Intermittent self catheterisation with hydrophilic, gel reservoir, and non-coated catheters: a systematic review and cost effectiveness analysis

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CRD summary
This review concluded that there was little evidence to indicate which type of catheter was most suitable for intermittent self-catheterisation based on risk of urinary tract infection; given the limited research, patients should be offered a choice between hydrophilic and gel-reservoir catheters. These cautious conclusions are likely to be reliable and reflect the need for further research.

Authors' objectives
To determine the most effective and cost effective type of catheter for patients who perform intermittent self-catheterisation in the community.

Searching
MEDLINE, EMBASE, The Cochrane Library and CINAHL were searched from inception to April 2011 for studies published in English. Search strategies were reported in a supplementary online appendix and in a 2012 National Clinical Guideline Centre (NICE) guideline (see Other Publications of Related Interest). The previous set of guidelines was used as a source for references of papers published before 2002 for one of the research questions.

Study selection
Randomised controlled trials (RCTs) of intermittent self-catheterisation in patients with long-term urinary catheters (longer than 28 days) were eligible for inclusion. Eligible interventions were: non-coated catheters, hydrophilic catheters, or gel reservoir catheters; or non-coated catheters used multiple times versus single-use catheter. All trials were required to report one of the specified outcomes of symptomatic urinary tract infections, bacteraemia, mortality, number of catheters used, or patient preference/comfort.

The included RCTs and randomised cross-over trials compared hydrophilic catheters versus non-coated catheters, gel reservoir catheters versus non-coated catheters, and clean non-coated versus sterile non-coated catheters. Most participants had spinal cord injuries. The age of participants ranged from 12 and 72 years; most were male. Most trials reported the number of urinary tract infections and patient comfort or satisfaction; none reported bacteraemia or mortality.

Assessment of study quality
One reviewer assessed trial quality using the NICE Guideline Manual checklist for risk of bias (for selection, performance, attrition and detection). The quality of evidence for each outcome was assessed using the GRADE (Grading of Recommendations Assessment, Development and Evaluation) criteria based on study design, limitations, consistency and directness of the evidence.

Data extraction
It appeared that one researcher performed the data extraction. Authors were contacted for further information about the intervention procedures where necessary.

Methods of synthesis
Dichotomous outcomes were pooled using a fixed-effect Mantel-Haenszel model to calculate risk ratios (RRs) and 95% confidence intervals (CIs); continuous outcomes were pooled using an inverse-variance model to calculate mean differences or standardised mean differences where scales differed. Heterogeneity was assessed using $I^2$ (values higher than 50% were significant) and $X^2$ (p<0.1). Prespecified subgroups were explored for differences when heterogeneity was significant.
Results of the review

Eight trials (461 patients) were included in the review; six were RCTs and two were randomised cross-over trials. Follow-up periods ranged from three weeks in each cross-over arm to one year.

Symptomatic urinary tract infections: There were no differences in the mean monthly number of urinary tract infections (one trial), total number of urinary tract infections at one year (one trial), or the total antibiotic treatment episodes at one year (one trial) for hydrophilic coated catheters versus sterile non-coated catheters. These outcomes were given a rating of moderate quality according to GRADE. Patients that used gel-reservoir or hydrophilic catheters (RR 0.80 95% CI 0.65 to 0.99; I² 0%; two trials) versus sterile non-coated catheters (RR 0.33, 95% CI 0.11 to 0.97; one trial) were significantly less likely to report one or more urinary tract infections. There was no significant difference in the incidence of urinary tract infections between patients that used clean versus sterile non-coated catheters (one trial for weekly use; one trial for daily use).

Patient preferences: Three trials reported on patient preferences and experiences using hydrophilic versus non-coated catheters. The results generally favoured the hydrophilic catheter for ease of use and satisfaction, although not all differences were statistically significant. Burning sensation or pain on removal was similar between groups. Gel reservoir catheters were associated with significantly greater patient satisfaction compared with non-coated catheters (mean difference in satisfaction 2.39, 95% CI 1.29 to 3.49).

Cost information

Results from the systematic review were incorporated into a probabilistic Markov model using the perspectives of the UK NHS and personal social services. Although the most effective in clinical terms, gel-reservoir catheters cost over £54,350 per quality-adjusted life-year (QALY) gained, so were not cost effective compared with clean non-coated self-catheterisation. If clean non-coated catheters were not considered a viable option, gel-reservoir catheters were the most cost effective. Compared with hydrophilic catheters, gel-reservoir catheters cost an extra £1,373 and 0.446 QALYs were gained, which gave an incremental cost-effectiveness ratio of £3,075 per QALY gained. Compared with hydrophilic catheters, gel-reservoir catheters were cost effective in 84.6% of model iterations.

Authors' conclusions

The type of catheter used for intermittent self-catheterisation seemed to make little difference to the risk of symptomatic urinary tract infection. Given large differences in resource use, clean non-coated catheters were most cost effective. However, because of limitations and gaps in the evidence base and the designation of non-coated catheters as single use devices, patients should be offered a choice between hydrophilic and gel-reservoir catheters.

CRD commentary

The review answered a clear clinical question with appropriate inclusion criteria. A reasonably comprehensive search of the literature was conducted. However, the exclusion of unpublished studies and non-English language papers was not fully justified, so it was unclear how many studies were excluded on these grounds. The review processes were partially described, but the lack of a second reviewer to check decisions and data extraction may have left the results vulnerable to error or bias.

The included trials were appropriately assessed for bias; this was incorporated into the synthesis. The clinical effectiveness synthesis appears to have been appropriate. The authors highlighted where outcomes were based on poor quality trials and/or available only from one or two trials.

The authors' cautious conclusions reflected the limited evidence base and seem likely to be reliable.

Implications of the review for practice and research

Practice: The authors stated that clean non-coated catheters were the most cost-effective method of intermittent self-catheterisation, where this was not a viable option, gel-reservoir catheters may be more cost effective than hydrophilic catheters, but patients should be offered a choice.

Research: The authors made detailed recommendations for further priority research involving a four- or five-arm RCT to compare each method of intermittent self-catheterisation with appropriate outcome measures, which should last at least a one year.
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