
A prospective, randomized clinical trial of universal WBC reduction

Dzik W H, Anderson J K, O'Neill E M, Assmann S F, Kalish L A, Stowell C P

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 clinical and economic implications of the universal use of white blood cell (WBC)-reduced blood for transfusions were considered. The patients in the intervention arm of this study received WBC-reduced red blood cells (AS-1 anticoagulant preservative) and process WBC-reduced apheresis platelets.

Type of intervention

Treatment.

Economic study type

Cost-effectiveness analysis.

Study population

The study population comprised all hospital inpatients who receive blood products, except those with a specific clinical indication for WBC-reduced blood. The clinical indications for WBC-reduced blood were:

patients aged less than one year,

patients with an immunodeficiency,

patients with a haematological malignancy,

patients with, or candidates for, renal, heart and lung transplants, and

the prevention of recurrent febrile reactions.

Setting

The setting was secondary care. The study was undertaken at the Massachusetts General Hospital, Boston (MA), USA.

Dates to which data relate

The effectiveness and resource use data related to February 2000 to August 2000. No price year was explicitly stated in the paper.

Source of effectiveness data

The effectiveness data were derived from a single study.

Link between effectiveness and cost data

The resource use data were collected retrospectively for the same patient sample that provided the clinical effectiveness data.

Study sample

A total of 2,780 patients were included in the study. Of these, 1,425 were allocated to the control group, and 1,355 were allocated to the WBC-reduced blood group. All patients who received blood products, and were not excluded for the clinical reasons detailed above, were included in the study. Informed consent was not sought and the patients were not told they were in a trial. The authors undertook sample size calculations. These indicated that a sample of 1,312 in each treatment group was required to have an 85% chance of detecting a 15% difference in post transfusion length of hospital stay with 95% confidence (two-sided).

Study design

The study was a randomised controlled trial that was conducted in a single centre. The patients were randomised to either the intervention or control group on the basis of their unique hospital number, which are consecutively allocated to patients on their first admission to the hospital. The allocation of hospital numbers is an administrative process that cannot be influenced by any individual involved in patient care. The patients were followed up for the duration of their hospital stay. There was no loss to follow-up as the data were collected from medical records. Clinical staff, patients and their carers were unaware that the study was taking place, and were therefore blind to the type of blood products received by the patient.

Analysis of effectiveness

The primary health outcomes assessed by the study were the length of hospital stay and in-hospital mortality. The primary analysis was undertaken on an intention to treat basis. The two patient groups were comparable in terms of gender, age, whether they were undergoing surgery and type of surgery, primary diagnosis, distribution of volumes of blood transfused, and the number of patients who received blood that did not match with their study allocation.

Effectiveness results

In-hospital mortality was 9.0% in the WBC-reduced group versus 8.5% in the control group (odds ratio, OR=0.94, 95% confidence interval, CI: 0.72 - 1.22; p=0.64).

The median length of stay after transfusion was 6.3 days in the WBC-reduced group versus 6.4 days in the control group, (p=0.21).

The median total length of stay was 8.8 days in the WBC-reduced group and 8.9 days in the control group.

Clinical conclusions

The authors concluded that there was no difference in clinical outcomes between the use of WBC-reduced blood and non WBC-reduced blood.

Measure of benefits used in the economic analysis

No summary measure of benefit was used in the economic analysis. In effect, a cost-consequences analysis was undertaken.

Direct costs

This study assesses the costs to the hospital. The quantities and costs of all resources used, except the cost of processing the WBC-reduced blood products, were taken from the hospital's cost manager database. The authors assessed the cost of processing the WBC-reduced products to be \$30 per dose. The quantities and unit costs of the resources used were not reported, nor was the price year. No discounting was undertaken since the duration of the study was less than one year.

Statistical analysis of costs

The statistical difference in median total costs of the two patient groups was tested using the Wilcoxon rank sum test. No statistical analyses of the resources used or unit costs were reported.

Indirect Costs

No indirect costs were included in this study.

Currency

US dollars (\$).

Sensitivity analysis

No sensitivity analysis was undertaken.

Estimated benefits used in the economic analysis

See the 'Effectiveness Results' section.

Cost results

The median hospital costs were \$19,200 for the WBC-reduced group and \$19,500 for the control group, (p=0.24).

Synthesis of costs and benefits

Not relevant.

Authors' conclusions

There was no difference in the clinical and cost-effectiveness of white blood cell (WBC)-reduced blood products and non WBC-reduced blood products.

CRD COMMENTARY - Selection of comparators

The comparator was the natural alternative to WBC reduction, that is, no reduction. You should consider how the authors' choice of the comparator relates to usual practice in your own setting.

Validity of estimate of measure of effectiveness

The clinical effectiveness data were taken from a randomised controlled trial and the results were analysed on an intention to treat basis. The two patient groups were shown to be comparable in terms of age, gender, primary diagnosis, distribution of volumes of blood transfused, and reason for transfusion. A comprehensive analysis of sub-groups and potentially confounding factors was undertaken. This provided a robust assessment of the clinical effectiveness of the intervention. The authors did not explicitly compare their patient sample with the patient population.

Validity of estimate of measure of benefit

There was no summary measure of benefit. In effect, a cost-consequences analysis was performed.

Validity of estimate of costs

The authors did not state the economic perspective adopted in the study, but a hospital view appears to have been used. It is not possible to say whether all the appropriate costs have been included, as insufficient details of the costs were given in the paper. The paper did not report the quantities of resources used and their unit costs separately. No

sensitivity analyses of resource use or unit costs were undertaken, and the statistical analysis of the costs was limited to the total costs. These factors limit the generalisability of the study findings. The generalisability and scope for future reflation exercises is also limited by the lack of a clear price year for the data.

The significance of the difference between the median total costs of treatment for the two patient groups was assessed with an appropriate statistical test. The majority of the cost data was taken from the hospital's cost database. However, this could not provide the cost of treating blood to make WBC-reduced products. The authors estimated the costs of this process, but did not provide any justification for their estimate, nor subject it to a sensitivity analysis. The costs were not discounted, which was appropriate as the time scale was less than one year.

Other issues

The authors compared their findings with the results of other relevant studies. Their conclusions reflected the data presented in the paper. They did not explicitly consider how their findings could be generalised to other settings. The authors accepted that their study was limited to hospital care and that it was not designed to consider the long-term implications of the two treatments.

Implications of the study

The authors called for further clinical trials before the universal use of WBC-reduced blood products is adopted.

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