Evaluation of the performance of fertiloscopy in 160 consecutive infertile patients with no obvious pathology

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We have defined fertiloscopy as the combination in one investigation of transvaginal hydropelviscopy, dye-test, optional salpingoscopy, and hysteroscopy, performed on an outpatient basis under local anaesthesia or neuroleptanalgesia. We have applied this approach in a routine manner to 160 infertile patients with no obvious pathology. Fertiloscopy was achieved in 154 patients (96.2%). In five patients visualization was not satisfactory because of technical problem or adhesions in the pouch of Douglas. We had one (0.6%) rectal injury, which was treated conservatively. Sixty patients (37.5%) had normal fertiloscopic examination. Endometriosis was discovered in 21 patients (13.1%) post-pelvic inflammatory disease (PID) lesions in 58 cases (36.2%), and subtle abnormalities in 15 cases (9.3%). Salpingoscopy was completed when post-PID lesions were encountered. In 39% of cases only partial examination was possible because of external tubal adhesions, but it was nevertheless sufficient to obtain a good view of the first one-third of the ampulla. In all, 74 patients (46.2%) were referred directly to in-vitro fertilization (IVF) procedures, and so avoided a further laparoscopy. Quality of imaging, accuracy of the pelvic examination in a physiological manner, and safety of the procedure are the main advantages of this minimally invasive technique. Selection of the patients for surgery is therefore enhanced, and indication for IVF is better balanced, avoiding the performance of extensive procedures in patients who should thus benefit from this less traumatic alternative. Key words: fertiloscopy/infertility/laparoscopy/outpatient/ transvaginal hydropelviscopy

Introduction

The diagnosis of unexplained infertility is not very easy, especially when it is necessary to establish the normality of the Fallopian tubes and the relationship between the tubes and the ovaries. Hysterosalpingography (HSG) is very often practised for this purpose, but even in its latest developments such as selective salpingography, this examination is of value only when it shows complete tubal blockage. In other cases, the existence of a degree of patency or apparent normality are very often false negatives, as shown by laparoscopy. Swart et al. (1995) in a meta-analysis found for HSG a point estimate of 0.65 for sensitivity, and 0.83 for specificity, and underline the fact that HSG was not suitable for the evaluation of peritubal adhesions.

In contrast, laparoscopy is the gold standard to explore tuboperitoneal infertility. Nevertheless laparoscopy is very often performed without discovering any significant pathology.

Unfortunately, laparoscopy presents some risks, which can be very serious, as recently shown in the French register of laparoscopic accidents, where six major injuries occurred in diagnostic laparoscopies (Chapron et al., 1997).

The results are either a delay carrying out laparoscopy, which can be prejudicial to the patient, for instance if an IVF procedure is decided on the basis of a wrong diagnosis, or the conducting of a great number of normal laparoscopies, with the potential risks that accompany such procedures.

Other diagnostic methods such as hysterosonography are not sufficiently accurate to support a therapeutic strategy. Culdoscopy could have been an alternative method, but was abandoned in the 1970s.

More recently improvements have been suggested such as the use of dorsal decubitus, (Mintz, 1987), the use of hydrofotation (Odent, 1973), and transvaginal hydrolaparoscopy, which provides very good imaging of the pelvis (Gordts et al., 1998).

Following this work we have defined the concept of fertiloscopy (Watrelot et al., 1997) as the combination at the same time of a transvaginal hydropelviscopy, a tubal chromopertubation, a salpingoscopy (when needed), and lastly a hysteroscopy performed on an outpatient basis under local anaesthesia or neuroleptanalgesia.

The aim of this work was to establish the value of the new approach of fertiloscopy in the management of patients with a suspicion of unexplained infertility.

Materials and methods

Patients

After having performed the 22 first cases of fertiloscopy, between July 1997 and September 1997, we then selected (between October 1997 and June 1998) 160 patients with a history of infertility of at least 2 years, in whom we wanted to know the exact tubo-ovarian status before referring these patients to an IVF programme.

This meant that these patients had had a hysterosalpingography considered as normal, sub-normal (i.e. bilateral patency and acceptable peritoneal spillage), or in some cases showing no tubal impregnation because of a probable tubal spasm. Ovulation was considered satisfactory, sometimes after ovulation stimulation; cervical mucus and semen were also checked and appeared normal.

Fertiloscopy was therefore performed instead of laparoscopy and dye chromopertubation (‘lap and dye’). Patient consent was obtained.
prior the procedure and patients also had the choice of standard laparoscopy instead of fertiloscopy.

The background characteristics of the patients are summarized in Table I. As mentioned, we excluded the 22 first cases, because at this stage laparoscopy was systematically added (performed by a second surgeon) to compare the relative values of fertiloscopy and laparoscopy.

We have previously described the technique using a specially designed disposable balloon introducer (Watrelot et al., 1998). The sequence of steps was as follows: the patient was placed in dorsal decubitus in the normal gynaecological position, a speculum was inserted to expose the cervix, asepsis was by polyvidone iodine (Astra, France), the first balloon introducer (FT 1-29 Soprane SA, France) was put in the uterine cavity, and the balloon inflated with 2–3 ml of air for the chromopertubation and the hysteroscopy. Local anaesthesia with 2 ml of lignocaine plus adrenalin (Astra, Sweden) was performed in the vaginal vault, 1 cm below the cervix, to secure analgesia and to diminish the bleeding of the vaginal mucosa in patients under neuroleptanalgesia. A Veres needle was inserted in the pouch of Douglas and 100–200 ml of pre-warmed (34–35°C) saline solution was instilled. The position of the Veres needle in the pouch of Douglas was controlled by the free injection of saline solution. The second balloon introducer (FTO 1-40 Soprane SA, France) was inserted in the pouch of Douglas; initially this was via a 4 mm incision, but is now performed by direct puncture with a dilatator trocar. The balloon was then inflated with 5 ml of air, using the syringe provided in the fertiloscopy kit.

The role of the balloon was very important in maintaining the introducer in the pouch of Douglas during the procedure, especially when the scope was pulled back to obtain a wider-angle view. The scope was finally inserted through the introducer. We used a 2.9 mm scope with a 30° lens (K. Storz SA, Germany). A single, inexpensive CCD camera was attached to the scope (K. Storz SA). Irrigation was performed through the sheath of the scope under gravity. A total amount of 500–600 ml of saline solution was routinely used. At this time the Pozzi tenaculum and speculum were removed in order to avoid discomfort for the patients under local anaesthesia, and to allow free movement for the scope. Examination started at the posterior part of the uterus, which represents the ‘roof’ of the explored space. Then the adnexae were examined, following every face of the ovaries and every tubal segment. Using the first introducer a dye test with diluted methylene blue was performed. The appearance of blue dye at the fimbria was used to assess the patency of the tube. If any tuboperitoneal pathology was discovered, a salpingoscopy was performed at this stage, using the same scope introduced in the ampulla either directly or after stabilizing the tube with a no. 5 French forceps introduced in the operative channel of the second introducer (FT 1-40). In case of hydrosalpinx a small incision was made using the same operative channel as the salpingoscopy.

After examination of the whole pelvic cavity, the last step was the hysteroscopy, performed with the same scope introduced in the uterus through the first introducer (FT 1-29). Endometrial biopsies were taken at this stage.

If any pathological conditions requiring surgical treatment were encountered, surgical laparoscopy was proposed at the same time (if fertiloscopy was performed under neuroleptanalgesia) or in a second procedure according with the wishes of the patient. If no pathology was found the procedure ended and the patient was discharged 2 h after the procedure, if she had only local anaesthesia. In case of neuroleptanalgesia, the patient was discharged 6 h later. If a surgical laparoscopy followed the fertiloscopy, anaesthesia was completed and the patient stayed 1 night in the hospital.

Every finding was recorded on a special form, and all the procedures were also recorded in real time on videotape (VHS-Pal or Hi-8). The background characteristics of the patients are summarized in Table I. The average time was 16 min (range 11–26). Thirty-eight cases (23.7%) were performed under local anaesthesia, 122 (76.2%) under neuroleptanalgesia; 158 patients (98.7%) were discharged on the same day, two patients (1.2%) stayed overnight and left the hospital the following day. In five cases (3.1%) visualization of the pelvic cavity was not satisfactory (3 cases due to adhesions in the pouch of Douglas, and 2 cases due to a misplacement of the introducer between peritoneum and the vaginal wall). In these cases a laparoscopy was performed to determine the pelvic status (which was normal in the 2 cases of misplacement, and confirmed severe pelvic adhesions in the other 3 cases). In one case (0.6%) a rectal injury occurred. No treatment was applied except antibiotics for 2 days. Thus in all, 154 of 160 (96.2%) patients were correctly documented.

Endometrial biopsy was routinely performed at the time of hysteroscopy. In six cases (3.7%) chronic endometriosis was found, in two cases (1.2%) endometrial polyps were removed and in one case a synchie was treated. All the fertiloscopic parameters were considered as completely normal in 60 cases.

<table>
<thead>
<tr>
<th>Table I. Clinical characteristics of the 160 patients studied</th>
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<tr>
<td>Characteristics</td>
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<tr>
<td>Age (years)</td>
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<tr>
<td>Number of years of infertility</td>
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<tr>
<td>Patient with primary infertility (%)</td>
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<td>Patients nulliparous (%)</td>
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*Values are medians (range).

Results

In total, 160 fertiloscopies were performed. The results are summarized in Table II. The average time was 16 min (range 11–26). Thirty-eight cases (23.7%) were performed under local anaesthesia, 122 (76.2%) under neuroleptanalgesia; 158 patients (98.7%) were discharged on the same day, two patients (1.2%) stayed overnight and left the hospital the following day. In five cases (3.1%) visualization of the pelvic cavity was not satisfactory (3 cases due to adhesions in the pouch of Douglas, and 2 cases due to a misplacement of the introducer between peritoneum and the vaginal wall). In these cases a laparoscopy was performed to determine the pelvic status (which was normal in the 2 cases of misplacement, and confirmed severe pelvic adhesions in the other 3 cases). In one case (0.6%) a rectal injury occurred. No treatment was applied except antibiotics for 2 days. Thus in all, 154 of 160 (96.2%) patients were correctly documented.

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<table>
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<th>Table II. Global results of 160 fertiloscopies</th>
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<td>Findings</td>
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<tr>
<td>Failure</td>
</tr>
<tr>
<td>Complications</td>
</tr>
<tr>
<td>Normal</td>
</tr>
<tr>
<td>Endometriosis</td>
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<tr>
<td>Post PID lesions</td>
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<tr>
<td>Subtle abnormalities</td>
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<tr>
<td>Total</td>
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PID = pelvic inflammatory disease.
(37.5%). As previously mentioned, due to a complication or instrumental misplacement, we had no correct information in six cases (3.7%).

In the remaining 94 cases, various pathological conditions were found. Endometriosis was discovered in 21 cases (13.1%). According to the AFSr classification, endometriosis was noted as stage I in 10 cases (6.25%), stage II in five cases (3.1%) stage III in three cases (1.8%) and stage IV in three cases (1.8%). A subsequent laparoscopy was performed.

Post-pelvic inflammatory disease (PID) lesions were found in 58 cases (36.2%). Tubo-ovarian adhesions were present in 27 cases (16.8%) associated with a phimosis in 17 cases (10.6%) and with a hydrosalpinx in eight cases (5%). Proximal obliteration of both tubes was found in four cases (2.5%), and bifocal localization (i.e. distal and proximal lesions) in two cases (1.2%).

Salpingoscopy was performed only when post-PID lesions were encountered because it was assumed to be normal in other cases. In 58 cases, 11 salpingoscopies (18.9%) were possible by entering directly in the ampulla without the need to stabilize the tubes. Using a grasping forceps introduced in the operative channel we performed 24 complete (up to the isthmo-ampullary junction) salpingoscopies (41.3%). In 21 cases (36.2%) salpingoscopy was considered as incomplete due to inability to enter more than 1–1.5 cm into the ampulla, which was fixed by extra-tubal adhesions. However, a satisfactory inspection of the folds was sufficient to decide whether or not to send the patient for surgery. In two cases (3.4%) of hydrosalpinx salpingoscopy failed because of the impossibility of opening the tube, which had a thick wall. Salpingoscopy was considered as normal in 44 cases (75.8%). In nine cases (15.5%) minor decreases in the folds were found and surgery was indicated. In five cases (8.6%) intra-ampullary adhesions and the thickness of the tubal wall precluded these patients from tubal repair.

According to the classification of Yablonski et al. (1990), some subtle abnormalities were found in 15 cases (9.3%). There were para-tubal cysts (more than 1 cm in diameter) in 10 cases (6.2%), sacculations in three cases (1.8%), and diverticulae in two cases (1.2%). No evidence of congenital phimosis was found in this short series.

According to the findings, therapeutic decisions (Table III) were that for the 60 patients having a normal fertiloscopy, IVF procedure was proposed. (In fact two patients became pregnant normally in the following 2 months.) Also, 14 (8.7%) patients were referred directly to the IVF programme. In seven cases it was due to the severity of tubal damage. In three cases it was for stage 4 endometriosis according to the AFSr score. In the four remaining cases, pathological findings were reckoned to be so minor that they would not have any influence on the patient’s fecundity (2 cases of peritubal cyst and 2 of slight peritubal adhesions); therefore these patients also went into the IVF programme. Thus, in all, 74 (46.2%) patients avoided further laparoscopy after fertiloscopy.

In the other 86 (53.7%) cases, the surgical option was preferred. This was a surgical laparoscopy immediately following the fertiloscopy in 52 (32.5%) cases, and delayed laparoscopy in 24 (15%) patients who had fertiloscopy under local anaesthesia. Among the laparoscopies performed at the same time as fertiloscopy, we have added the six performed as a result of failure of the fertiloscopy. When laparoscopy followed the fertiloscopy, the findings were always confirmative in the cases of PID lesions and subtle abnormalities.

In cases of endometriosis, one patient classified as stage II during the fertiloscopy, was reclassified as stage III because of a deep ovarian localization not previously noted. In three cases, additional foci of endometriosis were discovered in the anterior cul-de-sac, but these did not affect the initial AFSr score.

In four cases (2.5%), a laparotomy for proximal microsurgery of the tube was carried out, after an unsuccessful attempt at recanalization using a Falloposcope (Conceptus CA, USA).

### Discussion

Our study confirmed earlier studies using this technique (Watrelot, 1997; Gordts, 1998a). The failure rate was low, most cases occurring in the early attempts. It was even lower than those accepted in classical culdoscopic (4% for Hall, 1967) and in transvaginal hydrolaparoscopy (3 failures in 28 attempts for Gordts et al., 1998a). The difference is probably due to the increasing expertise of the surgeons, because in our hands also, failures mostly occurred at the beginning of our experience.

Moreover respect for contraindications and the practice of preoperative ultrasonography and clinical examination kept the complication rate low. We had only one rectal perforation in a patient with a deep endometriotic infiltration of the rectovaginal septum. This patient was probably badly explored because infiltration was clinically rather evident. Perforation was extraperitoneal and was therefore treated conservatively after laparoscopic control of the peritoneal integrity. This perforation occurred early in our work (case no. 26) at a time where the trocar was inserted directly into the pouch of Douglas. After that we used the Veres needle to create a ‘hydric space’. Therefore the penetration of the trocar became safer, and we had no more complications of this kind. We think that with some training, a strict respect to contraindications and of the different steps of the technique, and the help of clinical and ultrasonic examination, any rectal injury should be avoided in future.

We had no case of infection, which is a potential risk. Nevertheless this risk has to be taken in account in patients with post-PID lesions. Prophylactic antibiotic therapy at the

### Table III. Follow-up after fertiloscopy in 160 patients

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<thead>
<tr>
<th>Therapeutic option</th>
<th>n</th>
<th>%</th>
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<tbody>
<tr>
<td>No other surgical investigation</td>
<td>74</td>
<td>46.2</td>
</tr>
<tr>
<td>IVF when normal fertiloscopy</td>
<td>60</td>
<td>37.5</td>
</tr>
<tr>
<td>IVF for too damaged tubes</td>
<td>14</td>
<td>8.7</td>
</tr>
<tr>
<td>Subsequent surgical management</td>
<td>86</td>
<td>53.7</td>
</tr>
<tr>
<td>Immediate laparoscopy</td>
<td>52</td>
<td>32.5</td>
</tr>
<tr>
<td>Immediate laparoscopy for failure</td>
<td>6</td>
<td>3.7</td>
</tr>
<tr>
<td>Delayed laparoscopy</td>
<td>24</td>
<td>15</td>
</tr>
<tr>
<td>Laparotomy</td>
<td>4</td>
<td>2.5</td>
</tr>
</tbody>
</table>
time of fertiloscopy may avoid such infection. In all, our complication rate is no higher than the 2% reported in culdoscopy (Billingsley et al., 1963).

The risks of laparoscopy are very well established (Chapron et al., 1997). The fertiloscopic approach to infertility is very safe compared to the laparoscopic approach as there is no risk of injury to large vessels, the Trendelenburg position is not required, nor is CO₂ pneumoperitoneum with its risks of acidosis.

In comparison, fertiloscopy is a more physiological approach; there is no need to mobilize the tubo-ovarian structures so they can be observed in their normal positions. Quality of vision is excellent due to presence of fluid in which structures are freely floating. We confirm, for instance, that, as previously described (Gordts, 1998b), ovulation is rather frequently observed; in our series, we have documented ovulation in five cases without especially looking for it. The visualization of follicular fluid reaching the fimbria, the movement of the fimbria 'embracing' the ovarian follicle in slow motion show clearly that fertiloscopy does not perturb the tubo-ovarian physiology at all. It also means than in the future, fertiloscopy could be helpful to understand better the ovum pick-up phenomenon; we have for instance observed in one case the migration of follicular fluid from one ovary to the contralateral fimbria. Further studies will perhaps allow us to determine the minimum requirement for tubo-ovarian relationship, in order to obtain pregnancy as previously established in animal models (Beith and Winston, 1981; Watrelot and Regnier, 1983).

The value of salpingoscopy in selecting the patients for surgery is now well established (Brosens, 1996; de Bruyne et al., 1997).

Fertiloscopy also seems to be the best way to practice salpingoscopy. We have seen that because of the operative channel, salpingoscopy was possible in 97% of cases. Even if the isthmo-ampullary junction was not reached in 40% of cases, we obtained sufficient information to detect intra-ampullary adhesions, decrease of the folds or abnormal thickness of the tubal wall in every case. The procedure seemed surprisingly easy to perform, especially in comparison with salpingoscopy performed during a laparoscopy, where a second scope with additional light and irrigation are required. This probably explains the low rate of systematic salpingoscopy reported during laparoscopy. By using the same scope and its light and irrigation supply, salpingoscopy during fertiloscopy can be performed routinely and takes only a couple of minutes. If in some cases salpingoscopy is possible without maintaining the fimbria, in the majority of cases tubes have to be stabilized using a grasp forceps introduced through the operative channel. It is also through the operative channel that instruments such as scissors allow us to perform light procedures such as limited adhesiolysis.

Operative fertiloscopy is still under development, but seems promising for limited procedures and should reduce the number of operative laparoscopies for minor diseases. Best quality visualization is restricted to the posterior part of the uterus, but it is uncommon for pathology of the anterior part of the uterus only to be involved in infertility. It has also been stated that visualization is not panoramic. This may have been true at the beginning, but with the aid of the balloon introducer it is now possible to go out to the limit of the vaginal wall and thus obtain a good wide-angle view. Another risk is overestimation of the size of the lesions encountered because of the magnification of the scope at close distances. This is the case for para-tubal cysts, for instance, which can appear larger than they are. Increasing experience of the surgeon can overcome this problem, and at the beginning we recommend comparison of the size of structures that are easily measured by ultrasound, such as ovaries, with that observed during fertiloscopy.

Lastly, due to the lack of findings (3.7% of pathological aspects), endometrial sampling is not carried out systematically, but should be restricted to cases of suspicion of abnormalities in the uterine cavity on the HSG.

The acceptance of this procedure seemed very good, with the majority of patients declaring that they were ready to undergo a second procedure if necessary.

In our series, the majority of procedures (76.2%) were performed under neuroleptanalgesia. It was the result of a double choice from the patient, first of all because procedures under local anaesthesia are not very developed in France, and secondly because the patient often asked for a one-time procedure and wished to have laparoscopy at the same time if needed. The patients who opted for local anaesthesia were nevertheless satisfied. Only five of 23 (21.7%) had mild discomfort during the procedure. The only negative point was the level of stress, which was noted as high or quite high, due probably to the fact that French regulations require us to practise any surgical procedures in an operating theatre, which is known to be stressful for patients. In countries where regulations are different, fertiloscopy can be practised routinely under local anaesthesia as an office procedure. Nevertheless, in contrast to the majority of laparoscopies, fertiloscopy is regularly performed on an outpatient basis. In all, fertiloscopy allowed us to avoid 46.2% of unnecessary laparoscopies. The remaining 53.8% of patients underwent a further laparoscopy but in doing so were given a chance to become pregnant without being referred to an IVF procedure. This underlines once again the interest of salpingoscopy to select carefully the cases that can benefit from surgery. We consider that this study, even if preliminary, shows that fertiloscopy has a high level of acceptance among patients, and good feasibility and reproducibility in a fast and safe manner. It is a diagnostic sequence giving, in a one-time procedure, a complete and informative status of the uterus, tubes, ovary, and peritoneum. We used fertiloscopy in a routine manner in patients with no obvious pathology because it seemed that it was in this indication that the procedure could be most useful. In fact we think the technique can also be useful in other situations, as a second-look procedure after tubal surgery, to avoid a second laparoscopy, and for the selection of patients with evident tubal pathology, using salpingoscopy. However, we had too few cases with these indications to conclude anything further at present. This is why we have recently launched an international multicentre study on fertiloscopy to reach conclusions on a more sound basis.
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Received on July 29, 1998; accepted on November 23, 1998.