Effects of decision aids for menorrhagia on treatment choices, health outcomes, and costs: a randomized controlled trial


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 compared decision aids in the form of an information pack provided with or without a structured preference elicitation interview to women patients with uncomplicated menorrhagia. The information pack comprised a specially designed booklet and complementary videotape.

Type of intervention
Other: Patient decision aid.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised women who were referred from primary to secondary care with a new episode of uncomplicated menorrhagia, which their consultant deemed to be non-urgent.

Setting
The setting was secondary care. The economic analysis was carried out in the UK.

Dates to which data relate
The effectiveness and resources use data were collected between October 1996 and February 1998. The unit costs were derived from sources published between 1993 and 2000. The costs were adjusted to 1999-2000 UK prices.

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

Link between effectiveness and cost data
The costing was undertaken prospectively on the same sample as that used in the effectiveness study.

Study sample
Power calculations showed that a sample of at least 900 participants was required to detect differences of 5 points between the study groups, with a power of 80% at the 0.05 significance level. A total of 28 consultant gynaecologists from 6 hospitals in southwest England participated in the study. A research nurse identified the women by inspecting referral letters sent from general practitioners to the participating consultants. All the women identified from referral letters who fulfilled the criteria for inclusion were registered, and written consent was requested.
In total, 1,301 eligible women were invited between October 1996 and February 1998 to participate in the study. Of these, 407 (31%) refused consent and did not participate in the study. The authors reported that there was no significant difference in age between those granting consent (mean age 40 years, standard deviation, SD=7.0) and those who refused (mean age 41 years, SD=7.7), (p=0.56). The reasons for refusal were not reported. Post-randomisation no patients were excluded for any reason. The women were randomly assigned to one of the three groups. There were 298 in control group, 296 in the information group, and 300 in the information plus interview group. The mean age of the participants was 40 years (SD=7.0) in the control group, 40 years (SD=7.2) in the information group, and 41 years (SD=6.9) in the information plus interview group.

Study design
The basis of the analysis was a multi-centre, randomised controlled trial that was conducted in 6 hospitals. The women (patients) were randomly allocated using a form of random permuted block size, randomly set to 3, 6 or 9 to avoid selection bias. The allocation sequence was generated by computer and stratified by consultant and the age that the woman left full-time education. Using a central telephone randomisation system helped to ensure randomisation. Neither the patients nor the investigators were blinded.

The duration of follow-up was 2 years and was conducted using questionnaires sent at 6, 12 and 24 months post-consultation. Women who did not respond to the 24-month questionnaire after receiving 2 reminder letters were asked to take part in a short telephone interview covering key items from the follow-up questionnaire. The response rate to the 2 years' follow-up was 70%. The mean duration of follow-up was 26 months for each group. Although the rates of loss to follow-up varied between the groups, the differences were not statistically significant, (p=0.69). However, the authors did find statistically significant differences in baseline characteristics between non-responders and responders. These were reported in full. The authors stated that a statistical analysis would ensure that these differences would not affect comparisons between the trial groups. No reasons for the loss to follow-up were reported.

Analysis of effectiveness
The basis for the analysis was treatment completers only. The primary outcome of the study was health status measured by the 36-item short form health survey (SF-36). The secondary outcomes included treatments received during follow-up, severity of menorrhagia, and patient satisfaction. Severity of menorrhagia was assessed using a menorrhagia outcome scale (see Other Publications of Related Interest). The educational background of the sample was stated to be close to population averages. The three groups were generally well matched, although there were small between-group differences in the duration of menorrhagia and in experience of hormone and non-hormone treatments. It was not apparent whether any adjustment for these confounding variables was undertaken.

Effectiveness results
The role of physical dimension of the SF36 showed a significant difference between the interview, non-interview and control groups, (p=0.04). The other seven dimensions of the SF-36 and menorrhagia severity were stated to be non significant. The authors only provided a graphical depiction of the results obtained.

Among women who underwent hysterectomy, the interview group showed significant reductions in hysterectomy rate when compared with the control group (26% relative reduction; p=0.04) and with the information group (32% relative reduction), (adjusted odds ratio, OR=0.52; 95% confidence interval, CI: 0.33 - 0.82; p=0.008).

There were no statistically significant differences between the information and control groups, (p=0.53). No other treatments showed a significant between-group difference. However, the authors reported that the number of women who received endometrial destruction or other treatment was too small to rule out the effect.

The intervention groups may have been more likely to undergo drug therapy, but the differences were not statistically significant (information versus control, p=0.17; interview versus control, p=0.11).

As far as satisfaction was concerned, the interview group rated both the opportunities they had been given to take part in treatment decision-making (adjusted OR 1.49, 95% CI: 1.11 - 2.01; p=0.008) and the overall results of their treatments (adjusted OR 1.44, 95% CI: 1.03 - 2.01; p=0.03) significantly higher than did the control group.
The differences between the information group and the controls were smaller and not significant. The adjusted OR was 1.24 (95% CI: 0.91 - 1.69) for opportunities to take part in decision-making and 1.16 (95% CI: 0.85 - 1.60) for results of treatment. The differences between the intervention groups were not statistically significant.

**Clinical conclusions**

The authors concluded that neither of the intervention had a major impact on health status. In terms of the effects on treatment received, women who received the interview (plus information) were considerably less likely to undergo hysterectomy than those who received information alone.

**Measure of benefits used in the economic analysis**

No summary health benefit was used in the economic analysis. The study was, in effect, a cost-consequences analysis.

**Direct costs**

The direct costs to the health service were included in the analysis, more specifically, the costs of tests and treatment. The tests considered were dilation and curettage, endometrial biopsy, laparoscopy, hysteroscopy, ultrasound scan, blood test, colposcopy and examination under anaesthetic. The treatments covered were hormonal drug, non-hormonal drug, hysterectomy, endometrial destruction, polyp removal, fibroid removal, and levonorgestrel-releasing intrauterine contraceptive device. These costs included any inpatient stay, and outpatient or physician visit when required. In addition, the costs of inpatient days in gynaecology, surgery and medical clinics were included. These costs excluded any cost of stay associated with particular procedures, as well as the cost of outpatient or family physician visits for menorrhagia or other conditions. Discounting was not relevant, as the costs were incurred during 2 years, and was not performed. The unit costs and resource use were reported separately. The unit costs were derived from published sources.

A total cost per patient was reported for the information intervention and for the information plus interview. This included the cost of the booklet and videotape, plus 20 minutes of an experienced nurse's time for the interview. Although it was assumed that these costs were incurred for more than 2 years, they were not discounted.

**Statistical analysis of costs**

The total costs were treated deterministically, while differences in the costs between the two treatment groups and the control group were treated stochastically (mean difference and 95% CI reported). The CIs for the differential costs were obtained using bias-corrected and accelerated nonparametric bootstrapping. The problem of resource data being missing was addressed using multivariate multiple imputation methods, under the assumption that these data were missing at random.

**Indirect Costs**

The indirect costs were not reported.

**Currency**

US dollars ($). The costs were estimated in UK pounds sterling (£) and then converted into US dollars. The average exchange rate for 2000 was 1 £ = $1.52.

**Sensitivity analysis**

A sensitivity analysis was carried out on the cost data. The methods used were not reported. The authors appear to have assessed the sensitivity of the total cost to health service contacts, and variability in the data by varying the fixed costs of the interventions.
Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.

Cost results
The total mean costs for each group associated with the tests, drugs, surgery procedures, inpatient, outpatient and family physician visits provided was $2,751 for the control group, $2,026 for the information group and $1,566 for the interview group.

The mean difference of these total costs was:

- $1,184 (95% CI: -2,110 - -684) for the interview group minus the control group;
- $725 (95% CI: -1,628 - -214) for the information group minus the control group; and
- $461 (95% CI: -696 - -236) for the interview group minus the information group.

The costs reported in the analysis do not seem to have included the costs of the intervention for the participants in each of the groups.

Synthesis of costs and benefits
The costs and benefits were not combined.

Authors' conclusions
The provision of decision aids with information alone did not affect the health outcomes, patient satisfaction, or treatment choice. It was, however, less costly. "The addition of a structured interview helped women to use the information to clarify their values and preferences." This form of decision aid seems to have had a significant effect on the women's subsequent treatment management and long-term satisfaction, and also resulted in reduced costs.

CRD COMMENTARY - Selection of comparators
Although no explicit justification for the comparator was provided, it would appear to represent current practice in the authors' setting. You should decide if this represents a valid comparator in your own setting.

Validity of estimate of measure of effectiveness
The analysis was based on a randomised controlled trial. This design was appropriate for the study question as it helped to reduce potential systematic biases between the study groups that may affect the results obtained. However, the study sample does not seem to have been representative of the study population since, although it comprised women with uncomplicated menorrhagia, those patients lost to follow-up were significantly younger, had more cases of severe menorrhagia and a lower level of knowledge, and were less likely to have been treated with non-hormonal drugs. The authors reported that the statistical analysis showed that these differences would not affect the comparisons between trial groups, but that they should be taken into consideration when attempting to generalise the finding. In addition, the basis of the analysis was treatment completers only, which may introduce bias.

Validity of estimate of measure of benefit
The authors did not derive a summary measure of health benefit. The study was, in effect, a cost-consequences analysis.

Validity of estimate of costs
The authors estimated the costs from the perspective of the NHS. All the relevant categories of costs (tests, treatment,
Other issues

The authors compared their results with those of other studies, finding consistency for most of the results. Two inconsistencies were reported. First, in one systematic review, although a reduction in the rate of radical surgery due to intervention was also established, the effect size reported proved to be similar, irrespective of the content of the interventions. Second, the effect of the interview on satisfaction was not established in other studies that measured satisfaction. However, the authors stated that these other studies had limited power to detect between-group differences in satisfaction. The issue of generalisability to other settings was only raised as far as the observed differences in baseline characteristics between responders and non-responders were concerned.

The authors reported a number of limitations of their study. For example, according to the study design, contamination bias was possible since clinicians could have applied the experience gained from consultations with the intervention groups in their consultations with the control group. This bias could reduce any observed differences in outcomes between the intervention and control groups. In addition, another bias could have been introduced if there was a clustering effect in terms of the consultation style of particular consultants, or the types of patients referred to them. The authors attempted to deal with this bias by incorporating consultants as a random effect in the statistical analysis. A further limitation of the study was that the clinicians were not blinded to the allocation group.

Please note that the authors of this paper have pointed out that considerable further detail of this project, including information on adjustment for confounding variables and the methods and results of the full economic analysis, were included in the relevant HTA report. Because of the word-count constraints imposed by the publishers, these could not be included or explained in sufficient detail in the JAMA article on which this abstract was based. The HTA report can be accessed at the following url:

http://www.ncchta.org/ProjectData/3_project_record_published.asp?PjtId=898

Implications of the study

The authors stated "the model of information and interview used in this study could easily be adapted for use in other settings@. In their policy recommendations, they suggested "future decision aids should incorporate training for clinicians in the principles and practice of involving patients in treatment decision making@. The authors also anticipated further research in several areas. More specifically, the particular aspects of the interview that contribute to the observed effects, the most appropriate time during the decision-making process to integrate such interventions, and in which clinical settings these methods would be the most effective and cost-effective.

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Other publications of related interest


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