Ambulatory endoscopic treatment of symptomatic benign endometrial polyps: a feasibility study

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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
Ambulatory endoscopic polypectomy using a bipolar intrauterine system was studied in women with abnormal uterine bleeding symptoms, who had been diagnosed with an intrauterine polyp.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population consisted of women with abnormal uterine bleeding symptoms, who had been diagnosed with an intrauterine polyp and were undergoing polypectomy. Patients were ineligible if they were asymptomatic at the time of presentation, had hysteroscopic or histological diagnosis of malignancy, or had adjunctive medical treatment.

Setting
The setting was outpatient (ambulatory) and inpatient clinics. The economic study was carried out at the Birmingham Women's Hospital in Birmingham, UK.

Dates to which data relate
The effectiveness and resource use data were gathered in 1999. 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 conducted prospectively on the same sample of patients as that used in the effectiveness study.

Study sample
Power calculations to determine the sample size were not conducted. All eligible women referred during 1999 to the study centre were enrolled into the study. There were 31 women in the outpatient group and 27 women in the inpatient group. It was not stated whether any patient refused to participate or was excluded for any reason from the initial study sample. The mean age of those included in the final sample was 57 years (range: 45 - 79) in the outpatient group and 53 years (range: 41 - 64) in the inpatient group.
Study design
This was a prospective cohort study, which was carried out in Birmingham, UK. The patients were allocated to one of two clinics. The two clinics both had different consultants and offered different treatment options. Thus, the differing consultant practices facilitated the two separate cohorts for comparison. The patients were followed for 6 months after the intervention. Sixteen women (59%) in the outpatient group and 18 women (58%) in the inpatient group completed the study. The outcomes were assessed through questionnaires sent by post at the end of the follow-up.

Analysis of effectiveness
The analysis of effectiveness was limited to those who completed the study (defined as returning the questionnaire). The primary health outcomes used in the study were satisfaction with treatment and self-perceived improvements in bleeding symptoms (much better, little better, not changed, worse). The secondary outcomes were complications of surgery, time missed from work (through abnormal bleeding or pelvic pain) and quality of life, which was evaluated using the generic EuroQol 5D instrument. The two groups were shown to be comparable at baseline with respect to age, type of bleeding, presence of additional pathology and polyp characteristics.

Effectiveness results
The proportion of patients satisfied with treatment was 78% in the outpatient group and 88% in the inpatient group.

The overall improvement in bleeding symptoms was 92% in the outpatient group and 93% in the inpatient group. The "much better" response was reported as 75% in the outpatient group and 79% in the inpatient group. The "little better" response was 17% (outpatient) and 14% (inpatient), respectively, the "not changed" response was 8% (outpatient) and 0% (inpatient), and the "worse" response was 0% (outpatient) and 7% (inpatient).

There were no serious complications in any of the study groups.

The median score of the visual analogue scale, which was evaluated using the EuroQol instrument, was 80 in the outpatient group and 90 in the inpatient group.

The disease-specific quality of life median score was 78 in the outpatient group and 94 in the inpatient group.

The median number of days missed from work through abnormal bleeding was one in both groups. The median number of days missed from work through pelvic pain was zero in the outpatient group and two in the inpatient group.

None of the differences in the clinical outcomes used in the analysis reached statistical significance.

Clinical conclusions
The effectiveness study showed that the two treatments were equally safe and effective.

Measure of benefits used in the economic analysis
No summary benefit measure was used in the analysis. The two treatments were shown to have been similar in terms of effectiveness, thus a cost-minimisation analysis was conducted, although this was not the authors' intention.

Direct costs
Discounting was not relevant because the costs were incurred over a short period of time. The health services included in the economic evaluation were the endoscopic procedure and capital/maintenance expenses (outpatient group only), day case dilation and curettage (inpatient group only), staff, equipment, diagnostic tests, visits to the general practitioner (GP) or other health professionals, outpatient attendance and medication for abnormal bleeding. The cost/resource boundary adopted in the analysis appears to have been that of the NHS. The costs were estimated using actual data. These were derived from the study hospital financial data, the UK price list for the bipolar intrauterine system, and the Department of Health for health and social care expenses. Resource use was derived from the patients' charts. The price
year was 2000.

**Statistical analysis of costs**
The estimated mean costs of the two treatments were compared using the Mann-Whitney U test and unpaired Student's t-test.

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

**Currency**
UK pounds sterling (€).

**Sensitivity analysis**
Sensitivity analyses were not conducted.

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

**Cost results**
The estimated mean overall cost per patient was 490 (range: 458 - 523) in the outpatient group and 781 (range: 706 - 856) in the inpatient group, (p=0.0001). This difference was mainly due to hospitalisation costs and GP visits required after the intervention (20 in the inpatient group versus 7 in the outpatient group), (p=0.005).

**Synthesis of costs and benefits**
Not relevant as a cost-minimisation analysis was conducted.

**Authors' conclusions**
Ambulatory polypectomy represented a safe procedure and was effective in relieving symptoms in women with abnormal uterine bleeding. The costs were far lower in the outpatient setting. The authors pointed out that the clinical results of their study should not be used to guide clinical practice, as their analysis represented a preliminary feasibility assessment.

**CRD COMMENTARY - Selection of comparators**
The rationale for the choice of the comparator was clear. Inpatient treatment was selected since it represented the traditional approach for polypectomy. The authors stated that other approaches are available in the ambulatory setting. You should decide whether it represents a valid comparator in your own setting.

**Validity of estimate of measure of effectiveness**
The analysis of effectiveness used a prospective cohort study, which was appropriate for the study question. However, the main threats to the internal validity of the analysis, which were acknowledged by the authors, were the small sample size and the lack of power calculations. This could explain why none of the differences between the study groups reached statistical significance. Moreover, the effectiveness analysis was limited to the small proportion of women who completed the questionnaire, which further reduced the sample size. The sample was unselected and appears to have been representative of the study population. The method used to allocate the patients to the study groups was not reported. Due to the lack of randomisation, bias and confounding may have affected the study results, although the two
groups were comparable at baseline. The effectiveness outcomes were evaluated using self-reported information. These issues may limit the internal validity of the analysis. It should be noted that the authors’ intent was to conduct a feasibility study and, as such, they were aware of the limitations highlighted.

Validity of estimate of measure of benefit
No summary benefit measure was used in the economic analysis as the two treatments were shown to have been similarly effective. The analysis should therefore be categorised as a cost-minimisation study.

Validity of estimate of costs
The economic analysis appears to have been conducted from the perspective of the NHS. All the relevant categories of costs were included in the analysis and a detailed breakdown of the items was reported, although the unit costs were not mentioned. The price year was reported, thus simplifying reflation exercises in other settings. Statistical analyses were only conducted to compare the estimated costs, and sensitivity analyses were not conducted. The cost estimates were specific to the study setting.

Other issues
The authors made some comparisons of their findings with those from published studies, but did not address the issue of the generalisability of the study results to other settings. Sensitivity analyses were not conducted, thus the external validity of the analysis is low. The study enrolled a sample of women requiring polypectomy due to abnormal uterine bleeding, and this was reflected in the conclusions of the analysis.

Implications of the study
The study suggests that ambulatory endoscopic polypectomy may be safely, effectively and efficiently performed for women requiring polypectomy. However, caution is required when interpreting the clinical results of the analysis due to the limitations of the effectiveness study. The authors stated that there is an urgent need for a randomised controlled trial to evaluate the cost-effectiveness of outpatient polypectomy. They reported the detailed design for a such a randomised controlled trial (power calculations, length of follow-up, eligibility criteria, and so on).

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