

**Comparative Analysis of the Clinical Examination Methods of Proximal
Tubal Occlusion, and Evaluation of Related Patient Satisfaction**

PhD Theses

by

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Abstract

From among the patient records of the Second Department of Obstetrics and Gynecology at Semmelweis Medical School in Budapest, Hungary, we have analyzed examinations of passability of the fallopian tube. All together 500 HSG tests, 312 cases of laparoscopy with chromopertubation, 348 traditional hysteroscopy and 145 "no-touch" hysteroscopy examinations, 22 tuboscopies and 67 hysteroscopies with selective chromopertubation, as well as 100 video documented cases (endoscopic operations) comprise the basis of our study. In the course of HSG tests we have established unilateral occlusion in 25.2%, and bilateral occlusion in 5.8% of the cases. For LSCT these results were 22.7% and 8.7% respectively. By means of hysteroscopy 7.36 % of patients were diagnosed with unilateral, and 19.47% with bilateral blockage. Similarity of HSG and LSCT results corresponds to data available in literature. Minor differences may be due to the empirical fact, that the fallopian tubes open under different tubal perfusion pressure (TPP). This is also supported by the variation present between bilateral occlusions and unilateral occlusions in contrasting HSG and LSCT: sensitivity: 72.73 (56.52), specificity: 53.85 (65.52), positive predictive value: 20.77 (39.39), negative predictive value: 87.50 (79.17). A more marked variation of hysteroscopy results may be explained by the fact, that existing perfusion cannot be observed. Using our method for HSCPT however, the procedure proved successful in 66.66% of cases even when bilateral occlusion of the fallopian tubes was diagnosed by previous HSG or LSCT (as opposed to the former diagnose, we have established passability), while in cases of unilateral occlusion this was achieved in 80.95% of cases (deviations between the latter two may again be ascribed to different TPP values of the fallopian tubes). Using a tuboscope guided in subsequent to overall catheterization of the fallopian tube, tubal function can be judged successfully in 79.17% of cases, provided that the procedure is performed on sound tubes. In case of tubes showing pathology the rate of failure may reach as high as 49.9% depending on patient material. Thus we do not recommend tuboscopy for ruling out or therapy of a PTO. This type of intervention is only performed in selected cases. Nevertheless, we do recommend use of our HSCPT method, which may as well be performed with the "no-touch" technology. Through our study material we shall demonstrate, that the "no-touch" technology is easy to perform even on undelivered or No. I. infertility patients, without anesthesia, resulting in a low surgical impact on the patient. Thus, either as a first examination (as an alternative to HSG), or as a second line examination for reassertion or ruling out of a previously established

PTO diagnose, HSCPT makes diagnostics of tubal function more accurate. As a result of documenting the above endoscopic operations, we had the opportunity to consult patients adequately and in detail by presenting their surgical video recordings to them. Based on our study there is a demand for such guidance among patients and it significantly increases patient satisfaction as well. Exact video documentation may also be a decisive factor in planning possible interventions for the future.

Introduction

In one third of infertility cases a certain type irregularity of the fallopian tube stands in the background. At the same time, examinations of the fallopian tubes and the uterus in Hungary leave much to be desired, particularly in case of a PTO. Due to monetary and/or professional reasons we fail to apply relevant international experiences and recommendations. Consequently, patients may be diagnosed with a disease and go through unjustified therapy(ies). Furthermore, they miss out other internationally recommended and feasible methods aimed at preventing this exact situation for reasons beyond their control. From among the examinations of the fallopian tube HSG, laparoscopy with chromopertubation, and hysteroscopy for evaluation of tubal function are used in several Hungarian institutions on a daily basis. At the Second Department of Obstetrics and Gynecology of Semmelweis University, tuboscopy, hysteroscopic selective perfusion imaging, hysteroscopic selective catheterization, and overall cannulation of the tubes are applied in addition to the above interventions, with the possibility of digital recording and presentation of the procedure. Proximal Tubal Occlusion (PTO) – diagnosed upon a single HSG test – is in itself an indication for In Vitro fertilization in Hungary, regardless of the fact, that selective salpingography and different catheterizations and recannulation procedures restore the passability of the fallopian tube, and consequently fertility in a great percentage of cases. The IVF procedure is questionable in these cases both financially and emotionally, and it may as well have side effects such as hyperstimulation syndrome or the problem areas of multiple pregnancy, which may lead to complications to the mother and the infant both.

Objectives

1. We shall review the HSG test as a primary screening method and contrast our own results with international data.
2. We shall assess laparoscopy with chromopertubation and contrast it with HSG based on our own results.
3. We shall elaborate the issue of tubal function observable through hysteroscopy, and introduce the implementation and advantages of "no-touch" hysteroscopy based on the single national experiences of the author. We shall determine the position of the method within the examination procedure we have formulated.
4. We shall introduce the method developed by the author for the selective examination of a PTO in relation to the assessment and presentation of our own materials and results.
5. Based on the single national experiences of tuboscopy operations performed by the author, we shall comment and evaluate the method, and set its likely position within the examination procedure of the fallopian tube.
6. We shall present a patient guidance method developed at our clinic in order to increase patient satisfaction in relation to the afore mentioned endoscopic operations. We attempt to confirm the success and relevance of the approach in terms of our examinations.
7. We shall present the infertility examination protocol developed by the author, in view of the anatomical status of female genital organs, namely the fallopian tubes. We shall corroborate correspondence of the protocol with the relevant conclusions of the previous points, and shall formulate a recommendation to other institutions for an applicable sequence of examination methods.

Patients and Methods

1. The oldest developed method for examining the fallopian tubes is the HSG. From the patient data gathered at our clinic during a period of two years (2007-2009), we have collected retrospectively the first *500 HSG test cases*, which we have analyzed for the purposes of our study from the aspects of our subject issue.
2. We have compiled a database from the detailed assessment of all hysteroscopy examinations (with or without an LSC examination) performed at the SU Second Department of Obstetrics and Gynecology between 1st January 1998 and 31st December 2009 ($n=827$), as well as from the detailed assessment of all cases of laparoscopy with chromopertubation during the same study period ($n=312$). We have analyzed cases selected in accordance with our study subject along our choice of considerations. Through hysteroscopy ($n=348$), the proximal orifice of the fallopian tube can be observed adequately, and in most cases we can establish passability of the tube. Our team was the first to perform "no-touch" hysteroscopy in Hungary ($n=145$), results of which were also used in our retrospective analysis from the above mentioned database.
3. Furthermore, we have carried out a retrospective analysis of the one and only series of 22 *tuboscopy* (fallopscopy) examinations performed at our clinic and in Hungary. We shall evaluate the method in view of our observations and data obtained from literature.
4. A PTO diagnosed through HSG is among the most exciting issues of infertility diagnostics even in international literature. We shall introduce our method developed for the selective examination of tubal function, estimating its efficacy in light of a detailed overview of our results ($n=67$).
5. Digital recordings of operations of *100 patients* were prepared for educational and informational purposes with the prior consent of patients, and those were presented to them upon request. In relation to this, patients were asked to fill out a questionnaire, seeking an answer to the question, whether such forms of patient consultation are in demand, and if so, then for what reasons. Does the applied method help in a better understanding and handling of the disease?

HSG

After vaginal exposure and disinfection a Foley (8 Charrieres=2.66 mm) catheter was guided into the uterus cavity without fixation of the portio as possible. Depending on the size of the uterus cavity the Foley balloon was inflated with 0.7-2 ml NaCl physiological solution. Then at the radiology department water-soluble contrast medium was injected into the uterus cavity (Peritrast, Omnipaque 300-GE Healthcare) under X-ray radiograph (Siemens, Sirescop CX).

LSC-LSCT

Routine laparoscopy was performed by direct entry (umbilically), or with prior Veress Needle CO2 insufflation (at opposite McBurnay point) (approx.: 3000 ml, to reach 13-15 Hgmm intra-abdominal pressure). In the course of LSCT a Schultze-tool filled with methylene blue (Blue patenté v. 2ml, Sodique Guerbet 2.5%, Guerbet Bp, Cedex) was guided into the uterus cavity. Manifestation of the injected methylene blue in the peritoneal cavity was observed on a video-laparoscopy (Olympus visera) system. In case of pathological alterations we have carried out the indicated interventions using the appropriate LSC method.

HSC, "no-touch" method

With or without prior laminar dilation, we used 2.5-8.5 mm outer diameter, exclusively rigid hysteroscopes (with single flow or continuous flow filling). Either physiological saline, or anionic Purisol (27.0 g/l sorbitol, 5.4 g/l mannitol mixture) was used as a distending agent depending on the planned intervention (diagnostic or operative) and on the electronic tool applied (bipolar resectoscope, unipolar resectoscope, Olympus). Interventions were carried out without anesthesia, or with local, IVN or ITN anesthesia, after vaginal exposure, fixing of the portio, or hegar dilation. In case of the "no-touch" method these latter are unnecessary. The hysteroscope may be directly guided with the help of one finger.

HSCPT

Examinations were performed with a continuous flow (CF) 7 French (Fr) operating channel, 30 degree optical, rigid Olympus hysteroscope. After survey of the uterus cavity and placement of a 7 Fr (2.3 mm outer diameter) catheter (Conceptus CoAxess Uterin Catheter), the mandrin (guide wire) was removed. Methylene blue was carefully injected (1-2 ml/min) in the proximity of tubal orifices to dye the liquid discharged from the uterus cavity and allow

verification of perfusion and passability. In case no perfusion could be observed, a catheter was lead into the proximal section of the fallopian tube (Conceptus VS Catheter, Falloposcopy Giudewire/torquer), then a repeated dyeing, and when necessary, injection with increased pressure was performed (300-600 Hgmm).

Entire fallopian tube catheterization, tuboscopy

The whole fallopian tube was catheterized (Conceptus VS Catheter, Falloposcopy Giudewire/torquer), then with 15-25 Hgmm inherent perfusion, a 0.5 diameter, 120 long, 3000 pixel falloscope was guided into the catheter (Conceptus, Inc., San Carlos , CA, USA) until visible inside the peritoneal cavity (between the tubal fimbria). Then a retrograde tuboscopy of the inner surface of the fallopian tube was carried out in its entire length by slowly withdrawing the falloposcopic tool.

Designing the Survey of Patient Guidance and Consulting

During the period between September 2006 and January 2007, 100 gynecological endoscopy operations were documented at our clinic with the prior consent of patients. Recorded video material was presented to patients the day after the intervention on the bedside of the patient or in the surgery. Patients were asked to fill out questionnaires before and after the operation. (For endoscopy interventions we used the Olympus visera video system, data was saved on a Super rach ShuttleX PC. Recordings of the procedure were edited and saved with Windows Movie Maker, then copied onto a pen drive data carrier.) Edited recordings demonstrated the initial status and the type of disease (cysta, myoma, endometriosis, etc.), the most important operation techniques, and the final anatomy achieved. Editing was carried out by the operator in all cases. The video was presented to patients on the day after the operation with verbal explanation by one of the doctors performing the operation.

Statistical methods

We performed the analysis of the gained electronical data with the following methods: Student's two-tailed T-probe, we determined the significance threshold (p-value) at 5% according to the international consensus ($p \leq 0,05$). The diagnostic effectiveness of the instrumental examination methods (specificity, sensitivity, positive and negative predictive

value) was compared using Fisher's exact test, the significance threshold was 5% as well. ($p < 0,05$) We used the SPSS 17 statistical software package.

Summary of Key Results and Innovations of the Thesis and their Significance in Practice

1. In the course of HSG tests, when no pathology was demonstrated previously, we have established bilateral passability in 69.00% of cases, unilateral occlusion in 25.20%, and bilateral occlusion in 5.80% of cases. Overall fallopian tube involvement in our material was 42.6%. The rate of unilateral proximal tubal occlusion was 14.4%, and 4.8% of bilateral PTO. HSG was repeated in 4.8% of cases.

- Based on our study, pathological irregularities observed through HSG correspond to international literature in respect of a PTO. The so called tubal factor is equivalent in the investigation of any types of blockage (25.20%). Although, considering all irregularities recorded by HSG, the incidence we have established, is higher (42.6%). Nevertheless, the rate of a repeated HSG is inexplicably low.

2. In the course of laparoscopy with chromopertubation, both sides showed passable in 68.6% of cases, 22.7% showed unilateral, and 8.7% showed bilateral occlusion. HSG was previously performed in 26.6 % of all cases. Contrasting with LSCT in case of a bilateral PTO, HSG showed a sensitivity (s) of 72.73%, specificity (sp) of 53.85%, positive predictive value (pp) of 20.77%, negative predictive value of (np) 87.50%. In case of unilateral PTO (LSCT), with an open opposite side (HSG); s: 56.52%, sp: 65.52%, pp: 39.39%, np:79.17%.

- Regarding the indications of LSCT, it may be established, that only as few as 32-42% of 'justified secondary passability tests' are actually performed.
- The variation apparent in the quality factors of unilateral and bilateral tubal occlusion may be explained by technical reasons.

3. In the course of hysteroscopy both sides demonstrated tubal function in 73.15% of patients, with unilateral occlusion in 7.36% and bilateral occlusion in 19.47% of cases. Indications for our "no-touch" hysteroscopy were problems related to infertility in 42.7%, and other gynecological irregularities in 57.2% of cases. In terms of anesthesia interventions were

performed in 50 cases under ITN, 49 with IVN, 31 with local anesthesia, and 15 without anesthesia. Corresponding data within the No. I. infertility group was: 7, 9, 4, 2, and in the No. II. infertility group: 16, 12, 5, 7.

- Low-rate tubal perfusion cannot be established through hysteroscopy.
- The "no-touch" method may be used safely for the infertility diagnostics of undelivered women as well.

4. For HSCPT, in addition to 67 cases of selective dyeing and/or catheterization, we have carried out 26 other hysteroscopy interventions. In 28.5% of these the presumed diagnosis was not ascertained, although through hysteroscopy we did identify previously unrecognized irregularities in 14.9% of cases. In the course of synchronously performed LSC-s, the number of interventions apart from average LSCT-s was 1.536, and the rate of new diagnoses was on average 0.682 per case. Taking all PTO cases into account, our method proved successful in 66.66% of bilateral involvement, and in 80.95% of unilateral occlusion. Considering fallopian tubes diagnosed as blocked, selective dyeing was sufficient in 24.56% of cases to ascertain the alteration. In further 47.36% of cases subsequent catheterization was necessary. LSCT found unilateral occlusion in 5 cases, then followed by an immediate HSCPT, passability was established in all of these cases using our method. Perfusion of the fallopian tubes was achieved in 12.6% of cases above 300 Hgmm, in 9.5% between 200-300 Hgmm, in 10.5% between 150-200 Hgmm, in 46.3% between 120-150 Hgmm, and in 21% of cases below 120 Hgmm TPP value.

- Diagnostic variations revealed through hysteroscopy support the priority of the examination method as opposed to both HSG and LSCT.
- The frequency of other LSC type of interventions, and the number of newly identified alterations justify the central position of LSC in diagnostics of infertility.
- In case of a PTO diagnosed through HSG and/or LSCT, the efficacy of HSCPT is greater, than that of a repeated HSG. These compete with other top international, secondary, selective examination results.
- In event the first examination of tubal function of an infertile patient is HSC, and no perfusion is visible on either side, then with the perfusion imaging method we have

developed (selective chromopertubation), perfusion can be ascertained in 55.76% of cases. With the synchronous application of tubal catheterization, ease of passage may be demonstrated in an additional 36.53% of cases, while for another 5.76% this is achieved with higher TPP values. In 1.92% of cases blockage may be established with certainty. The fact that in the process of selective tests no LSC control is necessary in 38.80% of cases, again underpins priority of HSC ahead of HSG.

- The developed method provides for plotting a continuous TPP – expected PR curve up to 300 Hgmm pressure value, and with appropriate development of tools, even in the higher pressure ranges.

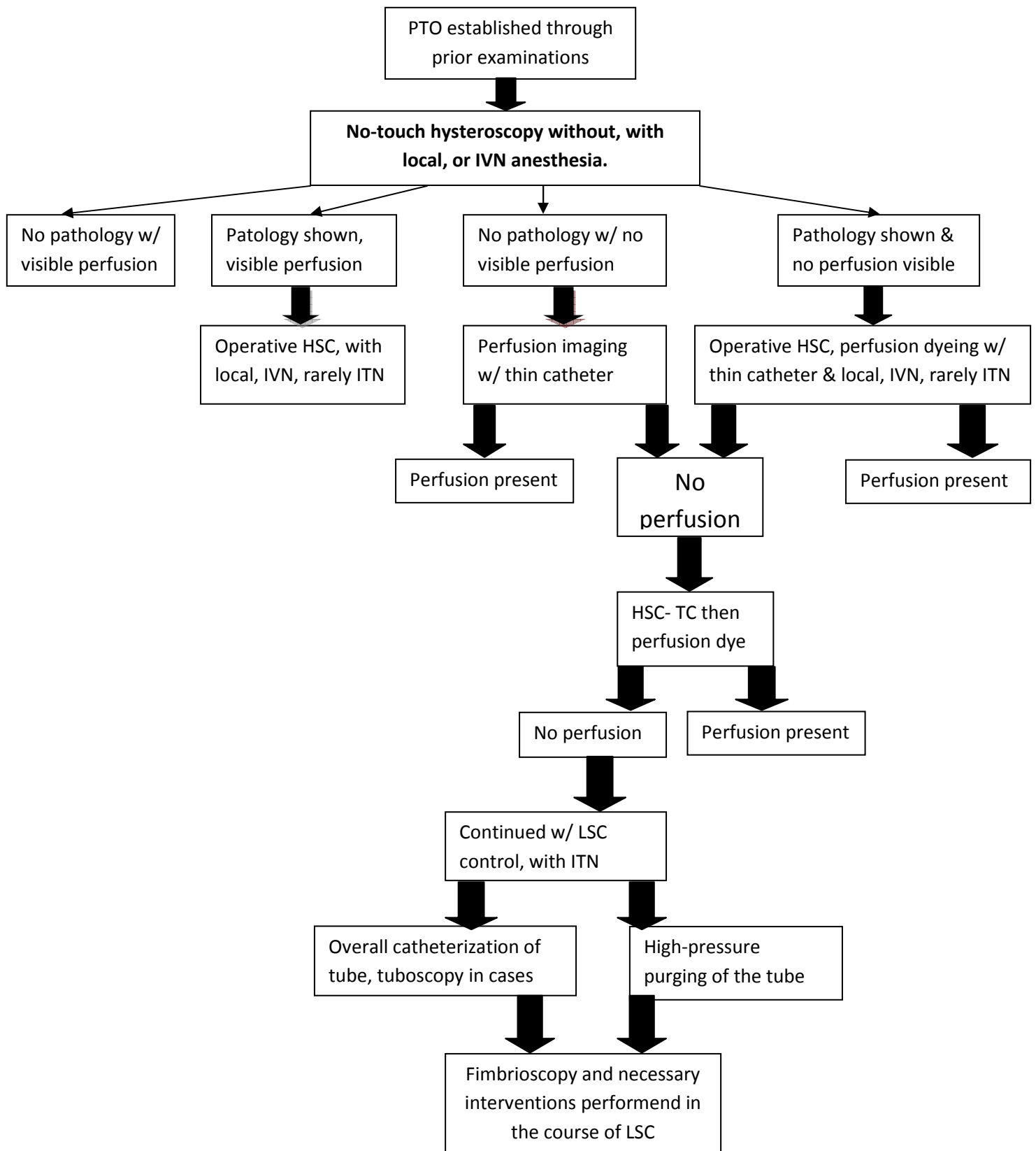
5. Diagnoses of our tuboscopic examinations agreed with preoperatively established pathological tubal diagnoses in 65% of cases, while differences appeared in 20% of cases (yet showing pathology). Tuboscopy failed to prove the presumed impairment in 15% of cases, and conversely it revealed previously unverified alterations in 5% of examinations. Considering all fallopian tube examinations, failure occurred in 20.45% of tests due to problems in catheterization, in 11.36% due to uninterpretable image results, and in 9.09% the image could only be interpreted with fimbrioscropy, totaling to 49.9% of all tests. In case of entirely sound fallopian tubes 79.19% of examinations were implemented successfully.

- The reason for this high rate of failure is that examinations were not generally applied on average subjects, but as a quasi "ultimum refugium" in the most problematic cases.
- Our success rate of 79.17% coincides with international data when appropriately contrasted.
- Application of tuboscopy is only recommended in assorted cases. Use of the method within the domain of PTO is not indicated.

6. By means of our patient guidance method the demand for review of operation recordings was verified in 92% of cases, patients finding the method worthy and helpful in understanding their diseases. 91% of patients believe, that the mere opportunity of being able to "inspect" what happens to them while under sedation, is in itself reassuring. 82% would even call for photographic and/or video documentations for taking home.

- Image and video (CD, DVD, pen drive) documentations are rather helpful for the doctor in event of planning either a second intervention, or another type of subsequent therapy.

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Following our recommended examination protocol, only those given patients will qualify for the IVF program on the basis of tubal pathology, whose impregnation is merely possible by such means beyond doubt. (By ruling out a bilateral occlusion, in addition to the possibility of a spontaneous impregnation, we also give way to other ART-s, such as insemination.)

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