A cost-utility analysis of microwave and thermal balloon endometrial ablation techniques for the treatment of heavy menstrual bleeding

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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
Two second-line surgical treatments for heavy menstrual bleeding, microwave and thermal balloon endometrial ablation, were examined.

Type of intervention
Treatment.

Economic study type
Cost-utility analysis.

Study population
The study population comprised a hypothetical cohort of women with heavy menstrual bleeding, who were eligible for each procedure.

Setting
The setting was a hospital. The economic study was carried out in the UK.

Dates to which data relate
The effectiveness data were derived from studies published between 1997 and 2004. The resource use data and costs were, in part, derived from sources published between 2000 and 2004. The price year was not reported.

Source of effectiveness data
The effectiveness evidence was derived from a synthesis of completed studies and opinions.

Modelling
A Markov model was constructed to assess the clinical and economic outcomes associated with thermal balloon endometrial ablation (TBEA), microwave endometrial ablation (MEA), rollerball (RB), transcervical resection (TCRE), TCRE plus RB (TCRE+RB), and abdominal hysterectomy (HYS) in a hypothetical cohort of 1,000 women eligible for all interventions. The starting age of the cohort was 43 years and it was assumed that all women would become menopausal at age 52. The time horizon of the model was 10 years and the cycle length was one month. The health states considered in the model constructed for women undergoing endometrial ablation were menorrhagia, endometrial ablation, complications, recurrent menorrhagia, second endometrial ablation, HYS, well and dead. The health states in the HYS branch were menorrhagia, HYS, complications, convalescence, well and dead.

Outcomes assessed in the review
The outcomes assessed from the literature were complication and death rates, recurrent menorrhagia (treatment failure) rates, and utility values for chronic and temporary states.

**Study designs and other criteria for inclusion in the review**
A systematic review of the literature was carried out to identify relevant primary studies. Basically, a published systematic review and published clinical trials were selected as the main sources of evidence. However, when randomised trials were not available, evidence from large, prospective, observational studies was used to populate the model. Survival came from UK life tables, while utility values were derived from a study where the time trade-off approach had been used.

**Sources searched to identify primary studies**
Not stated.

**Criteria used to ensure the validity of primary studies**
The validity of the primary sources was ensured by using mainly clinical trials.

**Methods used to judge relevance and validity, and for extracting data**
Not stated.

**Number of primary studies included**
Twelve primary studies were included in the review.

**Methods of combining primary studies**
Not stated.

**Investigation of differences between primary studies**
Not stated.

**Results of the review**
The complication rate was 0.035 after HYS, 0.0398 after TCRE+RB, 0.02 after RB, 0.0606 after TCRE alone, 0.0007 after MEA, and 0.0023 after TBEA.

The death rate was 0.00025 after HYS, 0.0002 after TCRE+RB, 0 after RB, 0.0003 after TCRE alone, 0 after MEA, and 0 after TBEA.

The rate of TBEA treatment failure was 0.11 (0.1 in years 2 and 3).

The proportion of women with recurrent menorrhagia who undergo HYS was 0.6, while the proportion of those who undergo repeat ablation was 0.4.

The rate of complications after repeat TCRE of RB ablation was twice the rate after first ablation.

The death rate after repeat TCRE+RB ablation was 0.0003. The rate of first year return of menorrhagia post TCRE+RB was 0.11.

The rate of second and third year return of menorrhagia following TCRE+RB was 0.1.

The rate of first year return of menorrhagia post TBEA or MEA was 0.11.
The rate of second and third year return of menorrhagia following TBEA or MEA was 0.1.

The utility values for chronic states were 0.55 for menorrhagia, 0.9 for premenopausal state following recovery from a successful TCRE, and 0.95 for premenopausal state following recovery from a successful HYS.

The utility values for temporary states were 0.95 for convalescence after HYS, 0.85 for MEA or convalescence after MEA, 0.85 for TBEA or convalescence after TBEA, and 0.85 for TCRE+RB or convalescence after TCRE+RB.

Recurrent menorrhagia occurred in the first three years after operation.

Methods used to derive estimates of effectiveness
Some assumptions were made and used in the decision model.

Estimates of effectiveness and key assumptions
Only perioperative complications were considered. If endometrial ablation failed, 90% of women with recurrence would have a repeat procedure, with 60% having repeat endometrial ablation and 30% having a HYS within 6 months of recurrence. Ninety per cent of women with recurrence after repeat endometrial ablation would have HYS within 6 months. There was no convalescence state after ablation as women were assumed to fully recover within one month.

The proportion of women with second endometrial ablation failure who undergo HYS within 6 months was 0.9. The utility values for temporary states were 0.55 for complications after HYS and 0.63 for HYS.

Measure of benefits used in the economic analysis
The summary benefit measure used was the quality-adjusted life-years (QALYs). These were derived using a modelling approach. Both survival and quality of life data were derived from the literature and from authors’ assumptions (see Estimates of Effectiveness and Key Assumptions). Utility weights, when obtained from the literature, were estimated using the time trade-off approach. An annual discount rate of 1.5% was applied.

Direct costs
Discounting was relevant because the costs were incurred during a long timeframe. An annual discount rate of 6% was applied. The unit costs were presented separately from the quantities of resources used for most cost items. A detailed breakdown of the costs was provided. The health services included in the economic evaluation were surgical procedures, anaesthesia, equipment, staff, and inpatient stay. The cost/resource boundary of the NHS was adopted. The costs were estimated using data derived from the literature and from the costings unit at Southampton University Hospital, and manufacturers’ prices. Resource consumption was based on published evidence and authors’ assumptions. The price year was not reported.

Statistical analysis of costs
The costs were treated deterministically in the base-case.

Indirect Costs
The indirect costs were not considered in the economic evaluation.

Currency
UK pounds sterling (£).

Sensitivity analysis
Extensive sensitivity analyses were carried out to deal with uncertainty in the model inputs, arising from the use of data.
from different sources. Univariate sensitivity analyses were performed by varying the most relevant model inputs. The source of the ranges of values was reported and a justification for the use of specific values was provided. A probabilistic sensitivity analysis was also performed, with the analysis being replicated 1,000 times with input values sampled from individual probability density functions.

**Estimated benefits used in the economic analysis**

In a cohort of 1,000 women and over a 10-year time horizon, the estimated QALYs were 8,360.77 with TBEA, 8,360.70 with MEA, 8,357.03 with TCRE, 8,357.99 with TCRE+RB, 8,359.92 with RB, and 8,774.34 with HYS. HYS was the most effective strategy.

**Cost results**

In a cohort of 1,000 women and over a 10-year time horizon, the estimated costs were 1,323,925 with TBEA, 1,448,470 with MEA, 1,731,734 with TCRE, 1,785,045 with TCRE+RB, 1,752,359 with RB, and 2,320,512 with HYS. HYS was the most expensive strategy.

**Synthesis of costs and benefits**

An incremental analysis was carried out to combine the costs and benefits of the alternative treatment strategies. The comparisons made were MEA versus TBEA, TCRE, TCRE+RB, RB, and HYS. Also, TBEA versus TCRE, TCRE+RB, RB, and HYS. Although differences in effectiveness were low, TBEA dominated MEA as well as nearly all other treatments. The exception was HYS, which was both more effective and more costly, resulting in an incremental cost of 2,410 per QALY saved in comparison with TBEA. Similarly, MEA dominated nearly all first-generation techniques. Again, the exception was HYS, which was both more effective and more costly, resulting in an incremental cost of 2,108 per QALY saved in comparison with MEA.

Owing to the small differences in effectiveness and costs, the sensitivity analysis showed that small changes in some model inputs, including procedure cost and time, frequency and duration of complications, and death rate, led to changes in the cost-effectiveness of MEA versus TBEA. However, in the comparison between second- versus first-generation techniques, only changes in the utility value for the “well” health state following ablation substantially changed the results of the analysis.

The probabilistic sensitivity analysis suggested that for very low values of willingness to pay for a QALY gained (about 2,000), TBEA was the most cost-effective strategy. For higher levels of willingness to pay, HYS was the preferred strategy. If HYS was excluded (since some women might refuse undergoing such a procedure), then TBEA was the most cost-effective option. However, differences between TBEA and MEA were very small beyond a willingness to pay of 5,000, and were negligible over 20,000.

**Authors' conclusions**

The authors concluded that, in women with heavy menstrual bleeding, both second-generation techniques, namely thermal balloon endometrial ablation (TBEA) and microwave endometrial ablation (MEA), were cost-effective over first-generation techniques. However, over the long-term, abdominal hysterectomy (HYS) was the most cost-effective approach, owing to the clear difference in terms of risk of recurrence of menorrhagia.

**CRD COMMENTARY - Selection of comparators**

The selection of the comparators was appropriate as both second- and first-generation techniques for the treatment of women with heavy menstrual bleeding were considered. The traditional strategy of HYS was also included in the comparison. You should decide whether they are valid comparators in your own setting.

**Validity of estimate of measure of effectiveness**

The effectiveness evidence came largely from primary studies of good quality, such as published systematic reviews or
clinical trials. The authors justified the use of non-randomised studies, which consisted of large, prospective, UK-based
data. This ensured the validity of the primary sources used. However, little information on the methods used to extract
and combine the primary estimates was provided. Further, the authors noted that head-to-head comparisons were not
available for all interventions under evaluation, which could reduce the validity of the comparison on account of
potential differences in the study samples. Some data were based on authors' assumptions. Extensive sensitivity
analyses were carried out to deal with the issue of uncertainty in the data.

Validity of estimate of measure of benefit
The use of QALYs as the summary benefit used in the economic evaluation was appropriate because QALY capture the
impact of the interventions on the two most relevant aspects of patient health, that is, survival and quality of life.
Discounting was applied, as recommended in UK guidelines. The source of the utility weights was reported, and the
authors highlighted the problems associated with using utility values for specific health states. QALYs are comparable
with the benefits of other health care interventions.

Validity of estimate of costs
The authors reported explicitly the perspective adopted in the study. As such, it appears that all the relevant categories
of costs have been included in the economic evaluation. The unit costs were accurately presented, as was resource use
consumption. This enhances the possibility of replicating the study in other settings. The source of the data was reported
for all items and a justification was provided for the choice of the sources. However, the price year was not explicitly
reported, which makes reflation exercises in other settings difficult. The costs were treated deterministically in the base-
case, but extensive deterministic and probabilistic sensitivity analyses were carried out.

Other issues
The authors did not compare their findings with those from other studies, as they stated that the current study was the
first evaluation of the cost-effectiveness of second-generation techniques. The issue of the generalisability of the study
results to other settings was not addressed. However, extensive sensitivity analyses were performed on the key model
inputs. These enhance the external validity of the analysis. The authors noted some drawbacks of their study, the main
issue being the lack of a published head-to-head comparison between MEA and TBEA. Likewise, the authors stressed
the variability in the utility values associated with some health states, which reduced the reliability of the base-case
results. These issues introduced some uncertainty in the model, which was then satisfactorily examined in the
probabilistic sensitivity analysis. It was also noted that some specific advantages of second-generation approaches were
not captured in the model. However, it was unclear how fast or extensive newer second-generation techniques could be
taken up in the current UK health care system.

Implications of the study
The study results suggested that second-generation techniques for the treatment of heavy menstrual bleeding are a cost-
effective option to first-generation approaches. However, HYS could be the preferred strategy in some scenarios. The
authors pointed out that future studies should compare MEA and TBEA directly. Utility values associated with episodes
of recurrent menstrual bleeding should also be determined.

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None stated.

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Other publications of related interest


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