A prospective, randomized trial comparing a transparent dressing and a dry gauze on the exit site of long term central venous catheters of hemodialysis patients.

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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 transparent dressing (TD) versus a dry gauze (DG) on the exit site of long-term central intravenous catheters (LTCC) of haemodialysis patients.

Type of intervention
Prevention.

Economic study type
Cost-effectiveness analysis.

Study population
The patient population studied were male and female haemodialysis patients who were at least 18 years old, and who required haemodialysis treatment for chronic terminal renal insufficiency. In addition, they had to have a tunnelled central venous catheter inserted in the jugular vein by a vascular radiologist, and be competent and able to sign the informed consent form. Patients were excluded if they had any permanent or temporary catheter other than a tunnelled central venous catheter, or a catheter inserted at a site other than the jugular vein. They were also excluded if they were on systemic antibiotic therapy, had a history of bacteraemia in the last 3 months, and their catheter was not changed. Patients were also ineligible to participate if they had known dermatitis at the exit site, or known hypersensitivity to a component of either dressing.

Setting
The setting was secondary care. The economic study was carried out in Canada.

Dates to which data relate
The dates during which the effectiveness and resource use data were collected were not reported. The price year was not stated.

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

Link between effectiveness and cost data
The costing appear to have been undertaken prospectively on a sub-sample of patients participating in the effectiveness study. The sub-sample was made up from 10 patients randomly selected from each treatment group, with resource use being measured over a 4-week period.
Study sample
Power calculations were not used in the planning phase of the study to assure a certain power, nor were they used retrospectively based on the existing sample size. The method of sample selection was not reported. The authors did not fully justify their choice of the patient sample. In total, 58 patients were enrolled, 29 to the TD group and 29 to the DG group. There was no report of patients refusing to participate in the study. The authors reported that, before the first day of the study, 2 patients voluntarily withdrew, 1 patient died (unrelated to the study), and 1 patient’s catheter was removed just prior to the onset of the study. Hence, the initial sample size was reduced from 62 to 58 patients.

Study design
This was a randomised controlled trial that appears to have taken place at a single centre. The randomisation was computer generated at a 1:1 ratio. The groups were followed up for 6 months. Thirteen patients in the TD group completed the 6-month follow-up period, versus 19 in the DG group. Seven patients were withdrawn from the TD group versus 10 in the DG group, owing to the removal of the catheter. In the DG group, 6 patients experienced pruritus and 2 of them also had erythema. They were not withdrawn from the study as there was no alternative to DG. In the TD group, 8 patients experiencing pruritus and erythema were withdrawn from the study and returned to standard treatment. These withdrawals occurred at the beginning of the study, and it was discovered that the chlorhexidine skin preparation solution had not been allowed to dry fully before the TD was applied. Once an appropriate drying time was implemented, pruritus and erythema were subsequently only observed in one patient. No method of blinding was employed in this study.

Analysis of effectiveness
The analysis of the clinical study was conducted on the basis of catheter-days. This form of analysis could be considered closer to an analysis based upon the results from treatment completers rather than data gathered on an intention to treat basis, as it considers all outcomes during the period in which the technology was applied. A cursory examination of the baseline characteristics of the two samples suggests that they appear to have been comparable. However, the small sample size means that even slight differences in baseline characteristics result in p values that are greater than 0.05.

Effectiveness results
The total number of catheter-days was 3,348 for the TD group versus 4,286 for the DG group, (p>0.05).

There was one case of bacteraemia in the TD group and 2 in the DG group, with corresponding incidences of 0.3% (TD group) and 0.4% (DG group), respectively, (p=0.44).

There were no cases of local infections in the TD group and one case in the DG group, with corresponding incidences of 0 (TD group) and 0.23% (DG group), respectively, (p=0.43).

The total incidence of infection was 3.5% in the TD group versus 10.3% in the DG group.

Clinical conclusions
The preliminary results obtained in this study found that a TD applied as a catheter cover dressing for a longer period of time than a DG was more frequently not associated with a higher incidence of bacteraemia or local skin infections.

Modelling
A model was not used in this study.

Measure of benefits used in the economic analysis
The primary health outcomes used were the number of cases (and incidence) of bacteraemia and the number of cases (and incidence) of local infections. Quality of life was assessed using the SF-36 questionnaire at the start of the study, at...
3 months and at the study end.

Direct costs
Discounting was not performed since the costs were incurred during less than 2 years. The unit costs were reported separately from the quantities used. The direct costs included in the analysis were for a mask, non-sterile glove, sterile glove, DG dressings (4x4 and 2x2), 2% chlorhexidine stick, 2% aqueous chlorhexidine, Mefix Tape 3M, Tegaderm 1635 IV Dressing, and the nursing cost for non-scheduled dressing changes. The source of the direct cost data was not reported, nor were the dates to which the price data referred. There was no explanation as to how the individual costs were derived.

Statistical analysis of costs
A non-parametric Wilcoxon two-sample t-test was used to compare averages. For comparisons of proportions, either Pearson's chi-squared test or Fisher's Exact Test was used. The SF-36 results were analysed using Quality Metric.

Indirect Costs
The indirect costs were not included in this study.

Currency
Canadian dollars (Can $).

Sensitivity analysis
Sensitivity analyses were not carried out.

Estimated benefits used in the economic analysis
The quality of life questionnaires revealed that there was no significant difference (all p values were between 0.22 and 0.62) between the two study groups as measured on two standardised scales (physical and mental) at the beginning, middle and end of the study. Patients receiving the TD reported unanimously that they experienced much greater level of comfort with the TD than with the DG they were using before the study. The dressing at the catheter site exit was too specific to have an impact on the questionnaire scores.

Cost results
The cost per patient per week was Can$4.72 in the TD group versus Can$7.60 in the DG group.

Discount rates were not used.

The costs of adverse effects or knock on costs were not reported.

Synthesis of costs and benefits
The costs and benefits were not combined since there was no significant difference between the SF-36 scores.

Authors' conclusions
In this preliminary study, there was no observed impact on the incidence of infection when using this particular transparent dressing (TD) on the study population. In particular, the incidence of bacteraemia was not increased in this particular population. In addition, the use of a TD allowed fewer dressing changes, lowered the total treatment costs, with no observed impact on the quality of life and without significant local complications of the exit site.
CRD COMMENTARY - Selection of comparators
It is unclear why the comparator used was chosen and the authors did not provide a justification for their choice. You should decide if this is a widely used health technology in your own setting.

Validity of estimate of measure of effectiveness
The analysis was conducted using results from a randomised controlled trial, which was appropriate for the study question. It was not explicitly stated whether the study sample was representative of the study population. The authors noted that the sample size was small and suggested that larger randomised studies should be carried out. The small sample size means that it is difficult to assess the degree to which the patient groups were comparable. Statistical analyses were not carried out.

Validity of estimate of measure of benefit
The analysis of benefits was based upon the therapeutic equivalence of the alternative dressings. Therefore, the economic analysis included only costs.

Validity of estimate of costs
All the relevant categories of costs appear to have been included in the analysis. The costs were reported separately from the quantities. The sources of the resource use quantities and the prices (unit costs) were not reported. Statistical (or other) analyses of quantities and prices were not performed.

Other issues
The authors did not compare their findings with those from other studies. They recognised that the results, as they stand, are not generalisable. Further study, to examine the cost-effectiveness of long-term use of TD dressings on catheter exit sites in other health care centres, is warranted. The authors did not present their results selectively. The study enrolled a small sample of patients from one centre and this was reflected in the authors' conclusions. The authors did not report further limitations of their study.

Implications of the study
The authors stated that further study, to examine the cost-effectiveness of long-term use of TD dressings on catheter exit sites in other health care centres, is warranted.

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