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Full length article

The capacity of transvaginal hydrolaparoscopy versus hysterosalpingography to diagnose tubal pathology in the work-up of subfertile women, a randomised clinical trial

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ABSTRACT

Objective: To assess the capacity of transvaginal hydrolaparoscopy (THL) versus hysterosalpingography (HSG) as a primary tool to diagnose tubal pathology.
Study Design: We performed a multicenter RCT (NTR3462) in 4 teaching hospitals in the Netherlands, comparing THL and HSG as first line tubal test in subfertile women. The primary outcome of the trial was cumulative live birth rate at 24 months. Here, we present the secondary outcomes, the diagnostic findings of both THL and HSG as well as performance defined as failures, complications and pain- and acceptability scores.
Results: Between May 2013 and October 2016, we allocated 149 women to THL and 151 to HSG, of which 17 women in the THL group (11.4%) and 12 in the HSG group (7.9%) conceived naturally before the scheduled procedure, while 13 HSGs and 5 THLs were not performed for other reasons (withdrawal of informed consent, not willing to undergo tubal testing and protocol violations). A total of 119 THLs and 134 HSGs were carried out. Failures were seen more in the THL group (n = 8, 5.6%) than in the HSG group (n = 1, 0.7%) (p = 0.014). Complications did not differ significantly between the groups (THL n = 4; 2.8% vs HSG n = 1; 0.7%) (p = 0.20). Bilateral tubal occlusion was detected in one versus three women (0.9% versus 2.2%) of the THL group and HSG group, while unilateral tubal occlusion was detected in seven (6.2%) versus eight (5.9%) women, respectively. Normal findings were seen in 96 (79.3%) women randomised to THL and in 119 (87.5%) in women randomised for HSG (RR 0.91 95%CI 0.81–1.01, p = 0.08). The pain score was significantly less for THL (VAS 4.7 (SD: 2.5)) than for HSG (VAS 5.4 (SD:2.5)) (p 0.038). The acceptability rate of THL and was high and comparable.
Conclusion: THL and HSG have a comparable capacity in diagnosing tubal pathology with comparable performance in safety, pain and acceptability.

Introduction

Tuboperitoneal pathology is found in around 15–25% of subfertile women [1–4]. To assess tubal function in these women, various diagnostic tests are available, of which hysterosalpingography (HSG) and transvaginal hydrolaparoscopy (THL) are both used. HSG was first described in 1914 by Carey [5]. HSG has a sensitivity of 65% and a

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specificity of 83% for diagnosing tubal pathology [6] and is in the Netherlands traditionally followed by diagnostic laparoscopy (DLS) if the HSG is abnormal or if a couple fails to conceive naturally after expectative management of 6–12 months.

THL on the other hand, was first described in 1998 by Gordts [7]. THL uses the transvaginal route and allows direct visualization of the pelvic cavity and tubes. Just like HSG, it can be carried out in an outpatient setting as a primary tool to assess tubal patency as well as to rule out other tuboperitoneal pathology such as endometriosis and adhesions. Sensitivity of THL is assessed as 70–100% and specificity as 100% [8–10].

Currently, HSG and THL have never been compared directly in RCTs. While THL seems promising, it is unclear what its effectiveness and costs are relative to the current first line diagnostic strategy, HSG. In view of this knowledge gap, we conducted a randomised trial on the subject.

Methods and materials

Trial oversight

The study was approved was by the institutional review board of the Amsterdam UMC location AMC Amsterdam, case number NL41088.018.12 and study number 2012_174, and by the board of directors of each of the participating hospitals. The Trial was registered in the Dutch trial register (NTR3462). All women provided written informed consent. Data collection and monitoring was performed according to Good Clinical Practice guidelines.

Trial participants

We included women trying to conceive for more than 12 months, who were over 18 years of age, in whom a transvaginal ultrasound performed in the follicular phase of the menstrual cycle showed no abnormalities and who had both ovaries present [11]. Women with positive *Chlamydia* status at PCR, prior tubal testing, women with a fixed retroverted uterus, masses in the pouch of Douglas or ovarian cysts (possibly interfering with THL), prior tubal surgery or a iodine or methylene blue allergy, were not eligible.

Trial randomization and intervention

Potential participants were recruited in four Dutch teaching hospitals (Amsterdam, Nieuwegein, Zwolle and Veldhoven). Women were informed about the trial by their doctors or dedicated research nurses. After providing written informed consent, eligible women were randomly allocated to a strategy starting with THL (experimental arm) or a strategy starting with HSG (control arm). An online and secured randomization program (Alea, FormsVision) with a permuted-block design, stratified for recruiting centre, was used for randomization. THL and HSG were scheduled in the follicular phase of the menstrual cycle. From the first day of the menstruation until the appointment of the tubal test, the women were told to abstain from unprotected sexual intercourse. Furthermore, they were instructed to take paracetamol and a non-steroidal anti-inflammatory drug two hours beforehand.

THL

THL was performed as described previously [12] in an outpatient setting. If a THL failed or was inconclusive an additional DLS had to be performed.

HSG

HSG was performed in the radiology department according to hospital specific protocols, by either gynaecologist, residents or fertility doctor.

Laparoscopy after THL or HSG

If a THL failed or was inconclusive an additional DLS had to be performed. When abnormalities were seen at HSG or when the initial test failed or failed to show a reliable result, a DLS had to be scheduled. Subsequently, in women with a normal HSG, a DLS had to be planned if a pregnancy did not occur after 6–12 months.

Management after THL or HSG

Subsequent management was comparable, with obviously management in the HSG-arm based on the HSG result and in the THL-arm on the THL result. Women were treated according to the Dutch national guidelines for subfertility [13].

Outcome measures

The primary outcome of this RCT was conception leading to a live born child within 24 months. As the follow-up of our trial for the primary endpoint was still ongoing at the time of writing, we here focused on secondary outcomes. These were diagnostic findings and performance of both procedures in terms of failures and complications. Failure of THL was defined as the inability to reach the pouch of Douglas. Failure of HSG was defined as the inability to infuse contrast into the uterus. Other secondary outcome measures were pain scores on a visual analogue scale (VAS) from zero (no pain) to ten (unbearable pain) and acceptability for patients. The latter was defined as the willingness to undergo the same procedure under the same circumstances again and as the willingness to recommend the procedure to friends or family on a VAS from zero (total willingness, total recommendation) to ten (no willingness nor recommendation at all).

Statistical methods

Baseline patient characteristics were reported as absolute number and percentage for categorical variables, and mean and standard deviation (SD) and median and interquartile range for normally and non-normally distributed continuous variables.

Descriptives of outcome variables within both groups were reported as absolute number and percentage, and mean and standard deviation. The independent *t*-test was used to compare continuous outcomes (VAS, time between randomisation and procedure) between groups. Fisher's exact test was performed to compare the proportion of women experiencing complications (bowel perforation, bladder perforation, bleeding, anaphylactic shock), because of the small cell expected counts. The same applied to the assessment of differences of failures, to the assessment of the number of laparoscopies (DLS) and to the assessment of concordance of the findings with DLS. In addition, the difference DLS between groups and the difference in the number of abnormal findings between water- and oil-based contrast within the HSG groups were quantified as relative risk including 95% confidence interval (CI). All analyses were performed according to the intention to treat principle. Statistical analysis were performed using SPPS for Windows version 24.0 (IBMCorp., USA) and R version 3.3.3. P-values below 0.05 were considered to indicate statistical significance.

Sample size

The sample size calculation was performed for the primary outcome of the main paper on this RCT: the percentage of women with a live born child within 24 months after randomization. We assumed a live birth rate of 70% in both groups. The initially

planned 1330 women (665 per arm) would have allowed us to exclude a difference larger than 6%, which was considered to be clinically meaningful by the clinical investigators in favor of the HSG strategy (alpha 0.05, beta .80).

Results

From May 2013 to November 2016, 542 women were approached, of whom 242 were not eligible or declined to participate. A total of 300 women were randomised to a strategy starting with THL (n = 149) or a strategy starting with HSG (n = 151). Because the inclusion rate was slower than anticipated, and because external funding could not be obtained, the study was halted after inclusion of 300 women, despite that the calculated sample size was not met. Five women in the THL group and one in the HSG group withdrew their informed consent. Thus leaving 144 women in the THL group and 150 women in the HSG group (Fig. 1). Baseline characteristics of the two groups were comparable (Table 1).

Performance

In the THL group 119 out of 149 women (79.9%) randomized to THL underwent the allocated procedure whereas 134 out of 151 women (88.75%) randomised to HSG underwent the allocated procedure (Fig. 1). The women who underwent the other procedure than randomised for (n = 2 in THL group and n = 2 in HSG group) were analysed according to randomization result.

The mean time between randomisation and THL was 42.7 days (SD: 59.0 days) and for HSG 24.9 days (SD: 23.8 days). The mean time difference between randomisation and HSG compared to THL was 17.9 days (95% CI 6.6–29.1; p = 0.002). Other procedure characteristics are shown in Table 2. THL could not be completed or failed in eight women (5.4%), while failure happened once in the HSG group (0.7%). The number of failed procedures was significantly higher in the THL group (n = 8; 5.4%) than in the HSG group (n = 1; 0.7%) (p = 0.014) (Table 2). Four (2.7%) women suffered complications after THL versus one (0.7%) after HSG (Table 3). This difference in complications was not statistically significant (p = 0.20).

The mean VAS score for pain during the THL procedure was 4.7 (SD: 2.5) and during HSG the VAS score for pain was 5.4 on average (SD: 2.5) (mean difference of -0.71 (95% CI -1.38 to -0.041; p = 0.038)). The acceptability, defined as the willingness to undergo the same procedure under the same circumstances again and as the willingness to recommend the procedure to friends or family, was high for both procedures and did not differ. For both scores, a score of zero meant total willingness or recommendation respectively, whereas a score of ten meant no willingness nor recommendation at all. The willingness to undergo the procedure again was rated 2.6 (SD: 3.1) in the THL group versus 2.0 (SD: 2.6) in the HSG-group (difference: 0.6, 95% CI -0.204-1.353, p = 0.395). The average recommendation score was 2.1 (SD: 2.6) for the THL-group versus 2.2 (SD: 2.7) for the HSG-group (difference: -0.1, 95%CI -0.820-0.575, p = 0.729).

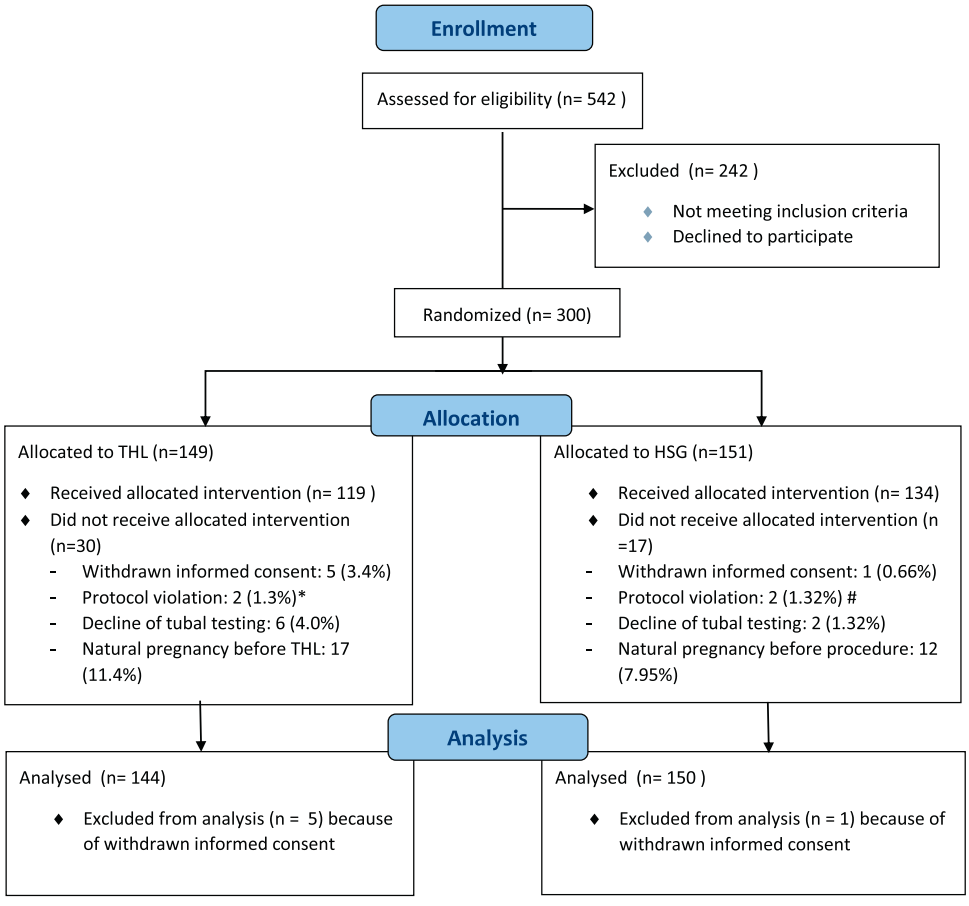

Fig. 1. Follow-up per randomization.
*two women underwent HSG because of a longer waiting period for the THL, but were analysed in the THL group according to the intention to treat principle.
one woman (0.66%) opted to undergo THL and one women (0.66%) underwent THL as the gynaecologist advised against HSG because of a recent chlamydia infection. These two women were analysed in the HSG group according to the intention to treat principle.

Table 1
Baseline characteristics.

Women n = 294	THL (n = 144)	HSG (n = 150)
Mean age (years; ± SD)	31.6 (±3.9)	31.9 (±4.0)
Median BMI (kg/m^2; IQR)	23.4 (21.0-26.9)	23.3 (21.2-26.2)
Intoxications:		
Smoking (%)	• 18.8%	• 16.7%
Use of alcohol (%)	• 25.7%	• 29.3%
Use of drugs (%)	• 0.7%	• 0.7%
Median duration of subfertility (months; IQR)	19 (16-26)	22 (17-30)
Primairy subfertile (%)	71.0%	82.7%
Positive Chlamydia serology (%)	11.1%	10.7%
Ovulatory cycles (%)	75.0%	86.0%
Median VCM semenanalysis (x 10^6; IQR)	47.5 (17.3-98.5)	51.0 (22-118.0)

Table 2
Procedure characteristics.

	THL n = 121 (%)	HSG n = 134 (%)
Procedure performed by:		
I Gynaecologists	I 120 (99.2%)	I 48 (35.8%)
II Residents	II 1 (0.8%)	II 17 (12.7%)
III Fertility doctors	III 0 (0%)	III 69 (51.5%)
Antibiotic prophylaxis	1 (0.8%)	4 (3.0%)
Contrast medium:		
I Water	n.a.	I 88 (65.2%)
II Oil		II 47 (34.8%)

Table 3
Failures and complications.

	THL n = 144 (%)	HSG n = 150 (%)
Failure due to:	Total n = 8 (5.6%)*	Total n = 1 (0.7%)#
I peritoneal tenting	I 5 (3.5%)	I 0 (0%)
II poor visualization of fornix posterior and cervix	II 2 (1.4%)	II 0 (0%)
III pain of speculum	III 1 (0.7%)	III 1 (0.7%)
Complication:	Total n = 4 (2.8%)	Total n = 1 (0.7%)
I Bleeding of vaginal wall that needed suturing	I 2 (1.4%)	I 0 (0%)
II Rectal perforation	II 1 (0.7%)	II 0 (0%)
III Prolonged period of pain requiring painkillers	III 1 (0.7%)	III 0 (0%)
IV Overnight hospital admission due to cervical bleeding	IV 0 (0%)	IV 1 (0.7%)

* Four of these women underwent HSG subsequently, one underwent a DLS with chromopertubation. The other three women did not undergo further tubal testing.
# This woman did not undergo further tubal testing.

Findings

THL was completely normal with bilateral tubal patency in 96 of 121 women (79.3%) undergoing THL. Abnormalities were seen in 17 women (14.0%) (Table 4). Out of 136 HSG-procedures, 119 women (87.5%) had bilateral tubal patency without other abnormalities (Table 4). Of women in whom oil-based contrast was used, we observed 2 abnormalities (4.3%) compared to 14 (15.9%) in women in whom water-based contrast was used. Nine women of the THL group with bilateral tubal patency were detected with abnormalities (enodmetrioses n = 5, adhesions n = 3, cyst n = 1. In the HSG group in 5 women with bilateral patent tubes abnormalities were found (intrauterine abnormalities n = 3, hydrosalpinx n = 2).

A total of eight laparoscopies were carried out (6.6%) in the 121 women of the THL group with a therapeutic laparoscopy in six of them (5.0%) (Table 5). Laparoscopic tubal findings were concordant with THL tubal findings in 5 out of 7 women (71.4%) in whom THL succeed. DLS was performed in 22 (16.2%) of the 136 women who successfully underwent HSG, twelve of which were therapeutic laparoscopies (8.8%) (Table 5). Concordant results in detection of tubal pathology was seen in 61.9% (n = 13) of the laparoscopies after HSG.

In the HSG group significantly more often DLS were performed (16.2% versus 6.6%, RR = 2.9, 95% CI: 1.32–6.23; p = 0.007). The concordance in findings during the initial tubal test and DLS later on did not differ significantly between the THL and HSG group (p = 1.00). With 79.3% normal findings in the THL group versus 87.5% in the HSG group, there might be a trend towards finding more abnormalities with THL although not significantly (RR 0.91; 95%CI 0.81–1.01, p = 0.08).

Discussion

In this randomised trial, we showed that THL and HSG as primary invasive diagnostic tool in a low risk group of subfertile women, have a comparable capacity in terms of diagnosing tubal pathology and performance. With THL a DLS might be avoided but to the cost of a higher failure rate compared to HSG. Furthermore, THL is associated with a slight advantage in pain scores but HSG is found as acceptable as THL. To our knowledge, this is the first study comparing these two strategies as first invasive tubal test. Other studies comparing outpatient THL with HSG, performed both procedures in the same woman after HSG showed abnormalities [14–18], most of them retrospective studies. Cincinelli et al. [19] performed a small RCT with 23 women who underwent subsequently HSG and THL in whom the investigation sequence was randomized. They showed a lower pain score for THL compared to HSG with concordant results in 95.5%.

Our study has limitations. The biggest limitation is the fact that the study is powered on our primary outcome and our sample size was not met. The latter was caused by the fact that the inclusion rate was much lower than anticipated, and attempts to fund our study to be able to continue recruiting were not successful. Furthermore, in this study we only included subfertile women with low risk for tubal disease. This might limit the generalizability in populations with high risk for tubal disease. Next, we observed a much higher DLS in the HSG group, which can be due to our study protocol, which stated that a DLS had to be performed after expectant management of six months or more when the Hunault model calculated a >30% chance of getting pregnant in 12 months. Nevertheless, DLS showed abnormalities in 5 out of 11 women with normal HSG.

The disadvantage of THL is the high failure rate compared to HSG. This study shows a THL failure rate of 5.6%, which is comparable to known literature when THL is performed by experienced gynaecologists [20,21] and lower than during the learning curve of these gynaecologists [12]. The advantage of THL however, is that it tends to

Table 4
Findings of THL and HSG.

Findings	THL (n = 121)	HSG (n = 136)	p-value
Bilateral tubal patency and no abnormalities	79.3% (n = 96)	87.5% (n = 119)	0.08
Unilateral tubal patency	5.8% (n = 7) Of which with adhesions 1.7% (n = 2)	5.9% (n = 8) Of which with intra uterine abnormality 0.7% (n = 1)	
Bilateral tubal occlusion	0.8% (n = 1) Of which with adhesions 0.8% (n = 1)	2.2% (n = 3) Of which with bilateral hydrosalpinx 0.7% (n = 1)	
Bilateral tubal patency with other abnormalities:	7.4% (n = 9)	3.7% (n = 5)	
• Adhesions	2.5% (n = 3)	n.a.	
• Endometriosis	4.1% (n = 5)	n.a.	
• Intrauterine abnormalities	n.a.	2.2% (n = 3)	
• Hydrosalpinx	n.a.	1.5% (n = 2)	
• Cyst	0.8% (n = 1)	n.a.	
Unknown due to failure	6.6% (n = 8)	0.7% (n = 1)	0.014

Table 5
Findings laparoscopy

Findings in initial test	THL (n = 8) or HSG (n = 22)	Reason for DLS	Findings DLS	Laparoscopic procedure
Bilateral tubal patency and no abnormalities	THL (n = 1)	Abdominal pain	Bilateral tubal patency with only a ovarian cyst (dls performed 14 months after THL)	Cystectomy
	HSG (n = 12)	I No naturally conceived pregnancy after expectant management of >6 months (n = 11) II Ectopic pregnancy (n = 1)	I -Concordant to initial test (n = 6) -Endometrioses ASRM grade I (n = 4) -Bilateral tubal occlusion with adhesions (n = 1) II Ectopic pregnancy	I -diagnostic (n = 6) -coagulation of endometrioses (n = 2) combined with adhesiolysis (n = 1) - leftsided tubectomy and right-sided tuboneostomy with adhesiolyses II tubectomy
Unilateral tubal patency	THL (n = 1)	Abnormal THL	Bilateral tubal occlusion with hydrosalpinges	Tuboneostomy at both sides
	HSG (n = 5)	I Abnormal HSG (n = 4) II Inconclusive HSG (n = 1)	I -Unilateral tubal patency with endometrioses (n = 1) -Bilateral tubal patency with endometrioses (n = 1) - Bilateral tubal patency with endometrioses and adhesions (n = 1) -Rudimentary uterine horn leftsided (n = 1) II anatomic abnormality with a missing right tube and an inactive right ovary	I -coagulation of endometrioses - coagulation of endometrioses - adhesiolyses and coagulation of endometrioses - clip placement on Fallopian tube left II diagnostic
Bilateral tubal occlusion	THL (n = 1)	Abnormal THL	Bilateral tubal patency with endometrioses and adhesions	Adhesiolysis and coagulation of endometrioses
	HSG (n = 4)	I Abnormal HSG (n = 3) II Inconclusive HSG (n = 1)	I -Bilateral tubal occlusion (n = 1) -Bilateral patency with endometrioses (n = 2) II Bilateral tubal patency and no abnormalities	I -diagnostic -coagulation of endometrioses (n = 2) II diagnostic
Bilateral tubal patency with other abnormalities	THL (n = 3)	Abnormal THL: I endometrioses (n = 2) II adhesions (n = 1)	I bilateral tubal patency and endometrioses (n = 2) II bilateral tubal patency and no abnormalities	I coagulation of endometrioses (n = 2) II diagnostic
	HSG (n = 1)	Abnormal HSG (suspicion of adhesions)	Endometrioses	Coagulation of endometrioses
Unknown due to failure / inconclusive	THL (n = 2)	I Failure (n = 1) II Inconclusive due to adhesions in Douglas (n = 1)	I bilateral tubal patency and endometrioses II bilateral tubal occlusion and adhesions	I coagulation of endometrioses II diagnostic
	HSG (n = 0)			

be able to show abnormalities as adhesions and endometriosis [22]. In our study population with low risk of tubal disease, we found adhesions and endometriosis in 7.1% despite the fact that the tubes were patent. In our opinion THL can be of benefit to these women as they might be helped with early treatment instead of expectant management. Van Kessel et al. showed a fecundity rate ratio of 0.42, which means less probability of a spontaneous intrauterine pregnancy per time unit for women with patent tubes but with the combination of endometriosis and adhesions, compared to women without endometrioses and adhesions [23]. On the other hand, however, HSG shows intrauterine abnormalities, that THL cannot detect. Furthermore, the usage of oil-based contrast during HSG could have had a therapeutic effect [24].

While we conclude that THL and HSG have a comparable diagnostic performance, with each of the procedures having a specific benefit, we have to wait for the live birth rates in both groups. This will determine whether one procedure should be preferred over the other.

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