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Oil-based or water-based contrast for hysterosalpingography in infertile women: a cost-effective analysis of a randomized controlled trial

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Objective: To determine the cost effectiveness of the use of oil-based versus water-based contrast in infertile women undergoing hysterosalpingography (HSG).
Design: Economic evaluation alongside a multicenter randomized trial.
Setting: Hospitals.
Patient(s): Infertile women with an ovulatory cycle, 18–39 years of age, low risk of tubal pathology.
Intervention(s): Use of oil-based versus water-based contrast during HSG.
Main Outcome Measure(s): Costs per additional ongoing pregnancy and per live birth within 6 months of randomization, incremental cost-effective ratios (ICERs).
Result(s): A total of 1,119 women were randomized to HSG (oil-based contrast, n = 557; water-based contrast, n = 562). After HSG, most women had no additional treatment; a minority had IUI or IVF. In the oil group, 39.7% women had an ongoing pregnancy within 6 months of randomization versus 29.1% women in the water group. There was a 10.7% increase in the live birth rate in the oil group. For ongoing pregnancy, the mean costs per couple were US$2,014 in the oil group and US$1,144 in the water group, with a corresponding ICER of US$8,198 per additional ongoing pregnancy. For live birth, the mean costs per couple were US$11,532 in the oil group and US$8,310 in the water group, with a corresponding ICER of US$30,112 per additional live birth.
Conclusion(s): Hysterosalpingography with oil-based contrast results in higher 6-month ongoing pregnancy and live birth rate. If society is willing to pay US$8,198 for an additional ongoing pregnancy, HSG with oil-based contrast is a cost-effective strategy compared with HSG with water-based contrast for infertile, ovulatory women at low risk for tubal pathology.
Clinical Trial Registration Number: Dutch Trial Register, NTR 6577 (www.trialregister.nl). (Fertil Steril® 2018;110:754-60. ©2018 by American Society for Reproductive Medicine.)
El resumen está disponible en Español al final del artículo.

Key Words: Cost-effectiveness, hysterosalpingography (HSG), oil-based contrast, water-based contrast, ongoing pregnancy

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One of six couples trying to conceive will be confronted with subfertility, defined as the inability to get pregnant after 1 year of unprotected intercourse (1). Traditionally, testing for tubal occlusion and other tubal pathology has been part of the diagnostic fertility workup. Although other tests for tubal testing, including hysterosalpingo contrast sonography and transvaginal hydrolaparoscopy, have been introduced in the past decade, many clinics still use hysterosalpingography (HSG) to evaluate tubal patency during fertility workup. Although HSG originally is a diagnostic test, the fertility enhancing effect of tubal flushing has been speculated on for decades (2).

A meta-analysis of five low quality and heterogeneous randomized clinical trials indicated a potential benefit of oil-based versus water-based contrast (odds ratio, 1.44; 95% confidence interval [CI] 0.84–2.47), although the difference was not statistically significant (3). In light of this uncertainty we conducted the H2Oil trial, a nationwide randomized controlled trial in the Netherlands, comparing the use of water-based contrast and oil-based contrast in subfertile women scheduled for HSG. In this trial, significantly more women became pregnant within 6 months after randomization (39.7% vs. 29.1%, relative risk 1.37; 95% CI 1.16–1.61) after an HSG with oil-based contrast compared with an HSG with water-based contrast (4). Based on these data, the use of oil-based contrast can be considered as a first-line procedure for women undergoing tubal testing in their workup for infertility.

In view of increasing healthcare costs, it is important to investigate and compare the costs and effects of different medical interventions (5). In the specific case of infertility, the control of costs is important to facilitate access to care. In this article we assessed the costs and effects of an HSG with oil-based contrast versus water-based contrast in a cost-effective analysis, which was performed alongside the H2Oil randomized clinical trial.

MATERIALS AND METHODS

The H2Oil study was a randomized clinical trial comparing the use of oil-based contrast and water-based contrast in infertile women undergoing an HSG (4). The H2Oil study was approved by the ethics committee and institutional review board of the Academic Medical Centre, Amsterdam, the Netherlands (MEC 08/362) and by the board of directors of all participating hospitals. Study oversight was provided by the ethics committee of the Academic Medical Centre, Amsterdam. The trial is registered in the Dutch Trial Register (NTR 3270, http://www.trialregister.nl). In the present article, we briefly discuss the trial essentials.

Patients and Study Procedures

Subfertile women between 18 and 39 years of age with a spontaneous menstrual cycle and an indication for tubal patency testing by HSG were eligible for the trial. Couples with male factor subfertility, endocrine disorders, iodine allergy, or a high risk for tubal pathology (a history of pelvic inflammatory disease, previous chlamydia infection, or known endometriosis) did not participate.

Consenting women were randomized for the use of oil-based contrast (Lipiodol Ultra Fluid) or water-based contrast (Telebrix Hystero) during HSG in a 1:1 ratio, and HSG was performed according to local protocol using a cervical vacuum cup, a balloon catheter, or a metal cannula (hysterophore). During infusion of 5–10 mL of contrast using a plastic syringe (Cook Medical), four to six roentgenograms were made to evaluate the patency of the fallopian tubes and were examined by a gynecologist or radiologist.

Infertility Treatments

The advised fertility treatment was dependent on the predicted likelihood for a natural conception within 12 months after HSG based on the prognostic model of Hunault et al. (6). This prediction model is widely used in the Netherlands as a fertility treatment decision aid. It is part of the Dutch guideline. Depending on the results of the HSG, women were managed expectantly if their prognosis for natural conception was >30% (6), or advised to undergo IUI if their prognosis was <30%. Women were advised to undergo IVF/intracytoplasmic sperm injection (ICSI) in case of tubal blockage or if semen analysis during IUI showed very poor semen quality (Supplemental Table 1, available online).

The primary outcome was ongoing pregnancy, defined as a positive fetal heartbeat on ultrasound after 12 weeks of gestation, with the first day of the last menstrual cycle for the pregnancy within 6 months of randomization. Live birth, defined as a live birth after 24 weeks of gestation, multiple pregnancy rate (PR) and miscarriage rate were secondary outcomes. Additional secondary outcomes measured in the trial were not considered in this economic evaluation, as they did not differ significantly between the two groups.

Economic Evaluation

The economic evaluation was performed from the perspective of the healthcare system and its patients using United States dollars. The analysis was done according to the ISPOR guidelines (7), and our report followed the Consolidated Health Economic Evaluation Reporting Standards statement (8).

We compared the direct medical costs of the contrast media intervention, infertility treatments, and miscarriage within 6 months of randomization for the primary outcome of ongoing pregnancy. An additional analysis included the direct medical costs related to pregnancy and delivery to assess the costs made to achieve a live birth.

Data on resource use were collected from the individual case record forms. For each woman, we registered the interventions received within the study period of 6 months, all types of pregnancies, and whether a single or multiple (twin) live births were achieved. The costs for each parameter were derived from two previous articles and a US-based fertility website (9–11) (Table 1). The cost parameters and unit costs included in the economic evaluation for the trial (expressed in US$) are presented in Table 1. All calculations were standardized to 2017 prices using consumer price index data. The unit costs were split into three main categories: contrast media, infertility treatments, and

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