A simple method for fallopian tube sperm perfusion using a blocking device in the treatment of unexplained infertility

Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
The use of fallopian sperm perfusion (FSP), a treatment for couples with unexplained infertility that is performed within cycles of controlled ovarian stimulation and intrauterine insemination (IUI). The intervention was based on a blocking device and the equipment consisted of a cervix adaptor, a bivalve speculum, forceps, and sterile 5-mL and 10-mL syringes.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients with unexplained infertility for at least two years. Unexplained infertility was defined as:

- spontaneous ovulation checked by at least two biphasic basal body temperature charts and normal serum progesterone concentrations (greater than 10 ng/mL) in the midluteal phase;
- normal FSH, LH, TSH and prolactine serum levels;
- normal hysteroscopic and laparoscopic findings with regular uterine cavity and tubes;
- normal sperm parameters according to the World Health Organisation standards; and
- no detectable anti-sperm antibodies.

Setting
The setting was a university hospital. The economic study was carried out at the Gynecology and Obstetrics Unit of the University of Trieste, Italy.

Dates to which data relate
The effectiveness and resource use data were gathered between January 1998 and March 2000. The price year was 2000.

Source of effectiveness data
The effectiveness data were derived from a single study.
Link between effectiveness and cost data
The costing was performed prospectively on the same patient sample as that used in the effectiveness analysis.

Study sample
Preliminary power calculations were performed to determine the appropriate number of cycles needed in the analysis. A sample size of at least 66 cycles was required to detect a statistically significant difference (80% power and 5% type I error) between the study groups in terms of the main outcome measure, a difference in the pregnancy rate of greater than 20%. The method used to select the sample was not reported. A total of 65 patients were enrolled into the study. There were 32 women in the IUI group and 33 women in the FSP group. In the IUI group, the mean age was 34.8 (+/- 4.6) years, the body mass index was 20.6 (+/- 2.9) kg/m2, and the duration of infertility was 42 (+/- 16.9) months. In the FSP group, the mean age was 35.5 (+/- 3.5) years, the body mass index was 21.1 (+/- 2) kg/m2, and the duration of infertility was 40.2 (+/- 15.8) months. A total of 66 cycles were given in both study groups.

Study design
This was a randomised controlled trial, which was carried out in a single centre. Randomisation was performed via a random-number generator using a 1:1 ratio. Women were given the same treatment over a maximum of three cycles. Three cycles were cancelled before randomisation and were excluded from the analysis, but no cycle was cancelled after patient allocation to the study groups. The patients were followed until birth took place. No loss to follow-up was reported.

Analysis of effectiveness
All patients included in the study after randomisation were taken into account in the effectiveness analysis. The health outcomes assessed in the analysis were:

- the clinical pregnancy rate, that is, the presence of foetal heartbeats on ultrasound examination or a positive histological identification of an ectopic pregnancy;
- the ongoing pregnancy rate, that is, the presence of foetal heartbeats beyond 14 weeks of gestation; and
- the prevalence of miscarriages, ectopic pregnancies, and twin and triplet pregnancies; and
- complications.

The study groups were shown to be comparable in terms of the patient characteristics, ovarian stimulation procedure and semen parameters before preparation.

Effectiveness results
The clinical pregnancy rate per cycle was 9.1% in the IUI group and 24.2% in the FSP group, (p=0.0339). The clinical pregnancy rate per patient was 18.8% in the IUI group and 48.5% in the FSP group, (p=0.0177).

The ongoing pregnancy rate per cycle was 7.6% in the IUI group and 21.2% in the FSP group, (p=0.0452). The ongoing pregnancy rate per patient was 15.6% in the IUI group and 42.4% in the FSP group, (p=0.0282).

In the IUI group, the prevalence of miscarriages was 16.6% and the prevalence of ectopic pregnancies was 0%. The corresponding figures in the FSP group were 6.3% (miscarriages) and 6.3% (ectopic pregnancies), (not significant).

In the IUI group, the rate of twin pregnancies was 16.7% and the rate of triplet pregnancies was 0%. The corresponding figures in the FSP group were 12.5% (twin) and 6.3% (triplet), (not significant).

No relevant complications were observed in the study groups.
Clinical conclusions
The effectiveness analysis showed that FSP was effective in improving the pregnancy rate in couples with problems of unexplained infertility.

Measure of benefits used in the economic analysis
The health outcomes were left disaggregated and no summary benefit measure was used in the economic analysis. A cost-consequences analysis was therefore conducted.

Direct costs
Discounting was irrelevant as the per patient costs were incurred over less than two years. The unit costs were not reported separately from the quantities of resources. The cost analysis included both the costs of the insemination procedure (sperm preparation, catheter) and the general hospital costs (staff time, use of surgery). The cost/resource boundary adopted in the analysis was not stated. The resource quantities were estimated from the trial data, while the source of the cost data was not reported. The quantities were measured from January 1998 to March 2000. The price year was 2000.

Statistical analysis of costs
The costs were treated deterministically.

Indirect Costs
The indirect costs were not included in the analysis.

Currency
The costs were calculated in euros and converted to US dollars ($). The conversion rate was 1 euro = $0.9553 at 31st March 2000.

Sensitivity analysis
No sensitivity analyses were conducted.

Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.

Cost results
Although the total costs of the two procedures were not reported, the authors stated that FSP cost only $3 per cycle more than IUI. Thus, the costs were similar in the two study groups.

Synthesis of costs and benefits
Irrelevant as a cost-consequences analysis was conducted.

Authors' conclusions
The fallopian sperm perfusion (FSP) approach led to higher pregnancy rates than the standard IUI procedure at similar costs. The intervention was well tolerated. The only difference in the costs was that associated with the extra consumption of media for sperm preparation and insemination.
CRD COMMENTARY - Selection of comparators
The rationale for the choice of the comparator was clear. IUI was selected as it represented the standard procedure for couples with unexplained infertility problems. You should decide whether this is a widely used procedure for infertility problems in your own setting.

Validity of estimate of measure of effectiveness
The analysis of effectiveness used a randomised controlled trial, which was appropriate for the study question. The study groups were shown to be comparable at baseline. In addition, the study sample appears to have been representative of the study population. Power calculations were performed in the planning phase of the study, thus greatly enhancing the internal validity of the analysis. However, as the observed difference in the main outcome measure was smaller than 20% (as targeted in the power calculations), the authors stated that the power of the results was only 54% for the clinical pregnancy rates and 58% for the ongoing pregnancy rates.

Validity of estimate of measure of benefit
No summary benefit measure was used in the economic analysis. The analysis was therefore categorised as a cost-consequences study.

Validity of estimate of costs
The perspective adopted in the study was not stated. Therefore it was not possible to assess whether all the relevant categories of costs were included in the analysis. Very limited details of the cost analysis were reported. A detailed breakdown of the costs was not given, and the unit costs were not reported separately from the resource quantities. The costs were treated deterministically and sensitivity analyses were not conducted. The price year was reported, but the source of the cost data was not.

Other issues
The authors reported the main findings of other published studies and some comparisons were made. However, the issue of the generalisability of the study results to other settings was not addressed and no sensitivity analyses were conducted. In addition, neither the unit costs nor the price year were reported. Thus, the external validity of the analysis was low. The study enrolled a sample of patients with unexplained infertility and this was reflected in the conclusions of the analysis.

Implications of the study
The main implication of the study is that the FSP procedure leads to higher pregnancy rates than standard IUI. However, due to some limitations of the analysis, the authors suggest that before replacing IUI with FSP, this finding should be confirmed in larger studies with adequate power.

Source of funding
None stated.

Bibliographic details

PubMedID
11730758

Indexing Status
Subject indexing assigned by NLM

**MeSH**
Adult; Chorionic Gonadotropin /blood; Estradiol /blood; Fallopian Tubes /physiology; Female; Humans; Infertility /therapy; Insemination, Artificial /economics /instrumentation /methods; Male; Pregnancy; Prospective Studies

**AccessionNumber**
22002000031

**Date bibliographic record published**
31/05/2003

**Date abstract record published**
31/05/2003