

Fertiloscopy – An Overview

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Abstract

BackgroundThe introduction of fertiloscopy has revolutionized the investigation and treatment of patients with unexplained infertility. Hitherto, this group of patients have been either been subjected to ineffective treatment, or been 'over treated'.
TechniqueAs fertiloscopy is a relatively new technique, it is essential for practitioners to be educated regarding the proper techniques in order to carry out the procedure successfully with minimal complications. The five important steps in fertiloscopy are described in detail.
Evidence Acquisition/ JustificationA multicentre prospective randomized study (FLY) was conducted to compare both fertiloscopy and laparoscopy as first line investigations for infertile patients. The conclusion of FLY study was that: "Fertiloscopy should replace laparoscopy in infertile women with no obvious pathology".
ConclusionFertiloscopy is at least as accurate as laparoscopy and dye test, with less risk and morbidity. In addition, fertiloscopy allows the evaluation of tubal mucosa. Hence, fertiloscopy should be seriously considered as the first line investigation for infertile patients.

BACKGROUND

The management of unexplained infertility has always been challenging. This is because if the cause of infertility is not established, treatment decision is basically based on therapeutic trial. This is far from ideal and will subsequently result in emotional, physical and financial strains. The diagnosis of unexplained infertility is established classically when no pathology is found with regards to the sperm quality, ovulation and the tubal patency. The status of tubal patency is frequently established by performing a hysterosalpingography (HSG) or an ultrasonography (USG), both of which have been proven to be inaccurate (1).

In general, most patients with 'unexplained' infertility are treated with either one of these intervention strategies:

- By offering a few cycles (often 3-6) of stimulated or unstimulated intra-uterine insemination [IUI] to see whether pregnancy occurs; if pregnancy does not occur, IVF will be offered. In these cases, IUI has wasted both the patient's time and the resources ;
- By offering IVF immediately, because of the possibility that IUI will not work for these group of patients. However, patients may run the risks of being 'over treated' and hence this approach may not be cost-effective.

A third alternative is by offering an abdominal laparoscopy. This is the currently the accepted "gold standard" for establishing causes of infertility due to pathologies in the fallopian tubes or the pelvis structures surrounding the uterus.(2,3) However, laparoscopy is a non-trivial surgical procedure with significant risks. Very often, no significant pathology is found during this procedure (negative laparoscopy), which means that patients are subjected to a surgical procedure which carries no extra benefit to them at both diagnostic and therapeutic level. Laparoscopy very often fails to identify pathology in tubal mucosa which can be detected via fertiloscopy, a procedure which allows salpingoscopy, microsalpingoscopy and tubal mucosal biopsy to be performed in the same setting.

Complications occur in about three out of every 1,000 abdominal laparoscopy.(4) These complications include:

- those related to general anaesthesia;
- injury to blood vessels or organs, resulting in haemorrhage and blood loss;
- injury to vital structures such as bowel, urinary bladder and ureter.

The risks and trauma associated with laparoscopy as well as the possibility of an unnecessary negative laparoscopy (because the woman has no relevant disease) make doctors

and patients understandably cautious about carrying out laparoscopy at an early stage. On the other hand, the failure in identifying the cause of the patient's 'unexplained' infertility may result in unnecessary treatment (for example, IVF which could have been avoided) or ineffective treatment (for example, intra-uterine insemination for a woman with blocked fallopian tubes or with tubal mucosa damage).

Therefore, it seems interesting to find an alternative which is safe, less invasive and reproducible with a relatively low cost. We thus introduce the concept of fertiloscopy in 1998 after the first work of Gordts on Transvaginal hydrolaparoscopy (THL).(5,6,7) This technique is almost equal to performing a laparoscopy through the vagina using saline solution instead of CO₂ as working medium.(8,9)

The main advantages of a fertiloscopy include:

- safety since as neither CO₂ nor Trendelenburg position is required, which translates to minimal cardiopulmonary compromise as seen in conventional laparoscopy
- low complication rate in terms of vascular and bowel injury, and there is virtually no serious or potentially fatal complication
- allowing perfect evaluation of the genital tract especially the fallopian tubes and ovaries which are observed in a true physiological position without any need to manipulate the structures, as required in laparoscopy
- a mini-invasive procedure which can be performed as an office procedure with local anaesthesia or under sedation as an ambulatory procedure.

TECHNIQUE

Prior to the procedure (10), it is essential to carry out a careful vaginal examination. This examination allows detection of pathology in the pouch of Douglas such as nodule of the recto vaginal septum or fixed retroverted uterus. These situations are important contra-indications to fertiloscopy because, when there is posterior endometriosis, there is a higher risk that the rectum will be adhered to the posterior vaginal vault and the risk of rectal injury is high when inserting the trocar. In the case of a fixed retroverted uterus, there is no space to penetrate the pouch of Douglas and very often, bleeding can occur due to trauma to the uterus caused by the veres needle or trochar.

Anaesthesia can either be strict local, or general sedation. Strict local anaesthesia is beneficial to the patients in countries where office surgical procedures are allowed and feasible. In other cases, general sedation is commonly used. Sometimes, patients are given the liberty to choose the mode of preferred anaesthesia. The advantage of general sedation is that operative or therapeutic fertiloscopy can be performed at the same setting when pathology is found.

Strict local anaesthesia is carried out by first inserting an anaesthetic swab (Emla gel) for 10 minutes, and then followed by a classical para-cervical block using lignocaine. General sedation is of the same kind as the one used in oocyte retrieval during IVF. In all cases, fertiloscopy is performed as an ambulatory procedure.

There are five steps in the procedure:

1. Hydropelviscopy
2. Dye test
3. Salpingoscopy
4. Microsalpingoscopy
5. Hysteroscopy

Hydropelviscopy is performed by first inserting a Veres needle into the pouch of Douglas. This needle is inserted 1cm below the cervix, and then saline solution is instilled through a perfusion line using no pressure other than the gravity. When 150-200 cc has been instilled, the Veres needle is removed and replaced by the fertiloscope (FTO 1-40-Fertility Focus Ltd -UK). The sharp end of the fertiloscope allows a direct insertion without any incision. In addition, a balloon fitted at the extremity of the fertiloscope prevents it from being inadvertently pulled out of the peritoneal cavity. The optic is then introduced via the fertiloscope, and the pelvic cavity and structures will be examined. (It is important to use a 30° degree telescope of less than 4mm outer diameter). Practitioners who perform a fertiloscopy for the first time will need some time to get accustomed to it as the view would appear to be inverted. Nevertheless, after a short learning curve, it becomes easy to see all the reproductive structures. It is important to have a systematic view of both ovaries, tubes, ovarian fossa, posterior part of the uterus, uterosacral ligaments and pelvic peritoneum

When the pelvis anatomy has been assessed, a dye test is

performed through the uterine fertiloscope (FH 1-29-Fertility Focus Ltd-UK). Tubal patency will thus be established.

Identification of tubal pathology such as intra ampullary adhesions or flattened mucosal folds is important because in these cases, the only valid therapeutic option is IVF. Therefore we systematically perform a salpingoscopy on both tubes. It is relatively simple to inspect the tubal ampulla using the same scope. Hence, salpingoscopy may be practiced as a routine evaluation which is not usually the case during laparoscopy where a second optic, a second cold light supply and a separate irrigation are needed. (11)

Microsalpingoscopy is a further step. The concept was described by Marconi and Quintana (12) (1998) who clearly demonstrated that after the dye test, the more the nuclei are dye stained by the methylene blue, the more pathological the tube is. (Fig 4-5) Every dye stained nucleus is a damaged cell (either inflammatory or as a result of apoptosis). In order to perform microsalpingoscopy, a special optic is used (Hamou II- K. Storz-Germany) which permits magnification up to 100 times, thus achieving real “in vivo” histology. Findings are classified as normal if none or few dye stained nuclei are seen, or pathological when many nuclei are dye stained. (13)

A standard hysteroscopy (through the same optic) is then performed in order to have a complete evaluation of the reproductive system.

At the end of the procedure, the scar is so small that it is not necessary to close the vaginal puncture site. Antibiotics are not necessary as the risk of infection in fertiloscopy is minimal. Introduction of Veres needle followed by a fertiloscope into the pouch of Douglas raises fear of rectal injury. Even if we have demonstrated that such an injury is avoidable and not of serious consequence, one may prefer to introduce the instrument under vision. In this technique, the instruments are introduced under ultrasound guidance.

OPERATIVE FERTILOSCOPY

In the beginning, fertiloscopy was purely used for diagnostic purposes. However, thanks to the development of operative channel in the Fertiloscope, several therapeutic procedures have been made possible. We can now routinely perform adhesiolysis for the treatment of minimal and sometimes mild endometriosis and ovarian drilling. (14)

In order to become generally accepted, it is important to establish that operative Fertiloscopy is as effective as laparoscopy. However, there are some limitations to

performing more complex therapeutic procedures using a fertiloscope. (15) The operative channel is unique, small (5 French, 1.5 mm diameter) and because of this, only relatively limited adhesiolysis can be performed (especially when adhesions are found between distal part of the tubes, ovaries and ovarian fossa). Similarly, endometriotic lesions can be treated only when they are minimal or moderate in severity.

Another challenge that we face is to ensure that bleeding during operative fertiloscopy is kept at a minimum level since even a small amount of blood will obscure the field of vision. For this reason, very careful haemostasis is necessary. For this purpose, a bipolar probe which is able to work in the liquid environment is essential. Several such probes are available in the market and we mostly use the disposable Versapoint (Gynecare-USA). For all these reasons, it is therefore evident that operative fertiloscopy is not designed to compete with operative laparoscopy: it is only an additional tool which may in some cases avoid unnecessary laparoscopy.

JUSTIFICATION OF FERTILOSCOPY

The fundamental question is to establish whether fertiloscopy is as accurate as laparoscopy, which was once considered as the “gold standard” in infertility investigation.

In order to answer this question, we designed a special study: the FLY study (acronym for fertiloscopy versus laparoscopy) (16). This was a multicentre prospective randomized study in which first fertiloscopy and then laparoscopy were performed on the same infertile patient by two surgeons A and B who are randomized for the procedure. Every procedure was video-recorded, the files being reviewed by two independent reviewers. This trial was approved by the French ethical committee under the Huriet law. Fourteen teaching hospitals centres were enrolled (12 in France, 1 in Belgium and 1 in Tunisia), and 92 patients were studied.

Calculation of sensitivity and specificity was performed as well as concordance test using kappa score on the results from 6 sites (both ovaries, tubes, peritoneum), the total number of sites for analysis being 552 (92 X 6). The kappa score varied between sites from 0.75 to 0.91

A correlation between two diagnostic tools is considered as excellent when kappa score reaches 0.75 or more. The conclusion of FLY study was that: “Fertiloscopy should replace laparoscopy in infertile women with no obvious

pathology”.

So, should fertiloscopy be used as a first line infertility test? For many years now, we are looking for a simple, reproducible, safe, mini-invasive and relatively cheap method to diagnose pelvic abnormalities in infertile patients. Non invasive tools such as Hysterosalpingography (HSG) and Hysterosonography (USG) or invasive procedures such as laparoscopy are readily available.

However, their ability to assess the four important parameters to be considered in infertility (i.e. tubal patency, tubo-peritoneal environment, tubal mucosa and uterine cavity) is variable. Fertiloscopy seems to be the best method that could give accurate and consistent assessment in all the four parameters, and hence should be considered as the first line infertility test.

STRATEGY FOR FERTILOSCOPY

According to the health system and the legislation concerning office procedure, two different strategies are available:

When office procedure is possible, fertiloscopy may be practiced early in the infertility work-up (i.e. after one year of infertility). In this case, fertiloscopy is performed under strict local anaesthesia. If no abnormalities are detected, then it is logical to practice expectant management until two years of infertility since the chances of pregnancy is 12% per cycle during the second year of infertility. After two years of infertility, the spontaneous pregnancy rate falls to around 5% and it is thus justifiable to propose IUI. If pathology is detected, the patient will be treated accordingly which may be in the form of further surgery in cases of endometriosis or pelvic adhesions, or IVF if the tubes appear to be damaged beyond surgical repair, especially so if the tubal mucosa is severely affected.

When surgical office procedures are not available or permitted, then fertiloscopy is performed under general anaesthesia in an operating theatre prior to the commencement of IUI or IVF (This means after 2 years of infertility except for patients over 38 where only one year of infertility is required or after 40 years where fertiloscopy is directly carried out). In this group of patients, whenever fertiloscopy is normal, patients are referred to Artificial Reproductive Technologies (ART) or treated according to the lesions encountered.

The advantages of local anaesthesia are obvious, and

besides, it is also a cheaper option. General anaesthesia, on the other hand, allows operative fertiloscopy or further laparoscopy to be carried out when required in the same setting. Indeed, the patient may choose between the two options. In general, the earlier the fertiloscopy is offered, the more likely any pathology can be treated and hence improve the chances of pregnancy.

COMPLICATIONS

These are very rare(17) if one respects firstly, the learning curve involved and the limitation of one's surgical skill and secondly, the contra-indications which include the pathology of the pouch of Douglas such as recto-vaginal endometriosis or fixed retroverted uterus. These pathologies are detected by vaginal examination prior to the procedure. Any doubt should lead to cancellation of the procedure and a laparoscopy should be proposed where relevant. The only real complication is possibility of rectal injury. However this injury may always be treated conservatively by antibiotics without the need of further surgical operation (17).

CONCLUSION

Our series demonstrate that fertiloscopy is useful in the diagnosis of tubal diseases which cannot be shown in non invasive exploration such as like HSG. Results of the FLY study have shown that fertiloscopy is at least as accurate as laparoscopy and dye test. However, fertiloscopy is less invasive and less risky when compared to laparoscopy and Dye. Moreover, fertiloscopy allows a careful evaluation of the tubal mucosa. In this respect, fertiloscopy shows superiority over lap and dye. Indeed salpingoscopy allows us to only explore the distal part of the tube. The proximal portion is too narrow to be explored except by falloposcopy which is still experimental due to the poor quality of imaging obtained. This disadvantage is counterbalanced by the fact that the distal part of the tube is not only the more common location where tubal lesions usually occur, but also is the most important part of the tube where most crucial events happen: oocyte retrieval and fertilization.

Microsalpingoscopy seems to have a good prognostic value but will require more studies before it is completely validated. Nevertheless, for the first time an “in vivo histological” appreciation of the tubal mucosa is available.

Patients who have been properly elected for tubal surgery after careful evaluation have pregnancy rates (after 6 months) which are not statistically different from the IVF group (respectively 35.2 and 35.6%). Tubal surgery remains

a valid option after proper selection. In addition, when tubal pathology is discovered, we may propose, in some circumstances, treatment by operative fertiloscopy in the same setting (in our series 105 patients - 40.2%).

At this stage we do believe that fertiloscopy should be widely adopted as a precise mini-invasive tool, as already been demonstrated by several teams. Sharma (3), considered fertiloscopy as a method safer than laparoscopy and which in addition allow salpingoscopy. Tanos, (19) performed 78 fertiloscopies and showed that the learning curve was short and the results were very accurate. More recently, Nohuz and al., (20) performed fertiloscopies in 229 infertile women and discovered a pathology in 28, 6% of cases. These results are similar to those observed in our study.

Fertiloscopy is an attractive alternative to lap and dye when tubal pathology is suspected. Accuracy of fertiloscopic findings has been demonstrated and allows a proper identification of patients with tubal or peri-tubal pathology. In doing so, pregnancy rate after tubal surgery could be the same as after IVF. A spontaneous pregnancy obtained after surgery has many advantages: it is cheaper, more physiological, and when the disease is treated, several pregnancies can be achieved without further treatment.

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