Cost-effectiveness of C-Leg compared with non-microprocessor-controlled knees: a modeling approach

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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.

CRD summary
This study determined if the microprocessor-controlled C-Leg artificial knee was cost-effective, compared with non-microprocessor-controlled knees, in patients with a femoral amputation and prosthesis. The authors concluded that the C-Leg appeared to yield positive health outcomes at an acceptable cost, given the existing limited evidence. The methods and the reporting were satisfactory and the results appear to be reliable, but the conclusion remains uncertain.

Type of economic evaluation
Cost-utility analysis

Study objective
This study evaluated if the microprocessor-controlled C-Leg artificial knee was cost-effective compared with non-microprocessor-controlled (NMC) artificial knees, for patients with a femoral amputation and prosthesis.

Interventions
The C-Leg unit had a microprocessor-controlled swing and stance phase. The C-Leg unit, with an expected working life of more than eight years, was compared with an NMC knee unit for active patients who required an artificial leg.

Location/setting
Sweden/primary care.

Methods
Analytical approach:
No randomised controlled trials comparing the interventions were found, so the authors used data from interviews with patients and prosthetists, in a simple two-state Markov model, to estimate the costs and outcomes of the two options. The time horizon was eight years from the delivery of the first prosthesis. The authors stated that a Swedish health care perspective was taken.

Effectiveness data:
The clinical evidence, including quality of life, was collected by interviewing patients with the C-Leg and their prosthetists. A total of 20 patients, from three clinics in Sweden and five clinics in Denmark, were interviewed, using a guide and predefined questions.

Monetary benefit and utility valuations:
The utilities were based on the visual analogue scale of the European Quality of life (EQ-5D) questionnaire. These estimates were obtained from the interview with the patients.

Measure of benefit:
The benefit measure was quality-adjusted life-years (QALYs), which were discounted at an annual rate of 3%.

Cost data:
The cost categories included the cost of the prosthesis, its foot, its production hours, and the additional costs of problems with the prosthesis and help from the prosthetist. The resource use data were from the interviews with the prosthetists and from manufacturers of the prosthetic components. The rates and duration of problems were from the...
interviews with patients, whilst the additional costs of problems were from the interviews with prosthetists. The currency was Euros (EUR), and the costs were adjusted to 2006 prices. An annual discount rate of 3% was applied.

Analysis of uncertainty:
One-way sensitivity analyses were performed for all parameters. Three two-way sensitivity analyses were performed, fixing parameters at the 99th percentile value that was most unfavourable to the C-Leg. Probabilistic sensitivity analyses were performed and the results were presented in a cost-effectiveness acceptability curve.

Results
The C-Leg was associated with EUR 25,146 and 5.98 QALYs per patient. NMC knees were associated with EUR 17,488 and 3.60 QALYs per patient.

The incremental cost-utility ratio for the C-Leg compared with NMC knees was EUR 3,218 per QALY gained.

The sensitivity analyses did not change the estimated cost-effectiveness of the C-Leg strategy. The one-way sensitivity analysis showed that the utility values associated with each of the two knee alternatives were the only parameters that influenced the results. The two-way sensitivity analyses showed that only the analysis with the low 99th percentile QALY value for the C-Leg and the low 99th percentile value for the number of problems with NMC knees increased the cost-utility ratio.

Authors' conclusions
The authors concluded that the C-Leg appeared to yield positive health outcomes at an acceptable cost, given the existing limited evidence.

CRD commentary
Interventions:
Both interventions were well described. The analysis included the usual practice, which was NMC prosthetic knees for active patients.

Effectiveness/benefits:
The effectiveness data were obtained by interviews with the patients and prosthetists. The methods of the interviews were reported. The authors stated that these interview data were the best available evidence, given a lack of evidence for transfemoral prostheses and the C-Leg. They did not report the methods used to search for relevant evidence, making it unclear if this claim was valid. It was not clear why the clinical trials that demonstrated the effectiveness of the C-Leg over NMC knees were not used. The methods used for the utility estimates were described, including the instrument used and the population interviewed.

Costs:
The perspective was stated and it would appear that all the relevant costs for this perspective and the study question were considered. The sources of the cost data were reported. The cost estimates were relevant to the population and setting. Other details, such as the price year and discounting, were given. Overall, the costs were well reported and seem to have been appropriate.

Analysis and results:
The incremental analysis was appropriate for determining the cost-effectiveness of the options and the incremental cost-utility ratios were correctly calculated. The uncertainty was appropriately assessed in one-way, two-way and probabilistic sensitivity analyses. The structural uncertainty of the eight-year time horizon was investigated. Given the use of interview data, uncertainty cannot be ruled out, but the extensive sensitivity analysis went some way towards characterising it. The results of both the base case and the sensitivity analyses were clearly reported. The authors highlighted the limitations of their study.

Concluding remarks:
The methods seem to have been appropriate and the reporting was transparent. The results appear to be reliable, but the conclusion remains uncertain.
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