Peri-operative tolerance to large-dose 6% HES 200/0.5 in major urological procedures compared with 5% human albumin

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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
A 6% solution of medium-molecular-weight, hydroxyethyl 200/0.5 starch (HES) administered in doses above 20ml/kg during major blood replacement therapy.

Type of intervention

Economic study type
Cost-effectiveness analysis.

Study population
Male urological patients who had to undergo radical prostatectomy or cystectomy with bladder replacement. The following exclusion criteria were applied: weight less than 60 kg, age under 21 years, ASA 1 or 2, haemoglobin below 12 g/l, a history of clotting disorders (prothrombin time below 75%, activated partial thromboplastin time (aPTT) longer than 45 seconds, platelet count under 100 g/l), liver function disorders (elevated transaminases), advanced renal insufficiency (creatinine greater than 250 mmol/l) or hypoproteinemia (total serum protein less than 45 g/l).

Setting
A hospital setting. The economic analysis was carried out in Germany.

Dates to which data relate
The dates of the data were not given.

Source of effectiveness data
The evidence for the final outcomes was based on a single study.

Link between effectiveness and cost data
Costing appears to have been prospectively performed on the same patient sample as that used in the effectiveness analysis.

Study sample
Power calculations were not used to determine the sample size. 50 patients were randomly assigned to either the HES group with a mean (SD) age of 65 (7.1) years or the ALB group with a mean (SD) age of 64 (9.1) years.
Study design
The study was a randomised-controlled trial, carried out in a single centre. The duration of the follow-up appears to have been up to the morning of the third postoperative day. Loss to follow-up was not reported. The patients were assigned to the ALB or the HES group using random numbers. During the peri-operative observation period, measurements were made pre-operatively, at the end of surgery and on the morning of the first and third postoperative days.

Analysis of effectiveness
The principle (intention to treat or treatment completers only) used in the analysis of effectiveness was not explicitly specified. The clinical outcome measures were colloid administration on the day of surgery; haemodynamic, coagulation and renal function parameters; total serum protein and the colloid osmotic pressure; blood loss and requirement for blood components. The study groups were comparable in terms of demographic data, pre-existing diseases and ASA risk classification.

Effectiveness results
Colloid administration on the day of surgery was 38.4 ml/kg in the HES group and 35.1 ml/kg in the ALB group. Haemodynamic, coagulation and renal function parameters were similar. Although total serum protein was still different on the third postoperative day (53.45 g/l in the HES group and 60.6 g/l in the ALB group, p< 0.01) the colloid osmotic pressure always remained above 19.5 (2.5) mmHg in the HES group. Blood loss (3,810 (1,632) ml in the HES group and 3,455 (1,733) ml in the ALB group) and the requirement for blood components were comparable.

Clinical conclusions
In this study, the authors found that the haemodynamic effect of HES was comparable to that of 5% albumin throughout the whole period, and that haemodynamic-related variables remained within physiological limits.

Measure of benefits used in the economic analysis
No summary benefit measure was identified in the economic analysis, and only separate clinical outcomes were reported.

Direct costs
Costs were not discounted because of the short time frame of the cost analysis. Some quantities were reported separately from the costs. Cost items were reported separately. Cost analysis covered the cost of 6% HES 200/0.5, 5% human albumin, packed red blood cells (PRBC), and fresh frozen plasma (FFP). The perspective adopted in the cost analysis appears to have been that of a health care system. The price year was not given.

Statistical analysis of costs
Student's t test was used to compare the difference in costs between the groups.

Indirect Costs
Indirect costs were not considered.

Currency
UK pounds sterling ( ).

Sensitivity analysis
A sensitivity analysis was not conducted.
Estimated benefits used in the economic analysis
Estimated benefits used in the economic analysis were not applicable.

Cost results
At the end of the study, the average cost per patient was 482 in the HES group and 750 in the ALB group, (p<0.05).

Synthesis of costs and benefits
There was no synthesis of costs and benefits.

Authors' conclusions
Using 6% HES 200/0.5 as the only colloid for treatment, even of large blood loss, is a safe and economic alternative to albumin.

CRD COMMENTARY - Selection of comparators
The strategy of using 5% albumin, a commonly used procedure, was regarded as the comparator. You, as a database user, should consider whether this is a widely used health technology in your own setting.

Validity of estimate of measure of effectiveness
Although the internal validity of the effectiveness results was enhanced by the randomised nature of the study design, the sample size appears to be small and no power analysis was performed. Additionally, it was not explicitly stated whether the effectiveness analysis was based on intention to treat or on treatment completers only. It was acknowledged that, although intolerance reactions were not noted, they were not expected in this study because of the small sample size and the low incidence described previously in the literature. The study groups were comparable in terms of demographic data, pre-existing diseases and ASA risk classification and the study sample appears to have been representative of the study population.

Validity of estimate of measure of benefit
The authors did not derive a summary measure of health benefit. The study may therefore be regarded as a cost-consequences analysis.

Validity of estimate of costs
Positive aspects of the cost analysis were as follows: some quantities were reported separately from the costs; the perspective adopted in the cost analysis was reported; statistical analyses were performed on cost data and resource consumption. Some of the limitations of the cost analysis were that adequate detail of the methods of cost estimation were provided, the price year was not reported, the effects of alternative procedures on indirect costs were not addressed and cost results may not be generalisable outside of the study setting.

Other issues
Given the limitations of the study and the uncertainties surrounding the data, the results should be treated with some caution. The issue of generalisability to other settings or countries was not addressed. Appropriate comparisons were made with other studies. The issue of whether the study sample is representative of the study population was addressed in the authors' general comments.

Implications of the study
The authors suggest that in terms of overall health-care costs, the use of artificial colloids provides an economical, low-
risk blood replacement alternative especially in procedures involving pronounced bleeding.

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