Acute normovolemic hemodilution can replace preoperative autologous blood donation as a standard of care for autologous blood procurement in radical prostatectomy


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 procurement in radical prostatectomy.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Patients who had clinically localised (stage A or B) prostate cancers and were ASA physical status I-III. Exclusion criteria included a history of unstable angina or congestive heart failure or the occurrence of a myocardial infarction within 6 months of surgery.

Setting
Hospital. This study was conducted in the USA.

Dates to which data relate
Effectiveness data relate to the period 1995-1996. Dates for resources used were not given. The price year was not stated.

Source of effectiveness data
Effectiveness data were derived from a single study and were calculated on the basis of a mathematical model.

Link between effectiveness and cost data
The costing was undertaken prospectively on the same patient sample as that used in the effectiveness study.

Study sample
The study sample comprised 250 patients who predonated less than 3 units of autologous blood before radical prostatectomy. 46 patients underwent ANH only (the 0 PAD group), 141 predonated 1 PAD unit (the 1 PAD group) and 63 patients predonated 2 PAD units (the 2 PAD Group).

The characteristics of the groups were as follows:

average age of 61, 60 and 59 years;
average weight of 87, 85 and 90 kg.

For the 0 PAD group, 17%, 61% and 22% of patients exhibited ASA physical status I, II and III respectively. For the 1 PAD group, these percentages were 19%, 65% and 16%. For the 2 PAD group, a distribution over the three physical states was detected of 21%, 63% and 16%. No details were provided regarding the sample selection or power calculation. All patients consented to enrolment. At analysis, patient groups were shown to be comparable in terms of all factors mentioned.

Study design
This was a prospective single-centre cohort study. No patients were lost to follow-up.

Analysis of effectiveness
The analysis of the clinical study was based on intention to treat. The primary health outcomes used included the number of blood units removed during haemodilution, duration of haemodilution, blood volume removed by haemodilution, haematocrit level during haemodilution, mean arterial blood pressure, heart rate, central venous pressure, estimated blood loss, duration of surgery, anaesthesia and hospitalisation, haematocrit levels during hospitalisation and the number of transfusions.

Effectiveness results
For all 250 patients, 3.3 (+/- 0.7) units of autologous blood was obtained from haemodilution. The mean duration of haemodilution was 49 (+/- 15) minutes. The haemodilution volume represented 29.6% of the whole blood volume. During haemodilution, the mean haematocrit level decreased from 39.7% (+/- 2.8%) at initiation to 28.3% (+/-1.7%) at completion. There was a concomitant decrease in mean arterial blood pressure during haemodilution. However, heart rate and central venous pressure remained constant. Only haematocrit levels on admission were statistically significantly different between the three groups (P<0.05). For all patients, the estimated blood volume lost was 1,555 (+/- 563) mL during radical prostatectomy of 233 (+/- 44) minutes. Duration of hospitalisation was 3.8 (+/-1) days. No patient died within 30 days of surgery. Although pre-ANH haematocrit levels were lower for patients who predonated 2 units of blood, haematocrit levels throughout the remainder of the hospitalisation were not different among the patient groups. There was a significant difference in the number of autologous blood units reinfused between the 2 PAD group (0.8 +/- 0.8 units) and the 1 PAD group (0.4 +/-0.5 units). The mean number of allogeneic blood units transfused was the same across the three groups.21% of patients in the 0 PAD group received allogeneic blood, compared to 6% and 0% of patients in the 1 PAD and 2 PAD groups (P<0.001).

Clinical conclusions
This study demonstrated that ANH was safe and effective in a large number of patients undergoing radical retropubic prostatectomy. Additionally, autologous blood collection techniques can be safely combined to achieve further decreases in allogeneic blood exposure.

Modelling
A computer program, derived from a previously published mathematical model which simulated the haemodilution, intraoperative bleeding and actual transfusion strategy, was used to calculate the volume of red blood cells saved with the autologous interventions.

Measure of benefits used in the economic analysis
The measures of benefit used included the volume of red blood cells saved and the post preoperative autologous donation haematocrit level.

Direct costs
Hospital transfusion costs were reported which amounted to the sum of blood acquisition, laboratory, administration and overhead costs. Costs were not discounted. Quantities and costs were not reported separately. The quantity/cost boundary adopted was that of the hospital. The estimation of quantities and costs was based on actual data. The price year was not stated.

**Statistical analysis of costs**
Data were analysed by using paired and unpaired two-sided t-tests, analysis of variance, or the Kruskal-Wallis test. Differences were considered to be significant if p<0.05.

**Indirect Costs**
No indirect costs were reported.

**Currency**
US dollars ($).

**Sensitivity analysis**
No sensitivity analysis was conducted.

**Estimated benefits used in the economic analysis**
For the ANH group, the mean savings in red blood cells were 112.0 mL (range: 67.0 - 253.9). For the PAD group, a net loss of -198.1 mL (range: -875.4 - 289.4) was found. PAD was accompanied by a lowering of the patients' haematocrit from a mean of 46.8% to 38.9% during the donation interval.

**Cost results**
for all patients, the overall estimated hospital transfusion costs were $184 (+/- 77). For the 2 PAD group, total transfusion costs per patient were $269 (+/- 11) in contrast with $103 (+/- 102) for the ANH group (p<0.05).

**Synthesis of costs and benefits**
Costs and benefits were not combined.

**Authors' conclusions**
This study indicates that compared with PAD, an equivalent clinical outcome at a lower cost may be achieved with moderate ANH in patients undergoing radical retropubic prostatectomy. A combination of autologous blood collection strategies (PAD and ANH) further decreases allogeneic blood exposure rates, but it increases transfusion costs and wastage.

**CRD COMMENTARY - Selection of comparators**
The rationale for the choice of the comparator is clear.

**Validity of estimate of measure of benefit**
The authors did not derive a summary measure of benefit. Hence, it was unclear on the basis of which measure the alternative procedures should be evaluated. Ultimately, the authors used an intermediate outcome measure, i.e. red blood cells saved. No attempt was made to gather data on final outcome measures.
Validity of estimate of costs
More details about the costing method could have been provided. This would help other authors assess the generalisability of the results. Although duration of hospitalisation was reported, hospitalisation costs did not seem to be included in total costs.

Other issues
It is difficult to assess the robustness of the results since no sensitivity analysis was carried out. More details could have been provided on the modelling approach.

Implications of the study
Further studies should be carried out to determine whether additional interventions can improve the benefit of ANH.

Source of funding
None stated.

Bibliographic details

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Other publications of related interest


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