Frozen preoperative autologous blood donation for heart transplantation at the Mayo Clinic from 1988 to 1999

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 preoperative autologous blood donation (PABD) for patients undergoing heart transplant. Donations of one unit of whole blood (about 450 mL) were planned up to once a month while the patient was awaiting transplantation. The collected blood was then separated into red blood cells (RBCs) that were cryopreserved using 40% glycerol.

Type of intervention
Other: blood transfusion technique.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients on the waiting list for a heart transplant between 1988 and 1999. The eligibility of patients for PABD was based on the opinions of a transfusion medicine physician and consultation with the patient's cardiologist, if necessary. Those experiencing angina or hypotensive episodes were not eligible for PABD. No exclusion criteria for allogeneic blood were reported.

Setting
The setting was a hospital. The economic study was carried out at the Mayo Clinic in Rochester (MN), USA.

Dates to which data relate
The effectiveness and resource use data were gathered from 1988 to 1999. The price year was not reported.

Source of effectiveness data
The effectiveness evidence came from a single study.

Link between effectiveness and cost data
The costing was performed retrospectively on the same sample of patients as those used in the effectiveness study.

Study sample
Power calculations to determine the sample size were not performed. All consenting eligible patients identified from 1988 to 1999 were included in the effectiveness analysis. The retrospective review of medical records identified an overall sample of 141 patients., of which 88 underwent PABD and 53 did not receive PABD. The mean age in the PABD group was 48.6 years (age range: 11 - 74) and the male-to-female ratio was 3.4:1. The mean age in the no PABD group was 44.9 years (age range: 8 - 65) and the male-to-female ratio was 3.8:1.
Study design
This was a retrospective cohort study, which was carried out in a single centre. The patients were allocated to the study groups on the basis of patient preferences and the judgement of a transfusion medicine physician. The patients were not followed after receiving the transplant.

Analysis of effectiveness
All of the patients included in the initial study sample were considered in the effectiveness analysis. The health outcomes used in the analysis were:

- the use of RBC units, PABD RBC units, allogeneic RBC units, or salvaged RBC units;
- the distribution of the average percentage of PABD units transfused per cardiac transplant patient;
- the total number of autologous units produced and transfused; and
- the trend in autologous donations.

The study groups were comparable at baseline in terms of their age and gender, but differences were noted in the mean pre-operative haemoglobin level and type of disease.

Effectiveness results
The total RBC units were 10.3 (+/- 7.2) in the PABD group and 10.5 (+/- 5.8) in the no PABD group, (p=0.834). The allogeneic RBC units were 5 (+/- 5.4) in the PABD and 7.13 (+/- 4.8) in the no PABD group, (p=0.02). The salvaged RBC units were 2.3 (+/- 3.4) in the PABD group and 3.4 (+/- 2.5) in the no PABD group, (p=0.0021).

The distribution of the average percentage of PABD units transfused per cardiac transplant patient was 28% PABD, 49% allogeneic and 23% salvaged in the PABD group, and 68% allogeneic and 32% salvaged in the no PABD group.

The total number of autologous units produced over the whole study period was 423 in the PABD group (average 5.1 +/- 1.5 units per patient), where 23% of the patients were transfused with autologous blood only. However, only 251 units were actually used. In terms of the trend in autologous donations, a mean of 21.58 (+/- 4) PABD units per year were collected at the study clinic. The numbers peaked in 1990 and 1991, but after 1995 there was a decrease in PABDs and in 1999 only one PABD was actually transfused.

Clinical conclusions
The effectiveness study showed that PDB represented an alternative and safe approach for preoperative transfusion in patients undergoing heart transplants.

Measure of benefits used in the economic analysis
The health outcomes were left disaggregated and no summary benefit measure was used. A cost-consequences analysis was therefore conducted.

Direct costs
Discounting was not performed since the costs per patient were incurred in a short time period. The unit costs were reported separately from the quantities of resources used. The health services in the economic evaluation were for PABD and allogeneic transfusion. These included testing, processing and labelling, as well as the recruitment of donors and collections for allogeneic transfusion. In addition, the costs of freezing and thawing the units were also considered. The costs of compatibility testing and blood component administration were not included. The cost/resource boundary adopted in the study appears to have been that of the hospital. The costs and resource use were estimated using data coming from the in-house work-load and cost-accounting data at the study hospital. The price year was not reported.
The costs were not inflated despite the fact that they were incurred over a long timeframe (11 years).

**Statistical analysis of costs**
The costs were treated deterministically, but statistical analyses were conducted on the quantities of resources used.

**Indirect Costs**
The indirect costs were not included.

**Currency**
US dollars ($).

**Sensitivity analysis**
Sensitivity analyses were not performed.

**Estimated benefits used in the economic analysis**
See the 'Effectiveness Results' section.

**Cost results**
The total costs of collecting and storing all PABD units was $283,500, although only 251 units were used.

The potential cost of 251 allogeneic units, which would have been used in the absence of a PABD programme, was $27,610.

**Synthesis of costs and benefits**
The costs and benefits were not combined because a cost-consequences analysis was carried out.

**Authors' conclusions**
The preoperative autologous blood donation (PABD) programme implemented at the authors' clinic was effective in reducing allogeneic blood exposure, but was financially expensive. The use of PABD decreased dramatically over time.

**CRD COMMENTARY - Selection of comparators**
The rationale for the choice of the comparator was clear. The use of PABD was compared with allogeneic blood because it represented the alternative blood supply for patients undergoing transplants. You should decide whether it represents a valid comparator in your own setting.

**Validity of estimate of measure of effectiveness**
The effectiveness analysis used a cohort study, which was appropriate for the study question. However, the retrospective nature of the design, and the lack of random allocation of the patients to the study groups, limits the internal validity of the analysis. In addition, power calculations were not conducted to justify the sample size and the study groups were not perfectly comparable at baseline. The study sample appears to have been representative of the study population.

**Validity of estimate of measure of benefit**
No summary benefit measure was used in the economic analysis. The analysis was therefore categorised as a cost-
Validity of estimate of costs
The perspective adopted in the study appears to have been that of the hospital, although this was not explicitly stated. A detailed breakdown of the costs was reported and the unit costs were analysed separately from the quantities of resource use. This makes it possible to reproduce the study in other settings. However, the price year was not reported, although it would have been useful since the economic data were collected over a long time period (11 years). The costs were specific to the study setting and sensitivity analyses were not conducted. This may limit the external validity of the results obtained. Statistical tests were only performed on the quantities of resources used. The source of the cost data was reported.

Other issues
The authors compared their findings with those of other studies that evaluated the impact of a PABD programme during heart transplantation, and similar results were obtained. However, the issue of the generalisability of the study conclusions to other settings was not addressed and sensitivity analyses were not performed. Thus, the external validity of the analysis was low.

Implications of the study
The study results suggest that the use of autologous transfusions during heart transplants is not an efficient option from the perspective of the hospital, and it should be limited to patients who have concerns about transfusion risks.

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