Autologous blood transfusion in total knee replacement surgery

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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
Autologous blood transfusion (transfusion using post-operative red cell salvage (PRCS)) was assessed. This involved the use of collected blood which was washed and re-suspended in saline before re-infusion using a centrifugal cell washing machine (Cell Saver 5 Haemonetics).

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients undergoing total knee replacement (TKR). No inclusion or exclusion criteria were stated. Informed consent was obtained from all participants.

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

Dates to which data relate
No dates to which data related were reported, either for the clinical or for the economic study. The price year for the economic study was 1998.

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

Link between effectiveness and cost data
Costing was carried out prospectively. The authors estimated the cost per patient, therefore the cost may relate either to the same sample as used in the effectiveness study, or to other patients.

Study sample
The authors did not report whether power calculations were carried out in order to determine an appropriate sample size and hence rule out the influence of chance on their results.

In total 231 patients (98 male), from whom informed consent was obtained, were included in the study. Although it was not clear how the patients were selected. This initial sample was appropriate for the clinical study question as it included patients who were undergoing TKR. A total of 115 patients were randomised to the PRCS (autologous) group and 116
to the allogeneic (homologous) group.

The authors reported that the characteristics of the two groups were 'comparable'. The mean age for PRCS was 70.5 (35-95) for females and 67.4 (38-85) for males. The mean age for Allogeneic was 70.2 (40-87) for females and 69.7 (48-88) for males. There were no statistically significant differences between the groups in terms of mean American Society of Anaesthesiology (ASA) grade, prevalence of smokers, previous transfusion, or Aspirin/NSAIDs use. The authors did not report whether any patients were excluded.

Study design
The analysis was based on a randomised controlled trial carried out in a single centre (Morriston Hospital, Swansea NHS Trust, UK). The unit of randomisation was not reported. Patients in the PRCS group received autotransfusion of wound drainage if the volume was greater than 125ml post-operatively and were also transfused with allogeneic blood if their haemoglobin fell below the preset trigger (9g dl^-1) after autotransfusion. Patients in the control group received allogeneic blood at the same transfusion trigger. Haemoglobin concentrations were measured on days 1, 2, 3, 4, and 7. Some outcomes were measured up to 6 months after surgery, suggesting that follow-up extended for this length of time. The authors did not report any loss to follow-up. Adverse events were considered by a blind assessor to determine whether they were related to the transfusion.

Analysis of effectiveness
Analysis was based on intention to treat. In addition to the intention to treat results, the authors also reported some results according to actual treatment received. Primary health outcomes were: length of stay, peri-operative and post-hospital discharge infection rates, adverse events, and wound healing rates. The authors reported that patients in the two groups were 'comparable' and their comparability in terms of anaesthetic used and prosthesis used was discussed. A total of 18 patients in the treatment group did not receive PRCS.

Effectiveness results
The authors did not report specific values for many primary outcome measures. However, they did report that "there was no significant difference in length of stay, wound healing, serious adverse events or mortality" and that there was no difference in post-operative mean haemoglobin concentration between the groups. The incidence of allogeneic blood transfusion was 7% in the PRCS group and 28% in the control group, (p<0.001). The authors also found fewer re-admissions to hospital, (p<0.008), and visits to GPs, (p<0.043), in patients in the PCRS group.

Clinical conclusions
The authors concluded that "a decrease in allogeneic blood could be achieved by using PRCS".

Measure of benefits used in the economic analysis
The authors estimated quality of life using the EuroQol EQ-5D the data being collected by research nurses. Valuations were obtained at 0, 1, 4 and 12 weeks (with week 0 presumably representing the time of treatment). No further details were reported.

Direct costs
A perspective for the costing analysis was not reported although costs relating to the hospital appear to have been estimated. A time horizon was not reported however the authors did state that this analysis was short term. In practice the study appears to have been concerned with the immediate costs associated with treatment. The time frame for readmission and further GP consultations was not given. Therefore, it is not possible to assess whether discounting should have been applied to these estimates. The authors reported that the end of study mortality in some cases indicated a 2-year follow-up. This estimate suggests that discounting should have been used. The authors reported costs per patient. Therefore, volumes of one unit appear to have been assumed, with the authors then reporting unit costs (certainly no quantities were reported separately). Direct costs comprised allogeneic blood, staff time, capital and
servicing, and disposables. The source of cost estimates was not reported. Therefore, it was not clear whether they were based on actual data. The price year was given as 1998.

Statistical analysis of costs
Costs were treated as deterministic.

Indirect Costs
The authors considered readmission and GP consultation as indirect costs. Indirect costs were considered and reported in the same way as direct costs.

Currency
UK pounds sterling ( ).

Sensitivity analysis
No sensitivity analyses were reported.

Estimated benefits used in the economic analysis
Quality of Life estimates were presented in graphical form; therefore it is not possible to report exact values. However, reading from the authors' graph:

At 0 weeks the EuroQol Health Status Score was 0.36 for the PRCS group and 0.4 for the control group.

At 1 week the EuroQol Health Status Score was 0.49 for the PRCS group and 0.44 for the control group.

At 4 weeks the EuroQol Health Status Score was 0.55 for both groups.

At 12 weeks the EuroQol Health Status Score was 0.63 for the PRCS group and 0.61 for the control group.

Cost results
The direct cost per patient was 165.78 in the PRCS group and 28.70 in the control group.

The indirect cost per patient (as considered by the authors) was 12.38 in the PRCS group and 36.20 in the control group.

The total cost per patient was 178.16 in the PRCS group and 64.90 in the control group.

Synthesis of costs and benefits
Although quality of life scores were estimated, they were not combined with the cost estimates.

Authors' conclusions
The authors concluded that "autologous transfusion was overall more expensive" and that, although PRCS was "not shown to be cost-effective", the analysis was short term and omitted factors such as the value attached to reduced risk of transmission of virus related illness.

CRD COMMENTARY - Selection of comparators
The authors aimed to show that a reduction in allogeneic blood transfusion could be achieved through the use of PRCS and a haemoglobin 'transfusion trigger'. They achieved this by comparing patients who received PRCS with patients
who received only allogeneic blood, which was the natural comparator in this case as well as being standard practice in the authors' setting. You should consider whether this represents a valid comparator in your own setting.

Validity of estimate of measure of effectiveness
The analysis was based on a randomised controlled trial, which was appropriate for the study question as it minimises the possibility of systematic differences between patients in the two groups. The study sample comprised patients who were undergoing TKR and were likely to receive some form of blood transfusion. This sample was representative of the study population. The authors reported that the two groups were comparable at analysis and provided some summary statistics to verify this. A total of 18 patients in the treatment group did not receive PRCS. The authors highlighted this and gave reasons why the intended treatment was not possible. Results were then provided both on the basis of intention to treat, and actual treatment received.

Validity of estimate of measure of benefit
The authors use the EuroQol as a summary measure of health benefit with valuations obtained by research nurses. It was not clear how estimates were elicited from patients. The authors provided little discussion of the ability of the EuroQol to detect health differences that may have arisen, and did not report which domains of the EuroQol were affected by treatment (i.e. mobility, cognition). This limits the understanding that the reader can gain from the limited results presented.

Validity of estimate of costs
A perspective for the costing analysis was not reported. Therefore, it is not possible to assess whether all costs relevant to the study were included. Those costs that were reported appeared to represent the perspective of the hospital, but as discussed by the authors, were limited to a short-term horizon. Nevertheless, the estimated cost per patient was substantially different (by almost a factor of three) between the treatment alternative, therefore small omissions in cost may not affect the principal results and conclusions drawn. There was some discussion of the costing analysis but this left a number of issues unaddressed. For instance, follow-up GP visits were cheaper for patients who had undergone PRCS. The reason for this is not apparent to the reader, and was not mentioned by the authors. Without such discussion the reader is not able fully to understand the results presented or the main cost drivers.

Other issues
The authors highlighted some similarities and differences between their own findings and those from other studies. In particular the current study did not support differences in immediate post-operative infection or earlier hospital discharge. Principally they drew comparisons with their own previous pilot study. The issue of generalisability to other settings was not explicitly addressed. However, there was some discussion of how the population in this study differed from the general population, allowing the reader to draw their own conclusions about applying the results to their own setting. The authors concluded that PRCS was “not shown to be cost-effective”. However, the results, as presented, do not appear to support this statement. The results confirmed only that PRCS was more expensive than treatment with allogeneic blood alone. This does not automatically imply that PRCS was not cost-effective, as the additional cost incurred may be acceptable given any potential improved outcomes and society's willingness to pay for such outcomes. Some limitations were presented, including the short-term nature of the study and the failure to include a value attached to reduced risk of transmission of virus related illness. Although, with the latter, it was not clear whether the authors referred to value in terms of monetary cost, or value to the patient in terms of piece of mind.

Implications of the study
The authors make no recommendations regarding policy or practice as a result of their study, and do not suggest the need for any further research.

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Other publications of related interest

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