Multicentre randomized clinical trial to investigate the cost-effectiveness of an allogeneic single-donor fibrin sealant after coronary artery bypass grafting (FIBER Study).

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Abstract:

BACKGROUND: Reduction of blood transfusion in cardiac surgery is an important target. The aim of this study was to investigate the cost-effectiveness of the use of CryoSeal, an allogeneic single-donor fibrin sealant, in patients undergoing coronary artery bypass grafting (CABG).

METHODS: This randomized clinical study involved seven cardiac surgery centres in the Netherlands. Patients undergoing elective isolated CABG with the use of at least one internal thoracic artery (ITA) graft were assigned randomly to receive either CryoSeal (5ml per ITA bed) or no CryoSeal. Primary efficacy endpoints were units of transfused red blood cells, fresh frozen plasma and platelet concentrates, and duration of intensive care unit stay. Secondary efficacy endpoints were 48-h blood loss, reoperation for bleeding, mediastinitis, 30-day mortality and duration of hospital stay.

RESULTS: Between March 2009 and January 2012, 1445 patients were randomized. The intention-to-treat (ITT) population comprised 1436 patients; the per-protocol (PP) population 1292. In both the ITT and the PP analysis, no significant difference between the treatment groups was observed for any of the primary and secondary efficacy endpoints. In addition, no significant difference between the groups was seen in the proportion of transfused patients. Estimated

CryoSeal costs were 822 (95 per cent c.i. 808 to 836) per patient, which translated to 72,000 per avoided transfusion (unbounded 95 per cent c.i.).

CONCLUSION: The use of the fibrin sealant CryoSeal did not result in health benefits. Combined with the high cost per avoided transfusion, this study does not support the implementation of routine CryoSeal use in elective isolated CABG.

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