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Economic Impact of rFVIIa in Management of Perioperative Bleeds in Burns Patients

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In addition to its more common, approved uses, activated recombinant coagulation factor VII (rFVIIa) can be beneficial to the treatment of burn injuries when excision and skin grafting are performed.

Introduction

At the Rigshospitalet, University Hospital of Copenhagen, we conducted a pilot study which aimed at investigating the effect of rFVIIa on the reduction of blood transfusion requirements in burn patients undergoing excision and skin grafting, as a possible way to reduce the cost of blood components. The results from this study enabled us to examine the overall economic impact of rFVIIa in the management of perioperative bleeds in burn patients, as well as its efficacy and safety in patients with major full thickness burn injury undergoing the treatment. The study we conducted was a single-center, randomized, double-blind, placebo-controlled trial, which took place between June 2001 and December 2003. The local Institutional Ethics Committee approved the trial protocol, and we obtained written patient consent.

Study Design

The study focused on the total number of units of blood components transfused per patient and percentage full thickness wound excised during and up to 24 hours after surgery. Furthermore, we analyzed the operating time, the number of patients with micro-vascular bleeding, percentage graft survival on day 7 after surgery, days spent in the intensive care unit (ICU) after surgery, days of hospitalization and patient survival rate on day 30 after surgery (see table 1). These observations enabled us to investigate in detail the cost of rFVIIa treatment and compare it to that of the placebo. Our study took into account 18 consecutive patients scheduled for surgery, who were randomized to receive either placebo or 40 µg/kg rFVIIa administered at first skin incision and a second dose (40 µg/kg) 90 minutes later.

Patient Outcome

The results showed that rFVIIa significantly decreased the total number of units of blood components transfused per patient and percentage full thickness burn wound excised compared with placebo (0.9 vs 2.2, p=0.0013) including significantly fewer red blood cell units (0.5 vs. 1.1, p=0.004). We further observed a trend towards improved graft survival and a reduction in multiple organ failures in the rFVIIa-treated group, possibly explained by the described association between red blood cells transfusion and infectious complications and mortality. Moreover, the number of days with sepsis was reduced in the rFVIIa-treatment group (total days: 20; mean 6.89 ±3.2) compared to the placebo group (total days: 62; mean 2.2 ± 0.8). The operating time, days spent in the ICU and days in the hospital were not significantly reduced by active treatment. Survival rate at day 30, however, considerably improved.

Cost Effectiveness

Our study showed that the mean cost of treatment using placebo or rFVIIa was similar – $65,353 for the placebo vs. $61,948 for rFVIIa treatment, at U.S. hospital discounted prices. Furthermore, although the mean cost of rFVIIa used in treatment was $7,896 (versus $0 for the placebo), the associated reduction in the mean cost of blood components exceeded $10,000 (see table 2). The increased survival rate for severe burn patients treated with rFVIIa implied a longer hospital stay, and thus a slightly higher hospital stay expense. Nevertheless, despite the cost similarities between the two treatment groups, the mean cost per survived patient was 33% lower with rFVIIa treatment (at $65,308) than in the placebo group (at $97,542).

Conclusion

Our study at Rigshospitalet reveals the potential effectiveness of rFVIIa in the treatment of severe burn patients, and we recommend further analysis on the topic with a larger dataset and/or trial data. We are confident, however, that rFVIIa is beneficial in decreasing blood transfusion requirements for excision and skin grafting, resulting in a significant cost reduction.

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