An economic evaluation of operative compared with nonoperative management of displaced intra-articular calcaneal fractures

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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 authors studied operative versus non-operative treatment of displaced intra-articular calcaneal fractures. No further details of the two technologies were reported.

Type of intervention
Treatment.

Economic study type
Cost-utility analysis.

Study population
The target study population comprised hypothetical "typical" patients with calcaneal fractures who had demographic characteristics comparable to patients included in a recent clinical trial (Buckley et al. 2002, see 'Other Publications of Related Interest' below for bibliographic details).

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

Dates to which data relate
The effectiveness data were taken from a single study published in 2002 (Buckley et al. 2002). Resource use was determined through a decision model, using data from the clinical trial retrospectively. The unit costs and prices were reported in 2002 prices.

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

Link between effectiveness and cost data
The estimation of the direct costs was carried out retrospectively, based on a sub-sample of that used in the clinical analysis. It was unclear whether the indirect costs were estimated for a different 'hypothetical' sample of patients.

Study sample
A parent study (Buckley et al. 2002) informed all of the inputs to the decision model. The authors provided full bibliographic details, enabling the reader to find out more about the primary study, but reported few details of the study itself. A total of 309 patients were recruited in that study from across Canada. These patients were reported to reflect typical patients with displaced intra-articular calcaneal fracture. The mean age of the patients was 40 years, 37% had a
work-related injury and 90% were male.

Study design
The authors stated that the parent study was a randomised controlled trial, but reported no further details.

Analysis of effectiveness
It was unclear whether the analysis was conducted on an intention to treat basis. Primary health outcomes for input into the authors' study were the risk of complication, the risk of arthrodesis after having a complication, and the risk of arthrodesis with no complication. These risks were calculated for operative and non-operative treatments. The authors estimated ranges by varying values from 50 to 150% of the baseline values. There were no summary statistics for patients in the two sample groups and, therefore, no details of the comparability of the groups at baseline.

Effectiveness results
The risk of complication was 14% (range: 7 to 21) for non-operative patients and 37% (range: 18 to 56) for operative patients.

The risk of arthrodesis after having a complication was 44% (range: 22 to 66) for non-operative patients and 4% (range: 2 to 6) for operative patients.

The risk of arthrodesis after no complications was 15% (range: 7 to 22) for non-operative patients and 4% (range: 2 to 6) for operative patients.

Clinical conclusions
Patients under the operative care group presented a higher risk of complications although, overall, they were less likely to require further arthrodesis after initial surgery.

Modelling
The authors defined a decision model that considered the management of patients over a 4-year time horizon for both treatment alternatives. The probabilities of events in the model were taken from Buckley et al. 2002. The model was based on the premise that a treatment was chosen and that either there was a complication or there was not, and either there was fusion and subtalar arthrodesis or there was not. The authors estimated the costs and outcomes for each of the possible resulting health states.

Methods used to derive estimates of effectiveness
The model was supported by some authors' assumptions.

Estimates of effectiveness and key assumptions
The authors assumed that patients with persistent pain associated with the injured hindfoot would go on to have a subtalar arthrodesis. They also assumed that the patient's health state remained stable after 2 years and that there was no improvement following subtalar arthrodesis.

Measure of benefits used in the economic analysis
The summary measure of health benefit used was the number of quality-adjusted life-years (QALYs). These were estimated using health-related quality of life, as measured by the Short-Form 36 (SF-36), during the randomised controlled trial. SF-36 scores were converted into utility scores for patients with a calcaneal fracture using a published regression model (Fryback et al. 1997, see 'Other Publications of Related Interest' below for bibliographic details). The health benefits were discounted at a rate of 5%. 

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Direct costs
The analysis was carried out from the perspectives of society and the health care payer. It focused on the direct costs of initial and follow-up care of the calcaneal fracture. Such costs were for inpatient visits, emergency room visits, related physician visits and nursing care, laboratory and diagnostic investigations, surgical care, surgical supplies, medications and support staff. Rehabilitation costs were not estimated as they were likely to be comparable between the two groups. The hospital costs were obtained for those patients recruited in the city in which most patients were recruited during the clinical trial. Hospital costs for these patients, calculated as described in current provincial and national guidelines, were obtained from the Calgary Health Region corporate database and covered the sub-set of patients who had valid current Alberta Health care insurance. Physician fees were collected from the Alberta Health and Wellness Schedule of Medical Benefits. The costing was carried out for the 4 years of the model, with costs discounted at a rate of 5% and inflated using the Consumer Price Index Inflator. The price year was 2002. The costs were presented as average or median costs per patient.

Statistical analysis of costs
Normally distributed variables (i.e. utility scores) were reported as means (with 95% confidence intervals), while non-normally distributed variables (i.e. costs) were reported as medians (with 25th to 75th percentile ranges). Hypothesis tests were carried out and p-values were reported.

Indirect Costs
The authors included an estimate of the cost of lost wages due to time off from work. These costs were discounted and refluttered in the same manner as the direct costs. All patients had a non-weight-bearing period of 6 weeks and time to return to work was gathered from a chart review, the results of which had been published (Tufescu et al. 2001, see 'Other Publications of Related Interest' below for bibliographic details). The unit costs were estimated from the average income for individuals aged between 35 and 44 years in 2001, as reported by Statistics Canada.

Currency
Canadian dollars (CAD).

Sensitivity analysis
One- and two-way sensitivity analyses were carried out to determine the impact on the results of changing variable inputs. The analyses systematically varied probabilities, costs and utilities through clinically plausible ranges. Scenario analyses were carried out to explore the impact of changing variables simultaneously.

Estimated benefits used in the economic analysis
Operative patients gained 2.5 QALYs and non-operative patients gained 2.43 QALYs. Operative treatment was associated with a gain of 0.07 QALYs.

Cost results
First-year median costs, including initial treatment and first-year follow-up, were CAD 3,100 for the surgery group and CAD 950 for the non-operative group, (p<0.001).

No significant difference was found in median subsequent 3-year costs for patients who did not have subtalar arthrodesis.

The estimated median costs of time off from work for patients not requiring an arthrodesis was CAD 19,000 for operatively treated and CAD 28,000 for non-operatively treated patients, while those for patients requiring an arthrodesis were CAD 58,000.
The total expected median costs per patient (including both direct and indirect costs) were CAD 32,000 for operative treatment and CAD 51,000 for non-operative treatment.

**Synthesis of costs and benefits**

Operative treatment was associated with a saving of CAD 19,000 and a gain of 0.07 QALYs per patient, and therefore represented a dominant strategy.

When time lost from work was not considered, the incremental median cost of operative treatment was CAD 2,800. This gave an incremental cost per QALY gained equal to CAD 40,000 when compared with non-operative treatment.

The incremental cost-effectiveness ratio was reported to be sensitive only to the estimates of time lost from work, when there was a cost of CAD 40,000 per QALY.

Detailed sensitivity analyses were reported. These showed that operative treatment was cost-saving in most of the cases (due to the fact that a lower percentage of patients would require arthrodesis). However, the results were sensitive to the exclusion of time lost from work and to the consideration of utilities favourable to the non-operative patients (i.e. upper and lower ends of the 95% confidence intervals for non-operative and operative patients, respectively). In these situations, non-operative treatment would become the most cost-effective option.

The authors reported that surgical treatment was cost-effective because it avoided arthrodesis.

**Authors’ conclusions**

When time off work was included in the analysis, operative treatment both cost less than non-operative treatment and was associated with improved health, as measured by quality-adjusted life-years (QALYs).

**CRD COMMENTARY - Selection of comparators**

The authors studied operative and non-operative treatment of displaced intra-articular calcaneal fractures. It was unclear which of the treatment alternatives represented current practice in the authors’ setting. The authors reported that previous studies had found no clinical difference between the treatments and, consequently, there was much uncertainty in the optimal treatment. You should decide whether any of these alternatives represent the current practice in your own setting.

**Validity of estimate of measure of effectiveness**

The authors used a single randomised controlled trial to inform their model parameter estimates. Relatively few details of the trial were reported, although the authors provided full bibliographic details so that the reader can ascertain more details for themselves. According to the authors, the study sample comprised "typical" patients with displaced intra-articular calcaneal fracture and so reflected the study population. However, it was not reported whether the study groups were comparable at analysis in terms of relevant clinical characteristics. The authors gave a clear report of their model and based their analysis on a 4-year time horizon, enabling them to take in both short- and medium-run outcomes.

**Validity of estimate of measure of benefit**

QALYs were used as the summary measure of health benefit. These were informed by utility values obtained through regression analysis based on preferences taken from published studies. The data were modelled to obtain the final expected benefits of the treatments of interest. These estimates appear to have been appropriate for the clinical question posed by the authors and provided a measure that was widely comparable both to similar and non-similar health-related technologies. However, as the authors highlighted, SF-36 scores may not be entirely accurate for the health states of the patient population considered at analysis. In addition, the regression model used to estimate utilities presents some additional limitations in terms of adjustments of the model to the data.
Validity of estimate of costs
The authors estimated the costs from the perspectives of society and the health care payer. The unit costs relevant to these two perspectives were incorporated. The societal perspective encompassed an estimate of time lost from economically productive work. Rehabilitation costs were excluded as they were common to both alternatives. Extensive statistical and sensitivity analyses were undertaken. The costs were reported at the patient level and the results were given as the expected median cost per patient. The resource quantities were not reported separately from the costs, which hinders reflation exercises in other settings. The costs were appropriately discounted and reflationed, and the price year was given. As the authors commented, the sub-sample of patients used to estimate the direct costs “was comparable to the complete study population”, which enhances the potential generalisability of the cost results. The authors highlighted several limitations in the cost analysis. For example, the retrospective collection of the cost data and the fact that costs were not available for all patients.

Other issues
The authors made appropriate comparisons of their work and, where appropriate, gave explanations of why the results might differ. For instance, they reported details of a study that had conflicting results but that was based retrospectively on a very small sample of non-randomised patients. These limitations were cited as potential reasons for differences in the results. The issue of generalisability was addressed in the sensitivity analyses, where the authors explored the impact of varying costs, because they acknowledged that the costs in Canada might be lower than those in other countries. The results were robust to changes in the cost parameters and the authors concluded that the results should therefore be generalisable to other countries. The authors presented their results very thoroughly and clearly, and discussed them at length. The conclusions were an accurate reflection of both the results presented and the scope of the study outline at the beginning.

Implications of the study
The authors did not make any recommendations for policy or practice following their study, but areas for further work were highlighted. These included the further exploration of the impact of time off work, and the collection of several measures of preference-based, patient-derived health-related quality of life in future randomised controlled trials.

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Other publications of related interest


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