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Title **Recombinant Activated Factor VII for Prevention of Bleeding Unrelated to Hemophilia: Clinical and Economic Systematic Review**

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Aim

To assess the clinical and cost effectiveness of using recombinant activated factor VII (rFVIIa) to prevent bleeding in individuals without hemophilia, inherited platelet disorders, or other coagulopathies during liver transplantation, prostatectomy, cardiac surgery, or when needing supratherapeutic anticoagulation.

Conclusions and results

No consistent benefit of rFVIIa therapy was detected among studies evaluating the prevention of bleeding in patients undergoing prostatectomy, liver transplantation, or cardiac surgery. The risk of adverse events after the prophylactic use of rFVIIa in surgical patients is unknown. No conclusions can be drawn about the effectiveness or safety of using rFVIIa to prevent bleeding in patients who have received supratherapeutic doses of anticoagulant agents. Conclusions regarding cost effectiveness of rFVIIa cannot be made based on the available data.

Recommendations

Not applicable.

Methods

We conducted a systematic review of the clinical and economic literature that compared rFVIIa to a different dose, to a placebo, to no treatment, or to other relevant indication-specific standard therapies. Clinical outcome measures included the following: all-cause mortality; health-related quality of life; serious adverse events; thromboembolic adverse events; need for blood transfusion; volume of red blood cells (RBCs), fresh frozen plasma, cryoprecipitate, platelets, or plasma volume expander solutions transfused; operation times; and length of hospital stay. In the supratherapeutic anticoagulated patient population, the number of patients with bleeding was also included.

Further research/reviews required

More research is needed to provide more and better quality data.

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