Use of the Dowell Bryant Incontinence Cost Index as a post-treatment outcome measure after non-surgical therapy

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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 the Femassist urethral occlusive device (FUOD) for women suffering from incontinence. This is a non-surgical treatment that can be applied to women suffering from different types and severity of incontinence.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised women suffering from incontinence who attended a community continence clinic. The exclusion criteria were uterovaginal prolapse beyond the introitus, obvious atrophic vaginitis, history of recurrent urinary tract infections and inability to speak English (or exhibited signs of dementia).

Setting
The clinical setting was a community continence clinic. The economic study was performed in Sydney, Australia.

Dates to which data relate
The effectiveness evidence and resource use data were gathered in one month, but no dates were given (correspondence with the authors has indicated that this was 1999). The price year was not reported (but is also likely to have been 1999).

Source of effectiveness data
The effectiveness evidence was derived from a single study.

Link between effectiveness and cost data
The costing was performed prospectively on the same sample of patients used in the effectiveness study.

Study sample
No power calculations to determine the sample size were performed. A sample of 100 consecutive women, who attended a community continence clinic for management by a nurse continence advisor, was considered for the analysis. Three women refused to participate in the study, while only 84 were actually fitted with the device and were included in the study after the exclusion criteria were applied. The median age of the participants was 66 years (interquartile range, IQR: 47 - 74). Fifty-seven of the 84 women completed the study and 27 dropped out. Reasons for drop-out were a...
dislike of using the device or to touch the genitalia (12), anatomically unstable (5), or illness or family problems (10). Only one third of the women in the final sample had severe incontinence.

**Study design**

This was a within-group comparison study, which was performed in a single centre. The patients received visits at weekly intervals for 5 weeks. At the first visit women completed the DBICI following the instructions of two nurse continence advisors. The DBICI was subsequently completed at weeks 1, 4 and 5. Also, baseline outcome measures were estimated for all participants at week 1, and final outcome measures were calculated at week 5. Each DBICI was stored separately in order to blind the investigator at each test. The duration of the study was 5 weeks and 57 women completed the study.

**Analysis of effectiveness**

The analysis of the clinical study was conducted on the basis of treatment completers only. The main outcome measures used in the analysis were the number of pads, leaks and voids per day, the International Continence Society (ICS) pad test, the Urogenital Distress Inventory (UDI) and the Incontinence Impact Questionnaire (IIQ). The severity of leakage on the pad test was classified as mild (2 - 9.9 mL/hour), moderate (10 - 50 mL/hour) or severe (greater than 50 mL/hour). The UDI and the IIQ are disease-specific questionnaires used to evaluate the impact of incontinence on quality of life. In addition, a visual analogue scale (VAS) compared the baseline and post-treatment impact of leakage on lifestyle. Baseline patient characteristics were presented separately for those who completed the treatment and those who dropped out. There was no statistically significant difference in any baseline characteristics (demographic and clinical) between the two groups.

**Effectiveness results**

There was a statistically significant improvement in all post-treatment outcome measures in comparison with the baseline.

- The median number of leaks per day decreased from 4 to 1 (median difference 3; 95% confidence interval, CI: 2.5 - 3.5; p<0.0001);
- the median number of pads per day decreased from 2 to 0 (median difference 1.5; 95% CI: 1.0 - 2.5; p<0.0001); and
- the median number of voids per day decreased from 10 to 7 (median difference 3; 95% CI: 2.0 - 4.0; p<0.0001).

The pad test showed a decrease in the median severity of leakage from 22 to 2 g/hour (median difference 20.5; 95% CI: 10.5 - 38.5; p<0.0001); and

the median VAS score decreased from 7 to 3 (median difference 3.5; 95% CI: 2.5 - 4.5; p<0.0001).

Finally, there was a significant decrease in the UDI and IIQ scores with median differences of 71 (95% CI: 56 - 88; p<0.0001) and 67 (95% CI: 35 - 99; p=0.0003), respectively.

**Clinical conclusions**

The effectiveness analysis showed that the use of the FUOD for women suffering from incontinence resulted in a statistically significant improvement in all outcome measures considered.

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

No summary benefit measure was used. A cost-consequence analysis was therefore carried out.

**Direct costs**

Discounting was not carried out, which was appropriate given the short time horizon of the analysis. The quantities of
resources used were partially reported, but only the unit cost of the FUOD was presented. The categories of costs included were the individual's expenditure in pads, laundry and miscellaneous costs. The FUOD was provided free of charge by the manufacturers for the duration of the study. The perspective adopted appears to have been that of the patient. However, it was unclear whether the cost of the device was sustained by the patient or by the health care system. Resource use data were gathered from the DBICI, which the patients completed weekly. The unit cost of the device was based on the manufacturer’s retail price. The dates during which the quantities of resources were measured were not reported, nor was the price year.

Statistical analysis of costs
The significance of differences in the pre- and post-treatment costs was assessed using the Wilcoxon signed-rank test. Also, the correlation between changes in clinical outcomes and changes in personal costs was investigated using Kendall's rank correlation.

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

Currency
Australian dollars (Aus$).

Sensitivity analysis
No sensitivity analyses were carried out

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

Cost results
Compared with pre-treatment, there was an overall median reduction in personal costs after the treatment (at week 5) of Aus$4.22 (95% CI: 3.00 - 5.63). The median weekly cost was Aus$6.52 pre-treatment and Aus$1.57 post-treatment, (p<0.0001).

However, given a retail price of Aus$12.50 for the FUOD and the recommendation to use a new device each week, the median increase per week in total costs with the treatment would be approximately Aus$8.50 (IQR: 7 - 9.8).

If only one device was used in a time horizon of 4 weeks (clinical experience suggested the device remained effective for a minimum of 4 weeks), then the median incremental cost of the treatment per week would fall to Aus$0.86 (IQR: -0.43 - 2.38).

A significant correlation was found between the reduction in personal costs and the clinical outcome measures.

Synthesis of costs and benefits
Not relevant because a cost-consequences analysis was performed.

Authors' conclusions
The Dowell Bryant Incontinence Cost Index (DBICI) was a useful and applicable instrument to assess the personal costs in women suffering from incontinence. The results obtained with the DBICI showed that the reduction in personal costs arising from the use of the Femassist urethral occlusive device (FUOD) did not completely offset the cost of the device.
CRD COMMENTARY - Selection of comparators
The authors compared the clinical outcomes and costs before and after the use of the FUOD, because this device had shown positive clinical results in published trials and it was a simple exercise to estimate the accuracy and the validity of the DBICI. The authors acknowledged that alternative treatments could have been used as the comparators in order to undertake a more sophisticated cost-effectiveness analysis. You should decide whether they are valid comparators in your own setting.

Validity of estimate of measure of effectiveness
The basis of the effectiveness analysis was treatment completers only because the statistical analyses showed no differences between the completers and drop-outs in terms of their baseline characteristics. Exclusion criteria were described, as well as the number of and reasons for exclusions and drop-outs. Also, the patients' visits and tests undertaken were described accurately. However, it was unclear why a decrease in the VAS should be considered a clinical improvement, and there was no information on the characteristics of the UDI and IIQ. Thus, it is difficult to judge the results of these questionnaires. Appropriate statistical analyses were performed to estimate the significance in clinical outcome differences. Median values and IQR were presented because the data were not distributed normally. The use of a within-group comparison study implied that no external comparison group was required, but factors other than the study intervention may have affected the effectiveness results.

Validity of estimate of measure of benefit
No summary benefit measure was used in the economic analysis. The analysis was therefore categorised as a cost-consequences study.

Validity of estimate of costs
The analysis of costs included only the personal costs and the cost of the device cost. This would be appropriate if the perspective of the study was that of the patient. Accurate statistical analyses of the costs were performed. The authors did not perform any currency conversion and the costs were presented only in Australian dollars. No sensitivity analyses of the costs were performed, but CIs were presented. The cost estimates were specific to the study setting. The dates when the resource use data were gathered and the price year were not given, thus limiting the possibility of replicating the study in other settings.

Other issues
The authors briefly reported the clinical results found by other published studies for the FUOD. They did not, however, compare their findings on personal costs with those of other studies because the DBICI had not been employed before as an outcome measure. The issue of generalisability was not addressed. No sensitivity analyses were performed, there were few details on the unit costs and dates, and the cost results were not compared with other studies. The authors pointed out that only a small percentage of the patient population considered in their study suffered from severe incontinence. A more severely afflicted population might have resulted in a higher cost reduction with the treatment, and thus might have resulted in cost-savings even when including the cost of the device. The authors noted that the main limitation of their analysis was the fact that the patients' disposable income was not assessed at baseline and this could have affected the interpretation of the results.

Implications of the study
The DBICI appears to have been a feasible instrument with which to measure personal costs in women with incontinence. A formal cost-effectiveness analysis should be performed to confirm this result.

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Other publications of related interest

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