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Use of recombinant factor VIIA for control of combat-related haemorrhage

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ABSTRACT

Background Recombinant activated human coagulation factor VII (rFVIIa), an intravascular strategy to promote clotting, is being used as an adjunct to surgical control of bleeding in combat trauma patients.

Objective To describe the initial experiences with rFVIIa administered to combat casualties at US Navy-Marine Corps medical treatment facilities in Iraq, and to compare survival outcomes of those treated with rFVIIa to controls not receiving rFVIIa.

Methods Medical encounter data from the US Navy-Marine Corps Combat Trauma Registry were retrospectively reviewed to identify all battle-injured patients documented as having received rFVIIa during the period May 2004 to January 2006 of Operation Iraqi Freedom. Available clinical and injury related data are presented to characterise the patients. To assess effects of rFVIIa on survival outcomes, rFVIIa cases were matched to controls on injury severity and age.

Results 22 battle-injured patients from the Combat Trauma Registry received rFVIIa. Primarily young US Marines, these patients typically had penetrating injuries from improvised explosive devices and gunshot wounds. Injuries were often abdominal. The average dose used was similar to that reported in another study of civilian trauma patients, although dosing varies widely in the existing experimental and anecdotal literature. Over two-thirds (68%) of the rFVIIa patients survived—an identical outcome seen for a matched control group of 22 patients.

Conclusions Survival of seriously injured combat casualties was good, although identical to that of a control group. Methodological limitations of this retrospective study preclude making firm conclusions about the effectiveness of rFVIIa. Future controlled studies are needed for safety and efficacy testing of rFVIIa in combat trauma patients.

INTRODUCTION

Blood loss is a major cause of death among combat casualties, accounting for nearly half of all deaths on the battlefield.[1 2] The great majority of these deaths is due to intracavitary haemorrhage that cannot be controlled by traditional methods such as tourniquets or pressure dressings.[3] Surgery remains the best method for controlling this type of haemorrhage and preventing death, although methods are needed to control bleeding until patients can get surgical intervention.

Although haemorrhage is responsible for a large number of combat deaths, published coagulation studies with combat patients are limited. Because of the challenges of treating haemorrhage during combat, it is important for military medical personnel to understand their options for treating haemorrhage quickly and efficiently.

Recombinant activated human coagulation factor VII (rFVIIa) is a serine protease that was originally developed for use in haemophiliac patients who have developed antibodies that inhibit or neutralise standard replacement treatment with clotting factor VIII.[3] Because of its procoagulant properties, the use of rFVIIa has been expanded to other types of patients to overcome a variety of coagulation and platelet disorders. For example, it has been used with trauma patients with massive haemorrhage and coagulation problems. Controlled animal trials, small case studies and anecdotal reports suggest that rFVIIa may slow down and even control massive bleeding in trauma, and possibly prolong survival and reduce mortality.[4] Two randomised controlled trials by Boffard and colleagues reported that, while rFVIIa resulted in reductions in red blood cell transfusion requirements among civilian severe trauma patients, survival outcomes were not significantly better than in a standard care group.[5] Regardless, rFVIIa is now being used in major trauma centres throughout the world on a case-by-case compassionate-need basis (ie, for seriously ill patients with no other treatment options).

Animal studies and civilian efficacy and safety data suggest that use of rFVIIa in the combat setting may widen the survival window of haemorrhaging casualties. Recombinant rFVIIa promotes coagulation at the site of the injury, and has other advantages that lend themselves to battlefield trauma, such as a rapid onset, short half-life[6] and ease of administration.[7] However, there may be potential drawbacks to using rFVIIa that should be considered, including complications such as unwanted thrombosis,[8] and the considerable expense of rFVIIa.[9]

Controlled trials of the effectiveness of rFVIIa in the combat setting are unlikely; therefore, assessments of rFVIIa in this environment will likely be based on descriptive data and observational studies. Spinella and colleagues recently reported results from a retrospective study of 124 combat casualties with severe trauma and massive transfusion who were admitted to a combat support hospital in Baghdad, Iraq.[10] The authors concluded that the early use of rFVIIa was associated with higher 30-day survival and not associated with increased risk of severe thrombotic events. However, another retrospective study of military and civilian trauma patients in Iraq found that early (vs late) administration of rFVIIa, while having a favourable effect on transfusion requirements, did not result in better survival.[11]

Physicians have been using rFVIIa at on-the-ground surgical units in Iraq on a compassionate-use basis, typically as an injectible adjunct to standard haemostatic manoeuvres.[4] However, there is little information about the clinical characteristics and outcome of combat casualties who receive rFVIIa. The purpose of the present study was to present available data from the Navy-Marine Corps Combat Trauma Registry (CTR) to describe the initial experiences with rFVIIa at Navy-Marine Corps medical treatment facilities (MTFs) near the front-line. We also present results of a small retrospective case-control analysis to examine outcome differences between rFVIIa patients and matched controls.

METHODS

Clinical features and disposition of rFVIIa patients are presented. In addition, a comparison group composed of casualties for the same time period that did not receive rFVIIa was used to estimate the benefit of rFVIIa on clinical outcomes.

Data for the present study came from the CTR, a deployment health database comprising trauma data captured from (1) Levels 1 and 2 Navy and Marine Corps MTFs, and (2) the Joint Theatre Trauma Registry. In addition, the CTR contains non-battle injury data, disease data, psychiatric data and routine day-to-day sick-call encounters.[12] One purpose of the CTR is to analyse combat injury patterns (particularly near the point of injury) and inform casualty management for wounded personnel throughout the medical chain of evacuation. Medical encounter forms are completed either on paper or electronically by health-care providers at Navy-Marine Corps MTFs in theatre and forwarded to CTR staff at the Naval Health Research Center (NHRC), in San Diego, CA, on an ongoing basis.

Medical encounter data from the CTR were reviewed to identify all battle-injured patients documented as having received rFVIIa during the period May 2004 to January 2006. CTR clinical staff at NHRC read narrative fields from the encounter form that were written by the provider in theatre and, in the case of evacuated patients, from clinical records completed at subsequent levels of care (ie, Army level 3 MTFs and Landstuhl Regional Medical Center). The narrative fields typically describe the injury, the circumstances surrounding the injury, treatment strategies and response to treatment. Inclusion criteria for the study included any mention of the use of rFVIIa in a narrative field. Those patients suffering a head/brain trauma exclusively were excluded from the study because they may require different treatment considerations and less is known about the safety of rFVIIa for these types of patients.[13]

The following clinical data were abstracted from each rFVIIa patient's medical record beginning with the encounter form: age at time of injury; mechanism of injury; anatomical location of primary injury; Injury Severity Score (ISS), an overall measure of severity, with scores ranging from 0–75[14 15]; rFVIIa dose; blood product utilisation near the time of rFVIIa administration; whether bleeding was stemmed as a result of any treatment (yes or no); and whether the patient survived longer than 48 h (yes or no).

To carry out the case-control portion of the study, clinical staff identified 22 contemporaneous control subjects from the CTR who were coagulopathic patients but who did not receive rFVIIa. Controls were matched to rFVIIa cases based on ISS and age. Two rFVIIa cases were missing ISS scores; therefore, the median ISS score of 24 was used to match to a control.

RESULTS

Twenty-two cases, all male, were identified as having received rFVIIa during the period of interest. Patients' mean age was 24 years (range of 19–32 years of age). Fifteen patients were Marines, five were Army personnel, one was a Navy service member and the service of one patient was unknown. About half received rFVIIa at a forward MTF (ie, level 2) and half at an Army level 3 facility.

Table 1 presents characteristics of the 22 casualties. Improvised explosive devices and gunshot wounds were the two most common mechanisms of injury (41% and 32%, respectively). Most patients were suffering from multiple anatomical site injuries at the time of rFVIIa administration. The anatomical region of the single most significant injury was the abdomen (55%) followed by injury to an extremity (27%). All but three patients received a penetrating wound (vs blunt force trauma) as their primary injury. The median ISS was 24.

Although details were incomplete, clinical records indicated that two-thirds of patients had a class 4 haemorrhage (the most severe blood loss, involving loss of more than 40% of circulating blood volume),[16] and almost all were documented as being in shock. Prior to the administering of rFVIIa, patients received 14 units of packed red blood cells on average (median) and 8 units of fresh frozen plasma on average (median). Information from clinical records was too incomplete to estimate the amount of whole blood, platelets and cryoprecipitate. Patients averaged two doses (median) of rFVIIa for a total average of 9.6 mg/kg.

A check of the matching procedure showed that the two treatment groups did not differ significantly by ISS, age, anatomical location of primary injury or mechanism of injury. Of the 22 rFVIIa patients, 15 (68%) survived for longer than 48 h. This survival rate was identical to that of the control patients. Cessation of bleeding was higher in the control group (100%) than in the rFVIIa group (75%), although the difference did not reach statistical significance ($\chi^2(1)=3.56$; $p=0.06$).

Table 1 Description of patients receiving recombinant activated human coagulation factor VII for control of bleeding

Patient number	Age	Mechanism of injury	Site of primary injury	ISS	Bleeding stemmed	Survived
1	27	IED	Extremity	34	Yes	Yes
2	19	Rocket	Pelvis	9	Yes	Yes
3	23	Mine	Extremity	10	Yes	Yes
4	24	RPG	Extremity	45	Yes	No
5	21	IED	Abdomen	29	No	Yes
6	26	IED	Extremity	9	Yes	Yes
7	22	GSW	Abdomen	32	Yes	Yes
8	21	GSW	Abdomen	41	Yes	No
9	Unk	Mortar	Abdomen	18	Yes	Yes
10	21	GSW	Flank	25	Yes	Yes
11	Unk	IED	Abdomen	17	No	Yes
12	30	IED	Flank	18	Yes	Yes
13	29	GSW	Abdomen	Unk	Unk	No
14	23	IED	Abdomen	32	Yes	No
15	22	Mortar	Abdomen	22	Yes	Yes
16	32	IED	Extremity	21	No	Yes
17	23	Mortar	Abdomen	34	Yes	Yes
18	24	IED	Abdomen	29	Yes	Yes
19	Unk	GSW	Head	Unk	No	No
20	Unk	GSW	Abdomen	26	Unk	No
21	32	GSW	Abdomen	25	No	No
22	31	IED	Extremity	10	Yes	Yes

GSW, gunshot wound; IED, improvised explosive device; ISS, Injury Severity Score; RPG, rocket propelled grenade; Unk, unknown.

DISCUSSION

Recombinant rFVIIa has largely been used in civilian trauma centres as a last-resort strategy after conventional treatments, such as large-volume resuscitation, transfusion and damage control procedures, have been tried.[4] Numerous anecdotal reports and animal models have generally supported the potential benefit of rFVIIa to treat uncontrolled bleeding, and recent randomised trials indicated a trend towards higher survival among civilian trauma patients receiving rFVIIa compared to standard care controls.[5 17–23]

Despite growing evidence from studies with civilian trauma patients, little is known about the circumstances and outcomes of the use of rFVIIa for combat-related trauma. The present 20-month retrospective study identified 22 casualties from the Navy-Marine Corps CTR who were wounded in Iraq and who received rFVIIa. Primarily young Marines, these patients typically had penetrating injuries from improvised explosive devices and gunshot wounds. The primary significant injury was often abdominal—a type of injury that is not conducive to compression/tourniquet. The typical dose used was similar to that reported by Benharash and colleagues' study of 15 civilian patients with ongoing massive bleeding.[9] However, dosing varies widely in the existing experimental and anecdotal literature, and no standard dose has been reported.[24]

We found no differences in survival outcomes between the rFVIIa group and a control group matched for injury severity and age. Over two-thirds (68%) of the rFVIIa patients and the control group survived; a notable overall percentage given that severely injured civilian trauma patients have up to a 50% mortality rate.[25 26]

While several studies have documented the benefits of rFVIIa in trauma patients, the results are somewhat mixed. For example, one study found a higher mortality among rFVIIa patients than among matched coagulopathic controls.[18] There may be a number of reasons why we did not find differences in clinical outcomes between rFVIIa patients and controls in the present study. One possibility is that there is no advantage to using rFVIIa. Another possibility is that the two groups were not matched on a missing critical variable (eg, serum lactate). The availability of rFVIIa and protocols for administering it in the combat setting during this time period are not known. In fact, rFVIIa use, timing and dosages may have occurred on a non-standard, case-by-case basis with surgeons unaware of any guidelines or policy governing the use rFVIIa.[27] It may be that rFVIIa was not used until conventional treatments had failed. Therefore, those receiving rFVIIa may have had a worse response-to-treatment history than controls, rendering the two groups non-equivalent (this point is somewhat supported by the better bleeding control outcome of the control group relative to the rFVIIa group). As one study pointed out, the use of rFVIIa as a treatment of last resort makes the identification of an appropriate control group difficult.[18] Assuming rFVIIa patients indeed had a worse response-to-treatment profile than their control counterparts, their identical survival rate is noteworthy and may be an indication of the effectiveness of rFVIIa. Clearly, this small descriptive study is not designed to formally test the efficacy of rFVIIa and results are inconclusive.

Other limitations of the study include the fact that coagulation parameters (eg, prothombin time, partial thromboplastin time, international normalised ratio) were not available from the clinical records to assess patients' haemostatic response to rFVIIa. These parameters, ideally collected both before and after administration of rFVIIa, would have been useful as a measure of rFVIIa effectiveness. The CTR is one of the first successful attempts to collect trauma data from the combat theatre so close to the time of injury. However, getting a complete clinical description of injured patients (particularly those injured in battle) is a formidable task and records are often only partially completed.

New methods of haemorrhage control are needed for use in remote surgical locations, such as the battlefield. CTR data show that rFVIIa, an intravascular approach to promote clotting at the site of vascular injury, is being used as an adjunct to surgical control of bleeding in trauma patients in the battlefield environment. The majority of patients receiving rFVIIa survived: a positive finding given that patients were in extremis. Our data did not show rFVIIa to be superior to standard care, although methodological difficulties and our small sample size preclude drawing conclusions about the relative effectiveness of rFVIIa. Additional combat studies with more complete clinical data and a larger sample are needed to evaluate the impact of rFVIIa and the conditions under which it is most effective.

The military surgeon has limited resources and the potential for being overwhelmed by many casualties, and, as a result, rFVIIa may make an important contribution to combat casualty care.[7] Recombinant rFVIIa may have a damage control role, quickly arresting blood loss until the casualty can be evacuated to a higher-echelon hospital for more definitive care. Potentially, rFVIIa could even be administered immediately after the injury by first-line medics/corpsmen, prolonging survival until surgical control of bleeding can be conducted. However, reports of unusually high rates of unwanted clots among civilians and military personnel treated with rFVIIa suggest that controlled studies are needed to establish the safety and efficacy of rFVIIa for trauma patients.[8 28]

A recent review of the evidence for rFVIIa concluded that although rFVIIa seems to be effective and safe for use with blunt trauma, its use for penetrating trauma is less convincing.[24] Those conclusions, along with results from the present small observational study, indicate that more rigorous, larger studies are needed to test rFVIIa before recommending its use in penetrating trauma.

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NHRC certifies that this research has been conducted in compliance with all applicable federal regulations governing the protection of human subjects in research (#NHRC-2003-0025).

Competing interests None.

Ethics approval This study was conducted with the approval of the Naval Health Research Center.

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Images in emergency medicine

Ultrasound scan in the emergency department revealed rare but potentially dangerous internal jugular vein thrombosis

A 39-year-old female presented in the emergency department (ED) with pain in the neck for 3 weeks and swelling on the left side of the neck over the previous 24 h. There was soft, cystic, non-tender swelling in the left side of the neck with normal overlying skin and no lymphadenopathy. An ultrasound scan was performed in the emergency department by the authors. It revealed a large thrombus occluding the lumen of left internal jugular vein (figure 1). Routine bloods revealed only raised C-reactive protein (CRP) (155). Departmental ultrasound, contrast CT and MRI confirmed internal jugular vein (IJV) thrombosis. She was given heparin and commenced on warfarin. A contrast CT for the abdomen and pelvis and a mammogram for malignancy was negative. Her CRP settled down spontaneously. She is well and under surgical follow-up. IJV thrombosis can be a manifestation of serious underlying conditions and itself can have potentially serious consequences.[1] This case illustrates the important role ultrasound can play in the ED setting in diagnosing rare but serious conditions.

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Competing interests None.

Patient consent Obtained.

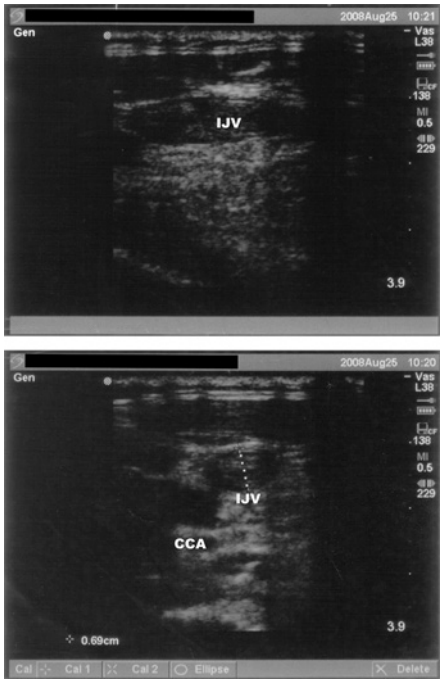

Figure 1 IJV demonstrating intraluminal thrombus in sagittal (top) and transverse (bottom) views.

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