An evidence-based model comparing the cost-effectiveness of platelet-rich plasma gel to alternative therapies for patients with nonhealing diabetic foot ulcers

Dougherty EJ

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 evaluated the cost-effectiveness of an autologous platelet-rich plasma (PRP) gel for patients with non-healing, full-thickness, diabetic foot ulcers. The author concluded that the PRP gel improved the quality of life and lowered the cost of care, over five years, compared with other treatments. The methods were good, but some of them were not well reported. The authors' conclusions should be considered with caution, particularly as the clinical trial had a small sample.

Type of economic evaluation
Cost-utility analysis

Study objective
The objective was to evaluate the cost-effectiveness of an autologous platelet-rich plasma (PRP) gel for patients with non-healing, full-thickness, diabetic foot ulcers that had been present for more than four weeks.

Interventions
The PRP gel was administered twice weekly until the wound healed or for 12 weeks. This was compared with a saline gel dressing.

Location/setting
USA/primary care.

Methods
Analytical approach:
A micro-simulation Markov model was used to combine the data from a variety of sources. The model had four health states: unhealed ulcer, healed ulcer, amputation, and death. The cycle length was one week and the time horizon was five years. The author stated that the study was carried out from the perspective of the health care insurers and providers.

Effectiveness data:
The effectiveness of the PRP gel was from a multicentre, prospective, blinded, randomised controlled trial (Driver, et al. 2006, see 'Other Publications of Related Interest' below for bibliographic details). This trial compared 16 patients, undergoing treatment with PRP gel, with 19 patients, undergoing treatment with saline gel. The ulcer healing rates were extrapolated based on the rates at 12 weeks and one year that were reported in this trial. The risks of recurrence, infections, first and second amputations, and death were from published literature. The main clinical effectiveness estimates were the incidence of total wound closure at 12 weeks and the ulcer healing rate.

Monetary benefit and utility valuations:
The utilities for each state were from a published study of diabetic patients.

Measure of benefit:
The primary measure of benefit was quality-adjusted life-years (QALYs).

Cost data:
The cost categories included the PRP gel, management of an uncomplicated ulcer, management of an ulcer complicated by severe infections, and first and second amputations. The cost of the PRP gel was from the manufacturer. The other costs were from published literature. All costs were reported in US dollars ($) and indexed to 2006 prices, using the medical care component of the Consumer Price Index.

Analysis of uncertainty:
One-way sensitivity analysis was conducted on the PRP gel cost (increasing from $450 to $600), and the ulcer healing rates at 12 weeks, from the clinical trial. The costs and QALYs gained were compared with those of other treatments, besides PRP gel and saline gel, reported in published literature.

Results
The mean total cost, with efficacy from the per protocol majority wound group, was $15,159 for PRP gel and $33,214 for saline gel. The mean QALYs were 2.87 for PRP gel and 2.70 for saline gel. PRP gel was dominant as it was less costly and more effective than saline gel.

When the cost of the PRP gel was increased from $450 to $600 the total mean cost was $16,835 and PRP gel remained dominant.

The sensitivity analysis estimated that the PRP gel was dominant over all the alternative treatments.

Authors’ conclusions
The author concluded that the PRP gel improved the quality of life and lowered the cost of care, over five years, compared with other treatments for non-healing diabetic foot ulcers.

CRD commentary
Interventions:
The interventions were well described and appear to have been appropriate comparators. It was unclear why standard care was not included in the main analysis, but it was included in the sensitivity analysis.

Effectiveness/benefits:
The method used to estimate the efficacy of PRP gel in the base case was well reported. The author did not report a systematic literature review to identify the efficacy estimates, and it is unclear whether the best available estimates were used. The sample for the main clinical trial was small and a power calculation could have confirmed that it had the statistical ability to detect any differences between the comparators. The methods used to estimate the efficacy of treatments other than PRP gel and saline gel were not reported; no systematic review was reported and the trials or studies were not described. It was unclear why these treatments were only included in the sensitivity analysis. The measure of benefit appears to have been appropriate; it is generalisable to other studies and includes mortality and morbidity, but little information was provided on how the utilities were valued. No discounting was reported and if it was not undertaken, this might increase the uncertainty in the estimates.

Costs:
The perspective was clearly stated and the costs appear to have been relevant to this perspective. The unit costs were clearly reported in a table and the sources for the resource use were clearly presented. The costs for treatments other than PRP gel and saline gel were not reported, which reduces the transparency of the sensitivity analysis. The costs were appropriately adjusted for inflation, but it was unclear if they were discounted.

Analysis and results:
The analytic approach was well described and a diagram of the model was presented. The results were adequately reported. The sensitivity analysis was not fully reported, particularly for the methods used to estimate the cost-effectiveness of treatments other than PRP gel and saline gel. No probabilistic sensitivity analysis was undertaken, so the overall uncertainty in the results is unclear. The author acknowledged the limitations of the study, including that the efficacy data were from a clinical trial with a small sample and that there was a lack of reporting of the recurrence rates.
Concluding remarks:
The methods were good, but some of them were not well reported. The authors' conclusions should be considered with caution, particularly as the clinical trial had a small sample.

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Other publications of related interest

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