Use of Avagard in pediatric urologic procedures

Palmer J S

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 study compared the use of Avagard (chlorhexidine gluconate 1% solution and ethyl alcohol 61% weight/weight), a waterless, brushless and scrubless hand antiseptic, versus traditional preoperative brush hand scrubbing (2 to 10 minutes) in preparation for inpatient and outpatient paediatric urologic operations.

Type of intervention
Primary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients who underwent paediatric urologic procedures. A single paediatric urologist conducted all of the procedures. Further inclusion or exclusion criteria were not reported.

Setting
The setting was secondary care (inpatient and outpatient surgery). The economic study was carried out in the USA.

Dates to which data relate
The dates of the effectiveness and cost data were not reported. The price year was also not reported.

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

Link between effectiveness and cost data
The costing appears to have been carried out prospectively on the same sample of patients as that used in the effectiveness study.

Study sample
The sample size was not determined in the planning phase and no retrospective power calculations were reported. A total of 1,100 patients were included in the study. The first 550 consecutive patients underwent surgery using Avagard as the antiseptic, while the last 550 consecutive patients were operated on using traditional antiseptic-impregnated brush hand scrubbing. All patients were operated on by the same paediatric urologist. However, details of the other surgical personnel involved in the study were not reported. The use of antiseptic among the surgical personnel, apart from the urologist, was arbitrary. No patients were excluded from the analysis and none were reported to have refused to participate.
Study design
This was a single-centre non-randomised controlled trial in which the patients were consecutively allocated to the intervention. Although it was reported that patients as well as surgeons were followed up, duration and losses to follow-up were not reported.

Analysis of effectiveness
It was not reported whether the analysis was conducted on an intention to treat basis. The primary outcome was incidence of wound infection (including signs of fever, erythema and induration). Side effects experienced by either patients or surgeons were also accounted for in the analysis. Such side effects included skin irritations and allergic reactions. The chi-squared test was used to compare the results. The current report did not compare the patients in the two groups.

Effectiveness results
The incidence of wound infection was 1 in the Avagard group and 2 in the hand scrub group.

It was reported that the incidence of wound infection did not differ significantly between the two groups.

No side effects were reported for either the patients or surgeons.

The completion time for preparation was around 2 minutes for Avagard and between 2 and 5 minutes for hand scrub, excluding time for hand-drying.

Clinical conclusions
The authors concluded that the analysis demonstrated that "Avagard is a fast, effective, easy to apply and safe surgical hand preparation for paediatric urologic surgery".

Measure of benefits used in the economic analysis
The authors did not derive a summary measure of benefit in the economic analysis. The effectiveness analysis demonstrated equal effectiveness and only costs were analysed in economic analysis. Therefore, a cost-minimisation analysis was performed.

Direct costs
Only summary costs per application for each preparation modality were reported. The sources of the costs and the price year were not reported. Discounting was not relevant as the costs were incurred during a short time (less than 2 years).

Statistical analysis of costs
No statistical analysis of the costs was undertaken.

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

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analysis was conducted.

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

**Cost results**
Avagard incurred a cost of $0.45 per application, while the antiseptic-impregnated handbrush incurred a cost of $1.04 per application.

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

**Authors' conclusions**
The analysis demonstrated that the use of the Avagard antiseptic hand preparation minimises costs in comparison with the traditional surgical scrub.

**CRD COMMENTARY - Selection of comparators**
A justification was given for the comparators used. Preoperative brush hand scrubbing appears to have represented standard practice in the authors' setting, while Avagard is a newly licensed product. However, if further preparation modules exist, which is likely, it would mean that the study was only a partial analysis.

**Validity of estimate of measure of effectiveness**
The analysis was based on a non-randomised controlled trial. Power calculations were not conducted, the patient groups were not compared, and the length of study and loss to follow-up were not reported. Statistical or sensitivity analyses, which could take potential biases and confounding factors into consideration, were also not described. All these factors contribute to the low internal validity of the study.

**Validity of estimate of measure of benefit**
The authors did not derive a summary measure of benefit in the economic analysis and, as equal effectiveness was demonstrated, a cost-minimisation analysis was performed. The comments in the 'Validity of estimate of measure of effectiveness' field (above) therefore apply.

**Validity of estimate of costs**
The authors reported very limited information on their costing study. As the perspective adopted was not reported, it was hard to determine whether all the relative categories of costs were included. In addition, the resource use quantities and the prices were not reported separately. These facts will limit the generalisability of the authors' results. No sensitivity analysis was performed to assess the robustness of the cost estimates used. Such lack of detail will limit the generalisability of the results and their internal validity.

**Other issues**
The authors did not compare their study findings with those of other studies. However, this might have been due to a lack of studies in the same research area. The issue of generalisability of the results was not addressed. The authors do not appear to have presented their results selectively. However, the effectiveness and the costing analysis were only sparsely reported, which introduces uncertainty and does not permit the derivation of robust conclusions. The authors acknowledged a number of limitations to their study. First, the operating room personnel did not use the same antiseptic for each case. Second, the distribution of the type of antimicrobial brush scrubs used and the use of Avagard by the
surgeon and other operating room personnel were not recorded. Although, the authors felt that these limitations were unlikely to have affected their conclusions, they do not allow a clear effect of the product to be demonstrated and introduce uncertainty into the results.

**Implications of the study**
Although the authors did not explicitly recommend further work, the analysis and discussion highlighted areas where more research-based evidence is necessary.

**Source of funding**
None stated.

**Bibliographic details**

**PubMedID**
16979714

**DOI**
10.1016/j.urology.2006.04.014

**Other publications of related interest**
Because readers are likely to encounter and assess individual publications, NHS EED abstracts reflect the original publication as it is written, as a stand-alone paper. Where NHS EED abstractors are able to identify positively that a publication is significantly linked to or informed by other publications, these will be referenced in the text of the abstract and their bibliographic details recorded here for information.

**Indexing Status**
Subject indexing assigned by NLM

**MeSH**
Anti-Infective Agents; Anti-Infective Agents, Local; Child; Chlorhexidine /analogs & derivatives; Ethanol; Hand Disinfection /standards; Humans; Preoperative Care; Urologic Surgical Procedures /standards

**AccessionNumber**
22006002088

**Date bibliographic record published**
30/04/2007

**Date abstract record published**
30/04/2007