Preoperative acute hypervolemic hemodilution with hydroxyethylstarch: an alternative to acute normovolemic hemodilution?


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
Techniques have been developed to minimise homologous blood transfusion during surgical operations because of the associated risks. Both the intervention and comparator are designed to minimise homologous blood transfusion. The comparator strategy was preoperative acute normovolemic hemodilution (ANH) in which the patient's blood is withdrawn prior to operation simultaneously with infusion of crystalloid or colloid solutions (in this study hydroxyethylstarch was used). The intervention strategy was acute hypervolemic hemodilution with hydroxyethylstarch (HHD), a simplified form of this technique, in which patients were preoperatively hemodiluted with hydroxyethylstarch without removing their autologous blood.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Patients undergoing hip arthroplasty. Patients were excluded if they met the following criteria: anaemia (hemoglobin < 11g), clinically evident limitation of cardiac or pulmonary function, untreated hypertension, and coagulation disorders.

Setting
Hospital. The study was conducted in Munich, Germany.

Dates to which data relate
No dates are given for effectiveness data or costs. The study was accepted for publication in August 1996. The price year was not stated.

Source of effectiveness data
Evidence for final outcomes was based on a single study.

Link between effectiveness and cost data
Costing was undertaken on the same patient sample at that used in the effectiveness study.

Study sample
49 patients undergoing hip arthroplasty gave informed consent to participate in this study. No details were given of any who refused to participate. It was not stated whether any patients who fulfilled the entry criteria were excluded. No
reason was give for the size of the study. Patients were allocated randomly to the 2 groups. There were 26 in the intervention (HHD) group and 23 in the comparator (ANH) group.

**Study design**
The study was a randomised controlled trial. There was no blinding during the operation but surgeons prescribing blood transfusions postoperatively were blinded. Follow up was until day 7 after the operation and no loss to follow up was reported.

**Analysis of effectiveness**
All patients completed the treatment. Measurements were given for hemoglobin, hemocrit, and platelet counts, prothrombin time, intraoperative and post operative blood loss, heart rate, mean arterial pressure and numbers of patients receiving postoperative homologous blood transfusion. No significant differences were found between groups in terms of age, sex, height or weight. No prognostic features were mentioned.

**Effectiveness results**
No significant differences (p<0.05) were found between groups for intraoperative blood loss:

- ANH: median 545 mL, minimum 295 mL, maximum 785 mL.
- HHD: median 520 mL, minimum 315 mL, maximum 825 mL.

No significant differences were found between groups for postoperative blood loss, postoperative hemoglobin, hematocrit, platelet count or coagulation variables, and transfusion requirements (ANH 43% versus HHD 35% of patients received homologous blood, p > 0.05).

Heart rate did not change significantly in either group. In the ANH group mean arterial blood pressure (MAP) decreased after hemodilution (p < 0.05) while in the HHD group MAP did not change over time. In the text the authors state that "Immediately after operation and on the third postoperative day in the ANH group PT values were lower than in the HHD group (table 2)". Table 2 however, gives no values for the third postoperative day and the postoperative PT values for the ANH and HHD groups were given as 79 (+/- 9) and 68 (+/- 7) (p < 0.05) respectively. This apparent discrepancy could not be resolved by reference to the remainder of the paper.

**Clinical conclusions**
Coagulation variables were similar in both groups throughout the study and there were no differences at the end of the study. Intra and postoperative blood loss was almost identical in both groups. The difference in numbers requiring homologous blood was not statistically significant.

**Modelling**
No modelling was used.

**Measure of benefits used in the economic analysis**
Since the effectiveness analysis showed no difference between the intervention and comparator the economic analysis was based on costs alone.

**Direct costs**
Prices and quantities were given for devices used during procedures. Times for procedures were given but were not costed. The source of the prices used was not clear, however the cost boundary was the hospital. The price year was not stated.
Statistical analysis of costs
Costs were not analysed stochastically. Times given for procedures were medians with the minimum and maximum values.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analysis was performed.

Estimated benefits used in the economic analysis
Not applicable.

Cost results
The totals for the groups were $63.60 for the ANH group and $32.75 for the HHD group. The median times taken to perform the 2 procedures were 58 minutes (46 minimum to 62 maximum) for the ANH group and 16 minutes (12 minimum to 19 maximum) for the HHD group (p < 0.05).

Synthesis of costs and benefits
Not applicable.

Authors’ conclusions
In orthopaedic patients undergoing hip replacement with a predicted blood loss of about 1000 mL, HHD seems to be a simple as well as time and cost saving alternative to ANH.

CRD COMMENTARY - Selection of comparators
The authors stated that because of ethical reasons they could not use a control group with no hemodilution. They also mention other possible techniques to avoid homologous blood transfusion but the choice of comparators was justified.

Validity of estimate of measure of benefit
The authors have given many clinical measurements but have not explained their importance. The lack of power calculation reports casts doubt about the adequacy of the study size and hence its ability to detect clinically significant differences between groups.

Validity of estimate of costs
The authors did not clearly state the source of their prices. Labour costs and overhead costs for the operating theatre were not included although, from the times given, the inclusion of these cost would not affect the cost results.

Other issues
The authors noted that the results may not be generalisable to other surgical disciplines or patient populations for which additional studies would be needed. The results, as presented, contained at least one possible misprint.

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