Clean intermittent catheterization: safe, cost-effective bladder management for male residents of VA nursing homes

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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
Clean versus sterile intermittent bladder catheterization for long-term male care patients, for example those with bladder outlet obstruction secondary to prostatic hypertrophy, those currently managed with an indwelling catheter, atonic bladder caused by neurologic disease or increased residual urine resulting from medication side-effects.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Male nursing home residents (mean age 72) with problems of urinary retention.

Setting
The practice setting involved long-term nursing homes. The study was carried out in Minnesota, USA.

Dates to which data relate
The dates for the resources used and the effectiveness data were not provided. 1993 prices were used.

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

Link between effectiveness and cost data
Costing was undertaken prospectively on the same sample as that used for the effectiveness analysis.

Study sample
The study was a randomized, controlled clinical trial. No power calculations were reported for the estimation of sample size. 203 possible subjects were screened and, of these, 82 entered the study and 80 formed the study sample. There were 38 patients in the clean and 42 in the sterile group. Exclusion criteria included subjects not expected to stay at the site for 110 days or more, circumstances in which long term indwelling Foley catheters were removed in preparation for the study and patients voided adequately with minimal residual urine, patients from whom consent could not be obtained or who refused to give consent, and cases in which a suprapubic catheter was in place which patients were unwilling to give up for the trial. In addition, one patient died during the assessment period.
**Study design**
The study was a randomized controlled trial taking place on three sites. Duration of follow-up ranged from 15 to 107 days. A total of 18 patients (47.5%) in the clean group and 19 (45%) in the sterile group did not complete the 90-day protocol. The reasons for drop out included death unrelated to the study, patient request for discontinuation within the study, hospitalization of the patient for more than 21 days because of an unrelated problem, subject discharged from facility, combativeness, reduction in volume of residual urine so that patient no longer required catheterization and end of study funding period.

**Analysis of effectiveness**
Although it was not stated, it appears that the study analysis was based on treatment completers. The primary health outcomes used were number of treatment episodes for symptomatic bacterium (urinary tract infection (UTI)) and time to first infection since the beginning of the study. Groups were comparable in terms of sex, age and prognostic features. The latter was due to the control for patients with history of previous UTIs (at least one) as a confounding variable.

**Effectiveness results**
There was no significant difference in incidence of UTI (treatment episodes) between intervention and comparator. Nor was there a significant difference in the number of days before the onset of UTI between the two groups (P= 0.400).

**Clinical conclusions**
No significant differences were found between the clean and the sterile group with regard to the number of treatment episodes, time to first infection and type of organism cultured.

**Modelling**
Not included.

**Measure of benefits used in the economic analysis**
Since the clinical study showed no difference in clinical benefit between technologies, the economic analysis was based on the difference in costs only.

**Direct costs**
The costs measured were nursing time and supplies required for every catheterization. Only costs were reported. The health service perspective was adopted. Quantity and cost estimations were based on actual data. Quantity data was captured through the use of a bar code scanner. Nursing time was costed based on the RN and LPN staff nurse salaries and the supply costs were based on Minneapolis VA pharmacy costs. 1993 prices were used.

**Statistical analysis of costs**
Not stated.

**Indirect Costs**
Not included.

**Currency**
US dollars ($).

**Sensitivity analysis**
No sensitivity analysis was reported.

**Estimated benefits used in the economic analysis**
As no significant differences were found between the clean and the sterile group in terms of the number of treatment episodes or time to first infection, the results of the economic evaluation were based on cost-minimization.

**Cost results**
The average cost per sterile catheterization was $6.25 compared to $4.00 for the clean catheterization approach ($p<0.0001).

**Synthesis of costs and benefits**
As benefits were found to be comparable between the two approaches evaluated, only the cost of each approach was provided. The use of clean intermittent catheterization resulted in cost savings of $2.00 per catheterization.

**Authors' conclusions**
The study suggests that clean intermittent catheterization may offer a safe and cost-effective alternative to sterile intermittent catheterization for selected male residents in long term care settings. It was estimated that by using the clean technique, annual savings per catheterized patient of around $1,460.00 would result, assuming that catheterization was undertaken, on average, four times per day.

**CRD Commentary**
Selection of comparator:

The reason for the choice of comparator is clear.

Validity of estimate of measure of benefit:

An RCT study design was adopted and randomization controlled for research site and presence/absence of UTI history, and hence the research findings are likely to be internally valid. Quality of life issues were not addressed.

Validity of estimated of costs:

Resource quantities used were not clearly stated and, because of this, cost results are not as transparent as they could have been.

Other issues:

The generalisability of the results is unclear.

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