The quality of life and cost utility of home nocturnal and conventional in-center hemodialysis
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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
Home nocturnal haemodialysis (HNHD) was compared with in-centre conventional haemodialysis (IHD) for the treatment of patients with end-stage renal disease.

Type of intervention
Treatment.

Economic study type
Cost-utility analysis.

Study population
The study population consisted of patients with ESRD. To be eligible for the study, patients needed to be proficient in English, have the capacity for self-care training, and have a life expectancy of longer than one year. Either the patient or someone living in their home needed to have sufficient dexterity, vision, and auditory acuity to perform this type of dialysis. Moreover, the patients had to have been performing the modality for at least 3 months prior to enrolment.

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

Dates to which data relate
The effectiveness data were derived from interviews with the patients, but it was not stated when these took place. The costs were derived from a related study, undertaken in 2001, which included this study sample as a sub-set (see Other Publications of Related Interest). The resource use data were probably from that year. All costs were expressed in year 2000 Canadian dollars.

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

Link between effectiveness and cost data
The effectiveness data were derived from interviews that were conducted concurrently with the cost study, using a sub-set of the same patients.

Study sample
The HNHD group was formed by patients on an HNHD programme run by a hospital in Toronto. Another large hospital in Toronto, that had a large IHD programme but no HNHD programme, formed the pool for the control (IHD) group.
The IHD medical director screened eligible patients and selected those who were appropriate for HNHD. Individuals in the control group were included in the study only if they expressed an interest in HNHD after the modality was described. The study sample was a sub-group of patients participating in a prior study. Power calculations were not used to determine the sample size.

Of the 34 patients attending the HNHD programme at one selected hospital during the study period, 31 met the entry criteria. Of these, 2 agreed to participate in the cost study, but refused to be included in the quality of life assessment. In addition, 2 were unable to schedule an interview and 3 were transplanted prior to being interviewed. Thus, the HNHD group comprised 24 patients. Out of 182 IHD patients at another large hospital, only 29 met the entry criteria and were judged to be appropriate for the study. Of these, 3 declined to participate, 3 showed no interest in HNHD, 2 were transplanted prior to being interviewed, 1 declined a quality of life interview, and 1 was unable to schedule an interview. The remaining 20 patients were interviewed. However, one refused on moral grounds to gamble against death and was excluded from the analysis. Thus, the IHD group comprised 19 patients.

Study design
This was a cross-sectional study. The two groups of patients (intervention and control) were derived from two different hospitals. The effectiveness data (quality of life weights) were derived from computer-assisted interviews with the patients. A single interviewer conducted all of the interviews in a standardised manner. The criteria for delaying an interview, such as distressful physical or emotional events, were set prospectively.

Analysis of effectiveness
The outcome assessed in the study was the quality of life of the patients in the two groups. All the participants were interviewed, and the standard gamble technique was used to measure their values and form utility scores. The patients were allowed to choose not to gamble. The baseline demographic features of the two groups were reported. They proved to be similar, with the exception of marital status. Pearson's correlation and regression analyses were undertaken to adjust for potential confounders. The variables examined were gender, age, diabetes, coronary artery disease, peripheral vascular disease, congestive heart failure, marital status, education, duration of ESRD, and HNHD as modality. The statistical analysis showed that, apart from HNHD as the modality of dialysis, the only baseline variables significantly correlated with higher utility scores were lower age and the absence of coronary artery disease. Marital status, which differed in the two groups, did not correlate with utility score in either study group or in the overall group.

Effectiveness results
The utility results were expressed as the quality-adjusted life-years (QALYs). They were reported as mean values, along with standard deviations (SD) and standard errors (SE).

The mean utility was 0.77 (+/- 0.23) QALYs (SE=0.0047) for the HNHD group and 0.53 (+/- 0.35) QALYs (SE=0.08) for the IHD group. This difference was statistically significant, (p=0.03).

Clinical conclusions
HNHD was associated with a higher utility than IHD.

Measure of benefits used in the economic analysis
All participants in the study were asked to evaluate health states, using the standard gamble technique. This took place possibly after the cost study was completed. The results were expressed in QALYs, as this was the outcome measure used in the cost-utility analysis. Moreover, the net monetary benefit of HNHD was calculated by assigning a hypothetical monetary value (lambda) to the incremental benefit achieved, and subtracting from this the incremental cost of achieving this benefit. The lambda value was supposed to express society's willingness to pay. As this value was controversial, a range of lambda from 0 to approaching infinity was used.
Direct costs
The perspective of the study was the health care provider. It would appear that all costs relevant to this perspective were included in the analysis. These included the costs of haemodialysis materials, medications, admissions and procedures, staff, laboratory tests and imaging, overhead and support, depreciation, and physician fees. A mean annual cost was estimated for each of these cost components. This was based on a prospective costing study that was conducted between January and March 2001 in the two hospitals participating in the study. Resource use items and costs were not reported separately. All the costs were expressed in year 2000 Canadian dollars. Discounting was not performed, which was appropriate as the costs were calculated for one year only.

Statistical analysis of costs
The costs were based on stochastic data. The bootstrap technique was used to estimate the distribution of the mean costs (and effectiveness). The SD and SE of the mean annual costs were provided.

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

Currency
Canadian dollars (Can$).

Sensitivity analysis
No sensitivity analysis was performed.

Estimated benefits used in the economic analysis
The mean utility was 0.77 (+/- 0.23) QALYs (SE=0.0047) for the HNHD group and 0.53 (+/- 0.35) QALYs (SE=0.08) for the IHD group. HNHD resulted in 0.24 more QALYs (SE=0.01) than IHD, (p=0.03).

Cost results
The mean annual health service costs per patient were Can$55,139 (+/- 7,651) (SE=1,562) for the HNHD group and Can$66,367 (+/- 17,502) (SE=4,015) for the IHD group. IHD incurred $11,227 additional annual costs (SE=4,321) in comparison with HNHD, (p=0.03).

It was not stated whether the costs of treating adverse effects were included in the analysis.

Synthesis of costs and benefits
A simple ratio of the mean costs to the mean utility score provided the cost-utility for each group relative to no treatment. This was $71,443/QALY for the HNHD group and $125,845/QALY for the IHD group.

An incremental cost-effectiveness ratio was provided for the comparison of the two alternatives. This was equal to -Can$45,932/QALY (95% confidence interval: -13,976 - 142,998). It was negative, as HNHD dominated (i.e. both cheaper and resulted in a higher mean utility score).

The net monetary benefit of HNHD ranged from Can$11,227 (lambda = 0) to Can$35,669 (lambda = $100,000), where lambda was the hypothesised society's willingness to pay. Acceptability curves were also calculated. These suggested that the probability that HNHD was cost-effective exceeded 99% across all values for lambda, even when this was adjusted for significant covariates.

Authors’ conclusions
Home nocturnal haemodialysis (HNHD) was the dominant strategy in comparison with in-centre conventional haemodialysis (IHD), as it both lowered the costs and improved the quality of life.

**CRD COMMENTARY - Selection of comparators**

The authors did not explicitly justify the choice of the comparator. However, this was not relevant since, apart from kidney transplantation, IHD is the only treatment for patients with ESRD and it reflects current dominant practice.

**Validity of estimate of measure of effectiveness**

The analysis used a cross-sectional study, which was appropriate for the study question, as the only effectiveness data needed were the patients’ views on their quality of life. One interviewer examined all the patients and this eliminated assessor bias. However, the authors admitted that the conditions under which the interviews took place (delayed in the event of experiences that could distress the patient) had intentionally biased the results. Moreover, the study sample was very small, as there was difficulty in identifying and interviewing eligible patients. The authors acknowledged that the study sample was not representative of the study population in terms of basic demographic features, which limits the generalisability of the results. Nevertheless, the patient groups were shown to be comparable at analysis. Appropriate statistical analyses were performed to take potential confounders into consideration.

**Validity of estimate of measure of benefit**

The estimation of benefits was derived from the results of the interviews. The quality of life weights, expressed in QALYs, were based on the standard gamble technique. This is a common technique for the valuation of health states. As the authors reported, utility methods reflect an individual’s preferences for health states, and thus tend to have greater variability than psychometric instruments. Nevertheless, according to the authors, the size and direction of effect in the study was of such magnitude and consistency, that it was unlikely that correcting for operative biases would change the result significantly.

**Validity of estimate of costs**

The perspective of the study was that of the health care provider, this was not stated in this paper but clearly reported in the costing study. The quantities and the unit costs were not analysed separately. The cost data were derived using a prospective costing study that lasted 12 months (1 year). Resource use was based on actual routine data. However, the authors acknowledged that the cost results for HNHD were derived from a large and established programme, and might not be applicable to new or small programmes that do not enjoy some of the economies of scale seen in the programme examined. A statistical analysis of the cost components was undertaken. Discounting was not relevant since the authors were concerned only with identifying the annual treatment costs. The price year was reported.

**Other issues**

The authors compared the HNHD group utility results with those of patients with a successful kidney transplant, and also with anecdotal results of patients on HNHD who remove themselves from the transplant waiting list. They found the results to be consistent. They also reported that the control (IHD) group utility results were similar to those seen historically, despite the fact that the control group was demographically skewed towards individuals expected to have a higher quality of life (younger age, higher functional status and lower co-morbidities).

A concern was expressed that people who chose HNHD might have immeasurable characteristics that might be associated with higher quality of life, thus potentially confounding the results. The authors highlighted another limitation in that both groups were not similar to the “average” haemodialysis patient, as they were in general younger, with less co-morbidities and had been on dialysis for longer than “typical” patients from most centres. This fact restricts the generalisability of results to patients with similar characteristics to the study sample. In general, the authors appear to have fully reported their results and their conclusions reflected the scope of the analysis.

**Implications of the study**
The authors suggested that further research is needed to prospectively measure quality of life in patients as they move from IHD to HNHD, as this was not addressed in this study. They expressed the opinion that other centres with HNHD programmes need to confirm this study’s utility results, to ensure that they are not related to an unmeasured selection bias. However, they recommended that dialysis centres consider offering HNHD to appropriate patients, in the hope of seeing better quality of life as well as reduced health care costs.

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