The effect of a preoperative exercise and education program on functional recovery, health related quality of life, and health service utilization following primary total knee arthroplasty

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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 study investigated the effectiveness of a 4-week preoperative exercise and education programme in patients scheduled for total knee arthroplasty (TKA), compared with a control group receiving "usual care".

Type of intervention
Other: Information and practical education in preparation for, and recovery from surgery.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients on the current waiting list for TKA. Patients were eligible for the study if they had a diagnosis of non-inflammatory arthritis, were scheduled for a primary TKA, and were aged between 40 and 75 years. Further inclusion criteria were a willingness to participate in the intervention and follow-up procedure, and the ability to understand verbal or written English, or have a translator. There were no stated exclusion criteria.

Setting
The setting was community physical therapy clinics. The economic study was carried out in Canada.

Dates to which data relate
The dates relating to the effectiveness evidence and resources used were not stated, although the resource data were collected one year after the study period. The unit cost prices for the health service costing were expressed in 1997/98 Canadian dollars.

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

Link between effectiveness and cost data
The costing and collection of resource data were carried out prospectively on the same patient sample as that used in the effectiveness study.

Study sample
Prior to the study, a power calculation was conducted to detect functional outcomes in relation to the Western Ontario McMaster Osteoarthritis Index (WOMAC). To detect a difference of 10 points in the functional evaluation of the
WOMAC, a sample size of 130 (65 per group) was needed (power = 0.80, 2-tailed test with alpha = 0.05). The patients were recruited from the current waiting list for TKA and were selected by a random method. There were 65 patients in the treatment group and 66 in the control group. The study sample comprised equal numbers of males and females, and the mean age was 67 years. The body mass index (BMI) was greater than 30 and over 95% of the patients were diagnosed with osteoarthritis. There was no clear justification for the choice of patient sample in relation to the generalisability of the findings. Sixteen patients (10 in the treatment and 6 in the control group) cancelled surgery prior to randomisation. Thus, 116 (89%) patients started the trial, 55 (85%) in the treatment group and 61 (92%) in the control group.

**Study design**
This was a single-centred, randomised clinical trial. The patients were randomised to the treatment or control group in blocks of 20, using consecutively numbered opaque envelopes. A physical therapist not involved in the intervention conducted a blinded assessment of the outcomes. The groups were followed up at 3, 6 and 12 months postoperatively. Loss to follow-up was 31% overall (35% in the treatment group and 26% in the control group). In addition to the patients who cancelled surgery, 2 patients died in the treatment group, and 2 patients in both treatment and control groups withdrew from the study (no reason given). A further 9 missed the 3-month follow-up appointment (2 in the treatment group and 7 in the control group) and 9 missed the 6-month appointment (7 in the treatment group and 2 in the control group).

**Analysis of effectiveness**
The primary health outcomes and measures used in the analysis were:

- the WOMAC (disease-specific index) quality of life score,
- the SF36 (general health questionnaire) scores,
- knee range of movement (using a goniometer), and
- strength (measured with a hand-held dynamometer).

The basis of the analysis was intention to treat. Missing data for the 3- and 6-month appointments (for all functional and quality of life measures except knee strength) were handled using the "cold decking" strategy (the input of a constant value from an external study with a sensitivity analysis to compare imputed and non-imputed results). The authors stated that the groups were comparable at baseline on demographic and all outcome measures. Some potential confounding factors were addressed at baseline through the even distribution of patients from high- and low-volume surgeons, different implant types, fixation methods and patellar resurfacing. It was unclear whether demographic comparability remained, or if confounding was addressed at analysis.

**Effectiveness results**
Within each study group, there were significant changes over time on all primary outcome measurements (WOMAC, SF-36, knee range of movement and strength), (p<0.005), except for the general health dimension of the SF-36.

However, there were no significant differences between groups on any outcome measure, except the vitality dimension of the SF-36. The control group had significantly higher scores for vitality throughout the study period, (p=0.004).

Most of the complications reported were in connection with circulatory problems, infections, or general medical complications.

Three manipulations due to poor range of movement were necessary (2 in the control group and 1 in the treatment group).

There were no significant differences between the groups in terms of length of stay, transfer to sub-acute rehabilitation, or readmissions.
Clinical conclusions
There were no significant differences between the study groups in terms of functional recovery or health-related quality of life during the 1-year study period.

Measure of benefits used in the economic analysis
No summary measure of benefit was used in the economic evaluation. The authors demonstrated therapeutic equivalence and only analysed costs in the economic analysis.

Direct costs
The health service costs (averages) included in the analysis related to institutional costs (costs of transfer and readmission in terms of days of stay), homecare costs (hours of provider care) and community rehabilitation costs (per-diem). The cost of the exercise and education programme (Can$240) in the treatment group was also included in the total cost. Health service resource use was collected from regional health authorities administrative databases during a 1-year period immediately following surgery. Costing (in 1997/98 Canadian dollars) was derived from standard unit costs, largely based upon the Capital Health Program costs from the authors’ setting. The cost of initial stay following surgery was excluded, as this was common to both study groups. The resource quantities were reported separately for length of stay only. Discounting of the costs was not deemed necessary since the study period was only one year.

Statistical analysis of costs
The cost and health service use data were reported as descriptive statistics (mean values plus standard deviations).

Indirect Costs
No indirect costs were reported.

Currency
Canadian dollars (Can$).

Sensitivity analysis
There was no reported sensitivity analysis of the costs or resources.

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

Cost results
The cost of the exercise and education intervention was Can$240.

The total health service costs were Can$1,369 (standard deviation, SD=1,274) in the treatment group and Can$1,366 (SD=1,415) in the control group, (p=0.99).

The total health service use (length of stay) was 10.2 (SD=4.5) days in the treatment group and 11.7 (SD=5.2) days in the control group, (p=0.10).

The costs of adverse effects were not stated. However, they were unlikely to be relevant because of their nature, being unrelated to the specific exercise-type in the intervention.
Synthesis of costs and benefits
The costs and benefits were not combined.

Authors' conclusions
There were no significant differences between the study groups in terms of functional recovery or health-related quality of life during the 1-year study period. There was no significant difference in health service costs between the groups. Despite the (insignificant) difference in costs for postsurgical hospital rehabilitation (lower in the treatment group), this difference was reduced further when the cost of the intervention treatment was included. However, the authors claimed that the study was underpowered to detect any differences in health service use.

CRD COMMENTARY - Selection of comparators
The choice of the comparators was justified on the basis of limited evidence that a preoperative exercise and education programme (treatment group) would speed up the recovery process from TKA, and also reduce health service use and costs. The procedure followed in the control group (regular activities and treatment where necessary) was chosen on the basis that this represented "usual care". You should decide if these represent widely used technologies in your own setting.

Validity of estimate of measure of effectiveness
The analysis was based on a randomised clinical trial. This was appropriate for the study question, owing to its ability to reduce potential biases in the treatment allocation process. It was unclear whether the study sample was representative of the study population (those on the waiting list for TKA), as the included patients were obese (mean BMI greater than 30) and, on average, at the older end of the age range stipulated in the inclusion criteria. This potentially limits the external generalisability of the results. Potential biases and confounding factors, such as those relating to age, BMI index and co-morbidities, were not addressed with appropriate statistical analyses. In addition, the failure to monitor exercise levels in the control group potentially reduced the strength of any intervention effects. Finally, the lack of clarity surrounding the demographic comparability of the groups at analysis also poses a threat to the strength of inference from this study. The internal validity of the study was strengthened by the reporting of a power calculation for the WOMAC outcome, the method of randomisation, blinding, length of study and loss to follow-up, and the adoption of an intention to treat analysis.

Validity of estimate of measure of benefit
No summary measure of benefit was derived for the economic analysis. As the effectiveness analysis demonstrated that the two treatments were equally effective, only the costs were assessed further.

Validity of estimate of costs
It appears that categories of costs relevant to the perspective of the Canadian health service (institutional, homecare, community rehabilitation) have been included in the analysis. The authors claimed that the exclusion of costs relating to initial surgical stay was appropriate. However, the reported shorter length of stay in the treatment group, although statistically insignificant, might present clinical and cost implications in practice. With the exception of length of stay, the costs and the quantities were not reported separately. This hinders the transferability of the results, although the price year was reported. The generalisability to other health service settings is further limited since the resource quantities were derived from regional health authorities administrative databases. An attempt was made to avoid the effects of cost variation between programmes and institutions, using standard unit costs from the Capital Health Program. However, the fact that there was no sensitivity analysis of the quantities, or statistical analysis or measure of variance on the costs, introduces potential uncertainty into the results.

Other issues
The authors compared their findings with those from other studies that, in general, showed the results for strength and conditioning outcomes to be in agreement. The authors acknowledged several limitations of their study. For example,
any early postoperative differences between the groups might have been missed as the first follow-up assessment occurred at 3 months. A further issue worthy of note is the lack of clarity on how compliance with the exercise and education programme was recorded. The authors mentioned the use of log-books, but it was unclear whether the data were collected by patient self-report or by an observer in the clinic. There is substantial literature that advocates the cautious interpretation of non-validated self-reported behaviour. The results were not selectively reported and the authors’ conclusions reflected the scope of the analysis.

Implications of the study
The authors suggested that health service use should be the primary outcome in future research. In addition, a less resource intensive programme content might also be explored, using different methods of education and delivery. Finally, the authors proposed that process evaluation, to explore patient expectations and satisfaction, should be conducted when determining the effects of preoperative education in preparation for surgery and postoperative recovery.

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