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Transvaginal sonographic tubal patency testing using air and saline solution as contrast media in a routine infertility clinic setting

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ABSTRACT

Tubal patency testing by transvaginal sonography has been implemented in our infertility clinic since 1991. We report our experience with this technique during the last year of routine outpatient activity. A total of 154 infertile patients, including three patients on two occasions, underwent tubal patency testing by transvaginal sonography; 36 also underwent laparoscopy or hysterosalpingography, with a further three undergoing both. A detailed account of the method used to visualize the passage of air and saline through the salpinx is described. The 'gold standard' for tubal patency was laparoscopy. In any cases that were doubtful or if there was tubal occlusion, laparoscopy was advised.

The diagnoses by transvaginal sonography in the 154 patients consisted of: 106 with bilateral tubal patency (68.8%), 34 with unilateral tubal occlusions (22.1%), and 13 with bilateral occlusion (8.4%); one case was undiagnosed. Tubal disease was present in 25 out of the 36 (69.4%) patients undergoing laparoscopy or hysterosalpingography (69.4%). The sensitivity, specificity, accuracy, positive and negative predictive values were respectively 80, 85, 82.7, 85 and 80% for the 29 patients undergoing transvaginal sonography and laparoscopy. When the number of tubes examined was considered, these values were respectively 85, 91.6, 89.3, 85 and 91.6%. No discordance was observed in the ten patients undergoing hysterosalpingography.

Demonstration of the tubal course relies on a positive contrast medium filling the tubal lumen. Air and saline were successful for this purpose. In our study, the results of tubal patency testing by transvaginal sonography were very similar to those of hysterosalpingography, but differed in about 10% of the cases from those of laparoscopy. The most difficult problem to rule out was distal tubal occlusion without hydrosalpinx. Tubal patency testing by transvaginal sonography can be used safely as a first-step examination of tubal patency. Easy tubal passage can allow medical treatment, while a doubtful or frankly occluded salpinx should be investigated by laparoscopy.

INTRODUCTION

Tubal disease is one of the most frequent causes of infertility[1,2], occurring in up to 30% of infertile patients. When there is tubal occlusion, invasive treatment such as tubal surgery or *in vitro* fertilization (IVF) is required. However, demonstration of tubal patency can allow less invasive treatment.

Transvaginal sonography can detect gross tubal disease[3] and is routinely used for follicular monitoring[4] and oocyte retrieval[5,6]. However, transvaginal sonography alone has, until recently, had no role in detecting normal tubes or demonstrating patency.

Attempts to show tubal patency by transabdominal[7,8] and transvaginal sonography[9–14] have been reported previously, but the technique described in these cases was different from ours. The introduction of the use of the contrast agent Echovist (Schering) has facilitated this technique[15–18]. However, in many countries, it is not available, and so interest in investigating cheaper, non-commercial contrast media has continued.

In our institution, tubal patency testing by transvaginal sonography using air and saline as contrast media was implemented in the routine infertility clinic in 1991. We now report our experience with this technique during the last year of routine outpatient activity and describe in detail the method used to visualize the lumen of the tube.

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MATERIALS AND METHODS

A total of 154 infertile patients underwent tubal patency testing by transvaginal sonography between September 1993 and September 1994. No patient was excluded from the analysis because of unsuccessful visualization of the cavity or of the uterine cornua. In three cases (1.9%), a second confirmatory transvaginal sonographic examination was carried out just before laparoscopy. In these patients, suspicion of tubal spasm could not be ruled out during the first scanning (i.e. there was very easy passage on one side while on the other there was proximal tubal occlusion). Informed consent was obtained from the patients.

An Aloka 680 and B&K 3535 were used with 5- and 7.5-MHz probes, respectively. The technique in these cases was similar to the one we have described previously[19–21]. All the patients receive antibiotic prophylaxis on the morning of the test and 10 mg Buscopan 1 h prior to the test. A preliminary scan is performed, the purpose of which is to precisely locate the ovaries and the interstitial part of the salpinx (normally the salpinx will have an oblique course from the interstitial part towards the ovary). A speculum is then passed, the cervix examined and disinfection performed using chlorhexidine (Savlodil, Zeneca). A catheter is positioned either in the cervical canal or in the uterine cavity. We use the Zinnanti Uterine Injector 2.0 (ZUI 2.0 mm) or the Ackrad catheter (5F). The catheter balloon is filled with 2 ml saline solution. This step is important to ensure complete closure of the uterine cavity, to prevent leakage of saline solution or air, and to prevent the possible withdrawal of the catheter from the cervical canal. A 30-ml syringe containing 15 ml of air and 15 ml of saline solution is prepared. No deliberate mixing of air and saline is required. Air is injected through the catheter before the saline solution. The syringe can then be tilted according to the needs of the operator (i.e. air as a contrast enhancement, saline solution to remove the contrast). Initially, when only air is injected, the lumen of the Fallopian tube is visualized as a continuous or dotted hyperechoic thin line, depending on the size of the lumen in the plane of the scanning probe. In the second part of the test, when saline solution is injected, air bubbles are disturbed and move rapidly through the saline solution. The process of scanning and searching for the salpinges during injection should be methodical and constant. Normally we start at the uterine cornu in a plane that also visualizes the interstitial part of the tube and then scan laterally very slowly during the first part of the examination. In the last part, the flow of air bubbles around the ovaries is observed.

Our criteria for demonstrating tubal patency are as follows:

(1) Passage of air through saline for at least 8–10 s in the interstitial part of the tube, according to Deichert and co-workers[15]. We consider this as the minimum criterion to diagnose tubal patency. It is exclusively used when it is impossible to follow the salpinx laterally towards the ovary.

(2) Visualization of the tube and displacement of air within it by saline solution (Figures 1 and 2).

(3) Detection of air bubbles moving around the ovary (Figure 3). Observation of flow around the ovaries may be possible even without visualization of the whole course of the tube.

(4) Detection of the fluid and air bubbles in the pouch of Douglas (Figure 4).

(5) Color Doppler evidence of the passage of air bubbles. As air passes through the tubal lumen and reaches the ovary, color Doppler signals are intensified in the same way as if caused by the movement of the probe (Figure 5). Therefore, if it is not possible to obtain a clear visualization of the tubal course, enhancement can be synchronized with the pressure pulses which the operator exerts on the plunger of the syringe and waves of color can be observed along the whole course of the tube to the ovary. In our clinic, color Doppler is usually only used if the examination is inconclusive and if the preceding criteria have failed.

Criteria 2 and 3 are the usual and most important criteria we use for demonstrating tubal patency.

Classical tubal patency tests were considered for comparison, but the 'gold standard' was taken to be laparoscopy. For any difficult case or frankly occluded Fallopian

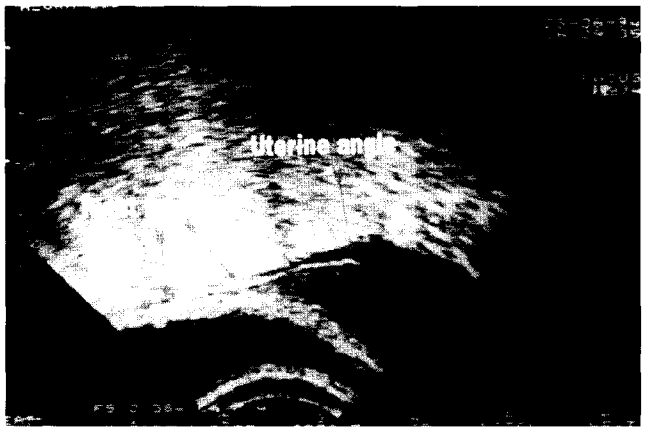

Figure 1 Right Fallopian tube from the uterine angle

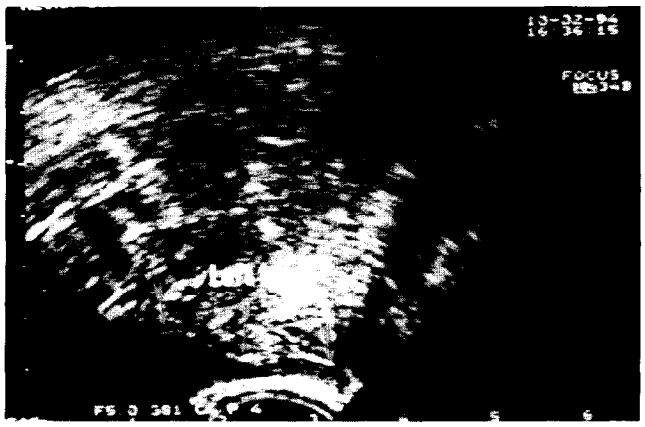

Figure 2 Left Fallopian tube in the lateral part

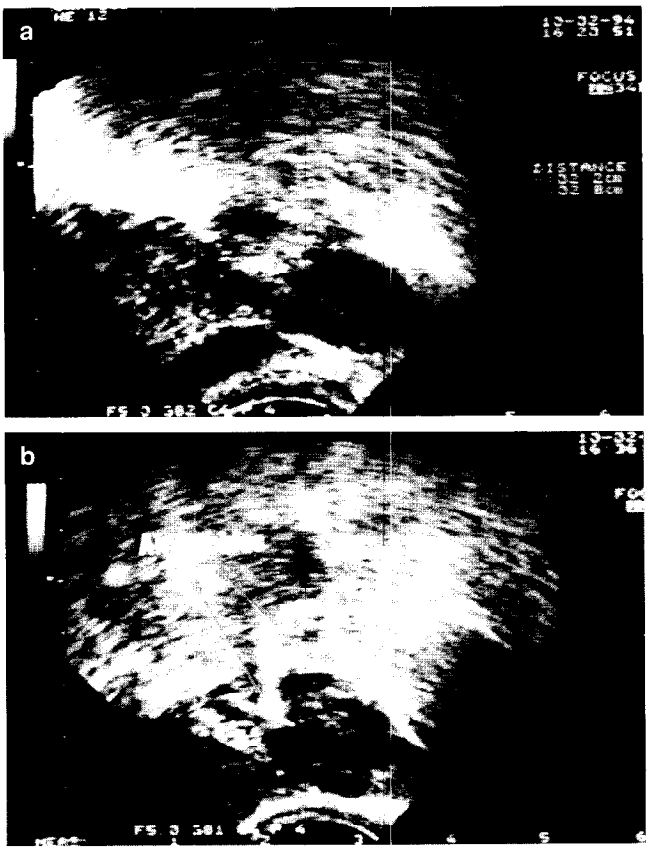

Figure 3 Same ovary in the same patient as in Figure 2 before (a) and after (b) the injection of air

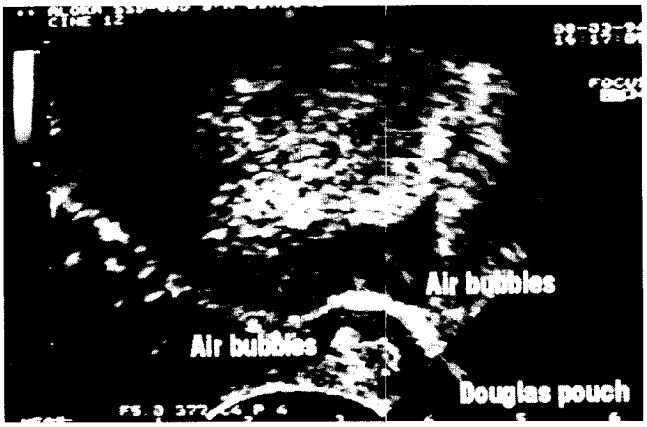

Figure 4 Pouch of Douglas with fluid and air bubbles

tube, laparoscopy was proposed to the patient, but the definitive decision about further examinations was made by the original physician who referred the patient to our center. Results of hysterosalpingography were analyzed before fluoroscopic catheterization was performed. Twenty-nine patients underwent laparoscopy and ten underwent hysterosalpingography; three had both control tests. Hysterosalpingography was always advised to the patient by the referring physician and not by our group.

An Epi-Info[22] file was set up to analyze the data. Both individual patients and individual tubes were considered for data analysis. The tubal patency test was considered to be positive when the tube was occluded.

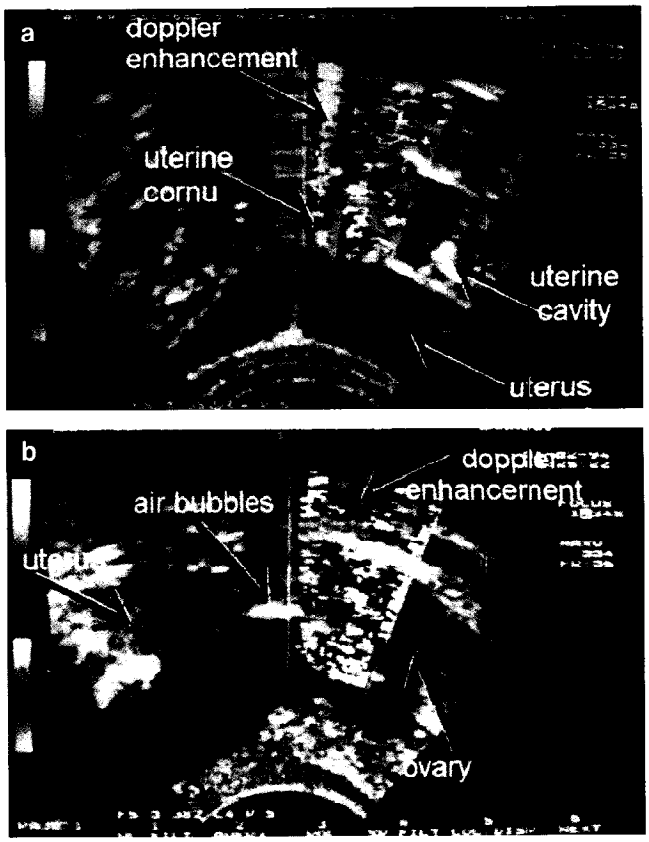

Figure 5 Color-coded visualization of the passage of air through the interstitial part of the salpinx (a) and beside the ovary (b)

RESULTS

The average age of the patients was 31.7 (SD 4.5) years. The median duration of infertility was 19 (range 6–108) months.

A total of 157 tests in the 154 patients was performed. In three cases (1.9%), transvaginal sonography was repeated on the same day as laparoscopy. In three cases (1.9%) it was impossible to achieve a satisfactory placement of the catheter, and so the procedure was postponed until the following month, when in each case the test was performed successfully. In two cases (1.3%), the examination was stopped almost immediately after the beginning of the injection: in one of these cases we diagnosed bilateral tubal occlusion and in one we were not able to predict the tubal state.

In the group of 154 patients, diagnosis by transvaginal sonography revealed: 106 cases with bilateral tubal patency (68.8%), 34 with unilateral tubal occlusion (22.1%), 13 with bilateral tubal occlusion (8.4%) and one case in which it was not possible to assess tubal patency.

Three cases were examined a second time before laparoscopy. Two patients had been diagnosed as having unilateral tubal occlusion and one as having bilateral occlusion at the first test. At the second test, one unilateral tubal occlusion was confirmed, but two cases were not, i.e. three tubes had discordant results. Laparoscopy confirmed the findings of the second test.

In the remaining patients undergoing laparoscopy, three cases of discordance were observed, all due to unilateral distal tubal occlusion. In total, in the 29 patients undergoing laparoscopy, five patients and six out of 56 Fallopian tubes had discordant results. The rate of agreement was 89.3% (50/56) when based on individual tubes, and 82.7% (24/29) when based on the patients.

We did not find any difference in the results between transvaginal sonography and hysterosalpingography (ten patients). In two patients, however, tubal catheterization under fluoroscopic control enabled recanalization of three tubes. Three patients underwent all three tests. In one case, laparoscopy showed distal tubal occlusion on one side when both transvaginal sonography and hysterosalpingography diagnosed bilateral tubal patency.

Tubal disease was present in 25 out of the 36 patients undergoing laparoscopy and/or hysterosalpingography (69.4%).

Table 1 shows the sensitivity, specificity, accuracy, positive and negative predictive values of the testing by transvaginal sonography. Data were calculated in comparison with laparoscopy (29 patients underwent laparoscopy and were analyzed as if the second transvaginal scanning in the three cases was not performed).

The mean duration of the whole examination, including the preliminary scan and positioning of the catheter, was 20–25 min.

Almost all the patients felt some discomfort when the catheter was inserted and the injection was performed. Pain was referred to as cramping, similar to that experienced during menstruation. Unbearable pain was very unusual and only one patient asked the operator to stop the procedure immediately before any diagnosis was made. After the test, many patients reported shoulder or back pain similar to that experienced after hysteroscopy or laparoscopy. No patient had to be hospitalized and all the patients were released within 30 min of the examination. Thirteen patients (8.4%), however, required treatment with Ketoprofen (100 mg, intramuscular injection).

Table 1 Statistics of tubal patency testing by transvaginal sonography vs. laparoscopy and hysterosalpingography for patients and individual tubes. Statistics were evaluated on the 29 patients undergoing laparoscopy, considered the 'gold standard' for patency testing. There were 36 cases with 39 investigations. Three patients underwent laparoscopy, hysterosalpingography and transvaginal sonography. *Two patients had a single tube because of salpingectomy

		Tubes	
	Patients	*Agreed*	*Non-agreed*
Laparoscopy			
Agreed	24	46*	
Differed			
partially	4	4	4
totally	1	0	2
Total	29	50	6
Hysterosalpingography			
Agreed	10	18	
Differed	0	0	
Total	10	18	
Statistics on patients undergoing laparoscopy			
Sensitivity	80% (12/15)	85% (17/17+3)	
Specificity	85.0% (12/14)	91.6% (33/33+3)	
Accuracy	82.7% (24/29)	89.3% (50/56)	
PPV	85.0%	85%	
NPV	80%	91.6%	

PPV, positive predictive value; NPV, negative predictive value

DISCUSSION

Demonstration of tubal patency can be reliably made sonographically only by observing air bubbles flowing through the tubal ostium to the interstitial part of the tube for 8–10 s (minimum criterion for patency). Demonstration of the length of the tube is possible, however, only if a positive contrast medium fills the tubal lumen. In our experience, air has been satisfactory in achieving such a result. Although others have demonstrated the passage of some air bubbles[11,13], we were the first to describe the use of as much as 15 ml pure atmospheric air[20]. By this means, the tubal course can be followed laterally in a high percentage of the patients, and flow can be detected in the tubal lumen and in the area around the ovary. These criteria for showing tubal patency are the most important in our experience. The procedure is easier if the uterus is small and at least part of the Fallopian tube is straight.

Demonstration of the tubal course depends not only on the location of the tube but also on the experience of the operator. We believe that efficient scanning can be achieved following some scanning experience, but that performing 20 examinations, as suggested for Echovist (Schering)[17], is not sufficient reliably to follow the tubal course laterally. We consider 20 examinations to be an adequate number to visualize the interstitial part of the salpinx consistently. Learning to scan the tube can be achieved by trying to locate the intramural part of the salpinx in every patient and then detecting the ovary by following the broad ligament laterally.

The use of air as a contrast medium should not be dangerous, because of the very small dose involved (15–20 ml). Allahbadia described a similar technique and reported no side-effects in his series[13]. A much larger dose of carbon dioxide is needed to perform hysteroscopy. A study using hysteroscopy has demonstrated that carbon dioxide flowing at a speed of less than 400 ml/min is safe in the dog[23]. Furthermore, in *in vitro* fertilization, a mixture of carbon dioxide with 90% nitrous oxide has been used to perform oocyte retrieval by laparoscopy[24,25], to overcome the problem of acidemia occurring during carbon dioxide insufflation. It is also possible to use carbon dioxide to enhance the contrast in the tube, but using a hysteroscopic insufflator can make the examination difficult, since a double-lumen fitting connection is required. Also, the operator would not have the same sensation of pressing the plunger to overcome the resistance of the tubal ostium. It has also been reported that air bubbles exceeding 8 μm do

not pass the pulmonary capillary bed[26]. In our series, although some patients did report shoulder pain, complications due to gas injection were minimal.

In our experience, the results of transvaginal sonography were very similar to those of hysterosalpingography, but the diagnosis differed in about 10% of the cases from those of laparoscopy. Discrepancies up to 45% between hysterosalpingography and laparoscopy have been reported[27–30]. Therefore, we may consider our results to be satisfactory for the routine use of tubal patency testing by transvaginal sonography, at least as a first-line ambulatory test. The most difficult problem to exclude was distal tubal occlusion without hydrosalpinx. Also, tubal spasm may give a false-positive result. A second transvaginal sonographic examination can rule this out before the patient undergoes laparoscopy. Since the test is easily repeatable without impairment of reproductive potential, transvaginal sonography could be performed twice before resorting to another classical tubal patency test. Adhesions are an important problem to rule out and both transvaginal sonography and hysterosalpingography have important limitations in detecting them[28–31], even if published results are not always in agreement[32]. A specific diagnosis of adhesive disease may be suggested indirectly by displacement of saline solution from the pouch of Douglas[19], or achieved by the Sion procedure as described by Allahbadia[13]. Hysterosalpingography has many disadvantages, but in some centers this technique permits selective tubal catheterization, which can recanalize some tubes and overcome spasm[33,34]. In our clinic, however, we decided to advise laparoscopy for the patients.

The first sonographic results reported[7,8] were obtained by transabdominal sonography and were limited to the observation of fluid in the pouch of Douglas. We believe that this method is not acceptable today. The results of our experience are very similar to those reported by Deichert and Degenhardt[17], who reported concordance of about 85–90% for salpinges examined using Echovist (Schering). Also, Huneke and colleagues[18] reported a concordance rate of 88% using the same sonographic contrast agent. According to Tufekci[14], complete concordance could be achieved in 76% of the cases using only saline solution as a contrast medium. In our series, this rate is confirmed by our accuracy for the total number of cases which was 82.7%. Similar results have been reported by Yarali and associates[10] and Allahbadia[13], also using saline solution. Lower concordance rates of about 70% had been reported by Deichert and colleagues[15] in their first paper using saline solution and by Mitri and co-workers[9]. Both these reports concluded that a simple sonographic approach for testing tubal patency was worthwhile as a first-line test.

Our technique is similar to the one described by Allahbadia[13] for the Sion test. In the Sion test, air is not injected before saline solution and the introduction of air in the first part of the examination allows better detection of the salpinx laterally. In the second phase, removal of the contrast by saline solution mixed with air bubbles permits the visualization of movement in the tubal lumen. We do not fill the pouch of Douglas as in the Sion procedure after tubal patency has been tested. We use color Doppler sonography only rarely to assist in the detection of patency, whereas other authors[10,12,13] use it as a first line. We firmly believe that implementation of tubal patency testing by transvaginal sonography in the routine infertility clinic can be achieved without color Doppler ultrasound.

We would like further to stress the advantages of an ultrasonographic approach to tubal patency testing, which has been previously discussed by Campbell and co-workers[17]. All the necessary equipment and expertise are present in any infertility clinic. Furthermore, the same clinicians will very frequently perform laparoscopy in the same patients. This technique may also help in the detection of uterine abnormalities such as malformations and myomata.

One of the main problems of transvaginal sonographic tubal patency testing is reporting the results to other clinicians. Photographs are not always sufficient to show the tubal course, the examination being dynamic and the images still. The problem may be overcome by producing a video recording of the examination and giving it to the patient. Our policy so far has been to record every transvaginal sonographic tubal patency test and store it to discuss it with the referring physician should it be necessary. The introduction of sonographic contrast media, such as Echovist, will improve the images, but the technical problems for scanning and preparation of the patients will remain the same.

In conclusion, tubal patency testing by transvaginal sonography has been used safely in over 150 patients as a first-step examination of tubal patency and to decide whether or not to perform a second test in selected cases. In our experience, the test was well tolerated by the patients and an acceptable rate of concordance with classical tubal patency tests, such as laparoscopy and hysterosalpingography, was achieved. The test is very inexpensive, relatively fast to perform and all the necessary experience and materials are already available in an infertility clinic setting; therefore, we believe that tubal patency testing by transvaginal sonography can be implemented routinely, although we admit that larger studies are needed to confirm these promising results. If patency is easily demonstrated, medical treatment can be instituted without further investigations. A suspicion of tubal occlusion requires established tests (for example, laparoscopy and dye intubation) to confirm the diagnosis and a doubtful result requires repeat transvaginal sonographic testing.

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