A comparison of dual dialyzers in parallel and series to improve urea clearance in large 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 dual dialysers (F-80), in parallel or series configuration, in large haemodialysis patients. Random numbers were used to determine the order in which the two types of dual dialysis were performed. Vascular access consisted of a native arteriovenous fistular or arteriovenous graft.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The patients were recruited from dialysis centres. Initially they had to weigh more than 80 kg, (this was later revised to 65 kg), be aged more than 18 years, and be undergoing dialysis 3 times a week with each session lasting more than 3 hours. For the 90 days preceding the study, the patients had to have been medically stable without acute hospitalisation, have stable vascular function and a predialysis blood urea nitrogen (BUN) level of less than 90 mg/dL (32 mmol/L).

Setting
The setting was secondary care (satellite dialysis centres). The economic study was carried out in California, USA.

Dates to which data relate
The effectiveness data related to 15 August 1999 to 31 August 2000. The dates for resource use were not given and 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 was carried out retrospectively on the same sample of patients as that which provided the effectiveness data.

Study sample
No power calculations to determine the sample size were reported. The sample comprised 18 patients who met the inclusion criteria. The mean weight was 92.4 kg and the mean age was 56 (+/-13.2) years. All of the participants were male. Forty-four per cent of the patients were African American, 39% were white, and 11% were Asian.
Study design
This was a randomised crossover trial in which all the patients received the two kinds of dual dialysis. A random number table determined the order in which the types of dialysis were received. All of the patients were treated in one geographical area, but it was unclear whether they were all treated at the same dialysis centre. The patients were assessed after 2 months on dual dialysis. There was no drop out during those 2 months and there was no follow-up after the 2 months. No blinding of the treatment took place.

Analysis of effectiveness
The basis of the analysis was intention to treat. The primary health outcome used to assess effectiveness was urea clearance, as measured by single-pool Kt/V(urea) and the urea reduction ratio (URR). The URR was calculated as 1 minus the change in BUN pre- to postdialysis BUN (expressed as a proportion of the predialysis BUN). Quality of life was measured by the Kidney Disease Quality of Life (KDQOL) Short-Form.

Effectiveness results
Before treatment, the mean single-pool Kt/V was 1.25 (+/- 0.22) (range: 0.89 - 1.68) and the mean URR was 65.6% (+/- 9.1) (range: 0.45 - 0.83).

After 1 month of dual dialysis in parallel, the mean single-pool Kt/V was 1.43 (+/- 0.29) (range: 0.69 - 1.80). The increase was statistically significant, (p<0.003). The mean URR was 0.68 (+/- 0.09) (range: 0.44 - 0.78). This increase was also statistically significant, (p<0.01)

After 1 month of dual dialysis in series, the mean single-pool Kt/V was 1.46 (+/- 0.26) (range: 0.96 - 1.79). The increase was statistically significant, (p<0.0003). The mean URR was 0.69 (+/- 0.07) (range: 0.55 - 0.77). This increase was also statistically significant, (p<0.0007).

There was no significant difference between parallel and series dual dialysis, (p=0.69). Fifteen of the 18 patients achieved a single-pooled Kt/V of greater than 1.2 after dual dialysis.

The authors did not report the results from the KDQOL questionnaire, although they reported that there was no significant difference apart from a significant improvement in the Staff Encouragement domain.

Clinical conclusions
In large haemodialysis patients, dual dialysers in parallel and series are equally effective in terms of urea clearance, without prolonging dialysis treatment times.

Measure of benefits used in the economic analysis
No summary measure of benefits was produced. A cost-consequences analysis was therefore conducted.

Direct costs
No discounting was carried out since the costs were incurred during less than one year. The authors did not break down the patient costs into costs and quantities. The cost of a dialysis session was broken down into its components. These comprised dialysate tubing/connectors, an F-80 dialyser (average reuse = 18 times), reprocessing, disposable blood tubing Y-connectors, disposable blood tubing straight connectors and additional staff time for set-up. The marginal cost of a dual dialysis session using the two methods was calculated. The total marginal annual costs for a patient using the two dialysis methods were also calculated. Medicare in-patient reimbursements were calculated by extrapolating the results of another study (see Other Publications of Related Interest), which showed that each 0.1-unit decrease in single-pooled Kt/V (urea) was associated with $1,880 in reimbursement. The price year was not stated.
Statistical analysis of costs
No statistical analysis of the costs was carried out.

Indirect Costs
No indirect costs were calculated.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analysis was carried out.

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

Cost results
The marginal costs of using dual dialysis, compared with single dialysis, for one year were $2,500 for dialysis in series and $2,800 for dialysis in parallel.

The costs of adverse effects were not dealt with in the study. Effective dual dialysis would result in lower inpatient costs and would be cost-saving in terms of the total medical costs (net savings of approximately $1,260 annually were projected).

Synthesis of costs and benefits
Not combined as the study was, effectively, a cost-consequences analysis.

Authors' conclusions
The dual dialysers were more effective than single dialysers in terms of urea clearance. There was no significant difference between the two kinds of dual dialysis. The authors hypothesised that, if the total hospital costs had been recorded, dual dialysis would have been cost-saving and would have been the dominant strategy.

CRD COMMENTARY - Selection of comparators
The selection of comparator, single dialysis, was justified by it often being current practice. You should decide if the comparator represents current practice in your own setting.

Validity of estimate of measure of effectiveness
The effectiveness data were derived from a single study. The analysis used a randomised crossover trial, which was appropriate for the study question. The authors noted an absence of women in the study and they did not show that, in other respects, the patients studied were representative of the study population. The authors did not report clearly when the exclusion criteria on weight grounds were changed. Also, they did not publish the results on quality of life, but presented them in summary form only. The sample size was not determined through power calculations and comprised only 18 patients. This factor may undermine the validity of the statistical analysis.

Validity of estimate of measure of benefit
The authors did not derive a summary measure of health benefit. The analysis was one of cost-consequences. The health
benefits are therefore those associated with the effectiveness outcomes.

**Validity of estimate of costs**
The authors used a narrow definition of costs (i.e. the costs of the dialysis) in their calculations of the costs. They then used another author's results on the implications for hospital costs. It would have been more valid had the authors calculated all the medical costs for the time period under consideration. The authors did not include the indirect costs in their analysis. The inclusion of these might have strengthened the argument for dual dialysis had it led to fewer days of hospitalisation. The unit costs were reported, but not separately from the resource quantities. The costs were estimates based on prices in the authors' setting. The estimated quantities of resources used were based on recommended practice in the authors' setting. Medicare reimbursements for inpatient care were also employed. It would have been more useful had the actual medical costs been known. The price year was not stated, thus limiting the feasibility of reflation exercises to other settings or time periods.

**Other issues**
The authors made appropriate comparisons of their results with the findings from other studies. However, the issue of generalisability to other settings was not addressed. The authors did not present their results on primary health outcomes selectively. The authors acknowledged that using the results from another study on hospitalisation costs was not the best way to calculate the hospital costs, but still believed their results to be valid. It was unclear whether the 18 patients studied were representative of all large dialysis patients who fail to achieve adequate urea clearance.

**Implications of the study**
The authors suggested that there was no significant difference between the two kinds of dual dialysis for larger patients who have not achieved satisfactory urea clearance with single dialysis, and that both are effective at improving urea clearance. They also suggested that dual dialysis for these patients could lead to a reduction in the total medical costs, even though the actual dialysis would be more expensive.

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None stated.

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**Other publications of related interest**

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