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
Microsurgical epididymal sperm aspiration/testicular extraction of sperm combined with intracytoplasmic sperm injection in the management of vasectomy-induced obstructive azoospermia.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients being treated for vasectomy-induced obstructive azoospermia. That for ICSI comprised those who were "not amenable to microsurgical reconstruction". No exclusion criteria were reported.

Setting
The study setting was hospital. The economic analysis was carried out in Germany.

Dates to which data relate
Effectiveness, resource use, and cost data on microsurgical VVS were collected between January 1994 and December 1997. Effectiveness, resource use, and cost data on MESA/TESE combined with ICSI were collected between September 1994 and September 1997. The price year was not reported.

Source of effectiveness data
Effectiveness data were derived from a single study.

Link between effectiveness and cost data
The costing was carried out retrospectively on the same patient sample as that used in the effectiveness analysis.

Study sample
157 men underwent microsurgical VVS. Sixty-two consecutive MESA/ICSI and 41 TESE/ICSI procedures were performed. The mean age of male patients in the MESA/TESE group was 37 years; the mean age of the female partners was 30 years. No power calculations were reported. No other baseline characteristics were given.
This was a retrospective cohort study carried out at a single centre. VVS patients were followed up for a median of 21 months (range: 2 - 60 months) (median follow-up after vasectomy was 7.6 years (range: 0.5 - 18 years)). The follow-up period was not given for the other group. Losses to follow-up were stated to have been 44 from the 156 patients for VVS (the other single loss not being mentioned) and 0 for ICSI.

Analysis of effectiveness
The analysis of the clinical study was based on treatment completers only. Primary health outcomes used were pregnancy rate, abortion, multiple gestations, and complications. The authors did not compare the groups in terms of baseline characteristics.

Effectiveness results
The effectiveness results were as follows:

pregnancy rates were 52% in the VVS group and 24.5% in the MESA/TESE with ICSI group, (p<0.002);

abortion rates were 2.4% in the VVS group and 15.8% in the MESA/TESE with ICSI group;

the percentage of multiple gestations was 1.2% in the VVS group and 15.8% (twins) in the MESA/TESE with ICSI group;

4.7% of male VVS patients and 3.9% of male ICSI patients experienced post-operative complications such as scrotal hematoma, wound infection, or post-operative pain lasting for as long as 18 days following surgery;

live birth rate was 81/112 for VVS and 19/69 for ICSI; and

complications associated with assisted reproduction such as mild ovarian hyperstimulation syndrome occurred in 5.7% of females, and severe ovarian hyperstimulation syndrome was observed in 1.4% of women.

Clinical conclusions
Microsurgical VVS was associated with statistically significantly higher pregnancy rates. Complications were higher for men, but lower for women.

Measure of benefits used in the economic analysis
The summary measure of benefit was number of live births.

Direct costs
Direct costs were not discounted due to the short time horizon of the study (less than one year). Quantities and unit costs were reported separately by procedure. Direct costs related to the costs of VVS, MESA, TESE, ICSI, and delivery. The quantity/cost boundary adopted was that of the hospital. Costs were based on hospital fees. The price year was not reported.

Statistical analysis of costs
The authors reported costs per delivery and performed statistical tests to identify significant cost differences between patient groups.

Indirect Costs
Indirect costs were not included.
Currency
German marks (DM) and Euros.

Sensitivity analysis
No sensitivity analyses were reported.

Estimated benefits used in the economic analysis
See effectiveness results above.

Cost results
The cost results were as follows:

cost per delivery was DM3,610.40 with VVS and DM3,610.40 with MESA/TESE and ICSI;

cost per VVS was DM1,800;

cost per MESA or TESE was DM720; and

cost per ICSI cycle was DM5,800.

Synthesis of costs and benefits
Total costs per live birth amounted to DM5,447.06 (2,793.36 Euros) with VVS and DM28,804.80 (14,547.88 Euros) with MESA/TESE and ICSI, (p<0.001).

Authors' conclusions
The authors argued that microsurgical VVS still represents the therapy of choice based on higher pregnancy rates, lower frequency of complications and significantly lower costs. VVS does not expose women to complications while treating a male-factor infertility and does not increase the risk of multiple births.

CRD COMMENTARY - Selection of comparators
A justification was given for the comparator used; namely that it represented the standard therapy. However, it is clear that these technologies have been employed for different populations. In particular, only those who were "not amenable to microsurgical reconstruction" were treated by ICSI. Therefore, the design of this study is highly questionable. As the authors concluded, "MESA/TESE combined with ICSI should be reserved for all patients who are not amenable to surgical correction."

Validity of estimate of measure of effectiveness
The analysis was based on a retrospective cohort study, which was appropriate for the study question. The authors did not show that the study sample was representative of the study population, and only reported a few demographic characteristics, which were incomplete by group. The authors did not report whether groups were comparable at analysis. In addition, the authors did not record the median follow-up for the ICSI group, which, as they acknowledge, could have been sufficiently shorter than that for VVS and have accounted for the different pregnancy rates.

Validity of estimate of measure of benefit
The measure of benefit was appropriate for these technologies, although it does not account for complications or allow comparison with other technologies e.g. through a measure of individual preference or quality of life.
Validity of estimate of costs
Good features of the costs were that the unit costs and quantities were reported separately for each procedure, and statistical analyses were conducted to investigate for cost differences between patient groups. However, no sensitivity analyses were reported, the price year was not reported, and quantities and unit costs, reported as fees, were not reported separately (which makes it difficult to replicate the results in other settings). Also, the resource consequences were not accounted for in terms of further treatment of complications or patient time.

Other issues
The authors did make appropriate comparisons of their findings with those from other studies, but did not address the issue of generalisability to other settings. The authors did not present sufficient results to assess suitability to reflect the population or to assess selection bias. The study considered patients being treated for vasectomy-induced obstructive azoospermia but indications differed between groups.

Implications of the study
"Reconstructive microsurgical correction still represents the treatment of choice of vasectomy-induced infertility, in post-inflammatory epididymal obstruction and in accidental ligation of the vas deferens during herniorrhaphy. MESA/TESE combined with ICSI should be reserved for all patients who are not amenable to surgical correction."

As stated above, the design of the study is seriously flawed in that the ICSI group patients were clearly different to the VVS group at baseline. At the time of the ICSI procedure, the indication was only when VVS was contraindicated. Therefore, either the comparison should not be made or patients with the same indications should have been used.

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