CASE SERIES

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Use of eptacog beta for perioperative haemostatic management in major surgery in people with haemophilia A and inhibitors receiving emicizumab prophylaxis: A US case series

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ABSTRACT

Introduction:

Bypassing agents are required for bleed management in people with haemophilia A and inhibitors (PwHAI) undergoing major surgery, including patients on prophylaxis. In the setting of prophylaxis with emicizumab, recombinant activated factor VII (rFVIIa) is the preferred bleed treatment class for these patients.

Eptacog beta is the newest addition in the rFVIIa product class in the United States (US) and is approved in the surgical setting in the European Union. The aim of this report is to describe the safety, effectiveness, and real-world use of eptacog beta for perioperative bleed control during major surgery in PwHAI in the US using emicizumab prophylaxis.

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Methods:

This is a retrospective case series describing eight PwHAI on emicizumab prophylaxis who used eptacog beta for perioperative bleed control during major surgery (six arthroplasties, one radical nephrectomy, and one transforaminal lumbar interbody fusion) from five centres in the US. Participant characteristics, medical history, perioperative eptacog beta usage, intraoperative surgical and haemostatic outcomes, and postoperative outcomes are described.

Results:

All participants achieved haemostatic control with eptacog beta during major surgery using doses ranging from 70 to 225 µg/kg (median: 76.9 µg/kg). A median of 17 doses (range: 9–77) was used per participant. Participants were treated for a median of 5.75 days (range: 2–29). One case included intraoperative tranexamic acid and thrombin. Four individuals were switched to other haemostatic agents postoperatively due to lack of sufficient eptacog beta stock in the hospital pharmacy. Three participants received eptacog beta for the entirety of the postoperative period. One participant received eptacog alfa pre- and intraoperatively and switched to eptacog beta in the postoperative period. Intraoperatively, there were no adverse bleeding events and no need for transfusions. Postoperatively, there were no bleeds, thromboembolic events, or hospital readmission within 30 days due to bleeding or thrombosis.

Conclusion:

The results of this case series suggest that eptacog beta provided adequate haemostatic control during and after major surgical procedures in PwHAI who were on prophylaxis with emicizumab, with no safety signals observed.

Keywords:

Eptacog beta, Haemophilia, Haemostasis, Recombinant FVIIa, Sevenfact, Surgery, Case series

PLAIN LANGUAGE SUMMARY

People with haemophilia A who develop inhibitors have a higher risk of bleeding, particularly during major surgery. Even when these individuals receive prophylaxis with emicizumab, additional treatments such as bypassing agents are often needed to help control bleeding during and after surgery. Eptacog beta is a newer bypassing agent that has been approved for use in people with haemophilia A and inhibitors. This study reviewed the medical records of eight people with haemophilia A and inhibitors who were receiving emicizumab prophylaxis and underwent major surgery at five treatment centres in the United States. The surgeries included six joint replacement procedures, one kidney removal, and one spinal fusion procedure. All patients received eptacog beta, a recombinant activated factor VII (rFVIIa) bypassing agent, to help control bleeding during and/or after surgery. All eight patients achieved successful bleeding control. No excessive bleeding events occurred during the operations, and no patients required blood transfusions. Following surgery, no bleeding episodes, blood clots, or hospital readmissions related to bleeding or thrombosis within 30 days of surgery were reported. In some cases, patients were switched to alternative treatments after surgery due to limited hospital supply of eptacog beta, and not due to treatment failure. These findings suggest that eptacog beta can provide effective and safe bleeding control during and after major surgery in people with haemophilia A and inhibitors who are receiving emicizumab prophylaxis. Although the study included a small number of patients, the results add to the growing evidence supporting the use of eptacog beta in the surgical setting.

INTRODUCTION

People with haemophilia A and inhibitors (PwHAI) present a significant clinical challenge during surgery, as neutralising anti-FVIII antibodies can render standard factor replacement therapies ineffective [1]. Prophylaxis is now widely used by PwHAI, driven largely by the adoption of emicizumab (Hemlibra®, Roche Genentech) and the emergence of novel rebalancing agents, which have demonstrated substantial improvements in bleeding outcomes [2,3,4]. However, emicizumab alone may not provide adequate haemostatic control for major surgical procedures in PwHAI, necessitating the use of bypassing agents, such as activated prothrombin complex concentrate (aPCC, FEIBA®, Takeda Pharmaceuticals) or recombinant factor VIIa (rFVIIa, eptacog alfa [NovoSeven®], Novo Nordisk Inc.; eptacog beta [Sevenfact®], HEMA Biologics and LFB S.A.), to maintain perioperative haemostasis [5,6].

The use of bypassing agents for bleed management in PwHAI using emicizumab prophylaxis requires careful consideration due to potential safety risks. The concurrent use of emicizumab with aPCC (at doses ≥100 U/kg/day for ≥24 hours) has been associated with thrombotic microangiopathy (TMA) and thrombotic events [5,7]. Due to a more favourable safety profile when used in combination with emicizumab [5], World Federation of Hemophilia (WFH) guidelines and the National Bleeding Disorders Foundation's Medical and Scientific Advisory Council (MASAC) [8,9] recommend rFVIIa as the preferred bypassing agent for PwHAI on emicizumab undergoing major surgery.

While this approach is supported by clinical evidence [6,10], studies of major surgeries in PwHAI have shown perioperative haemostatic responses to bypassing agents are highly variable [11-14]. Although this variability is often attributed to the bypassing agent, it likely reflects multiple patient- and treatment-related factors, including bleeding event heterogeneity, time to treatment, inter-individual variability in response, limited familiarity with bypassing agent use, and under-dosing due to thrombotic risk [15]. PwHAI should therefore have access to multiple safe and effective treatment options, enabling the selection of the most appropriate therapy to meet their individual needs.

The most recently licensed bypassing agent is the rFVIIa eptacog beta. It was approved in the United States (US) in 2020 for the treatment of bleeding episodes in people with haemophilia A or B with inhibitors (≥12 years) [16,17]. In the European Union, eptacog beta (Cevenfacta®, LFB S.A.) is approved in adults and adolescents (≥12 years) with haemophilia A or B with inhibitors for the treatment of bleeding episodes with dosing guidelines identical to the US label. It is also licensed for the prevention of bleeding during surgery or invasive procedures in the same population [18,19]. Recommended dosing of eptacog beta in the surgical setting is indicated by the procedure type [18]. For minor surgeries, an initial dose of 75 µg/kg is given immediately prior to surgery, with additional 75 µg/kg doses every 2 hours for the first 48 hours after the initial dose. For major surgeries, an initial dose of 200 µg/kg is given immediately prior to surgery, followed by additional 75 µg/kg doses every 2 hours for the duration of surgery. The frequency of additional doses of 75 µg/kg is tapered over the postoperative course as determined by clinician judgement [18]. It is also specified in the summary of product characteristics (SmPC) that the dose, frequency, and duration of eptacog beta therapy should be based on the patient's clinical response and haemostatic evaluation [18].

Perioperative safety and efficacy of eptacog beta were evaluated in the phase 3 PERSEPT 3 trial that included 12 people with haemophilia A or B and inhibitors who underwent six minor and six major elective surgical procedures [1]. Study participants treated bleeds on demand and were not using prophylaxis. Haemostatic efficacy was rated "good" or "excellent" (meaning blood loss was as expected or only slightly above expected) in 81.8% of all surgeries. Successful haemostasis was achieved in 100% of minor surgeries and 66.7% of major surgeries. No thrombotic events or inhibitor development occurred, demonstrating a favourable safety profile. However, given that this study predated the approval of emicizumab for prophylaxis treatment in this patient population, more evidence describing the efficacy and safety of eptacog beta use for major surgeries with concomitant emicizumab use is needed [17].

A case series that included three PwHAI using emicizumab and undergoing minor surgeries (two circumcisions and one dental procedure) showed that use of eptacog beta was safe and effective in the perioperative setting [20]. An interim analysis of ATHN 16, a phase 4 real-world effectiveness study of eptacog beta in people with haemophilia A or B with inhibitors, reported the use of eptacog beta for haemostatic control during minor surgery in two participants on emicizumab prophylaxis [21]. One participant used a single ~225 µg/kg dose to successfully manage each of two procedures to treat ingrown toenails. A second participant used a single ~225 µg/kg dose along with seven doses of tranexamic acid (TXA) to successfully manage circumcision. For both participants, eptacog beta offered effective haemostatic control with no observed treatment-related adverse events. The phase 3 SCOPE HIM study (NCT05695391), launched in 2024, was designed to prospectively evaluate eptacog beta for preventing excessive bleeding in people with haemophilia A or B with inhibitors undergoing major surgery [22]. Two patients enrolled in SCOPE HIM: one patient from South Africa undergoing bilateral elbow open synovectomy, and one patient from the US undergoing total arthroplasty of the left knee, with the latter patient being described in detail in this US case series. Both major surgeries were successful, with global haemostatic response being rated "good" or "excellent" as evaluated by the independent Data Monitoring Committee, based on an aggregate score from three timepoints. No serious adverse events were reported for either patient. Unfortunately, SCOPE HIM was terminated early due to enrolment considerations, leaving a need for additional real-world evidence describing the use of eptacog beta for perioperative management of PwHAI using emicizumab.

The aim of this retrospective case series is to describe real-world haemostatic effectiveness and safety of eptacog beta for perioperative bleed management in PwHAI using emicizumab prophylaxis undergoing major surgery. This report provides practical guidance for management that may allow clinicians to make informed decisions and to adapt treatment approaches to meet the specific needs of their patients.

METHODS

Study design and data collection

This multicentre retrospective case series reports the perioperative experiences of eight PwHAI in the US using emicizumab prophylaxis who were treated with eptacog beta to maintain haemostasis during major surgery. A standardised data capture form was used to extract information from electronic medical records regarding participant characteristics and medical history, baseline (preoperative) laboratory values, perioperative surgical and haemostatic details including eptacog beta usage, and postoperative outcomes. The following haemostatic outcomes during surgery were captured:

- use of antifibrinolytics (name, dose, duration),
- volume of blood loss (including physician rating if deemed expected or excessive),
- physician rating of haemostatic outcome (excellent, good, or poor, per WFH guidelines [8]),
- number of adverse bleeding events
- transfusion requirements (if packed red blood cells, plasma, or platelets were needed and, if so, how many units), and
- use of additional haemostatic measures.

All participants were followed for 30 days postoperatively. The following postoperative haemostatic outcomes were captured:

- surgeon assessment of bleeding in the first 24/48 hours after surgery (volume of blood loss and if deemed expected or excessive),
- need for additional haemostatic interventions (name, dose, duration),
- bleeding events post-procedure (description and if deemed expected or excessive),
- hospital readmission within 30 days due to bleeding or thrombosis (description and length of readmission), and
- occurrence of thromboembolic events (details of event, treatment, and resolution).

An additional open field was provided for other relevant notes relating to post-procedure outcomes and adverse events. The study was determined to be exempt from review by the central Institutional Review Board (IRB) and by the local IRBs at all participating institutions. Informed consent was not required due to the retrospective study design and the use of de-identified anonymised data. The study was conducted in compliance with the Declaration of Helsinki and US regulations for research involving human subjects.

Study participants

Inclusion criteria were: PwHAI in the US using emicizumab prophylaxis who received eptacog beta for haemostatic control during the perioperative period of major surgery. Participants were included from five haemophilia treatment centres across the US. Participants from the discontinued SCOPE HIM clinical trial were eligible for inclusion; one participant was included in the present case series. No exclusion criteria or date limits were imposed. All cases identified by the authors and meeting eligibility criteria were included in the study. No cases were excluded.

All surgeries took place between 2021 and 2025. Major surgery was defined as an invasive operative procedure where one or more of the following occurred: a body cavity was entered, a mesenchymal barrier was crossed, a fascial plane was opened, an organ was removed, or normal anatomy was operatively altered [23]. Perioperative eptacog beta treatment was determined by the haematologist based on local practice for all participants except the participant from the SCOPE HIM study; the latter received eptacog beta per the SCOPE HIM study protocol. Haemostatic control was assessed by the surgeon to grade blood loss intraoperatively, the haematologist for overall haemostatic effectiveness, or both when available.

RESULTS

Participant characteristics

A total of eight participants were included in this series: six participants underwent arthroplasty procedures, one underwent radical nephrectomy, and one underwent transforaminal lumbar interbody fusion. All participants were male PwHAI with significant comorbidities. Participants were classified as having severe (n=5), moderate (n=2), or mild (n=1) haemophilia A. The mean age was 48.0 years (median: 50.5 years, range: 33–60) and the mean inhibitor titre was 12.7 Bethesda units (BU) (median: 7.5 BU, range: 0.3–40.9). Participant characteristics are detailed in **Table 1** and in the individual cases below.

Eptacog beta use and concomitant haemostatic medications

Three participants had used eptacog beta for treating breakthrough bleeds prior to surgery. Eptacog beta use in the perioperative period is summarised in **Table 2** and described in detail in the individual cases below.

Seven participants received perioperative eptacog beta. The administered dose varied across participants, ranging from 75 to 225 µg/kg, with a median dose of 187.5 µg/kg. The preoperative dose was given immediately prior to incision for most participants, while Participant #4 received the dose 1 hour prior to incision. Participant #7 received an initial eptacog beta dose of 40 µg/kg for arterial and central line placement, which was followed by a 200 µg/kg dose shortly before incision. Participant #8 received a preoperative 180 µg/kg dose of eptacog alfa. Four participants received intraoperative eptacog beta using doses that ranged from 70 to 87.5 µg/kg (median: 75 µg/kg); all intraoperative doses were given 2 hours after the preoperative dose regardless of surgery duration. Participant #8 received an intraoperative 90 µg/kg dose of eptacog alfa.

Of the seven participants (Participants #1-7) who received preoperative eptacog beta with or without additional intraoperative doses, haemostasis was rated as "excellent" for all five participants where a rating was provided. Six participants (85.7%, Participants #1-6) experienced blood loss during surgery of 100 mL or less, similar to expected blood loss for such surgeries in individuals without a bleeding disorder. Participant #7, who underwent transforaminal lumbar interbody fusion, experienced blood loss of 500 mL, rated "as expected" by the surgeon. No transfusions were required, and no adverse bleeding events occurred.

All eight participants achieved effective postoperative bleed control using eptacog beta. Participant #5 experienced rebleeding at the surgical site due to trauma that was not considered to be related to inadequate treatment efficacy. Three participants (Participants #1-3) were treated with eptacog beta for the entire postoperative period, while four participants (Participants #4-7) initially used eptacog beta for postoperative haemostasis and then transitioned to eptacog alfa or octocog alfa, due to product availability. Conversely, Participant #8 used eptacog alfa for initial postoperative haemostasis and transitioned to eptacog beta for postoperative day (POD) 3–8, returning to eptacog alfa after discharge. Postoperative eptacog beta use was variable, including treatment duration (median: 5.75 days, range: 2–29 days), dose (median: 75 µg/kg, range: 70–87.5 µg/kg), and dosing frequency (range: 2–12 hours). There were no incidents of post-procedure bleeding or thrombotic events or hospital readmissions within 30 days due to bleeding or thrombosis.

Five participants did not receive eptacog beta throughout the full duration of the postoperative period. Due to limited hospital pharmacy supply of eptacog beta, Participants #5-7 were switched to eptacog alfa for postoperative haemostasis. Participant #4 was transitioned to octocog alfa 24 hours after surgery, as FVIII concentrates are preferred for low-titre PwHAI. Participant #2 used two 89.1 µg/kg eptacog alfa doses on POD15 following his last dose of eptacog beta as a precautionary measure before and after physical therapy. Participant #8 initially received eptacog alfa in the postoperative period and transitioned to eptacog beta for POD3-8 before returning to eptacog alfa after discharge as not to waste product available at home.

Concomitant haemostatic medications were used for perioperative bleed control by six participants, including intraoperative or postoperative oral or topical TXA (Participants #3, #5, #6, #7, and #8), intraoperative intravenous aminocaproic acid (Participant #1), and intraoperative topical thrombin (Participant #7) **(Tables 3 and 4)**.

Safety

All participants had complete 30-day follow up. Overall, the use of eptacog beta for haemostasis during major surgery in combination with emicizumab prophylaxis, including when administered at frequent (~2 hour) or multiple doses, used sequentially with eptacog alfa or rFVIII, or given concomitantly with antifibrinolytics or topical thrombin, was not associated with any safety concerns such as thrombosis or TMA. None of the participants required hospital readmission within 30 days of surgery due to bleeding or thrombosis, or experienced post-procedure thromboembolic events or hypersensitivity reactions. As expected for PwHAI, none of the four participants with measurements (Participants #3, #4, #5, and #6) showed the occurrence of anti-FVIIa inhibitors. Details regarding intraoperative haemostatic measures and bleeding outcomes are summarised in **Table 3**. Postoperative haemostatic interventions and outcomes are summarised in **Table 4**.

TABLE 1. PARTICIPANT CHARACTERISTICS AND HISTORY

	CASE 1	CASE 2	CASE 3	CASE 4	CASE 5	CASE 6	CASE 7	CASE 8
Type of surgery	TKA (right knee)	TKA (left knee)	TKA (right knee)	Radical nephrectomy (left kidney)	TAA (right ankle)	TAA (left ankle)	Transforaminal lumbar interbody fusion	THA (left)
Age, years	50	33	52	45	51	53	60	40
Haemophilia severity	Severe	Moderate	Severe	Moderate	Severe	Mild	Severe	Severe
Weight, kg	80	101	97.5	129.3	101.2	130	98.8	117.9
Most recent inhibitor titre	40.9 BU (4 months preop)	11.0 BU (10 days preop)	18.0 BU (14 days preop)	0.8 BU (7 days preop)	0.3 BU (22 months preop)	4.0 BU (20 days preop)	26.0 BU (98 days preop)	0.6 BU (2 days preop)
Peak inhibitor titre	42.0 BU	412.8 BU	176.0 BU	0.8 BU	NR	NR	NR	12.7 BU
Comorbidities	Arthropathy, HIV, HCV, hypertension	Osteoarthritis, chronic haemophilic arthropathy, obesity, neck and back pain, prediabetes, depression	Obstructive sleep apnoea, prediabetes, HCV with SVR after treatment	HCV with SVR after treatment	HIV, HCV with SVR after treatment, obstructive sleep apnoea on CPAP, chronic pain, hypertension, benign prostatic hyperplasia	Obesity, HCV with SVR after treatment, hypertension, bipolar disorder	Degenerative disc disease, haemophilic arthropathy, HCV with SVR after treatment, cirrhosis, CAD with MI, hypertension, T2DM, dyslipidaemia, obesity, benign prostatic hyperplasia	Obesity, diabetes, asthma, extensive venous thrombosis with SVC syndrome
Eptacog beta dosing regimen for breakthrough bleeding	225 µg/kg PRN (started ~3 months prior to surgery)	69.3 µg/kg PRN	225 µg/kg initial dose, then 6 hrs later 75 µg/kg Q3H PRN (started ~3.5 yrs prior to surgery)	NA	NA	NA	NA	NA
Emicizumab dosing regimen	1.5 mg/kg once every week	1.5 mg/kg once every week	1.5 mg/kg once every week	3 mg/kg once every 2 weeks	1.5 mg/kg once every week	6 mg/kg once every 4 weeks	1.5 mg/kg once every week	1.5 mg/kg once every week
Other haemostatic treatments for breakthrough bleeding	None	None	None	Octocog alfa 50 IU/kg PRN	Eptacog alfa 79.1 µg/kg PRN	Eptacog alfa 76.9 µg/kg PRN	Eptacog alfa 91.1 µg/kg PRN	Eptacog alfa 90 µg/kg PRN
Preop lab levels								
• **FVIII**	<1%	3.0%	0.90%	4.0%	<1%	6%	<1%	<1%
• **Fibrinogen, mg/dL**	ND	354	ND	354	ND	ND	338	236
• **Hb, g/dL**	16.7	16.9	15.9	13.9	13.3	ND	15.8	13.7
• **Platelet count, 10^3/µL**	265	259	207	322	352	ND	149	306

BU, Bethesda unit; CAD, coronary artery disease; CPAP, continuous positive airway pressure; FVIII, factor VIII; Hb, haemoglobin; HCV, hepatitis C virus; HIV, human immunodeficiency virus; MI, myocardial infarction; NA, not applicable; ND, not determined; NR, not reported; PRN, as needed; Q3H, every 3 hours; SVC, superior vena cava; SVR, sustained virologic response; T2DM, type 2 diabetes mellitus; TAA, total ankle arthroplasty; THA, total hip arthroplasty; TKA, total knee arthroplasty.

TABLE 2. PERIOPERATIVE EPTACOG BETA DOSING

	CASE 1	CASE 2	CASE 3	CASE 4*	CASE 5†	CASE 6‡	CASE 7§	CASE 8○
Length of usage for surgery, days	29	15	15	2	4	3	6	5.5
Total no. of infusions	NR	77	68	13	17	9	29	13
Preoperative dose	187.5 µg/kg immediately prior to incision	200 µg/kg immediately prior to incision	225 µg/kg 2 mins pre-incision	75 µg/kg 1 hr pre-incision	80 µg/kg immediately prior to incision	76.9 µg/kg immediately prior to incision	40 µg/kg given for arterial and central line placement, 200 µg/kg given 12 mins prior to incision	NA
Intraoperative dose	87.5 µg/kg (2 hrs after preop dose)	0	75 µg/kg at end of surgery (2 hrs after preop dose)	75 µg/kg 1 hr after start of surgery (2 hrs after preop dose)	0	0	70 µg/kg (2 hrs after preop dose)	NA
No. of intraoperative infusions	1	0	1	1	0	0	2	NA
Intraoperative dosing interval (if >1 dose)	NA	NA	NA	NA	NA	NA	~2 hrs	NA
POD1 dosage	87.5 µg/kg Q3H	75 µg/kg Q2H	75 µg/kg Q2H	75 µg/kg Q2H*	79.1 µg/kg Q2H x 4 doses, then Q3H x 2 doses	76.9 µg/kg Q2H x 6 doses	70 µg/kg Q2H	NA
POD2 dosage	87.5 µg/kg Q4H	75 µg/kg Q2H	75 µg/kg Q2H	NA	79.1 µg/kg Q3H x 6 doses	76.9 µg/kg Q3H x 2 doses‡	70 µg/kg Q2H§	NA
POD3 dosage	87.5 µg/kg Q6H	75 µg/kg Q2H	75 µg/kg Q2H	NA	79.1 µg/kg Q4H x 2 doses, then Q6H x 2 doses†	NA	NA	75 µg/kg Q8H x 1 dose
POD4 dosage	87.5 µg/kg Q8H	75 µg/kg Q2H	75 µg/kg Q4H	NA	NA	NA	NA	75 µg/kg Q8H x 2 doses
POD5 dosage	87.5 µg/kg Q12H	75 µg/kg Q2H	75 µg/kg Q6H	NA	NA	NA	NA	75 µg/kg Q8H x 3 doses

* Participant #4 received octocog alfa 50 IU/kg Q8H on POD2, then 50 IU/kg Q12H on POD3 through POD6.

† Final 2 doses on POD3 were eptacog alfa 79.1 µg/kg Q6H x 2 doses. Participant #5 continued eptacog alfa 79.1 µg/kg Q12H POD4 through POD14.

‡ On POD2, following 2 eptacog beta doses, Participant #6 was switched to eptacog alfa 76.9 µg/kg Q3H x 6 doses. On POD3, dosing was reduced to Q4H x 3 doses, then Q8H x 1 dose. On POD4, he received eptacog alfa 76.9 µg/kg Q8H x 2 doses, then Q12H through POD14.

§ Participant #7 switched to eptacog alfa on POD2 and received 90 µg/kg Q3H x 6 doses, then Q3H x 2 followed by Q4H x 4 doses on POD3, Q4H x 3 doses then Q6H x 2 doses on POD4, Q6H on POD5 through POD7. He switched to eptacog beta on POD8 until discharge on POD10, at which time he switched to eptacog alfa 90 µg/kg Q12H for 7 more days.

○ Participant #8 received one preoperative dose of eptacog alfa 180 µg/kg immediately prior to incision, one intraoperative dose of eptacog alfa 90 µg/kg 2 hours after the preoperative dose, then eptacog alfa 90 µg/kg Q3H on the day of the surgery, followed by eptacog alfa 90 µg/kg Q4H on POD1, eptacog alfa 90 µg/kg Q4H for 3 doses and Q6H for 3 doses on POD2, and eptacog alfa 90 µg/kg Q6H for 3 doses on POD 3. Participant #8 was switched to eptacog beta 75 µg/kg Q8H for 1 dose on POD3, and continued eptacog beta 75 µg/kg Q8H through POD8. On POD8, Participant #8 switched to eptacog alfa 90 µg/kg Q12H through POD15.

NA, not applicable; NR, not reported; POD, postoperative day; PT, physical therapy; Q2H, once every 2 hours; Q3H, once every 3 hours; Q4H, once every 4 hours; Q6H, once every 6 hours; Q8H, once every 8 hours; Q12H, once every 12 hours; QD, once daily.

	CASE 1	CASE 2	CASE 3	CASE 4*	CASE 5†	CASE 6‡	CASE 7§	CASE 8○
POD6 dosage	87.5 µg/kg Q12H	75 µg/kg Q2H	75 µg/kg Q6H	NA	NA	NA	NA	75 µg/kg Q8H x 3 doses
POD7–14 dosage	87.5 µg/kg Q12H	75 µg/kg Q8H	75 µg/kg Q8H–Q12H	NA	NA	NA	70 µg/kg Q8H from POD8 to POD10	75 µg/kg Q8H through POD8
POD15–28 dosage	87.5 µg/kg QD with physical activity	NA	75 µg/kg as needed prior to PT	NA	NA	NA	NA	NA
Was dosing lower/less frequent than if eptacog alfa had been used?	Lower throughout; less frequent as of POD 1	Lower throughout; less frequent as of POD 7	Lower throughout; less frequent as of POD 4	Lower throughout; same frequency	Lower throughout; less frequent as of POD 1	Lower throughout; less frequent as of POD 2	Lower throughout; less frequent as of POD 7	Lower throughout; less frequent POD3-8

* Participant #4 received octocog alfa 50 IU/kg Q8H on POD2, then 50 IU/kg Q12H on POD3 through POD6.

† Final 2 doses on POD3 were eptacog alfa 79.1 µg/kg Q6H x 2 doses. Participant #5 continued eptacog alfa 79.1 µg/kg Q12H POD4 through POD14.

‡ On POD2, following 2 eptacog beta doses, Participant #6 was switched to eptacog alfa 76.9 µg/kg Q3H x 6 doses. On POD3, dosing was reduced to Q4H x 3 doses, then Q8H x 1 dose. On POD4, he received eptacog alfa 76.9 µg/kg Q8H x 2 doses, then Q12H through POD14.

§ Participant #7 switched to eptacog alfa on POD2 and received 90 µg/kg Q3H x 6 doses, then Q3H x 2 followed by Q4H x 4 doses on POD3, Q4H x 3 doses then Q6H x 2 doses on POD4, Q6H on POD5 through POD7. He switched to eptacog beta on POD8 until discharge on POD10, at which time he switched to eptacog alfa 90 µg/kg Q12H for 7 more days.

○ Participant #8 received one preoperative dose of eptacog alfa 180 µg/kg immediately prior to incision, one intraoperative dose of eptacog alfa 90 µg/kg 2 hours after the preoperative dose, then eptacog alfa 90 µg/kg Q3H on the day of the surgery, followed by eptacog alfa 90 µg/kg Q4H on POD1, eptacog alfa 90 µg/kg Q4H for 3 doses and Q6H for 3 doses on POD2, and eptacog alfa 90 µg/kg Q6H for 3 doses on POD 3. Participant #8 was switched to eptacog beta 75 µg/kg Q8H for 1 dose on POD3, and continued eptacog beta 75 µg/kg Q8H through POD8. On POD8, Participant #8 switched to eptacog alfa 90 µg/kg Q12H through POD15.

NA, not applicable; NR, not reported; POD, postoperative day; PT, physical therapy; Q2H, once every 2 hours; Q3H, once every 3 hours; Q4H, once every 4 hours; Q6H, once every 6 hours; Q8H, once every 8 hours; Q12H, once every 12 hours; QD, once daily.

TABLE 3. INTRAOPERATIVE HAEMOSTATIC MEASURES AND BLEEDING OUTCOMES

	CASE 1	CASE 2	CASE 3	CASE 4	CASE 5	CASE 6	CASE 7	CASE 8
Use of antifibrinolytics	Aminocaproic acid 1000 mg IV	None	TXA 1000 mg IV	None	None	None	TXA 2000 mg applied topically at operative site	TXA 1000 mg IV
Additional haemostatic measures	None	None	None	None	None	None	Thrombin 10,000 IU applied intra-cavity at operative site	None
Volume of blood loss	100 mL; less than expected	100 mL	100 mL; expected	50 mL	<50 mL	<50 mL	500 mL; expected	150 mL
Physician rating of haemostatic outcome	Excellent	Excellent	Excellent	ND	Excellent	Excellent	ND	ND
Transfusion requirements	None	None	None	None	None	None	None	None
Number of adverse bleeding events	None	None	None	None	None	None	None	None

IV, intravenous; ND, not determined; TXA, tranexamic acid.

TABLE 4. POST-PROCEDURE HAEMOSTATIC INTERVENTIONS AND OUTCOMES*

	CASE 1	CASE 2	CASE 3	CASE 4	CASE 5	CASE 6	CASE 7	CASE 8
Preoperative haemoglobin	16.7 g/dL	16.9 g/dL	15.9 g/dL	13.9 g/dL	13.3 g/dL	ND	15.8 g/dL	13.7 g/dL
Haemoglobin 24 hrs after surgery	13.7 g/dL	12.5 g/dL (~10.5 hrs postop), 10.5 g/dL (~35 hrs postop)	13.4 g/dL	12.6 g/dL	11.5 g/dL	ND	12.9 g/dL (~11 hrs postop)	11.1 g/dL
Haemoglobin 48 hrs after surgery	14.8 g/dL	9.8 g/dL (45.5 hrs postop)	13.7 g/dL	10.9 g/dL	11.4 g/dL (72 hrs postop)	15.1 g/dL	10.6 g/dL (~34 hrs postop), 9.9 g/dL (~58 hrs postop)	11.4 g/dL
Post-procedure bleeding events	None	None	None	None	2 bleeds (following 2 falls) on POD3	None	None	None
Use of antifibrinolytics	None	None	TXA 1300 mg TID for 14 days postop	None	TXA 1300 mg PO TID starting 6 hrs postop and continuing through POD10	TXA 1300 mg PO TID starting 6 hrs postop and continuing through POD10	None	None
Additional haemostatic interventions	None	Eptacog alfa 89.1 µg/kg twice on POD15 (after last dose of eptacog beta) before and after physical therapy session (participant used product he had available at home)	None	Octocog alfa 50 IU/kg Q8H on POD2, then 50 IU/kg Q12H on POD3 through POD6 (less costly than eptacog beta, preferred over BPAs for individuals with low-titre inhibitors)	Eptacog alfa 79.1 µg/kg Q6H x 2 doses on POD3 plus 2 additional doses of 79.1 µg/kg (1 dose after each of 2 falls), then Q12H POD4 through POD14 (switched to eptacog alfa due to insufficient hospital supply of eptacog beta)	Eptacog alfa 76.9 µg/kg Q3H x 6 doses on POD2, Q4H x 3 doses and Q8H x 1 dose on POD3, Q8H x 2 doses on POD4, then Q12H through POD14 (switched to eptacog alfa due to insufficient hospital supply of eptacog beta)	Eptacog alfa 90 µg/kg Q3H x 6 doses on POD2, Q3H x 2 doses then Q4H x 4 doses on POD3, Q4H x 3 doses then Q6H x 2 doses on POD4, Q6H on POD5 through POD7; participant switched to eptacog beta on POD8 until discharge on POD10, then switched to eptacog alfa 90 µg/kg Q12H for 7 more days (switched to eptacog alfa due to insufficient hospital supply of eptacog beta)	Eptacog alfa 90 µg/kg Q4H on POD1, 90 µg/kg Q4H for 3 doses and Q6H for 3 doses on POD2, 90 µg/kg Q6H for 3 doses on POD 3, 90 µg/kg Q12H POD8 through POD15 (switched to eptacog alfa due to insufficient hospital supply of eptacog beta)

* Participants were followed for 30 days postoperatively. All participants had complete 30-day follow up.

BPA, bypassing agent; CTA, computed tomography angiography; DVT, deep vein thrombosis; HR, heart rate; IV, intravenous; MRI, magnetic resonance imaging; ND, not determined; PE, pulmonary embolism; PO, orally; POD, postoperative day; PRN, as needed; Q3H, every 3 hours; Q4H, every 4 hours; Q6H, every 6 hours; Q8H, every 8 hours; Q12H, every 12 hours; TID, three times daily; TTE, transthoracic echocardiogram; TXA, tranexamic acid; US, ultrasound

	CASE 1	CASE 2	CASE 3	CASE 4	CASE 5	CASE 6	CASE 7	CASE 8
Discharge day	POD5	POD6	POD5	POD2	POD3	POD4	POD10	POD8
Other relevant notes relating to post-procedure outcomes and adverse events	Pain levels controlled the first 24-36 hrs. After local anaesthesia wore off, participant had usual postop pain; controlled with oxyco-done and occasional IV hydromor-phone.	Developed sinus tachycardia with HRs in the 140 range. CTA negative for PE. HR improved with IV fluids. TTE unremarkable. US negative for DVT. Suspected to be multifactorial, secondary to pain, volume depletion, and anaemia.	Knee MRI obtained at ~12 weeks demonstrated synovitis/ swelling. Treated with eptacog beta Q4H–Q8H and PO TXA 1300 mg TID.	None	None	None	None	None

* Participants were followed for 30 days postoperatively. All participants had complete 30-day follow up.

BPA, bypassing agent; CTA, computed tomography angiography; DVT, deep vein thrombosis; HR, heart rate; IV, intravenous; MRI, magnetic resonance imaging; ND, not determined; PE, pulmonary embolism; PO, orally; POD, postoperative day; PRN, as needed; Q3H, every 3 hours; Q4H, every 4 hours; Q6H, every 6 hours; Q8H, every 8 hours; Q12H, every 12 hours; TID, three times daily; TTE, transthoracic echocardiogram; TXA, tranexamic acid; US, ultrasound

Case 1 – Total knee arthroplasty in a 50-year-old PwHAI

Participant #1 was a 50-year-old male with severe haemophilia A and inhibitors who underwent a right total knee arthroplasty (TKA). He was diagnosed with haemophilia A at the age of 9 months following a central nervous system (CNS) bleed. Comorbidities included arthropathy, human immunodeficiency virus (HIV), hepatitis C virus (HCV), and hypertension. His family history included an uncle with haemophilia A and a high-titre inhibitor.

Participant #1 had previously undergone two rounds of immune tolerance induction (ITI), the first at 16 years of age and the second at 44, both of which were unsuccessful. His highest inhibitor titre was 42.0 BU, recorded during the first round of ITI. His most recent inhibitor titre measured 4 months before surgery was 40.9 BU. Prior to the age of 46 years, his annualised bleed rate (ABR) was 30 to 36, and he used a combination of eptacog alfa and aPCC for on-demand treatment of bleeding episodes and/or short-term prophylaxis (100 IU/kg of aPCC three times weekly). At the age of 46, he started emicizumab prophylaxis (1.5 mg/kg weekly), reducing his ABR to approximately 4, and continued treatment with emicizumab for 2 years. At the age of 48, he developed unusual and lingering joint/muscle pain and opted to discontinue emicizumab due to concerns of persisting myalgia. Participant #1 resumed on-demand treatment of bleeding using eptacog alfa (250 µg/kg average infusion dose) and aPCC (93.75 IU/kg average infusion dose) as needed, with his ABR returning to approximately 30.

At the age of 49 years, Participant #1 requested TKA following admission for right knee haemarthrosis associated with worsening pain and decreased range of motion. Three months before the surgery, he began treating bleeding events with eptacog beta, using an initial dose of 225 µg/kg due to a documented history of inadequate response to 250 µg/kg eptacog alfa. Six weeks before the surgery, emicizumab (1.5 mg/kg weekly) was restarted to optimise haemostasis during the perioperative period.

TKA was performed one year after the initial request. Participant #1 received a single 187.5 µg/kg dose of eptacog beta immediately prior to incision, and an 87.5 µg/kg intraoperative dose was administered 2 hours later. The surgery lasted approximately 2.5 hours. He also received 1000 mg aminocaproic acid intravenously during surgery. Excellent haemostasis was achieved intraoperatively with estimated blood loss less than expected at 100 mL. No transfusion or other haemostatic measures were required during surgery, and no adverse bleeding events occurred.

On POD1, 87.5 µg/kg eptacog beta was administered every 3 hours, and was reduced to every 4 hours on POD2, every 6 hours on POD3, and every 8 hours on POD4. On POD5, he was discharged and continued on 87.5 µg/kg eptacog beta every 12 hours from POD5 through POD14. Joint mobilisation was initiated successfully on POD2, with range of motion significantly improved by discharge on POD5. Eptacog beta was well tolerated and no postoperative safety signals (including thrombosis or TMA) were observed. No post-procedure bleeding events, thromboembolic complications, hospital readmission, or hypersensitivity reactions occurred. The haematologist, surgeon, and participant cited satisfactory response to treatment with eptacog beta.

Case 2 – Total knee arthroplasty in a 33-year-old PwHAI

Participant #2 was a 33-year-old male with moderate haemophilia A and inhibitors who underwent TKA on his left knee. Comorbidities at the time of surgery included osteoarthritis, chronic pain of multiple joints, haemophilic arthropathy (left knee, left elbow, right ankle), obesity, and neck and back pain. His medical history included fatty liver disease, increased intraocular pressure, prediabetes, and depression. Participant #2 underwent one round of unsuccessful ITI approximately 7 to 8 years earlier, with an inhibitor titre of 412.8 BU before and a titre of 76.8 BU after ITI. His most recent inhibitor titre of 11.0 BU was measured 10 days prior to surgery. Leading up to surgery, he used emicizumab (1.5 mg/kg weekly) for prophylaxis and 69.3 µg/kg eptacog beta (average infusion dose) as needed to manage breakthrough bleeding.

Immediately prior to the surgical incision, Participant #2 received an initial dose of 200 µg/kg eptacog beta. No additional intraoperative dosing was given during the 1 hour and 43 minute procedure. Surgical haemostasis was rated as "excellent" by the surgeon, with an estimated 100 mL volume of blood loss. There were no bleeding-related adverse events, and no concomitant haemostatic medications or transfusions of blood products were required.

Participant #2 was on bed rest for 72 hours postoperatively per instructions from the treating haematologist. Bed-only mobility was initiated on POD1 and weight-bearing was started during occupational therapy/physical therapy sessions on POD4. Eptacog beta was used for 15 days postoperatively. From POD1 through POD6, he received 75 µg/kg eptacog beta every 2 hours, which was reduced to every 8 hours from POD7 through POD14. On POD15 following the last dose of eptacog beta, he used two 89.1 µg/kg doses of eptacog alfa (as this was the agent he had available at home) as a precautionary measure before and after physical therapy.

The surgeon's assessment of bleeding 24 hours after the procedure included a wound rating of "good" with zero drainage on the bandage; the drain output was 290 mL, exceeding expected levels by more than 20% but less than 50% compared with individuals without bleeding disorders undergoing the same procedure. He was discharged on POD6 and recovery was continued at home. No post-procedure bleeding events, thromboembolic complications, or hospital readmissions were recorded. On POD12, he experienced itching at the surgical site, which was managed with one 10 mg dose of cetirizine. The haematologist, surgeon, and participant all reported being satisfied with the response to treatment with eptacog beta.

Case 3 – Total knee arthroplasty in a 52-year-old PwHAI

Participant #3 was a 52-year-old male with severe haemophilia A and inhibitors who underwent TKA on his right knee. At the time of surgery, his comorbidities included obstructive sleep apnoea, prediabetes, and HCV with sustained virologic response (SVR) following treatment. His medical history included significant joint bleeding resulting in haemophilic arthropathy. Four years before surgery, he switched from eptacog alfa to eptacog beta due to requiring regular infusions with eptacog alfa to achieve haemostasis and recovery from joint bleeds. He reported using a 225 µg/kg initial dose of eptacog beta, followed by 75 µg/kg starting at 6 hours and continuing every 3 hours as needed to treat breakthrough bleeding. He underwent two rounds of unsuccessful ITI, the most recent approximately 10 years prior to surgery, with an inhibitor titre of 7.8 BU before ITI and a titre of 176.0 BU after ITI. His most recent inhibitor titre, measured 14 days before surgery, was 18 BU. He was receiving emicizumab 1.5 mg/kg weekly for prophylaxis for approximately 9 years prior to surgery.

Perioperative eptacog beta use lasted for 15 days. Participant #3 received one preoperative 225 µg/kg dose of eptacog beta 2 minutes prior to incision, and one 75 µg/kg intraoperative dose at the end of surgery. The surgery lasted 1 hour and 57 minutes. The surgeon's rating of haemostasis during surgery was "excellent", with a volume of blood loss of 100 mL. Antifibrinolytic therapy with TXA was initiated preoperatively at 1000 mg intravenously and continued postoperatively for 14 days at 1300 mg orally three times daily. During surgery, there were no bleeding adverse events, and no additional haemostatic medications or transfusions were required.

Postoperatively, Participant #3 received 75 µg/kg eptacog beta as follows: every 2 hours on POD1 through POD3, every 4 hours on POD4, every 6 hours on POD5 and POD6, every 8 to 12 hours on POD7 to POD14, and finally on an as-needed basis prior to physical activity from POD15 through POD28. The surgeon's assessment of bleeding 24 and 48 hours following the procedure was "as expected" with no need for additional haemostatic interventions.

Participant #3 was discharged on POD5. Though outside of the perioperative time frame, he experienced six breakthrough bleeds in the right knee between 7 and 12 weeks postoperatively. An MRI of the right knee at 12 weeks showed synovitis and swelling that was successfully treated with eptacog beta 75 µg/kg every 4 to 8 hours and TXA 1300 mg three times daily. No other bleeds, thromboembolic events, hospital readmission, or hypersensitivity reactions were noted. A satisfactory response to treatment with eptacog beta was reported by the haematologist, surgeon, and participant.

Case 4 – Radical nephrectomy in a 45-year-old PwHAI

Participant #4 was a 45-year-old male with moderate haemophilia A who underwent radical nephrectomy of the left kidney due to a lower pole renal mass. His comorbidities at the time of surgery included HCV with SVR after treatment. He reported approximately one bleed per year on average throughout his life and used 50 IU/kg octocog alfa (Advate®, Takeda Pharmaceuticals Inc.) as needed to manage breakthrough bleeding. Approximately 2 years prior to surgery, he began prophylaxis with 3 mg/kg emicizumab every 2 weeks for recurrent bleeding in the right knee (two bleeds 1 year before starting emicizumab and one bleed 1 month before starting emicizumab).

Two months before surgery, Participant #4 was diagnosed with FVIII inhibitors. He had no previous history of inhibitors. His peak inhibitor titre, considered low, was 0.8 BU, measured 7 days before surgery. His lowest FVIII level was 2%; thus, his haemophilia severity remained moderate. In the 5 months prior to the inhibitor diagnosis, he sustained five spontaneous haemarthroses in bilateral ankles and the right knee. His right ankle was identified as a target joint. Per physician assessment, FVIII inhibitors likely contributed to these haemarthroses. Following the inhibitor diagnosis, he continued to treat breakthrough bleeds with 50 IU/kg octocog alfa.

Following institutional medication policy, Participant #4 received one preoperative 75 µg/kg dose of eptacog beta 1 hour prior to incision, and one intraoperative 75 µg/kg dose 2 hours later. The surgery lasted 2 hours and 23 minutes, and the total estimated blood loss during surgery was 50 mL.

Postoperatively, Participant #4 received eptacog beta at 75 µg/kg every 2 hours for 24 hours for a total of 13 doses as a precaution against a potential unexpected rise in inhibitor titre. As the participant was clinically stable at 24 hours, therapy was transitioned to 50 IU/kg octocog alfa, which is less costly than eptacog beta and preferred over bypassing agents for individuals with low-titre inhibitors. Octocog alfa was administered every 8 hours on POD2 and continued every 12 hours from POD3 through POD6. Participant #4 did not require additional haemostatic medications or transfusions, and no bleeding adverse events were observed. He was discharged on POD2. No post-procedure bleeding, thromboembolic, or hypersensitivity events were reported. Satisfaction rating of surgeon, haematologist, and participant for response to eptacog beta was "satisfied".

Case 5 – Total ankle arthroplasty in a 51-year-old PwHAI

Participant #5 was a 51-year-old male with severe haemophilia A and inhibitors who underwent right total ankle arthroplasty (TAA). Comorbid conditions included HIV, HCV with SVR following treatment, obstructive sleep apnoea on continuous positive airway pressure (CPAP), chronic pain, hypertension, and benign prostatic hyperplasia. His medical history included chronic inhibitors. His most recent inhibitor titre was 0.3 BU, measured 22 months prior to surgery. Participant #5 experienced frequent bleeding episodes while treating on demand with eptacog alfa; bleeds were reduced with emicizumab prophylaxis (1.5 mg/kg weekly). He used eptacog alfa (79.1 µg/kg average infusion dose) as needed for the treatment of breakthrough bleeds.

Following the hospital formulary conversion to eptacog beta, driven by favourable clinical outcomes and cost considerations, Participant #5 received one 80 µg/kg preoperative dose of eptacog beta immediately prior to incision and no intraoperative dose during the surgery which lasted 1 hour and 12 minutes. No concomitant haemostatic medications or transfusions were used during surgery. Surgeon-rated haemostasis during surgery was "excellent" with an estimated blood loss volume of <50 mL.

Antifibrinolytic therapy with TXA (1300 mg orally three times daily) was started on POD1 and continued for 10 days. Perioperative eptacog beta use lasted 4 days for a total of 17 infusions. Eptacog beta (79.1 µg/kg) was administered from POD1 through POD3. On POD1, he received eptacog beta every 2 hours for four doses followed by every 3 hours for two doses. On POD2, eptacog beta was administered every 3 hours for six doses. At 24 and 48 hours postoperatively, the surgeon noted no worrisome bleeding and no need for additional haemostatic intervention. On POD3, eptacog beta dosing intervals were extended to every 4 hours for two doses then every 6 hours for two doses. On POD3, Participant #5 was switched to eptacog alfa due to insufficient hospital supply of eptacog beta and received two doses of 79.1 µg/kg every 6 hours prior to discharge that same day. On POD3, after leaving the hospital, he experienced two falls that resulted in trauma-related swelling at the surgical site, presumably from bleeding. He managed the bleeding with two additional 79.1 µg/kg doses of eptacog alfa as this was the product he had available at home. He continued 79.1 µg/kg eptacog alfa every 12 hours from POD4 through POD14. No other bleeds, thromboembolic events, hospital readmission, or hypersensitivity reactions occurred. Haematologist, surgeon, and participant satisfaction rating of response to eptacog beta was "satisfied".

Case 6 – Total ankle arthroplasty in a 53-year-old PwHAI

Participant #6 was a 53-year-old male with mild haemophilia A and inhibitors who underwent TAA on his left ankle. At the time of arthroplasty, his comorbidities included obesity, HCV with SVR following treatment, hypertension, and bipolar disorder. His medical history included a recent onset of inhibitors at the age of 53 (most recent inhibitor titre of 4.0 BU, measured 20 days prior to surgery). Participant #6 used emicizumab prophylaxis (6 mg/kg every 4 weeks) and treated breakthrough bleeds using 76.9 µg/kg eptacog alfa (average infusion dose) as needed.

Following the decision to proceed with major surgery, a management plan was developed based on institutional drug policy and eptacog beta was selected for perioperative bleed management due to safety, efficacy, and cost evaluations. Participant #6 received one preoperative 76.9 µg/kg dose of eptacog beta immediately prior to incision; no intraoperative dose was given. The surgeon rated intraoperative haemostasis as "excellent", indicating blood loss was <50 mL. He did not require a transfusion or other haemostatic measures during surgery.

Antifibrinolytic therapy with 1300 mg TXA orally three times daily was started on POD1 and continued for 10 days. Perioperative eptacog beta use lasted 3 days, with a total of nine 76.9 µg/kg infusions. Participant #6 received 76.9 µg/kg eptacog beta every 2 hours on POD1, and every 3 hours on POD2 for two doses before being switched to 76.9 µg/kg eptacog alfa due to insufficient hospital supply of eptacog beta. Eptacog alfa dosing was tapered through POD14. At 24 and 48 hours after surgery, no bleeding was noted by the surgeon and no additional haemostatic interventions were required. He was discharged on POD4. No bleeding-related adverse events were reported. The remainder of his recovery was unremarkable with no reports of bleeds, thromboembolic events, hospital readmission, or hypersensitivity reactions. The haematologist, surgeon, and participant reported a satisfactory treatment response with eptacog beta.

Case 7 – Transforaminal lumbar interbody fusion in a 60-year-old PwHAI

Participant #7 was a 60-year-old male with severe haemophilia A and inhibitors who underwent transforaminal lumbar interbody fusion to treat degenerative disc disease. He had several comorbid conditions including haemophilic arthropathy, HCV with SVR after treatment, cirrhosis, cardiovascular disease, hypertension, diabetes, dyslipidaemia, obesity, benign prostatic hyperplasia, and periodontal disease. His inhibitor titre was 26.0 BU, measured 98 days prior to surgery. He used 1.5 mg/kg emicizumab weekly for prophylaxis and treated breakthrough bleeds using 91.1 µg/kg eptacog alfa (average infusion dose) as needed.

With major surgery determined to be the appropriate course of action, the care team developed a management plan aligned with hospital pharmacy recommendations, selecting eptacog beta based on its established safety, efficacy, and cost profile. Participant #7 received one 40 µg/kg dose of eptacog beta prior to surgery for arterial and central line placement, and a second 200 µg/kg dose 12 minutes prior to incision, given 56 minutes apart. He received two intraoperative 75 µg/kg doses approximately 2 hours apart in addition to intraoperative TXA (2000 mg) and thrombin (10,000 IU) applied intra-cavity at the operative site, as per the surgeon's routine practice. The estimated blood loss during surgery was 500 mL and was rated "as expected" by the surgeon. No adverse bleeding events occurred and there was no need for transfusion or additional haemostatic medications during surgery.

Participant #7 received 70 µg/kg eptacog beta postoperatively every 2 hours for 12 doses on POD1 and five doses on POD2, before he was transitioned to 90 µg/kg eptacog alfa every 3 hours for four doses due to insufficient hospital supply of eptacog beta. On POD3, 90 µg/kg eptacog alfa was continued every 3 hours for three doses and then reduced to every 4 hours for four doses. On POD4, dosing was further spaced from every 4 hours (three doses) to every 6 hours (two doses) and maintained at that dosage until POD7. On POD8, Participant #7 was switched back to 70 µg/kg eptacog beta every 8 hours until POD10, at which point he was discharged with instructions to use 90 µg/kg eptacog alfa, the product he had available at home, every 12 hours for an additional 7 days. His recovery was uneventful, with no bleeding episodes, thromboembolic complications, hospital readmissions, or hypersensitivity reactions reported. The haematologist, surgeon, and participant reported a satisfactory treatment response with eptacog beta.

Case 8 – Total hip arthroplasty in a 40-year-old PwHAI

Participant #8 was a 40-year-old male with severe haemophilia A and inhibitors who underwent left total hip arthroplasty (THA). At the time of arthroplasty, his comorbidities included obesity, diabetes, asthma, and extensive venous thrombosis (bilateral brachiocephalic veins and the lower internal jugular veins) with superior vena cava (SVC) syndrome. He had an extended history of high-titre inhibitors, with a peak level of 12.7 BU recorded 13 years earlier. His most recent inhibitor titre was 0.6 BU, measured 2 days prior to surgery. Participant #8 used emicizumab prophylaxis (1.5 mg/kg once weekly) and treated breakthrough bleeds with eptacog alfa 90 µg/kg (average infusion dose) as needed.

In line with patient preference and to utilise existing inpatient stocks and prevent drug wastage, eptacog alfa was used for perioperative bleed control through POD3. Participant #8 was then transitioned to eptacog beta, the preferred rFVIIa in the institutional medication policy. He received one preoperative eptacog alfa dose of 180 µg/kg 38 minutes prior to incision, and one intraoperative dose of 90 µg/kg 2 hours later. The surgery lasted 1 hour and 22 minutes, and the estimated volume of blood loss was 150 mL. A single dose of 1000 mg intravenous TXA was given preoperatively. During surgery, there were no bleeding adverse events, and no additional haemostatic medications or transfusions were required.

Postoperatively, Participant #8 received 90 µg/kg eptacog alfa every 3 hours for four doses, followed by every 4 hours for nine doses through POD2 and every 6 hours for six doses on POD2-3. Thereafter, he was transitioned to 75 µg/kg eptacog beta every 8 hours until discharge on POD8. After discharge, he transitioned back to eptacog alfa as this was the rFVIIa product he had at home. A CT obtained on POD7 due to decreasing haemoglobin with persistent pain and swelling demonstrated no evidence for active arterial bleeding and he was discharged the next day. After discharge, Participant #8 was scheduled to continue 90 µg/kg eptacog alfa every 12 hours through POD14. However, he reported missing ~2 doses of 90 µg/kg eptacog alfa at home and subsequently presented to the emergency department on POD13 for groin pain and chest pain. An X-ray of his left hip was performed with no acute findings. A chest X-ray was unremarkable and acute coronary syndrome workup was negative (high-sensitivity troponin levels normal at 0 and 2 hours, B-type natriuretic peptide levels normal, and electrocardiogram [ECG] showed normal sinus rhythm, non-specific T wave abnormality, and prolonged QT not significantly changed from prior ECGs). Chest pain resolved while the participant was in the emergency department. He was discharged and continued 90 µg/kg eptacog alfa every 12 hours through POD15 due to pain. He administered a single preventative 90 µg/kg dose of eptacog alfa on POD16 due to increased activity at his follow-up orthopaedic appointment. Additionally, he administered a single 90 µg/kg dose of eptacog alfa on POD19 for hip pain, although the pain was considered unlikely to be bleeding-related due to the lack of improvement following eptacog alfa administration. The remainder of his recovery was unremarkable with no reports of bleeds, thromboembolic events, hospital readmission, or hypersensitivity reactions. The haematologist, surgeon, and participant reported being satisfied with the treatment response to eptacog beta.

DISCUSSION

Real-world data describing the use of eptacog beta for perioperative bleed control in PwHAI on emicizumab prophylaxis undergoing major surgery is needed to guide clinical decision-making and optimise haemostatic outcomes. This case series is the first to detail the experiences of eight PwHAI in the US receiving emicizumab prophylaxis who used eptacog beta for bleed control during and/or after major surgeries including six arthroplasty procedures, one radical nephrectomy, and one transforaminal lumbar interbody fusion. Overall, eptacog beta provided successful haemostasis for all participants, with no bleeding-related adverse events. Moreover, effective haemostatic control was achieved in all participants, irrespective of haemophilia severity. Of the eight participants included in this case series, five had severe haemophilia, two had moderate haemophilia, and one had mild haemophilia. These findings suggest that eptacog beta provided consistent perioperative haemostatic efficacy across disease severities, including in participants with severe haemophilia, who are at the greatest risk for bleeding complications during surgery.

For seven participants, an individualised pre-, intra-, and postoperative eptacog beta dosing protocol was selected by their clinician and tailored to their specific haemostatic needs that considered patient preference, the surgery type and duration, bleeding history, patient-specific risk factors, and institutional pharmacy guidelines. This approach is consistent with European Medicines Agency (EMA) guidance regarding the use of eptacog beta for perioperative bleed control, where dose and dosing intervals may be adjusted by the healthcare provider based on the clinical assessment and known patient responsiveness to rFVIIa-containing bypassing agents when used for major surgery [18]. The remaining participant was from the SCOPE HIM study, and eptacog beta dosing for this participant was determined by the study protocol.

The results of this study indicate that patients may safely transition between eptacog beta and eptacog alfa in the perioperative period without compromising haemostatic control and without experiencing bleeding adverse events. These data are clinically relevant as hospital formularies may choose to stock eptacog beta not only due to its lower cost but also because of its efficacy and safety profile. Thus, patients undergoing major surgery who use eptacog alfa for breakthrough bleeds prior to surgery could safely transition to eptacog beta for perioperative haemostatic control and could then safely choose eptacog alfa or beta upon discharge from hospital. These results also demonstrate that patients could be safely transitioned between eptacog alfa and beta in situations where hospital pharmacy stocks of either product are unavailable.

The observations from this case series showing perioperative haemostatic effectiveness of eptacog beta with emicizumab prophylaxis are clinically relevant, given observations that perioperative haemostatic control using emicizumab with or without alternative bypassing strategies may not be effective for all PwHAI undergoing major surgery. In the STASEY study, haemostatic efficacy of emicizumab with and without concomitant haemostatic medications was evaluated in 13 PwHAI who underwent 22 major surgeries [14]. Eighteen surgeries (13 orthopaedic and five non-orthopaedic) were managed with concomitant haemostatic medications (rFVIIa, aPCC, or standard half-life FVIII concentrate); of these, 76.9% (10/13) of orthopaedic surgeries and 40% (2/5) of non-orthopaedic surgeries resulted in postoperative bleeding. In a single-centre series of 21 major surgeries in PwHAI receiving emicizumab prophylaxis, perioperative haemostatic coverage was provided by eptacog alfa. Haemostasis was effective in the majority of cases; however, four participants required additional eptacog alfa to manage bleeding complications [11]. Of these, one participant failed to respond and died from uncontrolled bleeding.

There is a growing body of evidence that suggests that eptacog beta can be effective in individuals with a history of poor response to eptacog alfa or for the management of bleeds that are refractory to eptacog alfa. In a case series of 14 participants with haemophilia A or B and inhibitors or anaphylaxis to factor replacement, eptacog beta demonstrated effective haemostasis for the treatment of acute bleeds, both as first-line therapy and in cases refractory to eptacog alfa, with successful outcomes in 23 of 24 events [20]. When used prophylactically, two of three participants reported a reduced frequency of breakthrough bleeds compared with prior prophylaxis using eptacog alfa, while one participant experienced a bleed rate similar to that observed with aPCC. Eptacog beta also provided effective bleed control in three participants undergoing minor surgical procedures. A Spanish case series of four PwHAI with suboptimal response to FVIII reported eptacog beta use for perioperative bleed management in two participants and for treatment of severe haemorrhages in two participants [24]. Intraoperative haemostasis was rated as "excellent" in both participants undergoing surgery, although one participant suffered a post-procedure bleeding event that was treated with arterial embolisation. In the two participants suffering from severe haemorrhages, haemostasis was successfully achieved, with haemostatic efficacy being rated as "good" or "excellent". Similarly, in a retrospective chart review of 17 patients requiring 27 admissions for treatment with rFVIIa (11% receiving eptacog alfa, 78% receiving eptacog beta, and 11% receiving both eptacog alfa and eptacog beta), eptacog beta provided effective

haemostatic control without adverse bleeding outcomes [25]. Among major surgery patients, "good" or "excellent" haemostasis was achieved by 67% of individuals.

In addition to considerations of safety and efficacy, cost is also an important factor in the selection of a bypassing agent. The use of eptacog beta for prophylaxis and acute bleed control has been previously shown to be more cost-effective than eptacog alfa [20,25,26]. In a retrospective case series of 14 people with haemophilia A or B with inhibitors or anaphylaxis to factor replacement, Youkhana et al. estimated that eptacog beta was 46 to 72% more cost-effective than eptacog alfa due to lower dosage requirements and reduced wholesale acquisition costs [20]. A retrospective chart review of 17 people with haemophilia A or B with inhibitors requiring 27 admissions for rFVIIa reported an estimated cost avoidance of USD $554,400 with eptacog beta versus eptacog alfa over a 12-month period, based on equivalent dosing of eptacog beta and eptacog alfa, and using the hospital's wholesale acquisition cost [25]. When adjusted for differences in dosing between eptacog beta and eptacog alfa, the estimated cost savings increased to over USD $800,000. These results are consistent with a report from a decision analytic health economic model showing that eptacog beta required less unit utilisation per bleeding event and had lower wholesale acquisition costs than eptacog alfa [27]. In this case series, haemostatic control was achieved with fewer total doses of eptacog beta than would be expected with eptacog alfa, with seven participants (#1-3 and #5-8) achieving postoperative haemostatic control with lower and less frequent dosing than recommended for eptacog alfa.

Limitations to this study include the small sample size, variability in eptacog beta dosing regimen, and number of patients who received both eptacog alfa and eptacog beta during the perioperative period. Additional limitations inherent to case reports and real-world evidence apply, including the inability to establish causal relationships, and the limited generalisability of the findings to all PwHAI. Furthermore, data were not collected prospectively or reported uniformly across all cases, and some information may be incomplete.

While haemophilia A patients without inhibitors have access to a variety of FVIII concentrates for perioperative haemostasis, PwHAI are limited to bypassing agents. For PwHAI using emicizumab prophylaxis, concerns regarding thrombosis and TMA associated with concomitant aPCC use have further restricted bypassing agents to a preference for rFVIIa. The approval of eptacog beta in 2020 has expanded treatment options for PwHAI and allowed for more flexible dosing strategies. In this case series, each participant was treated using a haemostatic strategy tailored to their individual needs. Importantly, none of the patients experienced intraoperative bleeding, and postoperative bleeding was trauma-related and not considered a failure of the medication. No incidents of thrombosis or TMA occurred. In addition to safety and efficacy, improvements in cost-effectiveness may enhance treatment accessibility, with the possibility of reducing the incidence, severity, and long-term complications associated with surgical bleeding in PwHAI. Overall, the data from this case series suggest that eptacog beta may be used for perioperative haemostasis in major surgery in PwHAI using emicizumab prophylaxis and add to the body of literature that eptacog beta is safe in combination with emicizumab for perioperative use.

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Conflict of interest

MAE has received consultancy fees from Bayer, BioMarin, CSL Behring, HEMA Biologics, Inovio, LFB, Novo Nordisk, Pfizer, Regeneron, Roche/Genentech/Spark, Sanofi, Kedrion Biopharma and Takeda. DQ has received consultancy fees from and served on an advisory board for Bayer, CSL Behring, HEMA Biologics/LFB, Genentech/Roche, Novo Nordisk, Pfizer, and Sanofi, and has served on a speaker's bureau for CSL Behring, HEMA Biologics/LFB, Novo Nordisk, Pfizer, and Sanofi. KLM has no conflict of interest to declare. LS has no conflict of interest to declare. MO has served on an advisory board for HEMA Biologics. TWB has served as an advisory board member and received honoraria from BioMarin, Novo Nordisk, and Sanofi, and has served as local principal investigator for clinical trials or other studies sponsored by Genentech, Pfizer, Regeneron Pharmaceuticals, and CSL Behring. JCQ has received consultancy fees from Globus and Alpha Tech. DD has no conflict of interest to declare. SN has received consultancy fees from HEMA Biologics, Kedrion Biopharma, and Microhealth. SWP has received consultancy fees from Bayer, BioMarin, CSL Behring, Chugai, HEMA Biologics, Inovio, LFB, Metagenomi, Novo Nordisk, Pfizer, Regeneron, Roche/Genentech/Spark Therapeutics, Sanofi, Star Therapeutics, Takeda and Werfen; and holds a membership on a Scientific advisory committee for GeneVentiv and Equilibra Bioscience.

Author contributions

All authors made substantial contributions to the conception of this work or data acquisition, participated in drafting the article or revising it critically for important intellectual content, gave final approval of the version to be published, and agree to be accountable for all aspects of the work.

Use of AI

Artificial intelligence (AI) tools were not used in the conduct, analysis, or interpretation of this case series. AI tools were also not used in the preparation of the manuscript.

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