

Transvaginal hydrolaparoscopy

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IMPACT PARAGRAPH

Subfertility

Approximately one in six couples experience difficulties to conceive. A couple is subfertile if no pregnancy occurs after one year of unprotected intercourse. Possible explanations for subfertility are ovulatory dysfunction, sperm problems or pathology of the uterus or the fallopian tubes. Subfertility is called unexplained if after thorough examination no explanation for the subfertility is found. Tubal factors are found in 15-30% of subfertile couples. This thesis focuses on two different forms of diagnostic tests for tubal patency in the fertility work-up: transvaginal hydrolaparoscopy (THL) and hysterosalpingography (HSG).

THL and HSG

THL is an outpatient procedure under local anesthesia, where the pelvic organs are visualized with a small endoscope introduced in the pouch of Douglas through the fornix posterior of the vagina. The patency of the tubes is tested by chromopertubation with a methylene blue dye. HSG is a radiological diagnostic procedure, in which the patency of the tubes is visualized by a radio-opaque contrast medium. HSG is one of the most commonly used first-line tubal patency test in Dutch hospitals, although it has a low sensitivity and specificity in women with a low risk of tubal pathology. The gold standard for testing tubal patency is conventional diagnostic laparoscopy with chromopertubation, which is a more invasive procedure that requires general anesthesia and admission in the hospital.

One of the most important differences between THL and HSG is that THL is an endoscopic technique, with direct visualization of the pelvis and the tubes. The procedure gives not only information about the patency of the tubes but also about the presence of other pelvic pathology such as endometriosis and adhesions. HSG on the other hand is a radiological diagnostic procedure that demonstrates the patency of the tubes and the shape of the uterus, but does not allow to evaluate if there is other pelvic pathology.

Research questions and findings

Our main question for this thesis was if THL can be used as a first-line diagnostic strategy in the work-up of the subfertile couple. More specifically our research questions were to determine the prognostic capacity of THL to predict a non-IVF conception and to evaluate if a strategy with THL compared to a strategy with HSG in the work-up for subfertile couples is comparable in case of live births and time to pregnancy. Furthermore we wanted to evaluate if the two strategies are cost-effective and if there is a difference in quality of life after the two procedures. Moreover we wanted to examine women's preferences for different aspects of the tubal patency tests. Our most interesting findings indicate that:

1. THL can be used as a first-line diagnostic test in subfertile women. If a woman is found to have unilateral tubal occlusion at THL, her chances of non-IVF conception are comparable to those of a woman with 2 open tubes. If a woman is diagnosed with bilateral tubal occlusion, or if she has the combination of endometriosis and adhesions, her chances to have a non-IVF conception are significantly reduced.
2. In a randomised study with 300 subfertile women we found that THL was not inferior to HSG in terms of conception leading to live birth. After a follow-up period of 24 months we found a live birth rate of 58.5% in the THL-group versus 55.4% in the HSG-group (not significant) and no difference in time to conception leading to live birth. There was also no difference in miscarriages and twin-pregnancies.
3. We found that a strategy with THL is cost-effective to a strategy with HSG in the fertility work-up. The mean costs per woman for the diagnostic tests, fertility treatments and pregnancy were €4991 for the women in the THL-group, compared to €5262 in the HSG-group. The procedure of THL itself costs more than a HSG, but the women in the HSG group underwent more often a diagnostic or therapeutic laparoscopy and also had higher costs for their subsequent fertility treatments.
4. We found that there was no difference in fertility related quality of life between women that underwent THL or HSG 6 weeks after the procedure.
5. In our discrete choice experiment (DCE) we examined the preferences of subfertile women for different aspects of the tubal patency tests. We found that subfertile women when choosing THL preferred a lower chance of a false negative result, a lower failure rate and a shorter waiting time. If THL is not conclusive women prefer a conventional laparoscopy over an expectant management. Women choosing HSG preferred a lower chance of a false negative result, a shorter waiting time and a lower chance of complications.

RELEVANCE OF OUR FINDINGS

Societal relevance

In the Netherlands and also worldwide there is a large practice variation in the strategy and timing of tubal patency testing in the subfertility work-up. In this light the results of our research are relevant for both clinicians and patients, and for healthcare policy makers. For the clinician our research shows that THL could be used as an alternative to HSG in the fertility work-up. It is a feasible procedure with a low complication rate, and its'

prognostic capacity to predict non-IVF conception is comparable to the gold standard conventional laparoscopy. THL is cost-effective compared to HSG in the fertility work-up. Healthcare policy makers and guideline developers should evaluate THL as part of the possible strategies for tubal patency testing, and it should be included in guidelines for the fertility work-up.

In this research project, women's experience and opinion play an important part. It is well known that tubal patency testing in the fertility work-up can be stressful. We found that women undergoing THL in an outpatient setting had lower pain-scores than women undergoing HSG, but both procedures were evaluated as equally acceptable. Also there was no difference in fertility related quality of life between the two procedures. In our discrete choice experiment we found that a low chance of a false negative result, a low failure rate, a low chance of complications and a short waiting time. Knowing what is important for the subfertile woman, is necessary for shared decision making and therefore important for all stakeholders involved in fertility care.

Scientific relevance

Our research contributes to the field of knowledge about tubal patency testing in the subfertility work-up. Because there are various diagnostic techniques for testing tubal patency, our work needs to be seen in a bigger scope of research on tubal patency testing and fertility treatments. We compared THL and HSG as a first-line test in the fertility work-up. Although THL has been studied previously, a comparison with the most commonly used technique of tubal patency testing, HSG, has not been made previously in terms of fertility outcomes, cost-effectiveness, quality of life and the preference of subfertile women. Besides scientific publications, our main findings were also presented at conferences of both international fertility and gynecological endoscopic societies.

Further research

We found that if THL is used as a first-line patency in the subfertility work-up, women with mild endometriosis or adhesions but with open tubes, are diagnosed in an early stage of their fertility treatment. The chances of a natural conceived pregnancy are reduced in these women and more research is needed to evaluate if these women would benefit most from fertility enhancing surgery or from IVF treatment.

THL as a tubal patency test has been developed more than 25 years ago, but the technique has not been implemented in many hospitals. The practice variation on tubal patency testing is wide. Possible barriers for the uptake of the procedure by gynecologists, is that the transvaginal technique for endoscopic surgery is not part of the standard gynecological curriculum and that the learning curve needs to be taken into account. It

would be valuable to analyze what factors influence the acceptance of THL and other techniques for tubal patency testing.

Other aspects about THL that need to be investigated are the feasibility and cost-effectiveness of therapeutic procedures during THL, such as adhesiolysis and coagulation of endometriosis and to evaluate if there is an effect of tubal flushing during THL. There is evidence that tubal flushing with oil-based contrast medium compared to a water-based contrast medium at HSG leads to a higher percentage of live births after the procedure. The methylene blue dye to test the tubes at THL is water-based and it is yet still unknown if it would be feasible and effective to perform a tubal flushing with oil-based contrast medium after the procedure.