Review Article

Safety and Efficacy of Trans-Vaginal Laparoscope with Hysterosalpingography in the Infertility Assessment; A Systematic Review and Meta-Analysis

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ABSTRACT

Background: Hysterosalpingography (HSG) is a non-invasive diagnostic and therapeutic modality that has been used as the first-line tool for tubal patency assessment in cases of infertility. Trans-vaginal hydro-laparoscopy (THL) appears to become the new solution for HSG and standard laparoscopy's obstacles. This has not been evidenced yet; because there is a lack of medical literature directly comparing the diagnostic value and the fertility prognosis between THL and HSG.

Methods: We searched five databases; PubMed, Scopus, Science Direct, Web of Science, and Medline Plus. We included four studies. The applicable outcomes for meta-analysis were four outcomes; this includes; detection of tubal patency and tubal occlusion, in addition to the ability of detection of intrauterine anomalies, and finally the pain score during both procedures.

Results: The number of cases with endometriosis and adnexal adhesion was significantly higher in the THL group compared with the HSG group (RR= 12.36 [1.61, 95.06], *p*= 0.02) and (RR= 10.82 [1.38, 84.63], *p*= 0.02) respectively. Moreover, THL was associated with significantly lower pain scores compared with HSG (MD= -0.82 [-1.37, -0.26], *p*= 0.004).

On the other hand, there was no significant difference between THL and HSG regarding detected number of patent tubes (RR= 0.96 [0.91, 1.00], *p*=0.06), occluded tubes; (RR= 1.19 [0.70, 2.03], *p*= 0.51), and intrauterine anomalies (RR= 0.16 [0.02, 1.30], *p*= 0.09).

Conclusion: We conclude that THL has a potentially higher ability for accurate diagnosis of different adnexal abnormalities and less pain scoring compared with HSG.

Key Words: HSG, hysterosalpingography, infertility, THL, transvaginal hydrolaparoscopy.

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INTRODUCTION

Infertility is defined as failure of conception after 12 months of unprotected sexual intercourse[1]. Many causes; including uterine, ovarian, and tubal disorders lead to this problem. The tubal factor is one of the major causes of infertility; affecting up to 25% of infertile patients[2–4]. Tubal disorders occur due to different etiologies such as chlamydial infection, pelvic inflammatory diseases, post-operative adhesions, and adhesions from endometriosis[5–7]. So, assessment of the fallopian tubes remains the first line in the female infertility workup and good tubal evaluation leads to a higher possibility of conception among those couples.

Hysterosalpingography (HSG) is a non-invasive diagnostic and therapeutic modality that has been used as the first-line tool for tubal patency assessment. However, it showed a relatively low sensitivity (45%)[8]. On the other hand, diagnostic laparoscope has been considered the gold standard modality for tubal patency assessment, but it is an invasive technique that requires general anesthesia.

Trans-vaginal hydro-laparoscopy (THL) appears to become the new solution for HSG and standard laparoscopy's obstacles. It is first described by Gordts *et al* in 1998[9]. THL enters through the posterior vaginal wall reaching the Douglas pouch allowing the visualization of the pelvic cavity with the evaluation of the tubes, ovaries, uterus, and pelvic peritoneum as do the standard laparoscope[10,11].

THL is considered an outpatient endoscopic assessment tool with results that are similar to the standard laparoscopic assessment accuracy. Many studies have confirmed the concordance between the THL and standard laparoscope[12–14]. In addition, THL was compared with HSG regarding the accuracy of diagnosis of tubal disorders. Both modalities showed agreement on the visualized patent tubes[15]. However, THL seems to be more accurate

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than HSG in the diagnosis of endometriosis and peri-tubal adhesions but, HSG is more informative regarding the uterine abnormalities[15–17].

Although THL appears to be superior to HSG, this benefit has not been evidenced yet; because there is a lack of medical literature directly comparing the diagnostic value and the fertility prognosis between THL and HSG.

OBJECTIVES

We conduct this systematic review and meta-analysis aiming to do a direct comparison between THL and HSG and to evaluate the benefits and the tolerability of both modalities in the female infertility workup.

METHODS

We adhered to the Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) guidelines and the Cochrane handbook of systematic review and meta-analysis of interventions[18,19] while conducting this study.

Search Strategy

We searched five databases; PubMed, Scopus, Science Direct, Web of Science, and Medline Plus for the relevant studies using the following search strategy: "(hysterosalpingography) AND (transvaginal hydrolaparoscopy) AND ((infertility) OR (sterility) OR (subfertility)".

Selcetion Criteria

All studies applied to these criteria were included in our meta-analysis:

(I) participants: infertile or sub-fertile women undergoing fertility workup (II) Intervention: Transvaginal hydro-laparoscopy (THL) Comparator: Hysterosalpingography, (iv) Outcomes: number of endometriosis cases by both modalities, number of cases of adnexal adhesion, number of patent tubes, number of the occluded tubes, and intrauterine anomalies. (v) Study design: any study design. We excluded (1) Studies that did not directly compare between THL and HSG (single-armed studies), (2) studies with no available full text.

Data Collection

We imported the relevant studies from systematic search of the databases to an Excel workbook[20] using EndNote X8.0.1 version[21]. We conducted a two-phase screening process according to the eligibility criteria. The first one included the title and abstract screening. The second one included full-text screening. Any conflict about the eligibility of a specific study was solved by discussion between authors.

Following the screening process, we extracted data of three main categories: (1) General characters of the included studies and included patients. (2) Data of the outcomes eligible for analysis including the number of endometriosis cases by both modalities, number of cases of adnexal adhesion, number of patent tubes, number of the occluded tubes, and intrauterine anomalies. (3) Data for the main domains of quality assessment according to Cochrane's risk of bias tool[22].

Data Analysis

We performed our analysis using Review Manager Software (RevMan 5.4.1). We had only dichotomous outcomes, so we performed our analysis using event and total. For heterogeneous outcomes a random-effects model was used, while homogeneous data were analyzed using a fixed-effects model; using the Chi-square tests and I2 index to assess the heterogeneity[23]. Any Values of I2 > 50% or $P < 0.1$ or were considered heterogeneous. We tried Cochrane's leave-one-out method to resolve the heterogeneous outcomes[23].

Quality assessment of this meta-analysis was performed using the guidelines of the Grading of Recommendations, Assessment, Development, and Evaluations (GRADE). All included studies were clinical trials. We performed the quality assessment using Cochrane's risk of bias tool[22]. This tool comprises the following domains: 1) proper randomization, 2) blinding allocation of the included patients into each group, 3) blinding of patients only (single-blinding), blinding of both personnel and participants (double-blinding), or not blinding at all, 4) Attrition bias, 5) Selection bias (outcomes reported matches with that of the protocol or not), 6) Awareness of the outcome assessor (whether blinded or not), 7) Other bias. The total risk of bias for the studies has been assessed as well.

RESULT

We analyzed data obtained from 338 patients from four included studies[16,17,24,25]. (Figure 1) shows the PRISMA flow diagram of the literature search and included studies. The mean age of included participants was 31 years old and the mean duration of infertility was 27.2 months; Table 1 summarizes data of the included studies and population characteristics.

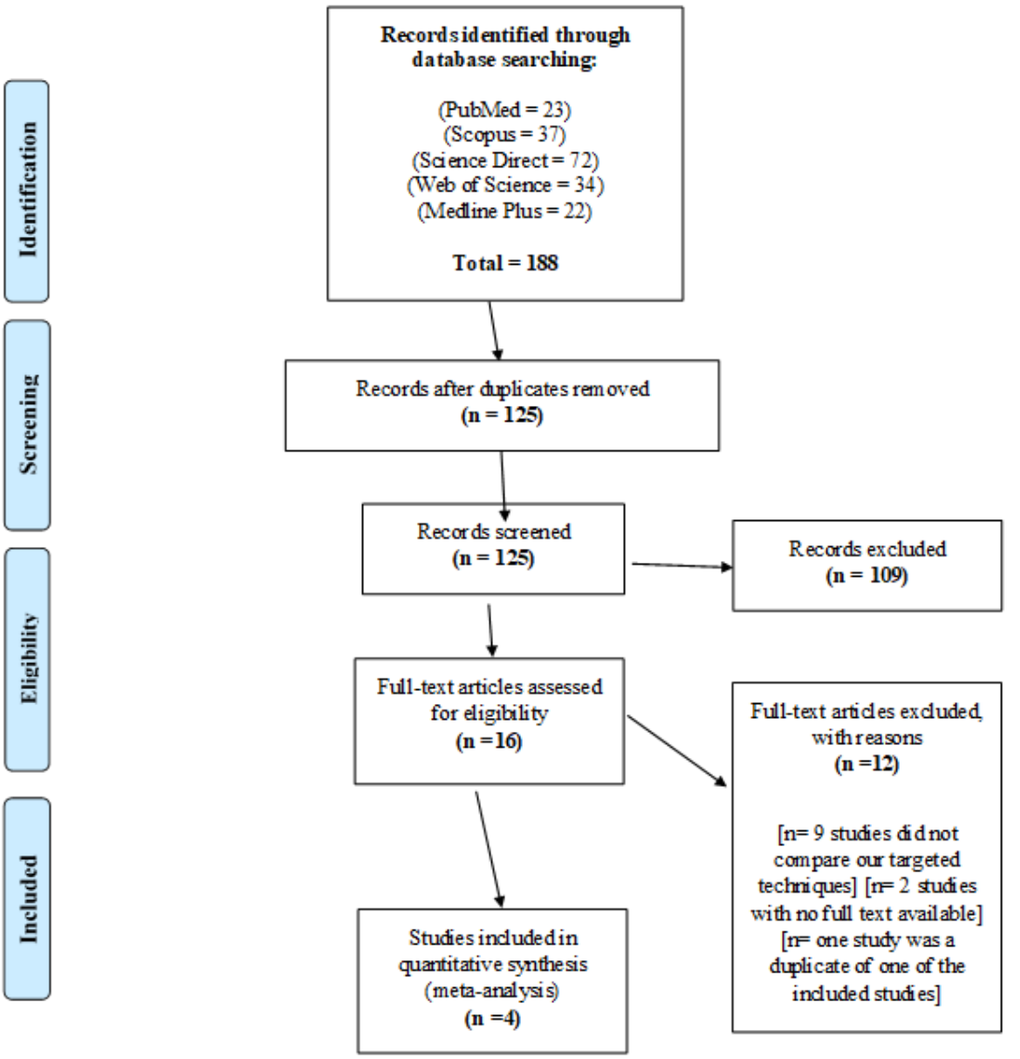

Fig. 1: prisma flow digram of included studies

Table 1: summarizes data of the included studies and population characteristics

Age(years), mean (SD)		BMI (kg/m2; IQR)		Infertility duration, months/years		Positive chlamydia serology	
THL	HSG	THL	HSG	THL	HSG	THL	HSG
31 (20-39)		NR	NR	12		NR	NR
29 (± 6.80)	30 (± 4.5)	NR	NR	2.90 (± 1.30) years	3.25 (± 1.21) years	NR	NR
32.3 (± 3.5)		NR	NR	48 (± 11.06)		85.70%	
31.6 (± 3.9)	31.9 (± 4.0)	23.4 (21.0-26.9)	23.3 (21.2-26.2)	19 (16-26)	22 (17-30)	11.10%	10.70%

NR= not reported

Results of Risk of Bias Assessment

The overall risk of bias results was high. (Figure 2) summarizes the results of the quality assessment of the included studies. Regarding randomization, all studies were at low risk except ahinko-hakamaa *et al*,[24] and Kataoka *et al*.[25] which did not report data about the randomization. Regarding allocation concealment, only Cicinelli *et al*[17] were at low risk of bias. The remaining studies did not report enough data about the concealment domain. As for blinding of both participants and outcome assessors, all studies are at high risk of bias. The attrition bias and selective reporting domains were at low risk of bias in most of the studies except for Kataoka *et al*.[25]. (Table 2) shows the summary of the risk of bias results.

Table 2: summery of the risk of bias for the included studies

study	Randomization	allocation concealment	blinding of participants and personnel	blinding of outcome assessment	Attrition bias	selective reporting	other bias
ahinko-hakamaa2009	unclear	unclear	high risk	high risk	low	low	high
cicinelli2001	low risk	low risk	high risk	high risk	low	low	high
Kataoka 2011	unclear	unclear	high risk	high risk	unclear	unclear	high
tros2019	low risk	unclear	high risk	high risk	low	low	high

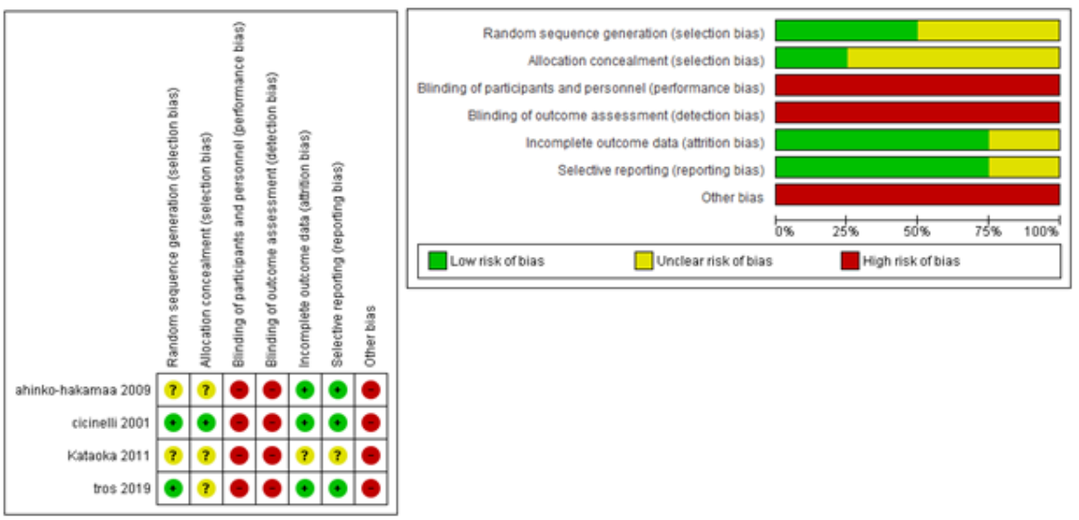

Fig. 2: shows summary of ROB

Analysis of Outcomes

1- Number of patent tubes

This outcome was reported by four studies[16,17,24,25]. THL detected 169 patients with patent tubes among the assessed 202 patients, while HSG detected 180 patients with patent tubes among the assessed 217 patients. However, there was no significant difference between both groups (RR= 1.06 [0.79, 1.43], *p*=0.71). Pooled data were heterogeneous (*P*= 0.01); I^2 = 72%; (Figure 3A). We performed a leave one out test to solve this heterogeneity; excluding ahinko-hakamaa *et al*.[24]. The pooled data turned homogenous (P= 0.55); I^2 = 0% and the outcome remained unchanged with no significant difference between both groups. (RR=0.95 [0.90, 1.01], **p**= 0.11); (Figure 3B)

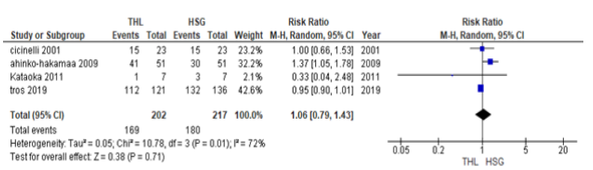

Fig. 3A: show analysis of patent tubes outcome

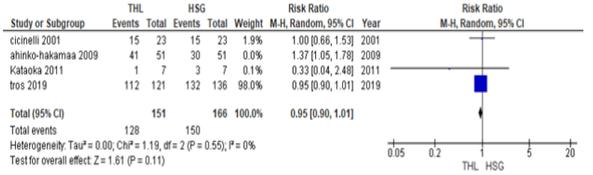

Fig. 3B: shows analysis of patent tubes outcome

2-nNumber of occluded tubes

This outcome was reported by four studies[16,17,24,25]. THL detected 12 patients with occluded ducts among 151 patients compared to HSG which detected 13 cases with occluded tubes among 166 patients. However, this difference between both modalities was not significant (RR= 0.67 [0.43, 1.05], *p*=0.08). The pooled analysis was homogenous (*P*= 0.26); I² = 26%; (Figure 4).

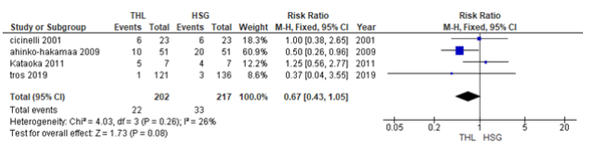

Fig. 4: shows analysis of occluded tubes outcome

3- Detected intrauterine anomalies

This outcome was reported by two studies[16,17]. THL can detect 12 cases with intrauterine abnormalities among 134 patients, while HSG can detect only 6 cases with intrauterine abnormalities among 149 cases, the overall risk ratio RR= 1.05 [0.04, 28.96]. there was no significant difference between both groups; *p*= 0.98. the pooled analysis was heterogenous, (*P*= 0.03); I² = 78%; (Figure 5). but we couldnot solve this by the leaveoneout test.

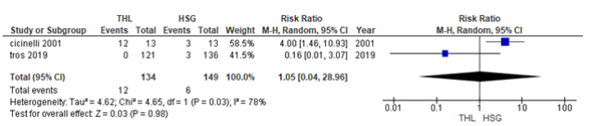

Fig. 5: shows analysis of intrauterine abnormalities outcome

4- Pain score

This outcome was reported by two studies[16,17]. THL was associated with significantly lower pain scores compared with HSG; the overall MD= -0.82 [-1.37, -0.26], *p*= 0.004. the pooled analysis was homogenous (*P*= 0.12); I² = 58%; (Figure 6).

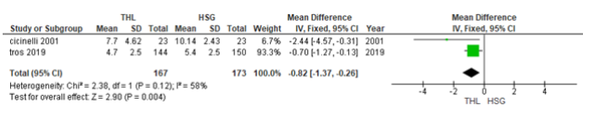

Fig. 6: shows analysis of pain score outcome

DISCUSSION

This is the first meta-analysis directly comparing the results of THL and HSG in the female infertility workup. We analyzed data obtained from 338 women in four studies. We found that during infertility workup, THL revealed less pain scoring compared with HSG. On the other hand, there was no significant difference between THL and HSG regarding the detected number of patent tubes, occluded tubes, and intrauterine anomalies.

In a 2019 trial, Tros *et al*.[16] conducted the first direct comparison of the performance and the diagnostic power of both THL and HSG. In their trial, they found that the THL finding during the tubal evaluation was concordant to the finding by the diagnostic laparoscopy by 71.4% (they were similar in 5 patients out of 7). On the other hand, the concordance of diagnostic laparoscopy with HSG was 61.9%. This difference between THL and HSG in comparison with laparoscope was not significant, *p*=1. Moreover, they observed that THL tends to detect more abnormalities than HSG, but this is not significant, too; *p*=0.08.

The major advantage of the THL is the capability of introducing a salpingo-scope that can accurately examine the tubal mucosa. This makes THL has a better prediction of conception success compared with HSG and the standard laparoscope[26,27]. Moreover, the use of THL as a first-line assessment tool in female infertility has made 96.8% of cases avoid HSG assessment and 93.2% of cases avoid laparoscopic assessment[28].

Van Kessel *et al*[29], was the only study that compared THL and HSG regarding different pregnancy outcomes. Out of 142 cases who underwent THL, 83 cases had an intrauterine pregnancy resulting in a live birth (within 24 months), compared to 82 cases out of 148 patients who did the HSG procedure. In addition, they reported no significant difference between both groups regarding the time to conception. Miscarriage was reported in 16 and 20 patients in the THL and HSG groups respectively, with no significant difference between them. In addition, Ectopic pregnancy was reported in two cases of the HSG group. Moreover, multiple pregnancies were reported in 12 and 19 cases of the THL and HSG groups respectively with no significant difference between both modalities.

These findings from different studies evaluating THL or those comparing it with HSG and laparoscope support the use of THL as a first-line assessment tool for female infertility. However, there is a lack of double-blinded randomized controlled trials directly comparing both modalities which are important to establish clear evidence on the accuracy and diagnostic power in addition to, the safety of each one. This will help choose the best modality for each case and to avoid unnecessary investigations and their complications.

Complications of both modalities are an important outcome that needs to be evaluated. However, among our included studies, only Tros *et al*[16] reported the incidence

of those complications. They reported THL complications in only four patients among 144 patients in this group. Two cases were complicated with vaginal wall bleeding that needed suturing, one case of rectal perforation, and one case suffering from a prolonged period of pain requiring pain killers. On the other hand, the HSG group revealed only one case of cervical bleeding requiring overnight hospital admission. However, the incidence of complications between both groups shows no significant difference between both modalities; p= 0.20.

Verhoeven *et al*.[28] reported no major complications but 23 cases with intraperitoneal bleeding among 1000 THL procedures, in addition to, five cases of bowel perforation. Similarly, Van Tetering *et al*.[30] reported the occurrence of complications in five patients among 272 performed THLs with two cases of rectal perforation, two cases of bleeding at the site of insertion of the laparoscope, in addition to a case of PID.

As for HSG complications, in a nationwide survey of two types of HSG, Roest *et al*.[31] reported complications in 167 (5.1%) patients among 3289 HSG with oil-based contrast, in addition to 34 cases (1.8%) among 1876 HSG using water-based contrast. Most of those complications were intravasation of contrast which was more frequent in the oil-based group.

Regarding procedures failure, Vankessel *et al*.[29] reported a failure rate of 6.7% during the THL procedure, and Verhoeven *et al*[28] showed failure rates of 3.2% in addition to 4% failure rate reported by Van Tetering *et al*.[30].

Verhoeven *et al*[28], reported that 1.1% and 2.1% of failures were due to failure of peritoneal access and poor visualization respectively. Moreover, they correlated the failure of the procedure with the experience of the gynecologist. The first 50 interventions were associated with failure of 5 cases of them. On the other hand, the other 950 interventions were associated with 26 failed cases; p=0.018. Nevertheless, the bleeding complications occurred in 5 cases of the first 50 cases (10%), but only in 18 cases (1.9%) of the other 950 cases; p =0.004. similarly, bowel perforation occurred in only one case among the last 950 (0.1%) cases compared with four cases in the first 50 cases.

This study poses some strength points. This is the first systematic review and meta-analysis directly comparing the role of THL and HSG in the infertility workup. In addition, we adhered to the Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) guidelines and the Cochrane handbook of systematic review and meta-analysis of interventions[18,19].

LIMITATIONS

The interpretation of our findings is limited by the small sample size of patients and the limited number of studies directly comparing both modalities. Also, there was a lack of evidence on different important outcomes that may affect the choice of the assessment tool. Another limitation was the heterogeneity in some outcomes, which weaken the certainty of evidence according to GRADE[32]. But we tracked down the attributing factors and managed to solve the heterogeneity through the leave-one-out method according to the Cochrane handbook[18,19].

CONCLUSION

We conclude that THL has a potentially higher ability for accurate diagnosis of different adnexal abnormalities and less pain scoring compared with HSG. However, there was no significant difference between both interventions regarding the remaining outcomes.

This signifies the role of THL during female fertility work-up and the possibility of replacing HSG and the invasive standard laparoscope as first-line infertility assessment tools. Moreover, THL may be used in integration with other non-invasive investigations such as HSG to reach a complete and accurate assessment of different intrauterine and extrauterine anomalies. But the interpretation and generalizability of data are limited by the small sample size and the lack of available literature directly comparing both modalities.

CONFLICT OF INTERESTS

There are no conflicts of interest.

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