The London, Ontario, Daily/Nocturnal Hemodialysis Study

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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 health interventions examined in the study were quotidian daily haemodialysis (HD), slow nocturnal HD, and conventional HD for patients with end-stage renal disease. HD frequency was 5-6 days/week for daily and nocturnal HD, and 3 days/week for conventional HD. Duration was 1.5 -2.5 hours for daily HD, 6-8 hours (asleep) for nocturnal HD, and 3.5-4.5 hours for conventional HD.

Type of intervention
Treatment.

Economic study type
Cost-utility analysis.

Study population
The study population comprised adult patients with end-stage renal disease (ESRD) who required HD. Patients had been on dialysis for a minimum of 3 months and had a reasonable expectation of surviving one year regardless of whatever other comorbidities they had.

Setting
The setting was home and hospital. The economic study was carried out in London, Ontario, Canada.

Dates to which data relate
Data on effectiveness and resource use were gathered from 1998 to 2001. The price year was not reported.

Source of effectiveness data
The effectiveness evidence came from a single study.

Link between effectiveness and cost data
The costing was carried out both prospectively (post-intervention period) and retrospectively (pre-intervention prevention) on the same sample of patients as that used in the effectiveness study.

Study sample
Power calculations were not reported. Patients involved in the Southwestern Ontario renal programme were contacted for participation. Of the 28 eligible patients who agreed to participate, 18 initially selected daily HD (but then 2 elected to be considered for nocturnal HD), and 10 selected nocturnal HD. Ten patients for each group were then selected by ballot. However, the total patient experience actually considered 11 daily HD patients (mean age: 45.3 +/- 11.4 years; age range: 33 to 67 years; 4 women) and 12 nocturnal HD patients (mean age: 44.2 +/- 6.4 years; age range: 38 to 56 years).
years; 3 women) because of replacements due to death, transplantation, and a switch from nocturnal to daily HD. A control group of 22 patients (mean age: 48.85 +/- 11.9 years; age range: 28 to 76 years; 8 women) receiving conventional treatment was also selected.

**Study design**
This was a prospective, cohort study. Before enrolment, patients were asked to indicate their preference for the HD system (daily, nocturnal, or no preference). Thereafter, patients were selected by ballot. For each patient who chose the daily or nocturnal HD, a control patient, matched by age, sex, comorbidity, and the original dialysis modality, was selected. It was unclear whether the study took place in a single hospital or if other centres were involved. Patients were followed up for 5 to 36 months. No loss to follow-up was reported. Outcome assessments were performed at months 1, 3, 6, 9, 12, and 15.

**Analysis of effectiveness**
All patients included in the initial study sample were taken into account in the analysis of effectiveness. The primary outcomes used in the analysis were grouped under seven headings: urea kinetic data, anaemia, calcium and phosphate metabolism, blood pressure and volume management, morbidity and mortality, blood access, and quality of life (which was estimated by means of validated questionnaires, such as the SF-36, among others). Controls were comparable with intervention patients because they were matched at baseline. The two groups of intervention patients appeared comparable and the authors reported the baseline comparability of each outcome measure.

**Effectiveness results**
Urea kinetic data suggested that nocturnal HD led to significant increases in delivered Kt/V weekly, while daily HD was significantly better than conventional HD after month 9.

The standard Kt/V values for urea were 2.4 +/- 0.1 for controls, 3.0 +/- 0.3 for daily HD, and 4.7 +/- 0.3 for nocturnal HD, (p<0.05).

Overall, urea kinetic data were suggestive of improved nutrition.

With respect to anaemia, recommended haemoglobin levels were satisfactorily maintained over the follow-up period. The differences in doses of erythropoietin were not statistically significant.

Calcium values were similar.

Phosphate metabolism was significantly better controlled in nocturnal HD patients than in daily or conventional HD patients.

Predialysis mean arterial pressure improved significantly in the daily HD group after 6 months, and in the nocturnal HD group after 9 months, in comparison with the conventional group. This was achieved with significantly less reliance on antihypertensive medication and because of a significant reduction in interdialytic weight gain in the daily HD group. This latter improvement was not observed in the nocturnal HD group.

There were 3 deaths in the nocturnal control group, 3 deaths in the nocturnal group, and no deaths in daily group the controls.

Hospitalisation rates were 0.49/patient-year in the daily HD group, 0.95/patient-year in the nocturnal HD group, and 0.93/patient-year in the conventional HD group.

The number of days hospitalized on average was 1.96/patient-year in the daily HD group, 4.8/patient-year in the nocturnal HD group, and 4.5/patient-year in the conventional HD group (none of the differences reached statistical significance).
Blood access was not statistically different at any time between the groups in terms of any of the outcomes used.

Quality of life improved significantly in the daily and nocturnal HD groups relative to the conventional HD group with respect to intradialytic symptoms, fatigue, time for full recovery from dialysis treatment, uremic symptomatology, and psychosocial stress scoring.

**Clinical conclusions**
The effectiveness analysis showed that both the daily and nocturnal HD led to significant improvements in terms of clinical and quality-of-life measures in comparison with conventional HD patients.

**Measure of benefits used in the economic analysis**
The summary benefit measure was quality-adjusted life-years (QALYs). Utility values were derived from quality-of-life questionnaires, as reported above. No discounting was applied.

**Direct costs**
Discounting was not carried out as annual costs were estimated. Unit costs and quantities of resources used were not presented separately. The health services included in the economic evaluation were hospitalisations, visits, consultations, laboratory tests, HD services, nursing time, etc. However, a detailed breakdown of cost items was not reported. The cost/resource boundary of the study was unclear. The estimation of resource use was based on actual data derived from the sample of patients involved in the effectiveness study. The source of cost data was not reported. The price year was not given.

**Statistical analysis of costs**
Costs were treated deterministically.

**Indirect Costs**
Indirect costs were not considered.

**Currency**
Canadian dollars (Can$).

**Sensitivity analysis**
Sensitivity analyses were not carried out.

**Estimated benefits used in the economic analysis**
The number of QALYs associated with each strategy was not reported.

**Cost results**
The estimated annual costs were Can$63,700 for daily HD, Can$74,400 for nocturnal HD, and Can$72,700 for conventional HD.

The changes in operating cost per patient-year relative to the previous year were -Can$9,800 for daily HD, -Can$17,400 for nocturnal HD, and Can$3,100 for conventional HD.

**Synthesis of costs and benefits**
Average cost-effectiveness ratios were calculated to combine costs and benefits of the study interventions. The incremental comparison with conventional HD was reported. The average cost per QALY was Can$85,442 with daily HD and Can$120,903 with nocturnal HD, which represented a marginal change of -Can$15,090 and -Can$21,651, respectively, in comparison with conventional HD. The authors stated that such cost-saving reflected both improved quality of life and reduced costs for both quotidian HD patients.

Authors' conclusions
The authors concluded that both quotidian forms of HD, daily and nocturnal, were more effective and led to cost-savings in comparison with conventional thrice-weekly HD in patients with ESRD in Canada.

CRD COMMENTARY - Selection of comparators
The rationale for the choice of the comparator was clear. Thrice-weekly HD was selected as the basic comparator as it represented the standard HD approach for patients with ESRD in the authors' setting. Both daily and nocturnal HD were two alternative strategies for HD. You should decide whether they are valid comparators in your own setting.

Validity of estimate of measure of effectiveness
The analysis of effectiveness was based on an observational study. The use of a randomised study would have been more appropriate but the authors deliberately allocated patients on the basis of their preferences because it was thought that randomisation could be fraught with difficulties and could influence patients' quality of life. However, groups were shown to be comparable at baseline with respect to demographics and all clinical outcomes that were used in the effectiveness study. The method of sample selection was reported and the sample of patients is likely to have been representative of the study population. The major threat to the validity of the analysis was the small number of patients who were enrolled in the study. Moreover, power calculations were not performed and no evidence regarding the appropriateness of the sample size was reported. The authors noted that the study was underpowered with respect to some outcome measures. Outcome assessment was not blind, which might have introduced some observer bias. These issues tend to reduce the internal validity of the analysis.

Validity of estimate of measure of benefit
The use of QALYs as the summary benefit measure was appropriate since the intervention had an impact on both survival and quality of life. Only limited details of the calculation of QALYs were reported and the final estimates were not presented. Discounting was not relevant and, appropriately, was not carried out.

Validity of estimate of costs
The authors did not explicitly report the perspective adopted in the study, and no breakdown of cost categories was provided. The information surrounding the economic analysis was scarce and unsatisfactorily reported. The price year was not presented, which makes reflation exercises in other settings difficult. The source of data was not reported. Unit costs were not presented separately from quantities of resources used, limiting the possibility of replicating the study in other contexts. Cost estimates were specific to the study setting and sensitivity analyses were not carried out. Costs were treated deterministically. Overall, the reporting of the economic evaluation was poor.

Other issues
The authors made some comparisons of their findings with those from other studies, showing patterns similar to those observed in the current study. The issue of the generalisability of the study results to other settings was not addressed and sensitivity analyses were not carried out. Therefore, the external validity of the analysis was low. The study referred to patients with ESRD requiring HD and this was reflected in the authors' conclusions.

Implications of the study
The study results support previous findings showing that quotidian HD represents a feasible, safe, and cost-effective
alternative to conventional HD. Future randomised studies should confirm the results of the current analysis.

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None stated.

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**Other publications of related interest**

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