The efficacy of tranexamic acid versus placebo in decreasing blood loss in pediatric patients undergoing repeat cardiac surgery

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
Tranexamic Acid (TA) in decreasing blood loss in pediatric patients undergoing repeat cardiac surgery.

Type of intervention
Primary prevention; treatment.

Economic study type
Cost-effectiveness analysis.

Study population
A cohort of children, male and female, undergoing repeat sternotomy and cardiopulmonary bypass.

Setting
Hospital. The economic study was carried out in Boston, USA.

Dates to which data relate
The main effectiveness data were taken from a single trial conducted between 1994 and 1996. Resource and costs data were derived from 1994-1996. The price year was 1996.

Source of effectiveness data
The estimates for final outcomes were derived from a single study.

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 population was a cohort of 43 children who underwent elective repeat cardiac surgery via sternotomy with cardiopulmonary bypass. The patients were randomly selected to receive either TA (21) or placebo (20). The age was estimated to be 3.1 years (+/- 1.8) and 3.2 years (+/- 2.2) in the placebo and TA groups, respectively (p=0.55). The preoperative hematocrit value and platelet count were estimated to be similar in the placebo and TA group (40 +/- 5 and 43 +/- 5 for the former and 261 +/- 60 and 311 +/- 59 for the latter). Power calculations to determine the patient sample were not undertaken. A multiple linear regression analysis was performed on independent variables relating to the patients' characteristics, clinical procedures, time and resources.
Study design
The study was a prospective, double-blind, randomized controlled trial. The duration of the follow-up was 24 hours. The loss to follow-up included 2 patients who were excluded from analysis due to profound intraoperative hemorrhage attributable to inadequate surgical hemostasis. One child was enrolled twice.

Analysis of effectiveness
The analysis of the clinical trial was based on treatment completers only. The primary health outcomes used in the analysis were: total blood loss, total blood transfusion volume, total red blood cell exposure, total donor exposure, time interval from aortic decannulation to sternal closure, total operating room time, duration of mechanical ventilation in the intensive care unit (ICU), hematocrit value, differences in prothrombin time (PT), partial thromboplastin time (PTT) and relevant multiple linear regression analysis results.

Effectiveness results
The total blood loss was reduced by 24% (p=0.03).
Total blood transfusion volume was reduced by 38% (p=0.04).
Total red blood cell exposure was 2 units in the TA group and 3 units in the placebo group (p=0.10).
Total donor exposure was reduced by 25% (p=0.10).
Time interval from aortic decannulation to sternal closure was 32% shorter in the TA group than in the placebo group (p=0.15).
The duration of mechanical ventilation in the ICU was 19 (+/- 2) minutes in the TA group and 17 (+/- 9) minutes in the placebo group.
The total time spent in the ICU was 48 (+/- 14) minutes in the TA group and 51 (+/- 13) minutes in the placebo group (p=0.07).
Hematocrit value was 40 (+/- 4%) in the TA group and 33 (+/- 5%) in the placebo group.
The PT values increased 0.3 (+/- 0.3) s (p<0.01)
PTT values increased 3 (+/- 5) (p=0.03).
Statistical difference was found only in bypass time (p=0.01).

Clinical conclusions
Children who received TA had less total blood loss compared with children who were treated with placebo. Furthermore, the total volume transfusion requirements and total unit exposure were less in the TA group than in the placebo group.

Measure of benefits used in the economic analysis
The outcome measures were total blood loss and total blood transfusion volume.

Direct costs
Total blood component cost was included in the analysis. Quantities were analysed separately from costs. Discounting was not applied. The quantity/cost boundary adopted was the hospital. The price year was 1996.
Statistical analysis of costs
G-squared-likelihood ratio chi-squared test, Shapiro-Wilk W-test, Mann-Whitney U-test, median +/- quartile deviation for continuous data, least-square means and p values.

Currency
US dollars ($).

Sensitivity analysis
A sensitivity analysis was not carried out.

Estimated benefits used in the economic analysis
The total blood loss was reduced by 24% (p=0.03), total blood transfusion volume was reduced by 38% (p=0.04), total red blood cell exposure was 2 units in the TA group and 3 units in the placebo group (p=0.10).

Cost results
The total blood component cost was estimated to be $495 (+/- 205) and $330 (+/- 90) in the placebo and TA group, respectively. Discounting was not applied because of the short period of follow-up.

Synthesis of costs and benefits
A synthesis of the estimated benefits and costs was not undertaken by the authors since the intervention was both more effective and less costly. An incremental analysis was not performed.

Authors’ conclusions
In pediatric patients who underwent repeat cardiac surgery, large-dose TA reduced perioperative blood loss and was therefore a cost-effective measure.

CRD COMMENTARY - Selection of comparators
The reason for the choice of the comparator was clear. TA acid decreases blood loss in patients who undergo cardiac surgery. You, as a user of this database, should consider whether these are widely used health technologies in your setting.

Validity of estimate of measure of benefit
The estimate of measure of benefit used in the economic analysis is likely to be internally valid. The data have not been used selectively.

Validity of estimate of costs
The resource quantities were reported separately from the prices. Adequate details of methods of quantity/cost estimation were given. Costs were not specifically listed.

Other issues
The authors’ conclusions were justified, given the uncertainties in the data. The issue of generalisability to other settings or countries was not addressed. Appropriate comparisons were made with other studies. Results were not presented selectively.
Implications of the study
More research into the reduction in transfusion requirements and into complications or other adverse events is required to improve its cost-effectiveness and wider use.

Source of funding
None stated.

Bibliographic details

PubMedID
9141920

Indexing Status
Subject indexing assigned by NLM

MeSH
Antifibrinolytic Agents /adverse effects /therapeutic use; Blood Coagulation /drug effects; Blood Loss, Surgical /prevention & control; Blood Transfusion; Cardiac Surgical Procedures; Child; Child, Preschool; Heart Defects, Congenital /surgery; Humans; Infant; Prospective Studies; Reoperation; Sternum /surgery; Tranexamic Acid /adverse effects /therapeutic use

AccessionNumber
21997000653

Date bibliographic record published
31/10/1998

Date abstract record published
31/10/1998