Is laparoscopy still the gold standard in infertility assessment? A comparison of fertiloscopy versus laparoscopy in infertility

Results of an international multicentre prospective trial: The 'FLY' (Fertiloscopy-LaparoscopY) study*

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BACKGROUND: The aim of this prospective multicentre study was to compare the two endoscopic techniques of laparoscopy and fertiloscopy in routine evaluation of the pelvis in infertile women. METHODS: A total of 92 women was selected in 14 University Hospitals to undergo fertiloscopy followed by transabdominal laparoscopy by a team of two surgeons in each hospital. RESULTS: A high degree of concordance was observed between these two techniques, in that if fertiloscopy did not detect any abnormalities, this was also confirmed by laparoscopy. Discordance was observed in similar numbers of cases: eight after laparoscopy and nine after fertiloscopy. The diagnostic index for fertiloscopy and laparoscopy was calculated; sensitivity (86 and 87% respectively) and negative predictive value (64 and 67% respectively) were similar. The kappa index was also calculated for each of the six structures/regions (right/left tube; right/left ovary; peritoneum of pouch of Douglas; posterior uterus), and concordance (0.78 to 0.91) was considered almost complete. CONCLUSIONS: These results confirm fertiloscopy as a minimally invasive safe procedure that may be considered as an alternative to diagnostic laparoscopy in the routine assessment of women without clinical or ultrasound evidence of pelvic disease. On the basis of the additional advantages of fertiloscopy, namely salpingoscopy or microsalpingoscopy, it is considered that fertiloscopy could replace laparoscopy as a routine procedure in such women.

Key words: fertiloscopy/hydrolaparoscopy/infertility/laparoscopy/multicentre trial

Introduction

Endoscopic examination of the female genital tract may be performed via either the abdominal or vaginal route. The vaginal approach was initially proposed in the USA (Decker, 1944) and was subsequently described (Kelly and Rock, 1956) using the term 'Culdoscopy', a technique in which the endoscope is introduced through the posterior vaginal fornix.

This procedure was later abandoned because transabdominal laparoscopy provided a panoramic view of not only the pelvic cavity but also the abdominal cavity, in addition to obviating the need for the knee-chest position, providing better access for surgical treatment, and also reducing the risk of infection. More recently, the concept of hydroculdoscopy was introduced (Odent, 1973); the technique was then modified (Mintz, 1987) to allow a dorsal decubitus position, and the procedure of transvaginal hydrolaparoscopy (THL) was described (Gordts et al., 1998) with abdominal distension with saline and exploitation of the newly developed smaller endoscopes.

The more global concept of fertiloscopy (which includes THL as well as salpingoscopy, microsalpingoscopy and hysteroscopy) was introduced in 1998 (Watrelot *et al.*, 1998a). An examination of the cul-de-sac (pouch of Douglas) in which the ovaries and their relation to the fimbriae of the Fallopian tubes are easily visualized, was the primary purpose of the investigation, as this is where (arguably) the major event in reproduction, oocyte retrieval by the fimbria, occurs.

Consequently, fertiloscopy was proposed as an alternative to diagnostic laparoscopy as the primary endoscopic procedure in the routine assessment of an infertile woman (Watrelot *et al.*, 1998b). Laparoscopy is currently considered to be the 'gold standard' of pelvic endoscopic procedures as it provides not only a panoramic view of the pelvic and abdominal cavities but also the opportunity to perform extensive surgery. More recently, it was emphasized (Brosens *et al.*, 2001) that transvaginal hydrolaparoscopy, from which fertiloscopy was derived, provides the opportunity to demonstrate fine peri-ovarian and peritubal adhesions, which are not easily detected using transabdominal laparoscopy. This statement could be interpreted to mean that laparoscopy should no longer be considered as a 'gold standard'.

As a result of these suggestions, it was felt appropriate to review whether laparoscopy should remain the primary diagnostic endoscopic procedure in the routine surgical assessment of infertile women.

Transabdominal laparoscopy will remain the preferred approach if pelvic pathology requiring surgical treatment is suspected when planning endoscopic surgery. However, as most subfertile women who undergo diagnostic laparoscopy have normal findings, fertiloscopy could be an attractive alternative. First, fertiloscopy has the advantages of simplicity, as it can be performed as an ambulatory procedure under strict local analgesia. This avoids the need for abdominal incisions and subsequent scars, the pneumoperitoneum obviated, and there is almost no risk of vessel injury. Second, it was shown recently that the procedure is considered less painful than standard hysterosalpingography (HSG) (Cicinelli *et al.*, 2001). Third, a greater degree of accuracy in evaluation of the ovaries and the distal region of the tubes is possible because of the high magnification used. Although the feasibility and reproducibility of fertiloscopy as the primary surgical diagnostic procedure has been demonstrated (Watrelot *et al.*, 1999a), there is as yet no prospective evaluation which compares the diagnostic performance of fertiloscopy with that of transabdominal laparoscopy.

The aim of the present study was to establish the diagnostic accuracy of fertiloscopy in relation to laparoscopy in the same patient, and to demonstrate concordance between the two procedures.

Materials and methods

Ninety-two women were recruited in 14 university hospitals (12 in France, and one each in Belgium and Tunisia) to participate in a prospective multicentre cross-sectional study to compare the diagnostic accuracy of fertiloscopy with abdominal laparoscopy in women who were scheduled for diagnostic laparoscopy as part of their routine infertility assessment. Each centre was asked to examine six women; some centres, having performed six procedures before the end of the inclusion period, were permitted to examine an additional six women. Patients were enrolled into the study after having provided their informed, written consent. The study protocol was approved by the Ethical Committee on December 21, 1999 (CCPPRB: comité consultatif pour la protection des personnes; Lyon, Léon Bérard, France). As the intention was to compare the two procedures, each patient acted as her own control. Randomization of the order of the procedures was not appropriate given the potential for laparoscopy to alter/disrupt the pelvic anatomy. Thus, fertiloscopy was performed first as there was either no, or less, risk of modifying the findings during fertiloscopy, it being essentially a 'no-touch' procedure.

Inclusion criteria for the study were: >1 year of infertility in women aged 18–43 years; indication for endoscopic evaluation of the pelvis, typically due to unexplained infertility; anovulation or repeated intra-uterine insemination (IUI) without success; unsuccessful tubal surgery with evidence of patent Fallopian tubes at HSG; or suspected proximal tubal occlusion. All couples underwent a complete infertility assessment comprising HSG, sperm analysis and hormonal profile.

Exclusion criteria included contra-indications either to pregnancy or to laparoscopy, or to fertiloscopy (fixed retroverted uterus, rectovaginal endometriosis, and mass in the pouch of Douglas) and evidence of adnexal pathology diagnosed via clinical examination, ultrasonography and/or HSG. At each centre, the surgical team comprised two surgeons, A and B; both had (perhaps limited) experience in the use of fertiloscopy and laparoscopy.

Instructions regarding the operating sequence of the surgeons were enclosed in a sealed envelope and revealed only after checking the inclusion criteria. Both surgeons agreed only to perform the procedure allocated by the randomization code, and independently completed their own observation sheet. Fertiloscopy was performed according to the technique previously described in detail (Watrelot *et al.*, 1999a) using single-use/disposable devices for fertiloscopy (Transvaginal uterine Fertiloscope® FH 1-29, and Transvaginal Douglas Fertiloscope® FTO 1-40; Wallace Portex, UK). The choice of any endoscope up to 4 mm in diameter, and with a 30° angle, was left to the surgeons. Laparoscopy was performed in a routine manner. The chromopertubation test for tubal patency was performed during both fertiloscopy and laparoscopy, but a smaller quantity of blue dye was injected during fertiloscopy. Salpingoscopy and microsalpingoscopy were optional and not considered in the analysis.

All surgeons were asked to comment in detail on the following six sites, structures or regions: right tube, left tube, right ovary, left ovary, posterior part of the uterus, and peritoneum of the pouch of Douglas. Each finding was to be noted as either normal, or with morphological abnormalities, endometriosis (according to the revised American Fertility Society classification), and adhesions. Tubal patency was noted in both methods.

Those surgeons performing fertiloscopy were asked if they thought a subsequent laparoscopy procedure would provide useful additional information, or could be avoided. Both surgeons were also asked to propose a treatment strategy after their respective procedure: expectant management, medical treatment, surgical treatment, IUI or IVF.

Every procedure was video-recorded on a commercial VHS tape which was sent to the coordinating centre with the observation file. At that time, every video tape was reviewed by two independent observers (C.R. and A.W.) in order to avoid discrepancies between what was written in the files and what was seen on the videotapes. These authors were involved neither in selection of the patients nor in the operative procedures.

Table I. Description of the discordant findings between fertiloscopy/laparoscopy in 17 infertile patients

Discordance negative/positive (n = 9)		Discordance positive/negative (n = 8)	
Patient no.	Finding	Patient no.	Finding
1	Isolated endometriotic peritoneal spot	10	Isolated right endometrial ovarian spot
2	Isolated endometriotic peritoneal spot	11	Uterine adhesions
3	Filmy right ovarian adhesions	12	Adhesions in the right fossa ovarica
4	Ovarian endometrioma	13	Left ovarian adhesions
5	Isolated endometriotic peritoneal spot	14	Left accessory fimbria
6	Isolated endometriotic left ovarian spot	15	Bilateral tubal ampullary sacculation
7	Right medial tubal adhesion	16	Left accessory fimbria
8	Left paratubal cyst	17	Right paratubal cyst
9	Left cornual myoma (1 cm) without tubal obstruction		

C.R. and A.W. together reviewed the observation files and videotapes in order to assess the anatomy of the pelvic structures, using the combination of both endoscopic procedures and controlling that the concordance or discordance described by the surgeons for the six structures/regions and tubal patency in each patient were confirmed by independent observers. They noted as 'negative' when there was no abnormalities (written and seen), and as 'positive' when any abnormality was described. The results were evaluated for each patient and marked as positive/positive or negative/negative for concordant examinations, and as positive/negative or negative/positive for discordant fertiloscopy and laparoscopy. In cases of discordance, the file was carefully re-evaluated in order to determine if the discordance may or may not have any clinical impact. In cases of protocol violation, the decision had to be made to reject the file, for example when the video recording was incomplete.

Statistical analysis

Statistical analysis was carried out using first, a unilateral binomial test in order to verify if the observed discordance rate was consistent with a theoretical rate between 1 and 5%. Second, the χ^2-test (Cochran and Cox, 1957) for paired series was performed to determine the distribution of discordant results.

The main analysis addressed the following: sensitivity and specificity of fertiloscopy versus laparoscopy and laparoscopy versus fertiloscopy. The crude concordance rate between fertiloscopy and laparoscopy was also evaluated, and the Kappa score for each structure/region (left tube, right tube, left ovary, right ovary, peritoneum of the pouch of Douglas, and posterior part of the uterus) was calculated.

Results

Description of the population

A total of 92 files was received between September, 2000 and May, 2001, from 14 centres; each centre forwarded a mean of 6.4 (range 3–12) files. Eleven files were withdrawn because of protocol violation in two cases, incomplete or no video-recording in four cases, and failure to enter the pelvic peritoneal cavity in five cases. Hence, a total of 81 complete case files and videotapes was analysed.

The mean ($\pm$ SD) age for the study population was 32 $\pm$ 4.8 years, and the mean duration of infertility was 4 $\pm$ 2.5 years. Among the women, 55 (68%) had primary infertility.

The primary diagnosis of infertility and indications for endoscopy were unexplained in 45 (56%) cases, tubal in 12 (15%), male infertility in 13 (16%) and ovarian disorders in 11 (14%). No primary diagnosis of endometriosis was made.

Description of endoscopic findings

After pooling data obtained from both the fertiloscopy and laparoscopy procedures, 16 patients (20%) were considered to have strictly normal findings. There were some morphological abnormalities, typically minor, seen in the remaining 65 patients (80%), as follows: 19 patients (23%) had endometriosis; 23 (28%) had adhesions; and 40 (49%) had miscellaneous findings. More than one abnormality was seen in 17 patients. The miscellaneous findings included lesions other than endometriosis and adhesion. Among the 19 patients with endometriosis, 17 had minimal or mild endometriosis (score rAFS <15) and two had moderate endometriosis (score rAFS at 18 and 25). The rAFS score was almost identical in both procedures, except in one case (see below). Adhesions were minimal in 21 patients and extensive in two, and their description was very similar after both procedures. The minimal discordances are detailed below. In the 'miscellaneous' group, in addition to minor findings, two cornual obstructions were diagnosed without discordance between the two methods. In total, among the 81 patients with abnormalities, 23 (28%) presented abnormalities that had a clinical impact (19 cases of endometriosis, two cases with extensive adhesions and two cases with cornual obstruction).

The findings using the two endoscopic methods were strictly concordant in 65 patients (80%), among whom 47 patients showed morphological abnormalities (positive/positive) and 16 had normal findings (negative/negative). There were 17 instances of discordant findings, either negative/positive in nine cases (11%) or positive/negative in eight cases (10%) (Table I).

The discordant findings, which were reported by nine centres, were considered not to have any clinical impact in 16 cases (19.7%). In one case (1.2%), the discordant finding of an ovarian endometrioma, which was not diagnosed on fertiloscopy (case 4 in Table I), was considered to have a clinical consequence.

Table II. Distribution of fertiloscopy findings in 81 infertile women

Procedure	Abnormalities (n)	Normal pelvis (n)	Total (n)
Fertiloscopy +	56	0	56
Fertiloscopy −	9	16	25
Total	65	16	81

Table III. Distribution of laparoscopy findings in 81 infertile women

Procedure	Abnormalities (n)	Normal pelvis (n)	Total (n)
Laparoscopy +	57	0	57
Laparoscopy −	8	16	24
Total	65	16	81

Table IV. Kappa scores for each structure/region investigated with fertiloscopy or laparoscopy

Structure/region	Kappa index	Confidence interval
Right tube	0.91	0.79–1.0
Left tube	0.86	0.75–0.9
Right ovary	0.80	0.63–0.97
Left ovary	0.84	0.70–0.97
Peritoneum	0.78	0.61–0.95
Uterus	0.86	0.73–0.99
Tubal patency	0.80	0.64–0.96

Calculation of diagnostic indices

The sensitivity only of each procedure was calculated. By definition, specificity was 100%, due to the fact that the pelvis was considered normal when both procedures showed no abnormalities. Similarly, the positive predictive value was 100% for both methods.

Fertiloscopy

Morphological abnormalities were noted at fertiloscopy in 56 of the 65 women in whom pathology was identified; this resulted in a sensitivity of 86% [95% confidence interval (CI): 80.5–93.5%]. The negative predictive value was 64% (95% CI: 53.5–74.5%) (Table II).

Laparoscopy

Morphological abnormalities were noted at laparoscopy in 57 of the 65 women in whom pathology was seen; this resulted in a sensitivity of 88% (95% CI: 81–95%). The negative predictive value was 67% (95% CI: 56.5–78%) (Table III).

The differences seen above with respect to sensitivity and the negative predictive value were not statistically significant.

Evaluation of concordant and discordant findings

It was observed that discordance was likely to have clinical consequence only in one woman (1.2%). A one-sided binomial test confirmed that this observed rate was consistent with a theoretical rate of discordance of 1%. The χ^2-test for paired series of MacNemar also confirmed a lack of discordance between fertiloscopy and laparoscopy.

The crude concordance rate was 65/81 cases (80.2%), though when the cases referred to above were taken into consideration the concordance rate was 80/81 cases (98.8%).

Among the 486 items of comparison made (i.e. six items each in 81 women), concordant findings were obtained in 467 (96.1%) and 19 discordant findings in 17 patients (3.9%). Only one discordant site was regarded to have a clinical impact, and this resulted in a concordance rate by site of 99.8%.

Calculation of the Kappa coefficient for each of the six studied structures/regions is listed in Table IV; values ranged from 0.78 to 0.91.

Moreover, tubal patency was estimated as being complete in 130 tubes (which means that patency was described and seen on the videotapes). Patency was positive in both sides in 52 cases (104 tubes), negative in both sides in seven cases (14 tubes), positive (fertiloscopy)/negative (laparoscopy) in four tubes, and negative/positive in two tubes.

Discordances were always limited to one tube; therefore, the concordance was 95.2% and the kappa index 0.80.

Avoidance of laparoscopy

Based on the opinion of the fertiloscopists, laparoscopy could have been avoided in 75 women (93%), seven of whom demonstrated some minor degrees of discordance that were considered to be without clinical consequence. In the only case where a discordance which might have any clinical impact was found, the opinion of the fertiloscopists was that laparoscopy could not have been avoided to complete the clinical evaluation of this woman.

Complications and failures

In five cases (5/92; 5.4%), the pelvic peritoneal cavity was not entered using the Veress needle; one of these patients incurred a rectal perforation that was managed conservatively as recommended (Gordts *et al.*, 2001). One other patient required a suture to be placed transvaginally when a suspected epiploon hernia was noted at the subsequent laparoscopy. Another patient incurred a piercing injury to the posterior wall of the uterus which was managed conservatively. No complications were reported during laparoscopy in this series.

Discussion

The present study refers, for the first time, to a prospective randomized multicentre study where fertiloscopy was compared with laparoscopy. Herein, the procedures were performed by teams of two surgeons who were blinded to the technique which, in turn, was allocated at random. In addition, mandatory video-recording allowed an objective assessment to be made by two independent reviewers of the accuracy of the surgeons' reports. To the present authors' knowledge, no such comparison has yet been made between two endoscopic

procedures when evaluated using this accurate prospective methodology.

As fertiloscopy is a recently 'revisited' technique, it is not surprising that the experience of the surgeons appeared in some centres to be very limited. Given this situation, it was gratifying that it was possible to perform a satisfactory evaluation by fertiloscopy in such a high number of cases. The rate of failure to enter the pelvic cavity with the Veress needle appeared to be quite high (5/92), and is most likely a reflection of the lack of experience in this technique. In these five cases, insertion of the needle was extra-peritoneal, and this rendered safe insertion of the trocar impossible. Successful introduction of the Veress needle into the pelvic cavity requires a firm stabbing inward movement for about 2 cm; any hesitance in movement tends to dissect the space between the vaginal mucosa and peritoneum. Instillation of the saline solution into this extra-peritoneal space causes major problems in any subsequent attempts to enter the pelvic peritoneal cavity. The complication rate here was consistent with that reported previously (Watrelot *et al.*, 1999b; Darai *et al.*, 2000) and will be analysed in a further report. It is nevertheless important to underline that any complications were rare and, to date, not serious. The most important was rectal injury (1/92), though as this was extra-peritoneal it was treated successfully and non-surgically using antibiotics. The other complications, piercing of the uterine and vaginal hernia which has not been reported previously, appeared to be without reported consequence.

The population of women recruited seemed to have the range of conditions typically seen in an infertile population. A mean duration of 4 years of infertility indicated the need for an endoscopic evaluation of the pelvis, and only patients without obvious cul-de-sac pathology were included, as fertiloscopy was regarded as a diagnostic tool in this comparative trial with laparoscopy. When pelvic pathology was suspected, patients were excluded from this study and advised that laparoscopy was the appropriate procedure because of its greater therapeutic and operative possibilities. For that reason, 56% of the cases were considered prospectively to have 'unexplained' infertility, and although there was no pre-operative evidence of endometriosis, this condition was seen in 23% of patients at fertiloscopy/laparoscopy.

In order to compare the diagnostic performance of each of the two endoscopic procedures, it was not sufficient to estimate sensitivity and specificity of both methods, because only the study of concordance allows an estimation of whether there is, or is not, any similarity between the two sets of information about the same parameters. The Kappa score was seen as the most appropriate statistical method to achieve this purpose.

In all, abnormalities in one and/or both endoscopic procedures were observed in 65 patients (80%), and this rate is likely to be representative of a western European and/or Mediterranean population. The majority of abnormalities were subtle and had an unknown impact on fertility. Nevertheless, it seemed of great methodological interest to take into account the description of such minimal abnormalities in order to compare the accuracy and the degree of concordance of both procedures, hitherto not reported (Darai *et al.*, 2000; Brosens *et al.*, 2001).

Many studies have already demonstrated the limits of procedures such as HSG in the diagnostic of tuboperitoneal infertility, thus underlining the role of endoscopy in infertility assessment (Querleu and Leroy, 1990; Cundiff *et al.*, 1995; Mol *et al.*, 1996). Therefore, the aim of the present investigation was not to discuss the place of endoscopy, but rather to evaluate and compare the accuracy of fertiloscopy with that of diagnostic laparoscopy.

Surprisingly, almost the same number of patients with discordance were found between fertiloscopy and laparoscopy (*n* = 9) and between laparoscopy and fertiloscopy (*n* = 8). In only one woman (1.2%) did the discordance (ovarian endometrioma not diagnosed at fertiloscopy) seem likely to have clinical consequence. However, this discordance became evident during laparoscopy and the diagnosis was made by puncturing an enlarged ovary. Strictly speaking, this patient would have been excluded from analysis, if the ultrasound recommended before fertiloscopy would have been performed. If it had been performed, the endometrioma would have been discovered and the patient excluded from the study, because in this situation there is no place for fertiloscopy, and a surgical laparoscopy would be mandatory. This case emphasizes the important role of pre-operative assessment before deciding whether fertiloscopy alone, fertiloscopy preceding to laparoscopy, or laparoscopy alone should be the procedure of choice. The fact that there were eight cases where laparoscopy was not able to detect subtle lesions seen during fertiloscopy confirmed the results of previous investigations (Brosens *et al.*, 2001), and this provides encouragement to review whether laparoscopy should still be considered the gold standard in infertility assessment.

Consequently, the diagnostic index could be calculated for both procedures, the reference being given by combination of the findings. A very similar sensitivity was found for fertiloscopy and laparoscopy (respectively 86 and 88%), as well as negative predictive value (64 and 66%). By definition, the specificity and positive predictive value were 100% for both procedures. As expected, the MacNemar test confirmed the absence of differences between the diagnostic indices of the two procedures.

In addition, the unilateral binomial test confirmed, if it was necessary, that the discordance rate with clinical impact was consistent with the hypothesis of a discordance rate no greater than 1%.

Moreover, concordance was assessed not only with respect to each patient but also with respect to six selected sites in each woman. The six chosen sites appeared to be the most important involved in the reproductive process. Once again, the crude concordance rate was very high, namely 467 out of 486 sites (96.1%).

The kappa score ranged from 0.78 to 0.91 (right tube), with kappa scores of 0.61–0.80 being considered 'good', and 0.81–1.0 'excellent'. In the present study, five results were in the range 'excellent' and one in the range 'good'.

The present data show that the performance of fertiloscopy can allow laparoscopy to be avoided in up to 93% of women, as the relevant information can be obtained by this less-invasive procedure. In the remaining 7%, the findings at fertiloscopy

indicated the need for laparoscopic evaluation. Thus, patients may be advised that an assessment of the internal genitalia and tubal patency can be completed by fertiloscopy alone, thereby avoiding the need for transabdominal surgery. Given the unique capacity of fertiloscopy to identify those patients with fine and filmy peri-ovarian and peri-tubal adhesions (due to previous infection or endometriosis), and who may benefit from surgical excision of these lesions, fertiloscopy could be considered as an important diagnostic tool. As lesions such as moderate peritubal adhesions or minimal endometriosis can be treated successfully by operative fertiloscopy, (Watrelot, 2001), it may not be necessary to commit couples to IUI treatment (which is less effective in the presence of such lesions) or IVF, which could be avoided. Other options for treatment are available.

In the presence of more severe pathology, it is necessary to convert fertiloscopy into laparoscopy in order to perform more extensive surgery.

The results of previous studies have shown firstly, that fertiloscopy is less invasive and safer than laparoscopy (Gordts *et al.*, 2000), and secondly that it allows easier evaluation of the tubal mucosa because of the capacity to perform salpingoscopy and microsalpingoscopy (Marconi and Quintana, 1998; Watrelot *et al.*, 2002).

The results of the 'FLY' study strongly suggest that fertiloscopy should replace diagnostic laparoscopy in the routine assessment of infertile women without obvious lesions of the ovary or in the pouch of Douglas.

Acknowledgements

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