Randomised trial comparing hysterectomy and transcervical endometrial resection: effect on health related quality of life and costs two years after surgery

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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
The study examined two method of dealing with menorrhagia: hysterectomy and endometrial resection.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population consisted of women requiring surgical treatment for menorrhagia. Women under 52 years complaining of menorrhagia which had been successfully treated using 'conservative means' were considered eligible for the trial as long as their uterine size was less than 12 weeks or if there was no information that made hysterectomy the preferred treatment.

Setting
The study setting was secondary care; the economic study was carried out in a teaching hospital in the United Kingdom.

Dates to which data relate
Full details on the data are contained in preceding papers, details are given below. Dates for the effectiveness evidence were 1990-1993. Dates for resources used were 1990-1993. The price year was 1994.

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

Link between effectiveness and cost data
The costing was undertaken prospectively on the same patient sample as that used in the effectiveness study, although full cost information was not available for all patients.

Study sample
Power calculations were carried out to determine the sample size. (Details were given in an earlier paper). It was assumed that the satisfaction rate after hysterectomy should be about 95%. The type I value was set at 0.05 and the type II value at 0.1. With confidence limits of 95% and accepting a 10% difference in satisfaction between the groups as acceptable it was determined that 100 women would be required for each type of treatment. Women under 52 years complaining of menorrhagia which had not been successfully treated using 'conservative means' were considered
eligible for the trial as long as their uterine size was less than 12 weeks or if there was no information that made hysterectomy the preferred treatment. 216 women were considered eligible for the study and 200 women agreed to be enrolled; after randomisation 4 women withdrew from the study prior to surgery, three from the hysterectomy group, and one from the resection group. 155 of the 196 women, (82 endometrial resection and 73 abdominal hysterectomy) who undertook surgery, gave a comprehensive response to the postal questionnaire that was sent out approximately two years after surgery, (three respondents gave incomplete responses). Complete cost information was available for 148 women, (78 resection and 70 hysterectomy). Some cost information for missing respondents was obtained from other sources such as hospital records.

Study design
This was a randomised controlled trial carried out in a single centre. Each patient had the same probability of being assigned to either treatment group. 41 women from 196 were lost in the follow up of the trial in that there were only 155 completed questionnaires (mean follow-up time 2.8 years, range: 1.8 - 3.8). However the authors stated that the mean follow up for all women was 2.2 years, (range: 0.3 - 3.8), and this presumably included women for whom information was available from other sources.

Analysis of effectiveness
The analysis was based on treatment completers only. The initial randomisation (details in earlier paper) was stated to have produced groups of women who were comparable in terms of age, ethnic group, marital status, social class, employment and parity. Menstrual characteristics showed no significant difference between the two groups. A General Health questionnaire score of 12 or more, (suggesting psychiatric morbidity) was found in 43 of the women just before hysterectomy and 34 of the women just before endometrial resection. Health outcomes were measured by bleeding and extent (categories), using a description of change in menstrual symptoms (not as bad, about the same, worse) and patient questionnaires which measured health related quality of life (the Short Form 36(SF36) and the EuroQol visual analogue scale) and patient satisfaction. The SF36 had not been used before surgery. In addition, life tables were used to estimate the rate of repeat resections or hysterectomies following resection. Data that were unavailable were censored.

Effectiveness results
The effectiveness results were as follows:

In terms of menstrual symptoms the women in the resection group were worse off than the women in the hysterectomy group: 46 out of 72 (64%) versus 0 reported flooding episodes, 10 out of 46 (22%) versus 1 out of 13 (8%) were experiencing worse menstrual pain (than before surgery) and 13 out of 71 (18%) versus 3 out of 68 (4%) worse pre-menstrual symptoms (than before surgery). No statistical tests were reported.

The SF36 scores showed better scores except for physical (RL) in the hysterectomy group than in the resection group, with pain having a p value of 0.01.

The EuroQol visual analogue scale showed a difference of 1.5 (range: -3.4 - 6.4).

The satisfaction questionnaire showed that, in the hysterectomy group, there was significantly more satisfaction (chi² p=0.002). 19 (24%) of the resection group said they would not have the operation again in the same situation, whereas 4 (6%) of the hysterectomy patients said they would not (chi² p=0.002).

At 2 years the cumulative probability of repeat resection was 12% and of hysterectomy, 16%.

Clinical conclusions
On average, women in the hysterectomy group were in better physical and mental health than women in the resection group when their health was assessed two years after surgery, and there was a significant risk of repeat surgery.
Measure of benefits used in the economic analysis
No summary benefit measure was reported, implying a cost-consequences analysis (CCA).

Direct costs
Discounting was carried out on costs, using a 6% annual discount rate. All costs were expressed in terms of June 1994 prices. Quantities and costs were analysed separately (full details given in the preceding paper). Estimation of quantities and costs was based mainly on data from the original follow up of 4 months. In order to extrapolate to repeat procedures beyond 4 months, the pre-4 month unit cost was combined with data from the questionnaire or hospital data on resource use post-4 months. Non return of questionnaire and no hospital data were treated as missing data. Pre-4 month costs were: preoperative, operative, postoperative, hotel and those related to average complications. Post-4 month costs also included hormone replacement therapy and those ‘...associated with other related resource use.’ No difference between marginal and average costs was reported.

Statistical analysis of costs
No statistical analyses of hypotheses were carried out but 95% CIs were reported.

Indirect Costs
Indirect costs were not reported.

Currency
UK pounds sterling (€).

Sensitivity analysis
No sensitivity analysis was reported. Communication with the author has revealed that this was reported in another paper (See Other Publications of Related Interest below).

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

Cost results
The total cost of resection was given as mean: 790 (SD 493), median 523 (range: 446 - 2,148).

The total cost of hysterectomy was mean: 1,123 (SD 210), median 1,053 (range: 876 - 2036).

A discount rate of 6% was used to evaluate the total costs from surgery to a mean of 2.2 years follow up.

Synthesis of costs and benefits
This was not applicable given the fact that a cost-consequences analysis was carried out.

Authors' conclusions
The authors concluded that it was not clear which treatment was more cost effective. Although the costs were lower for resection, it was not clear whether the benefits were higher or lower. One reason was that, since the time pattern of gain and losses for women has not been systematically evaluated or quantified, women have to face a short-term consequence of higher pain and inactivity in one option and compare that with a longer term risk of dissatisfaction with the procedure and the possibility of repeat surgery.
Adequate justification was given for the selection of comparators.

**Validity of estimate of measure of effectiveness**

The source of the effectiveness data was postal questionnaires sent out 2 years after surgery. The study design was appropriate for the question, but unfortunately, as the authors discuss, there has been a loss of information due to an incomplete response to the postal questionnaires. 17% of the resection patients and 25% of hysterectomy patients were lost to the study. Also, the length of follow-up might have differed between groups. This might have seriously biased the effectiveness measures. The fact that the follow up period for some women was as short as 0.3 years means that the picture of the long-term effects of surgery is incomplete. No power calculation was reported and therefore the differences in effectiveness, although clear in direction, might have had greater statistical significance had the sample size been greater. Also, lack of baseline SF36 data prevents analysis of selection bias.

**Validity of estimate of measure of benefit**

No summary measure of benefit was reported, but the authors acknowledge that further research is needed on the trade-off between the various measures of outcome, which might lead to one. The estimates of benefit were derived directly from the effectiveness analysis.

**Validity of estimate of costs**

The costs to the health service of the two types of intervention were comprehensively covered and costs were reported separately from quantities at the level of the procedure. The indirect costs to the women in terms of lost time were not covered. Although the loss of time immediately after surgery might have been much higher for the hysterectomy group, women in the resection group would lose more time as a consequence of treatment failure (taking time off work due to menstrual problems) and having to undergo repeat treatment. It would have been helpful to have such information. Serious biases could have occurred due to missing data on repeat procedures, given that the analysis was based on treatment completers.

**Other issues**

The authors referred to other studies which compared hysterectomy with endometrial resection. However they did not state whether their results were similar. Neither did the authors state whether their results were similar to previous studies that evaluated hysterectomy. In the paper's abstract there appears to have been a mistake in that 88 were stated to have had a resection as opposed to 99 in the method.

**Implications of the study**

The authors have demonstrated the importance of follow up in assessing the costs and benefits of surgery, and their study also shows how difficult it is to achieve a comprehensive follow up 2 years after the operation. The authors regard the study as showing that, even when re-treatment costs are taken into account, resection costs less than hysterectomy. However, they feel that at the time of their study resection did not provide a satisfactory treatment. They acknowledge that there could be improvements in this technique in the future. The authors make the following recommendations for further research:

- to establish women's preferences between the undesirable short-term post-operative consequences of hysterectomy and long-term success versus a 23% risk of treatment failure of resection after two years.

- to establish whether there are any pre-operative risk factors which predispose women undergoing endometrial resection to treatment failure and to find out women's preferences as regards to all the consequences of the treatment on offer, for example sterilisation, cancer prevention.

The authors state that it is likely that both procedures will have a role and that future research will help to indicate the
optimal treatment for each woman.

Source of funding
Funded by the South Western Regional Health Authority and by the Department of Health.

Bibliographic details

PubMedID
8616131

Other publications of related interest


Indexing Status
Subject indexing assigned by NLM

MeSH
Adult; Cost-Benefit Analysis; Endometrium /surgery; Female; Follow-Up Studies; Health Care Costs; Humans; Hysterectomy /adverse effects /economics /psychology; Menorrhagia /economics /psychology /surgery; Menstruation Disturbances /etiology; Middle Aged; Patient Satisfaction; Quality of Life; Recurrence; Reoperation; Treatment Failure

AccessionNumber
2199600306

Date bibliographic record published
31/12/2001

Date abstract record published
31/12/2001