

DOI: <https://dx.doi.org/10.18203/2320-1770.ijrcog20252173>

Original Research Article

Early intervention with recombinant factor VIIa in severe postpartum hemorrhage: a retrospective observational study for evaluation of safety and efficacy of recombinant activated factor VII

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Received: 20 June 2025

Accepted: 05 July 2025

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ABSTRACT

Background: Postpartum hemorrhage (PPH) is a critical obstetric emergency and leading cause of maternal death worldwide and in India. Despite the availability of several measures to treat PPH, maternal mortality from severe PPH remains high, highlighting the unmet need in the management of PPH. One promising development is the use of recombinant activated factor VII (rFVIIa), which has been recently approved for treatment of severe PPH in India.

Methods: This retrospective observational study compared the requirement of blood products, requirement of invasive procedures, and blood loss before and after rFVIIa administration in patients of severe PPH from two tertiary care centres in Bihar. rFVIIa was given when there was a persistent bleeding (blood loss > 1000 ml) post-sequential uterotonics administration.

Results: Only one of 47 patients with severe PPH required an invasive procedure after receiving rFVIIa; the remaining 46 responded without needing further surgical intervention. rFVIIa administration resulted in a significant reduction in blood loss, from 1215 ml pre-administration to only 219 ml post-administration ($p < 0.001$). rFVIIa administration also resulted in a significant reduction in requirement of blood products, from 3.67 units pre-administration to only 1.44 units post-administration ($n = 34$) ($p < 0.0001$). No Thromboembolic events were reported in 30 days of follow-up.

Conclusions: The study demonstrated that early use of rFVIIa in patients with severe PPH significantly reduced blood loss, blood product requirements, and the need for invasive procedures to control bleeding. When administered early in the management of severe PPH, rFVIIa offers a rapid, non-invasive, lifesaving, and fertility-preserving treatment option.

Keywords: Postpartum hemorrhage, rFVIIa, Blood loss, Invasive procedures

INTRODUCTION

Postpartum hemorrhage (PPH), a critical obstetric emergency, is a leading preventable cause of maternal mortality and morbidity worldwide, accounting for >20% of all maternal deaths.¹⁻³ The world health organization (WHO) data shows that 800 women die daily from preventable pregnancy or childbirth-related causes.⁴ The majority of maternal deaths are seen in low and middle-income countries.⁴ India and Nigeria contribute to one-

third of the global maternal mortality, and India alone contributes towards 12% of global maternal mortality.^{5,6}

The sustainable development goals (SDG) set by the United Nations aim to reduce the global MMR to less than 70/100,000 live births by 2030.³ However, Indian data shows that 70% of Indian districts (448/640) record an MMR above 70/100,000 live births, highlighting India's shortfall in achieving the UN SDG target. Obstetric hemorrhage contributes to 47% of maternal deaths in India, and the proportion is higher in poorer states.⁶

Maternal mortality and morbidity from severe PPH can be proactively reduced with active management of the third stage of labor.^{2,7-9} However, even if women survive severe PPH, they may need risky surgical interventions (compression sutures, uterine artery embolization, uterine or internal iliac artery ligation and hysterectomy) to control bleeding, resulting in loss of fertility or long-term reproductive disabilities and complications.^{1,2,9} A meta-analysis indicated that women with a history of uterine artery embolization had a higher risk of placenta accreta spectrum and PPH in subsequent pregnancies.¹⁰ Another systematic review and meta-analysis showed that emergency peripartum hysterectomies are associated with complications such as wound infection, febrile morbidity, hematological, genitourinary, gastrointestinal, cardiovascular, and thromboembolic complications.¹¹

Massive transfusions in severe PPH, while vital, carry high mortality risks due to the lethal triad (acidosis, hypothermia, coagulopathy) and other complications like electrolyte imbalances, citrate toxicity, SIRS, infection, TRALI, and multiple organ failure.^{12,13}

Recombinant factor VIIa is a newer addition into the treatment armamentarium of severe PPH and is approved by Indian health authority CDSCO in November 2022 for the treatment of severe PPH when uterotonics are insufficient to achieve hemostasis.^{14,15} European medicines agency has also approved rFVIIa for use in severe PPH with a similar indication.¹⁶ rFVIIa is already approved for the treatment of bleeding in patients with congenital hemophilia with inhibitors, acquired hemophilia, congenital factor VII deficiency and Glanzmann's thrombasthenia.¹⁵

rFVIIa works locally only at the site of injury where tissue factor (TF) and activated platelets are present. At physiological levels, rFVIIa binding to TF initiates limited thrombin production. However, pharmacological doses of rFVIIa directly activate factor X on platelet surfaces, resulting in a rapid thrombin burst. This surge facilitates the formation of a stable hemostatic plug, effectively controlling bleeding.^{17,18}

The recommended dose range for the treatment of bleeding is 60-90 mcg/kg body weight administered by intravenous bolus injection. Peak coagulant activity can be expected at 10 minutes. A second dose can be administered based on the clinical response of individual patient. It is recommended that in case of insufficient haemostatic response, a second dose can be administered after 30 minutes.¹⁵

Evidence shows that rFVIIa has the potential to improve severe PPH outcomes rapidly and quickly stabilize patients.^{2,8,19,20} rFVIIa use has also demonstrated a significant reduction in the requirement of second-line invasive procedures and blood transfusions in severe refractory PPH.^{21,22} Here, we share our experience of treating severe PPH with rFVIIa from our centres.

METHODS

This retrospective observational study aimed to evaluate the impact of rFVIIa on the requirement for blood products, the need for invasive procedures, and the extent of blood loss in severe PPH cases. The incidence of thromboembolic events as a safety outcome was also assessed. Data were collected from two tertiary care centres affiliated with government medical colleges in Bihar.

This study comprised a retrospective analysis of medical records of 47 patients with severe PPH who received rFVIIa as part of their management between August 2024 to July 2025. Patients were followed up for 30 days to monitor for any thromboembolic events.

rFVIIa was given at a dose of ~60 mcg/kg. rFVIIa was administered when persistent bleeding exceeded 1000 mL despite the sequential administration of uterotonics (oxytocin, misoprostol, methylergometrine, carboprost) and implementation of mechanical interventions (balloon tamponade, laceration repair, aortic compression, SR cannula etc). Invasive procedures (compression sutures, uterine artery embolization, and uterine or internal iliac artery ligation and hysterectomy) were considered if the bleeding was persistent after 20 min post rFVIIa administration.

Quantitative variables were analyzed using descriptive statistics, presented as mean±SD. Comparisons of quantitative variables before and after rFVIIa administration were performed using the paired samples t test or the Wilcoxon signed-rank test, as appropriate based on data distribution. A $p < 0.05$ was considered statistically significant.

RESULTS

Baseline characteristics

Forty-seven patients with severe PPH were included in the study; mean age 25.31±5.56 years; mean hemoglobin 7.36±2.81 mg/dL; 28 had vaginal delivery and 19 had caesarean section. Condition was complicated by disseminated intravascular coagulation (DIC) and jaundice in four patients each and eclampsia in one patient. Baseline characteristics of subjects are captured in (Table 1).

Table 1: Baseline characteristics.

Parameters	Value (Mean±SD)
Age (in years) (n=45)	25.31±5.56
Weight (kg) (n=27)	52.16±13.25
Hemoglobin (mg/dl) (n=45)	7.36±2.81
Platelets (cell/μl) (n=36)	1,23,929±87253

Weight, hemoglobin, and platelet level data were not available for all patients. The reported values for these parameters represent the mean calculated from the subset of patients with available data (N).

Uterine atony was the most common cause of severe PPH in 46.8% of subjects. Other causes of severe PPH are included in (Table 2).

Blood loss

Total blood loss before rFVIIa administration was 1215 ml, while it was only 219 ml after rFVIIa administration ($p<0.001$).

Requirement of blood and blood products

Total blood and blood products administered before rFVIIa administration was 3.67 units, while it was 1.44 units after rFVIIa administration. There was significant mean decrease of 2.23 units ($p<0.0001$) in requirement of

blood and blood product requirements after rFVIIa administration.

The efficacy of rFVIIa in arresting bleeding and reducing the requirements of blood and blood products is shown in Table 3.

Table 2: Causes of severe PPH (n=47).

Cause	N (%)
Trauma	9 (19.1)
Atony	22 (46.8)
Placental abnormalities	3 (6.4)
Coagulation abnormalities	4 (8.5)
Multiple causes	9 (19.1)

Table 3: Efficacy of rFVIIa.

Parameters	Before rFVIIa	After rFVIIa	Mean difference (95% CI)	Significance (P value)
Blood and blood products (n=34)	3.67±2.80 units	1.44±1.60 units	2.23 (95% CI: 1.11-3.35)	<0.0001
Blood loss (n=47)	1215.32±378.56 ml	219.57±94.73 ml	995.74 (95% CI: 885.75-1105.74)	<0.0001

(Blood products numbers were not available for all patients. The reported values for these parameters represent the mean calculated from the subset of patients with available data (N)).

Requirement of hysterectomy and invasive procedures after rFVIIa

Forty-six of 47 subjects did not require any invasive procedures (compression sutures, uterine artery embolization, and uterine/internal iliac artery ligation and hysterectomy) after rFVIIa administration to control the bleeding. One patient required compression sutures to control bleeding. Hysterectomy performed in 2 patients before administering rFVIIa. However, hysterectomy was not required in any patient after rFVIIa administration.

Efficacy outcome in patients with thrombocytopenia (platelet<50,000 cells/μl)

Platelet values were available for 36 patients; 12 of these patients had platelets<50,000 cells/μl. In those 12 patients, Total blood loss before rFVIIa administration was 1219.17 ml, while it was only 201.67 ml after rFVIIa administration ($p<0.0001$). Total blood and blood products administered before rFVIIa administration was 4.82 units, while it was 1.91 units after rFVIIa administration ($p<0.0001$).

Safety

No thromboembolic events were reported in any patient in 30 days of follow up.

DISCUSSION

This retrospective observational study reports our experience with rFVIIa in 47 cases of severe PPH from the

two centres in Bihar conducted after CDSCO approval of rFVIIa for severe PPH. The study showed that a significant reduction in blood loss and the need for blood and blood products after rFVIIa administration in subjects with severe PPH. Only one patient required invasive procedure after rFVIIa administration.

Ample evidence from international RCT, prospective studies, retrospective observational studies, registry-based studies, and case series have demonstrated the efficacy and safety of rFVIIa in significantly reducing or arresting bleeding in severe PPH.²¹⁻²⁸ Further, the use of rFVIIa significantly reduced the need for blood and blood products, invasive procedures, and hysterectomies.²¹⁻²⁸ The RCT by Lavigne-Lissalde et al demonstrated a significant relative risk reduction of 44% in the requirement of specific second-line surgical interventions (uterine compression sutures, uterine/iliac artery ligation, uterine artery embolization, or peripartum hysterectomy) in patients treated with rFVIIa versus those who were not; 52% treated with rFVII versus 93% not treated with rFVIIa required second-line treatments ($p<0.0001$).²¹ In a retrospective study, rFVIIa was administered explicitly to prevent hysterectomy in 21 cases of severe PPH. The study reported success in preventing hysterectomy in 76% of the 21 cases.²²

Early use of rFVIIa had significantly better outcomes than late use in severe PPH. A retrospective study compared the outcomes of second-line rFVIIa (after conventional modalities failed) administered within 6 hours of bleed (early use) versus after 6 hours (late use). The study

showed a significant reduction in fertility preservation ($p=0.03$), transfusion requirement ($p=0.03$), and ICU ($p=0.04$)/ hospital stay ($p=0.01$) duration in patients who received rFVIIa early compared to patients who received rFVIIa after 6 hours.²³

RCTs and registry-based studies are lacking in India. However, various retrospective studies and case series reported from India demonstrate that rFVIIa use reduced the need of blood blood products, invasive procedures, and hysterectomies.²⁹⁻³¹ A recently published study of 41 severe PPH cases from India also reported that bleeding decreased or stopped one hour after rFVIIa administration in 63% of patients.³² There was a decrease in the requirement of median number of blood component (PCV, platelet concentrates and FFP) units after rFVIIa administration.³²

With a young study population (mean age 25 years) where 40.90% of the women were primigravida, uterus preservation and the prevention of complications from invasive procedures are supremely important for their future fertility. Forty-six of the forty-seven recruited women did not need an invasive procedure after rFVIIa. Hysterectomy was not required in any women in our study after rFVIIa administration.

As discussed in the beginning, rFVIIa works on activated platelets.¹⁷ There are concerns regarding to efficacy of rFVIIa in patients with thrombocytopenia and different guidelines recommend different platelet levels to maintain before administering rFVIIa.⁸ In our study, rFVIIa was administered with 4 units of platelet concentrate if platelet counts were below 50,000/mL rFVIIa significantly reduced blood loss and blood product requirements in patients with thrombocytopenia, and none required invasive procedures to stop the bleeding.

It should be noted that a majority of women in this study were anemic at presentation, with a mean hemoglobin value of 7.36 ± 2.81 mg/dL. PPH in these women further increased the requirement of blood transfusion, over and above that would have been sufficient for low hemoglobin. Blood products were administered after rFVIIa administration mainly to improve the hemogram, not due to persistent blood loss.

Existing research shows a single rFVIIa dose can resolve severe PPH bleeding in 76-80% of cases.^{20,26,35} In our study, a single dose of ~60 mcg/kg controlled bleeding in all the patients.

Pregnancy is a hypercoagulable state, leading to an overall increased risk of thromboembolic complications during pregnancy and for up to 6 weeks postpartum. In women with PPH, this risk is further elevated, particularly in combination with operative deliveries or when massive transfusions are necessary. Consequently, establishing a definitive causal relationship between rFVIIa administration and the occurrence of a thromboembolic

event (TE) is challenging.³⁶ However, available literature do not indicate an increased risk of thromboembolism with rFVIIa use in severe PPH.^{8,36} A meta-analysis found no significant difference in thromboembolic events between women who received rFVIIa and those who did not (1.5% vs 1.6%).³⁷ Notably, this study reported no incidence of thromboembolic events despite presence of risk factors such as abruptio, C-section, eclampsia and DIC in study population.

rFVIIa can be used in various severe PPH clinical scenarios, regardless of the cause. In our study, rFVIIa was found to be effective for all causes of severe PPH (tone, tissue, trauma, thrombin). Rather than being a last resort, rFVIIa should be used early in the course of severe PPH to potentially avoid invasive procedures and their associated complications. Based on our experience, rFVIIa can serve as a bridge between initial mechanical methods and more invasive procedures, which aligns with guidance provided in the FOGSI focus document for positioning of rFVIIa.³⁸

The authors suggest that rFVIIa holds significant potential for managing PPH in rural areas of India and in small clinical setups where advanced radiological and surgical interventions and proper blood banks are unavailable. Administering rFVIIa during referral can improve a patient's condition upon arrival at a tertiary care hospital, facilitating necessary invasive procedures if required. Vertical integration between tertiary care centres and peripheral centres can optimize rFVIIa use, ensuring timely identification of appropriate cases.

The study was limited by its retrospective design and control arm. Missing data can limit data collection from medical records in government hospitals in India.

CONCLUSION

The study demonstrates that early use of rFVIIa in severe PPH significantly reduced blood loss and the need for invasive procedures and blood products. The study highlights that early rFVIIa administration can be uterus-saving and lifesaving. These results should also be extrapolated to other larger centers in India.

ACKNOWLEDGMENTS

The authors would like to express their sincere gratitude to Mediception medical writing service for their support in medical writing and editorial assistance.

Funding: No funding sources

Conflict of interest: None declared

Ethical approval: Not required

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Cite this article as: Shahi P, Pritam A, Sinha A, Pratima, Sinha G, Bibha K, et al. Early intervention with recombinant factor VIIa in severe postpartum hemorrhage: a retrospective observational study for evaluation of safety and efficacy of recombinant activated factor VII. *Int J Reprod Contracept Obstet Gynecol* 2025;14:2504-9.