Bacteriological safety and cost-effectiveness of a nonrefluxing valve in the irrigation system during outpatient flexible cystoscopy

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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 a nonrefluxing irrigation system for outpatient flexible cystoscopy (Setguard, Mediplus Ltd). This involved using a new sterile 'giving set' for each flexible endoscopy. The comparator was conventional irrigation systems. These involved the use of a single irrigation set consisting of a sterile bag of irrigant and a 'giving set' at the beginning of the list.

Type of intervention
Diagnosis

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised all male and female patients undergoing flexible cystoscopy in the inpatient and outpatient departments over a 4-month period. Patients were excluded if they had taken antibiotics within the previous 72 hours for any reason, including prophylaxis, or they had indwelling catheters in situ. They were also excluded if their residence was too far from the hospital to allow the MSU sample to be collected, or if they had declined to participate in the trial and to provide a follow-up sample of urine.

Setting
The setting was an institution. The economic study was carried out in Manchester, UK.

Dates to which data relate
The dates during which the effectiveness and resource use data were collected were not reported, nor was the price year.

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 patient sample as that used in the effectiveness study.

Study sample
No mention was made of power calculation being used to determine the sample size. Of the 220 patients, 143 fulfilled the study inclusion criteria while 77 patients were excluded for the reasons above ('Study Population' section). Sixty-
nine patients were randomised to the intervention group and 74 to the control group. The mean age of the patients was 63.9 years (range: 17 - 90), and the male-to-female ratio was 2.5:1.

**Study design**
This was a randomised controlled trial. The patients were randomised by ascribing half of the lists to the two arms of the study. An equal distribution of routine follow-up endoscopy sessions was assigned to each arm of the trial. The patients were booked onto lists according to the clinical indication, by staff who were unaware of the randomisation of the lists.

**Analysis of effectiveness**
Although not explicitly stated, the basis of the analysis of the clinical study was intention to treat. The primary health outcome used was the infection rate. Bacterial urinary tract infection was deemed to be present if there was a pure growth of at least $10^5$ organisms/mL with pyuria of greater than or equal to 10 pus cells per high-power microscopy field. The groups were considered to be comparable, as there were no significant differences between them in terms of age or gender.

**Effectiveness results**
There were only four patients (3%) with urinary tract infection attributable to flexible cystoscopy. Of these, one patient was from the intervention (Setguard) group, which represents an infection rate of 1.7% (95% confidence interval, CI: 0.09 - 10.14). The remaining three patients were from the standard group, giving an infection rate of 4.7% (95% CI: 1.22 - 13.69).

There was no statistically significant difference in the infection rates between the groups (Fishers exact test, p=0.62).

**Clinical conclusions**
The authors concluded that the results suggested that there was little evidence of reflux occurring across the single flow valve into the irrigating system during flexible cystoscopy, and that this did not pose a bacteriological infection risk. Therefore, the use of a nonrefluxing valve in the irrigation does not increase the risk of complicating bacteriological infection during cystoscopy, compared with replacing the entire irrigating procedure for each procedure.

**Measure of benefits used in the economic analysis**
No summary benefit measure was used in the economic analysis. A cost-consequences analysis was therefore carried out.

**Direct costs**
No discounting was undertaken, which was appropriate as the costs were incurred over less than 2 years. The quantities and the costs were analysed separately. The costs of the standard treatment included those of single irrigation (intravenous). The 'giving set' cost 3.20 and a 1-L bag of saline cost 0.56, producing a cost of 3.96. The Setguard equipment included the cost of the valve (replaced for each patient; 1.50), the irrigation 'giving set' (4.95) and a 3-L fluid bag (3.32). The costs and quantities were estimated from actual data. The price year was not stated.

**Statistical analysis of costs**
No statistical analysis was carried out.

**Indirect Costs**
The indirect costs were not considered since the study was conducted from a provider perspective.
Currency
UK pounds sterling (£).

Sensitivity analysis
A sensitivity analysis was not undertaken, and the resource use and costs were treated as point estimates.

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

Cost results
The total cost of the Setguard was 271.74 (£99.24 for the 3-L bags used and 172.50 for the valves).

The cost per patient was 2.37, which represents a saving of 1.39 (37%) per procedure. Four Safeguard procedures were required to produce a cost-saving.

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

Authors' conclusions
The nonrefluxing valve caused no detectable increase in patient morbidity, as there was no significant difference between the overall rate of bacterial infection when compared with conventional irrigation systems for flexible cystoscopy. Considerable cost-savings (greater than 37%) can be made (in disposables) if 10 patients are examined per flexible cystoscopy.

CRD COMMENTARY - Selection of comparators
The choice of the comparator was justified, mainly on the grounds that it was the current practice. You should consider whether this technology is appropriate or applicable to your own setting.

Validity of estimate of measure of effectiveness
The study used a prospective randomised controlled trial, which was appropriate for the study question. The study sample was representative of the study population. In addition, the groups were comparable since there were no statistically significant differences between them. However, although a randomised controlled trial was conducted, no statistical or sensitivity analyses were carried out to take into account potential biases and confounding factors.

Validity of estimate of measure of benefit
The benefits were estimated directly from the effectiveness analysis, within a cost-consequences approach.

Validity of estimate of costs
All the categories of cost relevant to the provider perspective seem to have been included in the analysis. The costs and the quantities were reported separately, but no statistical analysis of the quantities and prices (unit costs) was undertaken. Since all of the costs were incurred in less than two years, discounting was not necessary. The actual prices of the resources were given in the study, but the date to which the prices related was not reported. The authors did not, however, report the costs of both interventions. It is difficult to see from the paper how they arrived at their conclusions concerning the cost results.
Other issues
The authors made appropriate comparisons of their results with findings from other studies, but the issue of generalisability to other settings was not addressed. The authors may have presented their results selectively, as they did not provide all the relevant information. The authors did not report any limitations to their study.

Implications of the study
The findings of the study tend to support the use of the nonrefluxing irrigation system in terms of clinical outcomes and economic considerations. The results, however, need to be treated with some caution as highlighted above. The annual savings of the Safeguard procedure, based on a total of 1,000 scheduled flexible cystoscopies per annum, exceeds 1,350 in the authors' setting. No recommendations on the need for further research were made.

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