Randomised controlled trial of nurse continence advisor therapy compared with standard urogynaecology regimen for conservative incontinence treatment: efficacy, costs and two year follow up

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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 use of nurse continence advisors in the treatment of mild to moderate urinary incontinence in women.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised women with a urodynamic diagnosis of genuine stress incontinence, idiopathic detrusor instability, sensory urgency or a mixture thereof, and a 1-hour pad test loss in the mild (2 - 9.9 mL/hour) or moderate (10 - 50 mL/hour) range.

Setting
The setting was secondary care. The study was undertaken in the regional referral unit at the St. George Hospital, Kogarah, NSW, Australia.

Dates to which data relate
The date of the study was not reported. Therefore, the dates to which the effectiveness and resource use data relate cannot be determined. The price year was not explicitly stated, but it appears to have been 1998.

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

Link between effectiveness and cost data
The clinical data and resource use data were taken from the same patient sample. The resource use data were collected prospectively.

Study sample
A consecutive sample of patients attending the outpatients department for mild to moderate incontinence, as determined by a 1-hour pad test, was recruited to the study. The study planned to recruit 150 patients to have an 80% chance of detecting a 20% increase in a cure rate of 35%. Overall, 145 patients were randomised to the treatment groups. Of these, 74 were allocated to the nurse advisor group and 71 to the urogynaecology team. A further 5 patients
were eligible to be recruited to the study, but were not randomised. Three of these did not agree to participate in the study and 2 did not complete the pad test. The authors did not present any evidence of whether this patient sample was appropriate to the clinical question.

Study design
The study was a randomised, controlled trial that was carried out in a single centre. The patients were randomised using block randomisation, stratified according to whether the patient had mild or moderate incontinence. The outpatient clerk administered opaque envelopes containing computer-generated random numbers. Neither the patient nor the health professionals in the study were blinded to the treatment group. The patients were assessed at the end of the 12-week trial, then followed up for at least 2 years. The overall loss to follow-up at the end of the 12-week trial was 24.1%, 21.6% in the nurse advisor group versus 26.7% in the comparator group. At the 2-year follow-up, the overall loss was 33.8% of all randomised patients, 36.5% in the nurse advisor group versus 31.0% in the comparator group.

Analysis of effectiveness
The primary analysis of the study appears to have been based on treatment completers only. However, a further analysis, which included those patients who were lost to follow-up, was undertaken. One analysis assumed that all those who were lost to follow-up were cured, while another assumed that treatment failed for all of these patients.

The effectiveness of the two treatments was assessed at the end of the 12-week trial. The outcomes assessed were the change in the level of incontinence, use of incontinence pads and quality of life. Measures for these included a pad test (dry indicates overall cure), the number of voids per day, the number of leaks per week, the number of pads used per day, a 20-point incontinence score, and the long and short forms of two disease-specific quality of life tests.

There appears to have been differences in the baseline characteristics of the two patient groups. Those allocated to the urogynaecology team were older than those in the nurse advisor team. They also had lower scores on some of the quality of life indicators and a small urinary loss on the initial pad test.

Effectiveness results
The overall cure rate (dry pad test) for women was 64% in the nurse advisor group versus 52% in the comparator group. This gave an odds ratio of 1.63 (0.71 - 3.75) in favour of the nurse advisor group. However, this result was not statistically significant. At the end of the 12-week trial there were no statistically significant differences between the two groups in any of the other outcome measures. There were also no statistically significant differences between the two groups in the measures of effectiveness used at the 2-year follow-up.

Clinical conclusions
The authors concluded that there was no difference in the effectiveness of conservative treatment delivered by urogynaecologists and specialist nurse advisors.

Measure of benefits used in the economic analysis
No difference in the effectiveness of the two treatment groups was found. In effect, a cost-minimisation analysis was undertaken.

Direct costs
The hospital costs were included. The study examined the staffing costs incurred by the hospital for the two treatment groups. The hourly costs of the nurse advisors, the urogynaecology team and the physiotherapists were reported, but the source of these unit costs was not. The number and duration of visits to nurse advisors and the urogynaecology team were recorded prospectively in the medical notes of the patients included in the trial. The number and duration of physiotherapy appointments were obtained by asking the relevant patients. Discounting was not undertaken since the duration of the trial was 12 weeks. The price year was 1998. The study originally aimed to assess the personal costs
incurred by patients for items such as incontinence pads, but the patients experienced problems in completing the questionnaire.

**Statistical analysis of costs**
The costs were treated deterministically.

**Indirect Costs**
No indirect costs were included in the study.

**Currency**
Australian dollars (Aus$).

**Sensitivity analysis**
No sensitivity analysis was undertaken.

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

**Cost results**
The total staffing costs were Aus$59.20 (interquartile range: 48.10 - 77.70) for patients treated by the nurse advisors and Aus$189.70 (interquartile range: 120.60 - Aus$250.70) for those in the comparator group.

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

**Authors' conclusions**
The conservative treatment of mild to moderate incontinence by nurse advisors was no less effective than that provided by a urogynaecology team, but it was cheaper.

**CRD COMMENTARY - Selection of comparators**
No explicit justification was given for the choice of the comparator. However, it appears to have represented current practice in the authors' setting. You should consider how this relates to your own setting prior to applying the results of this study to your own area of work.

**Validity of estimate of measure of effectiveness**
The effectiveness data were taken from a randomised controlled trial, which was appropriate for the clinical question. The baseline characteristics of the patients were reported and there appear to have been some differences between the groups. The patients allocated to the urogynaecology team were older than those in the nurse advisor team. They also had lower scores on some of the quality of life indicators and a small urinary loss on the initial pad test. This suggests that these patients had less severe incontinence at the start of the trial, which could bias the results since it has not been taken into consideration in the analysis. There was a planned sample size, but the drop-out rates were higher than expected. Since the study failed to produce any statistically significant results, despite apparent differences in the point estimates, it is likely that the study was underpowered.
Validity of estimate of measure of benefit
No difference in the effectiveness of the two treatment groups was found. Thus, a cost-minimisation analysis was undertaken.

Validity of estimate of costs
The paper did not explicitly state the perspective of the study. However, the costs incurred by the hospital appear to have been assessed. The inclusion of the costs of any equipment used in the treatment would have provided a more comprehensive assessment of the costs incurred by the hospital. However, their inclusion is unlikely to have altered the conclusion of the study. The study would also have been improved had the authors been able to include the personal costs incurred by the patients, as originally planned. This element had to be abandoned due to the patients having problems in completing the questionnaire designed for this purpose. The sources of the unit costs were not stated, which hinders any assessment of the generalisability of the results.

The unit costs and the median resource use of the three categories of staff included in the study were reported separately. This increases the generalisability of the study. On the other hand, the lack of any sensitivity analysis and the deterministic treatment of the cost and resource use data, reduce the generalisability. The study was further limited by the fact that the source of the unit costs for the staff was not reported.

Other issues
The authors compared their findings with other studies that found similar levels of effectiveness between nurses with specific training and medically trained staff. The study sample consisted of women with mild to moderate incontinence, but the authors appear to have generalised their findings to all women with incontinence.

Implications of the study
The authors suggested that nurse continence advisors could be more widely used in the conservative treatment of mild to moderate incontinence.

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