An evaluation of two methods of pre-cannulation skin disinfection

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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
Povidone iodine was compared with a combination of chlorhexidine gluconate solution and alcohol wipes for disinfection of haemodialysis cannulation sites. In the case of the use of povidone iodine, patients or nurses prepared a disposable sterile pack for use by adding povidone iodine. A nurse placed a sterile paper towel under the arm, applied the solution to the access area using sterile gauze swabs, blotted the area dry with a sterile gauze pad 30 seconds after applying the iodine and immediately inserted the fistula needle. In the case of chlorhexidine gluconate solution and alcohol wipes, the patient washed the skin around the access device with chlorhexidine gluconate and running water for one minute and dried it using a clean paper towel. A nurse then placed a clean protective sheet under the arm and wiped the cannulation site with an alcohol impregnated wipe (AlcowipeTM), the skin was allowed to air dry and the nurse inserted the fistula needle.

Type of intervention
Primary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
The study population included patients with end stage renal disease undergoing regular haemodialysis.

Setting
The setting was secondary care. The economic analysis was carried out in a dialysis unit of a Melbourne teaching hospital, Victoria, Australia.

Dates to which data relate
The dates for the effectiveness evidence, resource use and price data were not stated although they seem to refer to the same time period.

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

Link between effectiveness and cost data
The costing was carried out for the standard disinfection consumables and was not individually calculated for the patients in the study.

Study sample
The inclusion criteria were that a patient had an A-V fistula in an arm; that the fistula had been functioning for three or more months; that the patient was having two or more dialysis treatments per week in the unit and that the cannulation site was being disinfected with povidone iodine solution prior to the commencement of the study. Patients with grafts (artificially constructed veins) or shunts were excluded from the study. 15 men and 2 women aged between 25 and 81 years (median 71 years) participated in the study. The adequacy of the sample was demonstrated using methods defined by Cohen. It was determined that with effect size set at 0.2, where effect size was likely to be small, a power value of 0.95 was achieved with the number of treatments observed and significance level set at 0.01.

Study design
This was a one year single centre prospective study with cross-over design in which all patients were treated by one of the analysed options (povidone iodine as option A and chlorhexidine gluconate and alcohol as option B) for three months with changes of the alternatives every three months starting with povidone iodine (A-B-A-B). During the study the number of participants was reduced from 17 to 9. 4 patients died of cardiac-related conditions, 2 chose to discontinue dialysis treatment and 2 received kidney transplants.

Analysis of effectiveness
The method used for the analysis of effectiveness was not stated. The primary health outcome was the inflammation or infection of the cannulation site. If patients developed symptoms of infection at the fistula site they were to be reviewed by medical practitioners for the degree of infection, the causative factor and their willingness to continue in the study. Although the age, sex and primary diagnosis of participants differed, the patients were a homogeneous group with respect to having end stage renal disease and related susceptibility to infection. No adjustments for confounding factors were made. No cases of poor personal hygiene were observed and no patients received antibiotics while they were participating in the study.

Effectiveness results
No inflammation or infections of cannulation sites were observed at the 971 sites treated with povidone iodine or the 840 sites treated with chlorhexidine gluconate and alcohol.

Clinical conclusions
As there was no inflammation or infection of pre-cannulation sites with chlorhexidine gluconate and alcohol or with povidone iodine neither method was shown to be a more effective skin disinfectant than the other. Treatment with chlorhexidine gluconate and alcohol was more acceptable to patients than treatment with povidone iodine.

Measure of benefits used in the economic analysis
No measure of benefits was employed. The cost consequences of the different alternatives were analysed.

Direct costs
The cost of the consumer items used for each method of disinfection was estimated. For disinfection with povidone iodine the costed items were iodine solution and dialysis packs; for chlorhexidine and alcohol treatment the items were paper towels, chlorhexidine solution and alcohol wipes. Discounting of costs was not relevant due to the duration of the study (12 months). The costing was retrospective and was based on a standard set of consumable items. The costs were not treated stochastically.

Indirect Costs
No indirect costs were included in the analysis.
Currency
Australian dollars (Aus$).

Sensitivity analysis
No sensitivity analyses were carried out.

Estimated benefits used in the economic analysis
Not relevant.

Cost results
The estimated cost of consumable items was Aus$1.68 per treatment with povidone iodine and Aus$0.68 per treatment with chlorhexidine gluconate and alcohol. No adverse effects were observed but the knock on costs of nurses' time were not dealt with.

Synthesis of costs and benefits
Not relevant.

Authors' conclusions
Neither method of disinfection (chlorhexidine gluconate and alcohol or povidone iodine) was shown to be a more effective skin disinfectant. Treatment with chlorhexidine gluconate and alcohol produced less disposables and was less expensive.

CRD COMMENTARY - Selection of comparators
A justification was given for the analysis of chlorhexidine gluconate and alcohol or povidone iodine as possible methods of disinfection of haemodialysis cannulation sites. You, as a user of this database, should decide whether this is a widely used health technology in your own setting.

Validity of estimate of measure of effectiveness
A single-centre prospective study of cross-over design was employed and no cases of inflammation or infection were observed. The authors stated that the number of observed treatments and the use of a cross-over design increased the probability that the results were not due to chance. It should be noted that the study design may not be able to account for unknown confounding factors. However, as neither intervention was associated with infection or inflammation, this issue is not paramount in this case. A possible study effect could have been introduced due to improved compliance with the application of the disinfection technique. It was stated that the study populations were comparable at baseline, but no statistical analyses were provided. Finally, it was not clear how the analysis of effectiveness was handled.

Validity of estimate of measure of benefit
The authors did not derive a measure of health benefit. The analysis was therefore categorised as a cost-consequences study.

Validity of estimate of costs
The costs were analysed from the perspective of health care provider. Costs of the resources were calculated for a standard set and were not treated stochastically. Sensitivity analyses on resource use and prices were not conducted. The authors acknowledged that some possibly relevant costs (i.e. nurses' time, costs for disposal of items) were not included in the analysis. Costs and quantities were not reported separately. The price year was not reported.
Other issues
The authors compared their findings with those from other studies. The issue of generalisability to other settings was not addressed but seems to depend mainly on the cost of disinfection consumables.

Implications of the study
The authors suggested the adoption of use of chlorhexidine gluconate and alcohol as a cheaper, equally efficient and more acceptable to patient method of precannulation skin disinfection.

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