44255 - APROTININ SIGNIFICANTLY DECREASES TRANSFUSION RATES IN EXTRAPLEURAL PNEUMONECTOMY

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INTRODUCTION: Aprotinin (Trasylol™ - Bayer Corporation, West Haven, CT) is a serine protease inhibitor, which inhibits all serine proteases including plasmin. It has been used to significantly decrease blood loss during repeat cardiac surgery utilizing cardiopulmonary bypass and is currently the only pharmacologic agent approved by the FDA for this purpose. The operation of extrapleural pneumonectomy (EPP), done almost exclusively for mesothelioma, is associated with the potential for significant blood loss due to the large raw surface of the hemithorax left behind after resection of the parietal pleura. We investigated whether aprotinin would decrease blood loss and transfusion requirement in this major operation.

METHODS: After IRB approval fifteen patients were studied in this prospectively randomized, double-blind and controlled trial. Aprotinin was administered after a precautionary test dose. A loading dose of 2 million KIUs was infused over one hour followed by a maintenance infusion of 500,000 units per hour, which was continued throughout the operation until two hours into SICU admission. General anesthesia was administered per institutional routine, which included thoracic epidural analgesia for postoperative pain relief. The majority of patients were extubated in the operating room. Analysis of historical data revealed that the fourth root of estimated blood loss (EBL) was normally distributed.

RESULTS: Of the 15 patients, 5 were excluded from data analysis: 3 did not undergo EPP because of advanced disease, one died intraoperatively due to laceration of the superior vena cava, and one was withdrawn after central line trauma postponed surgery. In the 10 studied patients aprotinin significantly decreased intraoperative transfusion requirements (RR = 4.0, 95% CI 0.7–21.9; $p = 0.03$, Fisher's exact test). Only one of four aprotinin-treated patients required any transfusion (2 units). In contrast, all six placebo patients required transfusion (average 2 units, range 1 - 4). Blood loss reduction by aprotinin was clinically significant but failed to reach statistical significance (850 ± 803 mL vs. 1358 ± 761 mL; $p = 0.221$, Students t-test, mean $\pm$ S.D).

At postoperative follow-up: One aprotinin-treated patient had a CVA at 24 hours postoperatively. Median survival favors the aprotinin group (11.5 vs. 5.5 months; survival ratio = 2.1 [95%CI, 1.9 – 2.3]) but failed to reach statistical significance ($p = 0.27$).

DISCUSSION: This ongoing study suggests that aprotinin decreases blood loss and transfusion requirements during extrapleural pneumonectomy. Data will be re-analyzed after 20 patients have been appropriately studied.

REFERENCES:

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