VENTURA COUNTY MEDICAL CENTER
Protocol for Use of
VCMC Use of Recombinant Activated Factor VII (r FVII a)

The contents of this clinical practice guideline are to be used as a guide. Healthcare professionals should use sound clinical judgment and individualize patient care. This CPG is not meant to be a replacement for training, experience, CME or studying the latest literature and drug information.

Procedure: Recombinant activated Factor VII (r FVII a)

Guidelines for Appropriate Use of Factor VII:
Purpose: Recombinant activated Factor VII (r FVII a) is intended for hemostasis by activation of the extrinsic coagulation cascade. It is a vitamin K dependent glycoprotein structurally similar to human VIIa.

FDA approved indications include the treatment of severe bleeding episodes in hemophilia A and B patients with inhibitors to factor VIII or factor IX. FVII has also been shown to be useful in several animal trials and in human studies for ongoing coagulopathic bleeding despite surgical control following major trauma. This represents an off label use of r FVII a. All instances of use of this agent will be reviewed at the monthly multi-disciplinary surgery/medical conference as part of the regular blood bank report.

Policy:
When Factor VII (r FVII a) is requested a consultation with Pathologist or Hematologist is required and the following criteria must be met:

1. The patient has been transfused with one complete blood volume of PRBC (8 to 10 units)
2. Surgical control of all bleeding has been performed or in process.
3. Documented coagulopathy.
4. Attending Surgeon in presence determines that bleeding is not responsive to surgical treatment and coagulopathy will lead to death if not reversed immediately. Note: every effort shall be made to diagnose the cause and quantify the severity of the coagulopathy with laboratory tests: PT, PTT, and Fibrinogen. These laboratory tests must be ordered and samples obtained prior to administration of Factor VII a. The medication may be delivered and administered with the specific order of the attending surgeon while the laboratory tests are pending.
5. Efforts to keep patient normothermic in progress.
6. Efforts to correct acidosis in progress.

Relative Contraindications:
1. Known history of atherosclerotic coronary artery disease, ischemic cerebrovascular disease (CVA), or thromboembolic disease.
2. Patient with DIC, crush injury or septicemia.

Absolute Contraindications:
Ongoing uncontrolled surgical bleeding (e.g., Grade V splenic laceration)

Dosage:
1. Initial dose: Recombinant Factor VII (r FVII a)
   90 mcg/kg reconstituted and given as IV bolus.
2. If hemostasis is not achieved in 20 minutes, consider a second dose of 60 – 90 mcg/kg IV.
3. If second dose is not effective, consider additional PRBC, platelet, FFP, cryoprecipitate transfusion prior to a third dose.
4. Supplied as 1.0 mg/vial (1000 ug/vial), 2.0 mg/vial (2000 ug/vial), 5.0 mg/vial (5000 ug/vial).

Potential Adverse Events (<1%):
1. Myocardial infarction
2. Ischemic CVA
3. Ischemic nephropathy
4. Mesenteric ischemia
5. Development of Factors VII inhibitors

Information for Patients:

Patients receiving Novoseven should be informed of the benefits and risks associated with treatment. Patients should be warned about the early signs of hypersensitivity reactions, including hives, urticaria, tightness of the chest, wheezing, hypertension and anaphylaxis.

Reference:

LAC+USC Medical Center
Surgical ICU Handbook
Fourth edition, January 2005

Prepared by: Javier Romero, MD; Evan Slater, MD; Robert James, MD

Review/approval*:*

Blood Cmte: 3/2005; ICU - 4/2005; 8/2006; 12/2008; 3/2009
Med 4/2005; 8/2006; 12/2008 ;10/2009
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