A randomized trial comparing acute normovolemic hemodilution and preoperative autologous blood donation in total hip 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 use of acute normovolemic haemodilution (ANH) and preoperative autologous blood donation (PABD) in orthopaedic surgery.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients who were scheduled for total hip arthroplasty. Patients who were pregnant or were aged under 18 years were excluded. Also excluded were those with a recent (less than 6 months) myocardial infarction or clinically significant myocardial disease, and/or uncontrolled hypertension (diastolic blood pressure of at least 100 mmHg).

Setting
The setting was secondary care (a hospital). The economic study was carried out at the Washington University School of Medicine, St. Louis (MO), USA.

Dates to which data relate
The dates to which the effectiveness and resource use data related were not reported. The price year was also not reported.

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

Link between effectiveness and cost data
The costing was carried out prospectively on the same sample of patients as that used in the effectiveness study.

Study sample
Power calculations were reported. A sample size of 16 patients for each cohort was required to assure a power of 0.80 in the detection of a 100% increase in transfusion outcomes between PABD and ANH cohorts. A single surgeon identified eligible patients at the study hospital. A group of 48 consecutive patients scheduled for total hip arthroplasty was included in the study. Of these, 23 were assigned to the ANH group and 25 to the PABD group. The patients in the
ANH group had a mean age of 60 (+/- 17) years and 11 were women. The patients in the PABD group had a mean age of 67 (+/- 9) years and 11 were women.

**Study design**
This was a prospective, randomised cohort study that was carried out in a single centre. The period of follow-up was unclear, but it was likely to have been until discharge. No loss to follow-up was observed. The patients were allocated to their respective groups by random number selection.

**Analysis of effectiveness**
It appears that all the patients included in the study have been accounted for in the analysis of effectiveness. The health outcomes used in the study were:

- the total anaesthesia and surgery times,
- the number of autologous units procured,
- intraoperative blood loss,
- red blood cell (RBC) loss,
- complete blood count,
- reticulocyte count,
- Hct levels, and
- autologous and allogeneic blood units transfused.

The study groups appear to have been comparable at baseline in terms of age, gender, weight distributions and mean Hct levels.

**Effectiveness results**
There were no statistically significant differences between the two groups in the following:

- total anaesthesia, (p=0.84) and surgery times, (p=0.69),
- the number of autologous units procured, (p=0.72),
- the estimated intraoperative blood losses, (p=0.29), or
- the calculated RBC losses for surgical hospitalisation, (p=0.74).

In patients undergoing ANH, the systolic, diastolic and mean arterial blood pressures were statistically lower after phlebotomy of 1 and 2 units than at baseline, (p<0.05), without changes in heart rate.

On the day of surgery, the Hct levels were lower in the PABD group than in the ANH group. The mean Hct (+/- the standard deviation, SD) was 37.0 (+/- 4.0) in the PABD group versus 40.0 (+/- 3.7) in the ANH group, (p=0.02). Subsequent Hct levels were significantly lower in the ANH group until discharge.

No difference was found in allogeneic blood exposure among ANH (17%) and PABD (0%) cohorts, (p=0.30). However, the mean number of allogeneic units transfused, 0.4 (+/- 0.9) versus 0, reached statistical significance, (p=0.03).
Clinical conclusions
ANH proved to be a safe procedure and was equivalent to PABD in effectively reducing exposure to allogeneic RBCs.

Measure of benefits used in the economic analysis
Since the effectiveness analysis showed no significant differences in clinical effectiveness between the two groups, the economic analysis was based on the difference in costs only (i.e. a cost-minimisation analysis).

Direct costs
The perspective of the study was not reported. The categories of costs included in the analysis were blood procurement from the regional blood centre, laboratory processing, administration, professional fees, and overheads. The resource use data were estimated using actual data coming from the sample of patients involved in the effectiveness study. The unit costs and the quantities of resources used were presented separately. The source of the unit costs and the price year were not reported. Discounting was not relevant since the costs were incurred during less than 2 years.

Statistical analysis of costs
The costs were presented as mean values with SDs. Statistical tests were conducted to compare the costs observed in the study groups.

Indirect Costs
No indirect costs were included.

Currency
US dollars ($).

Sensitivity analysis
Sensitivity analyses were not performed.

Estimated benefits used in the economic analysis
Not applicable.

Cost results
The total costs for blood were $151 (+/- 154) in the ANH group and $680 (+/- 253) in the PABD group. The ANH procedure was significantly less costly than PABD, (p<0.05).

Synthesis of costs and benefits
The authors did not produce a summary measure of benefit that combined the costs and effectiveness, as it was likely that there was therapeutic equivalence of the ANH and PABD procedures. Therefore, the economic analysis included the costs alone.

Authors' conclusions
In patients undergoing total hip arthroplasty, acute normovolemic haemodilution (ANH) was safe and was equivalent to preoperative autologous blood donation (PABD) in reducing exposure to allogeneic red blood cells (RBCs). ANH was also less costly than PABD.
CRD COMMENTARY - Selection of comparators
The choice of PABD as the basic comparator was explicitly justified. It represented the standard approach for patients undergoing total hip arthroplasty. You should decide whether it represents a valid comparator in your own setting.

Validity of estimate of measure of effectiveness
A prospective randomised study, which was appropriate for the study question, was performed. Power calculations were carried out and these justified the size of the sample used in the study. The study groups were comparable at baseline. Hence, confounding factors may be low. The investigators were not blinded to the allocation of the patients to the study groups. Therefore, assessment biases might have had some impact on the results of the analysis. The data came from a single centre and the method used to select the sample was unclear. For example, the number of patients who refused to participate, or who were excluded from the initial study sample, was not stated. Statistical analyses were undertaken to compare transfusion outcomes between the groups.

Validity of estimate of measure of benefit
The authors did not derive a summary measure of benefit.

Validity of estimate of costs
The perspective of the study was not stated. Thus, it was not possible to assess whether all the relevant categories of costs were included in the analysis. The cost estimates were derived from a single centre and were specific to the study setting. Discounting was not relevant and, appropriately, was not carried out. Although details of the unit costs and quantities of resources used were reported, which may ease the transfer of the economic analysis to other settings, the price year was not reported. This limits the possibility of carrying out reflation exercises. Sensitivity analyses on the costs were not performed. Statistical tests of the costs were performed when the cost estimates were compared.

Other issues
The authors compared their results with other published studies, showing consistent effectiveness results. However, they did not address the issue of the generalisability of the study results to other settings. The results were not reported selectively and the effectiveness conclusions reflected the scope of the study. The authors reported no limitations of the study. Sensitivity analyses, to account for variability in the cost or effectiveness data, were not performed. Consequently, caution should be exercised when extrapolating the study results to different contexts.

Implications of the study
The authors did not make any recommendations for policy or practice as a result of their study.

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