Exercise during hemodialysis decreases the use of antihypertensive medications
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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 role of exercise for patients undergoing haemodialysis, as opposed to no exercise, was investigated. The patients exercised on a rehabilitation trainer stationary cycle (Monark 881E), which was placed in front of the haemodialysis chair. The patients were told to exercise as long as possible during each treatment, and were encouraged to increase the time by 1 to 5 minutes per session per week. When the patients reached 30 minutes, they were encouraged to increase resistance, but the ultimate decision to do so rested with the patient.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised all haemodialysis patients (n=107) at the Barnes-Jewish Hospital Dialysis Centre in St. Louis (MO), USA. The participants had to be long-term haemodialysis patients on dialysis for at least 1 month before enrolment. The exclusion criteria for the exercise and control groups were angina, cardiac or pulmonary disease requiring oxygen therapy, myocardial infarction or bypass surgery within 3 months, cerebrovascular accident or transient ischaemic attack within 3 months, or the inability to pedal on a stationary cycle.

Setting
The setting was secondary care. The study was carried out at the Barnes-Jewish Hospital Dialysis Centre, St. Louis (MO), USA.

Dates to which data relate
The authors did not state when the clinical study was carried out. The acquisition costs of the PBM company were reported in year 2000 prices.

Source of effectiveness data
The evidence for the final outcomes was derived from a single study.

Link between effectiveness and cost data
The costing was undertaken prospectively on the same patient sample as that used in the effectiveness study.

Study sample
No sample size was determined in the planning phase of the study. In addition, no power calculations were performed.
retrospectively. Forty of the 107 patients agreed to participate and were enrolled in the exercise group, while 35 patients acted as controls. Of the 40 patients in the exercise group, 16 (40%) were excluded from the analysis as they did not complete 6 months of exercise. Three patients from the control group were also excluded due to death (1), transplant renal artery stenosis requiring nephrectomy (1) and transplant rejection requiring nephrectomy (1). In the exercise group, the mean age was 52.8 (+/- 16.0) years and 58.3% of the patients were women. In the control group, the mean age was 56.1 (+/- 15.2) years and 56.3% were women.

Study design
This was a prospective cohort study that was carried out in a single centre. The patients were followed up for 6 months. As already stated, 16 (40%) patients in the exercise group were lost to follow-up due to death (2), cocaine use requiring rehabilitation (2), kidney transplantation (2) and voluntary withdrawal (10). The attending nephrologists were not blinded to the participants because the exercise occurred in the dialysis unit.

Analysis of effectiveness
All of the patients included in the study were accounted for in the analysis. The primary health outcomes were blood pressure and antihypertensive use. All blood pressure measurements were taken from the patient's flow sheets before and after each dialysis session. Systolic and diastolic blood pressure measurements were made in the arm while sitting, immediately before and after the haemodialysis session. Two investigators reviewed blood pressure medications with the patients at the start of the study and at month 6. These correlated with the medical record. No formal measure of compliance was performed. The groups were shown to be comparable at analysis in terms of their age, gender and prognostic features.

Effectiveness results
No significant difference in blood pressure was observed at 6 months, (p=0.12), but at 3 months the predialysis blood pressure and postdialysis systolic pressure were significantly lower in the exercise group.

Changes in the usage of blood pressure medication at 6 months resulted in statistically significant dosage decreases among the exercise patients, compared with the control patients. The mean number of antihypertensive medications per patient before the study was 2.13 in the exercise group and 1.91 in the control group. At the end of the 6-month study, this had fallen to 1.5 in the exercise group, but remained at 1.91 in the control group. Thus, exercise resulted in an average relative benefit of -0.71 medications per patient, or a 36% reduction in medication use at 6 months, (p=0.018).

Clinical conclusions
Exercise during haemodialysis produced a significant reduction in blood pressure medication use. However, despite this decrease in medication, no change in actual blood pressure was seen at 6 months.

Measure of benefits used in the economic analysis
No summary benefit measure was used in the economic analysis. In effect, a cost-consequences approach was adopted.

Direct costs
The resource quantities and the costs were not reported separately. The direct costs in the analysis were those of the PBM company, including their pharmaceutical acquisition costs. It was assumed that the lowest priced generic substitute would be used when such a generic was available. Discounting was irrelevant, as all the costs were incurred in a 6-month period, and was not conducted. The price data referred to 2000.

Statistical analysis of costs
The costs were treated stochastically. The authors used a two-tailed Student's t-test, with significance set at the 0.05 level.
**Indirect Costs**
No indirect costs were included in the analysis.

**Currency**
US dollars ($).

**Sensitivity analysis**
No sensitivity analyses were conducted.

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

**Cost results**
The cost analysis associated with the decrease in antihypertensive medication showed an average relative cost-saving of $885 in the exercise group. The costs were $1,687/patient-year at baseline and $1,034 at 6 months for the exercise group, compared with $1,160/patient-year at baseline and $1,392 at 6 months for the control group, (p= 0.005).

**Synthesis of costs and benefits**
The costs and benefits were not combined as the authors undertook a cost-consequences analysis.

**Authors' conclusions**
The authors concluded that their study added further evidence of the benefit of exercise in chronic renal failure. Even if no change in actual blood pressure was seen at 6 months, exercise during haemodialysis produced significant reductions in the use of blood pressure medication and cost-savings.

**CRD COMMENTARY - Selection of comparators**
No explicit justification for the comparator used was given. However, it would appear that no exercise programme during haemodialysis represents current practice in the authors’ setting. You should decide if the comparator represents current practice in your own setting.

**Validity of estimate of measure of effectiveness**
A randomised controlled trial would have been a more appropriate study design than the prospective cohort study used, as it would have minimised the role of any potential biases and confounding. However, the authors pointed out that the study was not randomised since it was agreed that willing participants in exercise should not be excluded. The authors also pointed out that the exercise patients also acted as their own controls over time, with the 0-month and 6-month data comparison not being affected by the absence of randomisation. A further limitation of the study was the fact that the nephrologists were not blinded. According to the authors this was due to practical considerations in the dialysis unit. In addition, compliance was measured through verbal confirmation rather than pill counts. There is, however, no reason to believe that this led to different compliance rates between the two groups, as both groups were shown to be comparable at analysis. Even though there were some limitations as to the validity of the study, the analysis of effectiveness was handled credibly. The authors fully acknowledged and reported all the limitations, and conducted appropriate statistical tests to test for statistically significant differences between the two groups.

**Validity of estimate of measure of benefit**
The authors did not derive a summary measure of health benefit. The analysis was therefore categorised as a cost-
Validity of estimate of costs
The lack of detailed information on the costs made it difficult to determine whether all the categories of cost relevant to the perspective adopted were included in the analysis. However, the authors did state that the shipping and filling costs and patient co-payments were not included in the analysis, as they were relatively small, widely variable and offsetting components of a PBM company’s realised cost of delivering medications. The costs and the quantities were not reported separately, thus hampering the generalisability to other settings. Appropriate statistical analyses of the costs were undertaken to test for significant differences between the two groups, although uncertainty in the cost data was not investigated. The authors, appropriately, did not discount the costs as they were incurred in a 6-month period. The dates to which the prices related were reported, thus facilitating reflation exercises.

Other issues
The authors made appropriate comparisons of their findings with those from other studies, which also found short-term benefits due to exercise. The finding that there was no change in actual blood pressure at 6 months was also supported by prior observations. The authors addressed the issue of generalisability to other settings. They stated that no extra personnel were employed during the study, so that most units and patients would have the potential to replicate their results. The authors did not present their results selectively and their conclusions reflected the scope of the analysis. No further limitations were reported.

Implications of the study
The authors recommended encouraging and investing in exercise and equipment for patients undergoing haemodialysis. However, the authors also pointed out that low exercise participation should be investigated and tested.

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