Prognostic capacity of transvaginal hydrolaparoscopy to predict spontaneous pregnancy

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BACKGROUND: In 1998, transvaginal hydrolaparoscopy (THL) was introduced as a new outpatient procedure for exploration of tubo-ovarian structures and tubal patency in subfertile patients. At present, there are no large studies that relate the findings at THL to fertility outcome. METHODS: Consecutive patients undergoing THL for subfertility between 2000 and 2004 were included in this prospective cohort study. Follow-up ended when ongoing pregnancy or tubal surgery occurred or at the day of last contact. Kaplan–Meier curves for the occurrence of intrauterine pregnancy (IUP) (spontaneous or after intrauterine insemination) were constructed for a normal THL, a THL with a one-sided tubal pathology and a THL with a two-sided tubal pathology. Fecundity rate ratios (FRRs) were calculated to express the association between THL findings and the occurrence of IUP. Patients rated their pain experiences and acceptability on a visual analogue scale (VAS). RESULTS: We included 272 women. In 96% (261) of the patients, access to the pouch of Douglas was achieved. Complications occurred in 2% of the procedures. In 203 (78%) patients, both tubo-ovarian structures could be visualized and tubal patency was shown. One-sided tubal occlusion was found in 10%, whereas two-sided tubal occlusion was seen in 4% of the patients. Adhesions and/or endometriosis were observed in 8% of the patients. The FRRs for one-sided tubal pathology, two-sided tubal pathology and adhesions/endometriosis were 0.59, 0 and 0.80, respectively. The VAS scores showed pain to be limited and the procedure to be acceptable. CONCLUSION: THL is a feasible technique. Its capacity to predict spontaneous ongoing pregnancy is comparable to that of laparoscopy.

Key words: laparoscopy/pregnancy/subfertility/transvaginal hydrolaparoscopy/tubal pathology

Introduction

Assessment of the Fallopian tubes is one of the cornerstones of the work-up for subfertility. At present, the most frequently used tests are Chlamydia antibody titer (CAT), hysterosalpingography (HSG) and diagnostic laparoscopy with dye. Both HSG and CAT alone are inaccurate tests to diagnose tubal pathology. In a meta-analysis, HSG had a sensitivity of 0.65 and a specificity of 0.83 in the diagnosis of tubal pathology (Swart et al., 1995). HSG was not a reliable method for the evaluation of peritubal adhesions. The accuracy of CAT is reported to be similar to that of HSG (Mol et al., 1997). Despite recent advances, CAT is still not a perfectly accurate test (den Hartog et al., 2005).

At this moment, laparoscopy is considered to be the ‘gold’-standard procedure for the diagnosis of tubal pathology. However, laparoscopy is an invasive procedure that requires day care and general anaesthesia. In 1998, Gordts et al. introduced the transvaginal hydrolaparoscopy (THL) as a new procedure to evaluate the tubo-ovarian structures and tubal patency in subfertile women (Gordts et al., 1998). After the introduction of THL, studies with large populations were performed to evaluate this method. (Verhoeven et al., 2004; Gordts et al., 2005). This procedure was first performed under general anaesthesia and later under intravenous sedation or local infiltration. In a study comparing HSG to THL, it was shown that the latter provides more information and was better tolerated by the patient. (Cicinelli et al., 2001).

The aim of tubal testing is to distinguish between women who can conceive either spontaneously or after insemination and women who cannot and need IVF or tubal surgery. For diagnostic laparoscopy, spontaneous pregnancy rates are reduced by 49% in the case of one-sided tubal pathology and by 85% in the case of two-sided tubal pathology (Mol et al., 1999). It is therefore important to know whether findings at THL can predict occurrence of intrauterine pregnancy (IUP). In our department, we started using the THL procedure in 1999, initially under general anaesthesia, to switch quickly to an outpatient setting with local anaesthesia. The aim of the
present article is to relate findings at THL to the occurrence of treatment-independent pregnancy.

Material and methods
This prospective study was performed from January 2000 to December 2004 at the Máxima Medical Center in Veldhoven, The Netherlands. We included subfertile couples who were scheduled for THL. In our department, all subfertile patients have a CAT measured as part of their basic fertility work-up. Those with a positive CAT are immediately scheduled for THL. In those with a negative CAT, THL is scheduled either prior to insemination or if the couple fails to conceive within 6–12 months. All patients had to have a negative Chlamydia PCR prior to the procedure. Contraindications for the procedure were a fixed retroverted uterus, a history of severe pelvic inflammatory disease (PID) and pelvic masses in the ovaries or pouch of Douglas. A positive CAT with a negative Chlamydia PCR was not a contraindication.

The THL procedure is performed in our clinic by three gynaecologists (C.K., M.W., M.B.) with special interest in reproductive medicine or by registrars under supervision of one of these gynaecologists. All patients undergoing a THL at the outpatient clinic received oral and written information about the procedure. The evening before the procedure, patients were advised to take two tablets of bisacodyl and 500 mg naprosyne, and in the morning of the THL procedure, a mild rectal laxative was given. One hour before the procedure, 500 mg naprosyne was given, and just before the procedure, 0.5 mg atropine was injected intramuscularly. Antibiotics were not provided on a routine basis, but only in case of complications or observed tubal pathology.

Procedure
The procedure was performed in the outpatient operating room with the patient in dorsal decubitus position. After insertion of a Trelat speculum, the vagina was disinfected with aqueous chlorohexidine solution. The central part of the posterior cervix was infiltrated with 1–2 ml of ulracaina. A tenaculum was placed on the posterior cervix and a balloon catheter was put in the uterine cavity and the balloon inflated with 1–2 ml of air for the chromopertubation. Local anaesthesia with 2–3 ml of ultracain was performed in the vaginal vault, 1–2 cm below the cervix. A small incision was made at this place and a specially designed trocar system (Circion ACMI, Stanford, CA, USA) was introduced. The system consists of an adapted Verres needle of 25 cm in length, a dilatation device and a 3.9 mm outside diameter trocar. All three parts fit together, but the Verres needle is 50 cm longer than the dilatation device. The Verres needle was inserted briskly to avoid tenting of the peritoneum. Progressively, the dilator and trocar were inserted transvaginally into the pouch of Douglas, after which the dilator and the Verres needle were removed and replaced by a rigid 2.7 mm wide-angel optical system, which is placed in the 3.9 mm shaft system, ensuring irrigation during the procedure. Infusion with saline solution at 37°C was then started.

After infusion of saline and some orientation, the investigation started at the posterior uterine wall. Then the scope was moved laterally to identify the tubo-ovarian structures. The ovarian surface was inspected, from the ligamentum ovarium propium going to the fossa ovarica and the dorsal part of the ovary. The fimbrial part of the fallopian tubes was inspected as well as the tubo-ovarian contact, and a dye test was performed to test the tubal patency. The contralateral side was inspected similarly. Throughout the whole procedure, irrigation with warm saline was continued, keeping the bowel and the tubo-ovarian structures afloat.

After the procedure, the fluid was removed from the abdomen through the trocar.

The puncture site in the fornix posterior was not sutured. After the procedure, women were asked to rate both the pain experienced and acceptability on a visual analogue scale (VAS) from 0 (no pain, perfectly acceptable) to 10 (unbearable pain, completely unacceptable). Patients were informed that some vaginal leakage or bleeding could occur and were advised not to use vaginal tampons or have sexual intercourse for a few days. The patients left the outpatient clinic immediately after the procedure.

Follow-up
Data on fertility outcome were collected by reviewing the medical records. Follow-up ended with an IUP, spontaneous or after intrauterine insemination (IUI), at the estimated moment of conception or on the day IVF started or tubal surgery was performed. An IUP was defined as an intrauterine sac detected on ultrasound. If a patient did not conceive and was not treated, follow-up ended on the last day of contact. A patient was presumed to be ‘at risk’ for spontaneous conception as long as she visited our clinic. In case the last day of contact at our clinic was within 3 months after the THL, the patient’s general practitioner was contacted for additional information on both the continuation of the desire of the patient to become pregnant and fertility outcome.

Analysis
One and a half year cumulative pregnancy rates were calculated for each category of THL findings, using the Kaplan–Meier analysis (Collett, 1994). Subsequently, fecundity rate ratios (FRRs) and 95% confidence intervals (CI) for the occurrence of ongoing pregnancy (spontaneous and IUI) were calculated for THL findings through Cox regression modelling (Cox, 1972). An FRR expresses the probability of ongoing IUP per time unit for patients with a particular feature, relative to the probability in those without that feature. In addition, we determined FRRs for other potential prognostic factors. To adjust the FRRs of THL findings for these prognostic factors, a multivariable analysis was performed.

Results
In total, 272 THLs were performed. Mean maternal age was 31.5 years (SD 4.0) and median duration of subfertility was 17 months (range 10–104 months). There was one woman with a history of PID, and 74 couples (27%) had previously conceived. The semen analysis showed a median total motile count of 53 millions (range 2–70 millions).

Successful access into the pouch of Douglas was obtained in 261 (96%) of the patients. Among the 11 failures, there were 9 cases of retroperitoneal insertion and 2 cases of rectal perforation. Complications occurred in five (2%) patients: two rectal perforations, two bleedings at the puncture site and one case of PID. The two rectal perforations occurred, in one case, in a woman with a mobile but retroverted uterus and, in the second case, in a patient with a distended rectum. In both women, the procedure was stopped immediately. These women were treated expectantly and received antibiotics for 7 days. One of the bleedings at the puncture site stopped after local pressure, whereas the other one needed to be stitched. One patient was readmitted because of pain and suspicion of a PID. She received antibiotics, and the cultures taken were negative and recovery was uneventful.
In 203 (78%) patients, both tubo-ovarian structures could be visualized and tubal patency was shown. In 27 cases (10%), only one of the fallopian tubes was patent. Double-sided tubal occlusion was seen in nine (4%) patients. Adhesions and/or endometriosis were diagnosed in 22 (8%) of the patients (Table I).

Of 261 patients, 108 started IUI during the follow-up, 61 were referred for IVF and 5 had tubal surgery. The mean follow-up was 295 days (range 1 day to 2 years). There were 82 patients who conceived an IUP (spontaneous and IUI), of which 58 had an ongoing pregnancy and 24 had a recurrent spontaneous abortion. Two patients suffered from an ectopic pregnancy, one in a patient with one-sided tubal occlusion and one in a patient with adhesions.

Figure 1 shows time-to-treatment-independent pregnancy (IUI included) in patients without tubal pathology and in patients with one-sided tubal occlusion and adhesions. The cumulative pregnancy rates after 1.5 years were 47% in the patients without tubal disease, 38% in the patients with adhesions/endometriosis and 42% in patients with one-sided tubal occlusion, whereas none of the patients with two-sided tubal occlusion conceived.

Table I shows the results of the Cox regression. In the univariate analysis, the FRR for one-sided tubal occlusion was 0.59 (95% CI 0.24–1.5), 0 for two-sided tubal pathology (95% CI 0–0.80) and 0.80 for endometriosis and/or adhesions (95% CI 0.37–1.7). These FRRs changed only marginally in the multivariate analysis.

These 159 women were in the initial group of 272 patients (159/272 = 58%) who rated pain and acceptability. As pain and acceptability were measured in a limited time period as shown in Figure 2, the mean pain score rated on a VAS from 0 to 10 was 4.3 in our study. The mean tolerability of the procedure was rated as 1.8 on the same scale.

**Discussion**

We studied the use of THL as a first line investigation in the fertility work-up in an outpatient setting and found the technique to be feasible. One-sided tubal occlusion was found in

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**Table I. Results of successful transvaginal hydrolaparoscopy in 261 patients**

<table>
<thead>
<tr>
<th>Number (%)</th>
<th>Univariable analysis</th>
<th>Multivariable analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>FRR</td>
<td>95% CI</td>
</tr>
<tr>
<td>No abnormality</td>
<td>203 (78)</td>
<td>1</td>
</tr>
<tr>
<td>One-sided occlusion</td>
<td>27 (10)</td>
<td>0.59</td>
</tr>
<tr>
<td>Two-sided occlusion</td>
<td>9 (4)</td>
<td>0</td>
</tr>
<tr>
<td>Adhesions and/or endometriosis</td>
<td>22 (8)</td>
<td>0.80</td>
</tr>
<tr>
<td>Female age (per year)</td>
<td>1.0</td>
<td>0.95–1.05</td>
</tr>
<tr>
<td>Total motile sperm count (10^6)</td>
<td>1.001</td>
<td>0.999–1.003</td>
</tr>
<tr>
<td>Previous pregnancy</td>
<td>74 (27)</td>
<td>1.6</td>
</tr>
<tr>
<td>Subfertility period (per year)</td>
<td>0.86</td>
<td>0.69–1.1</td>
</tr>
</tbody>
</table>

FRR, fecundity rate ratio; CI, confidence interval.

*Cox regression analysis.

**Figure 1.** The Kaplan–Meier curve showing time to pregnancy after transvaginal hydrolaparoscopy (THL) in patients with and without tubal pathology.
10% of the patients, whereas in 4%, two-sided tubal occlusion was seen. Adhesions and/or endometriosis were observed in 8% of the patients. The FRRs for one-sided tubal pathology, two-sided tubal pathology and adhesions/endometriosis were 0.59, 0 and 0.80, respectively. The VAS scores showed pain to be limited and the procedure to be acceptable.

We had a similar number of complications in our study compared with other studies (Darai et al., 2000; Moore et al., 2003; Watrelot et al., 1999; Dechaud et al., 2001). Despite this low number, a learning curve could be detected. Three out of five complications occurred in the first 100 procedures. The mild complications had no further consequences on fertility.

The success rates, defined as the number of procedures that revealed adequate vision of both tubes, were also high and comparable to the literature.

We found that almost 80% of the patients had completely normal tubes, whereas only 4% of the patients had severe tubal pathology. Those with mild pathology, i.e. those with one-sided tubal pathology or adhesions/endometriosis, had a fecundity that was almost half of that of patients without tubal pathology. The prognostic capacity of THL is, therefore, probably better than that of HSG, since in patients with one-sided tubal pathology at HSG, fecundity is also marginally declined (HRR 0.80) (Mol et al., 1999).

One-sided tubal disease at diagnostic laparoscopy decreases the probability for spontaneous pregnancy by 50%, a rate that is similar to the one that we find for THL. Although both observations have wide CIs that overlap, this suggests that laparoscopy and THL have a comparable predictive capacity.

This issue can only be answered in studies in which THL and laparoscopy are performed in the same group of patients with a short time interval. Only in such a study would discordance between findings at THL and abdominal laparoscopy become apparent, and subsequent assessment of time to ongoing pregnancy would reveal which of the two tests is the better predictor of pregnancy. Unfortunately, such studies are not available and, due to the invasiveness of both procedures, it is unlikely that large groups of patients will give informed consent for this type of study.

We found two-sided tubal pathology to be present in 4% of the patients. This implicates that the number needed to diagnose is 25, i.e. 25 women have to undergo THL to detect one woman in whom management will be changed by the result. We think that such a rate is rather low, especially if one takes into account that we already scheduled high-risk patients by the use of CAT. Assessment of patient preference studies are required to decide whether such a number need to test of 25 weights the burden of this procedure Another question that needs to be addressed is whether mild pathology, which reduced fecundity by 50%, has clinical consequences. In our opinion, randomized clinical trials comparing spontaneous pregnancy, IUI and IVF are needed to establish the importance of mild tubal pathology.

In conclusion, we have shown that THL is a feasible procedure. When two-sided tubal pathology is found, pregnancy chances are virtually zero, but the probability of this finding is rather low. The capacity of THL to predict spontaneous ongoing pregnancy is comparable to that of laparoscopy.

**References**


Submitted on July 15, 2006; resubmitted on September 21, 2006; accepted on September 27, 2006.