The effect of overnight storage of leukapheresis stem cell products on cell viability, recovery, and cost


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 overnight storage of peripheral blood stem cell products (PBSC) obtained by leukapheresis, for patients in need of haematopoietic progenitor cells for transplantation.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population consisted of cancer patients undergoing autologous PBSC transplants.

Setting
The setting was secondary care. The economic study was carried out in a hospital in the USA.

Dates to which data relate
Two studies were carried out: a prospective study with 12 patients for which no dates were given, and a retrospective study of 124 patients who were treated between January 1995 and June 1997. The effectiveness data and resources used in the retrospective study were from the period January 1995 to June 1997. No price dates were given.

Source of effectiveness data
The evidence was derived from two single studies, a prospective study of 12 patients and a retrospective study of 124 patients.

Link between effectiveness and cost data
The cost data were derived from the retrospective study.

Study sample
No power calculations were reported. The method of sample selection was not discussed. In the prospective study 12 patients were analysed. In the retrospective study there were 124 patients.

Study design
The design of the prospective study was a before and after study in one group of patients. The retrospective study was a
retrospective cohort study. The study took place in one centre. In the retrospective study, 38% of patients were lost to follow-up, the reason not being specified, although it appears to have been due to the availability of data. The duration of follow-up was not reported.

**Analysis of effectiveness**
In the prospective study, all the patients included in the study were accounted for in the analysis. The primary health outcomes used in the prospective study were the cell viability, cell recovery and engraftment success. Cell recovery was measured in percentage recovery of nucleated cells (NC) and percentage recovery of CFU-GM cells. Engraftment success was measured in days for absolute granulocyte count (AGC) to be greater than 500/microl and days for the patients’ platelet count to be greater than 20,000/microl. In the retrospective study data were presented for 78 patients. The primary health outcome used in the retrospective study was engraftment success measured as in the prospective study but stratified by CD34+ cell dose.

**Effectiveness results**
In the prospective study, 100% cell viability was achieved. 99.5% (range: 88% - 100%) of nucleated cells were recovered and 98% (range: 61% - 100%) of CFU-GM cells were recovered. The median time for patients to reach an AGC level greater than 500/microl was 11 days; the median time for patients to reach a platelet count greater than 20,000/microl was 12 days.

In the retrospective study, the median time for patients to reach an AGC level greater than 500/microl was 10 days (range: 9 - 11); the median time for patients to reach a platelet count greater than 20,000/microl was 12 days (range: 7 - 70). All engraftments were successful.

**Clinical conclusions**
PBSC products were not adversely affected by overnight storage and patient recovery was not affected by using those products.

**Modelling**
No modelling was conducted.

**Measure of benefits used in the economic analysis**
The authors stated that the use of overnight storage of PBSC products had no effect on patient outcome, therefore the economic analysis was based on cost differences only (cost-minimisation).

**Direct costs**
The costing was only performed on the retrospective study. Some quantities of resources were specified separately from costs (staff time for processing PBSC products). The perspective adopted was that of the stem-cell laboratory. Direct costs included were staff time, materials, and disposables. The method used to estimate quantities and unit costs was not reported. Discounting was not conducted as the time frame of the study was less than a year. The price year was not reported.

**Statistical analysis of costs**
Statistical analyses of costs were not performed.

**Indirect Costs**
No indirect costs were included.
Currency
US dollars ($).

Sensitivity analysis
No sensitivity analysis was carried out.

Estimated benefits used in the economic analysis
See effectiveness results above.

Cost results
In the retrospective study, cost savings were calculated on the basis of the difference in the number of final PBSC products being processed after overnight storage compared to the number of products that would have been necessary without overnight storage. There was a 33% cost saving for the processing laboratory resulting from the fact that 150 final products instead of 224 were processed and cryopreserved. A total saving due to the reduced number of products was estimated to be approximately $40,000.

Synthesis of costs and benefits
Not applicable.

Authors’ conclusions
Overnight storage and pooling of two consecutive PBSC products is safe, reduces cost and allows for optimum laboratory staffing.

CRD COMMENTARY - Selection of comparators
The implicit selection of comparator, where no overnight storage takes place, was valid. You, as a user of the database, should determine whether these are widely used health technologies in your own setting.

Validity of estimate of measure of benefit
In the prospective study, the results showed that the clinical outcomes for the patients were unaffected by the procedure of overnight storage. The authors referred to other published papers, which they stated would support their view. However it would have been helpful to have information on a comparator group in the study. The validity of the results may be affected by the presence of unknown confounding factors that may arise in before-and-after studies. In the case of the retrospective study, there may be some selection bias in the sample, as the method of sample selection was not fully reported. Analyses to account for confounding factors were not undertaken. The retrospective study only gave information on the recovery of 78 patients out of a total of 124. There may be some bias in the results if the data for missing patients were not missing randomly.

Validity of estimate of costs
Information on costs was given only for the retrospective study and this was incomplete. It was not clear exactly how the authors had reached their conclusions on cost reduction. Quantities and costs should have been reported separately. In order for other institutions to be able to benefit from adopting the procedures described by the authors, more detail needs to be given, for example on the amount of labour time used, wages, the amount of other materials used and their price. A statistical analysis of costs was not conducted. Sensitivity analyses were not conducted. The price year was not reported.

Other issues
The authors did not make appropriate comparisons of their results with findings from other economic studies and did not address the issue of generalisability to other settings. The authors did not report any limitations to their study.

Implications of the study
The authors suggest that using overnight storage for PBSC can produce significant cost-savings for high-volume stem cell laboratories.

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