A study comparing sterile and nonsterile urethral catheterization in patients with spinal cord injury

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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
Non sterile and sterile intermittent urethral catheterization in patients requiring management of neurogenic bladder after spinal cord injury as a strategy for preventing urinary tract infections.

Type of intervention
Treatment; Secondary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
Adult patients with spinal cord injuries receiving intermittent catheterisation for neurogenic bladder dysfunction.

Setting
Hospital (a rehabilitation centre). The economic analysis was conducted in Miami, Florida, USA.

Dates to which data relate
Dates for effectiveness and resource data and the price years used were not stated.

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 patient sample as used in the effectiveness study.

Study sample
29 patients were included in the study of which 15 were in the non sterile catheterisation group and 14 in the sterile group. Patients were randomly allocated to either group and power calculations were not used to determine the sample size. The mean ages of patients in the non-sterile and sterile catheterisation groups respectively were 38 (SD +/- 22) and 34 (SD +/- 14). In the non sterile group 60% were men and 60% of patients were tetraplegic with the remainder being paraplegic. In the sterile group 50% of patients were men and 64% were tetraplegic with the remainder being paraplegic. 66 urinary cultures were taken from the non sterile group and 56 from the sterile group.

Study design
Prospective single centre randomised controlled trial. Patients were followed up over a three month period. The method of randomisation was not reported and no information was provided on any patients excluded from the trial.

**Analysis of effectiveness**
The analysis of effectiveness was based on intention to treat. The primary health outcome was the incidence of UTI, bacteriuria and pyuria.

**Effectiveness results**
An incidence of 42.4% for UTI was reported in the non-sterile group compared with 28.6% in the sterile group. This difference was not statistically significant using the chi squared test. Similarly for bacteriuria these rates were 51.5% and 39.3% and for pyuria 54.5% and 34.0% respectively for the non sterile and sterile catheterisation groups. These differences were also not significant.

**Clinical conclusions**
The authors concluded that the incidence of UTI and other infections was lower in the sterile group and that this was similar to that reported by other studies. The authors also concluded that the small study size prevented this difference from being statistically significant.

**Measure of benefits used in the economic analysis**
Since no significant difference was found in the study between the intervention and the comparator, the analysis was based on the difference in costs.

**Direct costs**
The costs of antibiotic therapy and catheterisation costs were estimated. The price used and the source of cost data were not stated. Costs were estimated from the perspective of the hospital.

**Currency**
US dollars ($).

**Sensitivity analysis**
No sensitivity analysis was performed.

**Estimated benefits used in the economic analysis**
Not applicable.

**Cost results**
The total costs of antibiotic therapy in the non-sterile and sterile groups respectively were $640.01 and $274.56 for the three month study period. Similarly the costs of catheterisation kits were $1,584 and $5,880 for the two groups. Total costs were estimated to be $2,224.01 for the non-sterile and $6,154.56 for the sterile group.

**Synthesis of costs and benefits**
Not applicable.

**Authors' conclusions**
The authors concluded that the total costs of the sterile catheterisation programme were 277% of the costs of the non-sterile programme. The authors felt, however, that if an accurate cost-effectiveness analysis, including indirect costs, were conducted, the use of the sterile catheterisation method might have been justified due to less need for more intensive care, rehabilitation time and need for treatment of adverse events.

**CRD COMMENTARY - Selection of comparators**
A justification was given by the authors for the use of the comparator, as sterile methods of intermittent catheterisation have been demonstrated to be efficacious and represent an alternative to non-sterile intermittent catheterisation.

**Validity of estimate of measure of benefit**
Although a randomised controlled trial was used to collect data on effectiveness, the sample size was too small to demonstrate statistical significance between the intervention and the comparator.

**Validity of estimate of costs**
Insufficient details were provided of the source and nature of costs, and the price dates used. In addition costs were estimated only from the perspective of the health service and excluded other costs to society such as patients and caregivers.

**Other issues**
The dates during which the study was conducted were not stated, no sensitivity analysis was performed and the small sample size, as admitted by the authors, prevents any conclusions being reached on the cost effectiveness of the non-sterile and sterile catheterisation systems. In addition the information on costs may not be generalisable outside the study’s institution.

**Implications of the study**
There is a need for well designed economic and clinical evaluations to compare non-sterile and sterile catheterisation systems.

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