup>14</sup> | Sensitivity: 85.2, <sup>22</sup> 90.4, <sup>24</sup> 100% <sup>23</sup><br>Specificity: 55.6, <sup>23</sup> 70.3, <sup>24</sup> 85.2% <sup>22</sup><br>Agreement: 82.5, <sup>25</sup><br>84.4%–85.2% <sup>22</sup> –85.8% <sup>24</sup> –91.6% <sup>23</sup> –86% <sup>5,3</sup><br>Right 88.1% <sup>26</sup><br>Left 85.7% <sup>26</sup><br>Kappa: Right 0.24% <sup>26</sup><br>Left 0.18% <sup>26</sup><br>Discordance: 21.8% <sup>28</sup> –16.9% <sup>4</sup> | Sensitivity: 85.2% <sup>22</sup> –96% <sup>38</sup><br>Specificity: 83.6% <sup>22</sup> –94% <sup>38</sup><br>Agreement: 84.1% <sup>22</sup><br>Kappa: 0.4 to 0.36% <sup>27</sup><br>Right 0.52% <sup>26</sup><br>Left 0.51% <sup>26</sup><br>Discordance: 24% <sup>6</sup> –37.5% <sup>36</sup> | Not available               |

\*Current study.  
 Not available: No study has been found in the literature comparing these two modalities.  
 Sensitivity = 100 · TP/(TP + FN)  
 Specificity = 100 · TN/(TN + FP)

**Table 7:** Comparison Between Air-Sonohysterography Studies

|                              | Current Study (n = 115)*  | Volpi et al <sup>14</sup> (n = 154)   | Chenia et al <sup>6</sup> (n = 71) | Inki et al <sup>5</sup> (n = 32)   |
|------------------------------|---|---------------------------------------|------------------------------------|--|
| Average age (years)          | 31.9  | 31.7 (SD = 4.5)                       |                                    | 31 (SD = 4)  |
| Average infertility (months) | 25.5  | 19                                    |                                    |  |
| Cervical stenosis            | 5   | 3                                     |                                    |  |
| Procedure                    | Saline solution then air  | Air then saline solution              | Air and saline solution            | Air + saline solution then saline solution                                       |
| Hysteroscopy-laparoscopy     | 15 patients<br>29 tubes   | 29                                    | 15                                 | 53 tubes   |
| Sensitivity                  | 85.7 [87.5]   | 85                                    |                                    | 90.2   |
| Specificity                  | 77.2 [80.9]   | 91.6                                  |                                    | 83.3   |
| PPV                          | 54.5 [63.6]   | 89.3                                  |                                    | 94.9   |
| NPV                          | 94.4 [94.4]   | 85                                    |                                    | 71.4   |
| Kappa                        | 0.53 [0.61]   |                                       |                                    |  |
| Agreement                    |   |                                       | 86.6% (26/30 tubes)                |  |
| Discordance                  |   | 10%                                   |                                    |  |
| Disadvantages                | Abdominal pain<br>Shoulder pain<br>One vasovagal reaction<br>No infection | Cramping,<br>shoulder or back<br>pain |                                    | Abdominal pain<br>One vasovagal<br>reaction<br>One shoulder pain<br>No infection |

\*Results are presented with the "released tube" considered open in the left-sided results and with the "released tube" considered closed in the right-sided results (brackets).

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