

Poster Sessions

401. Basic Science and Clinical Practice in Blood Transfusion: Poster I

Replacement Therapy for Minor Surgery and Invasive Procedures in Factor VII Deficiency: The STER Experience

Mariasanta Napolitano, MD^{*1}, Alberto Dolce, PhD^{*2}, Jorgen Ingerslev^{*3}, Muriel Giansily-Blaizot, MD, PhD^{*4}, Matteo ND Di Minno^{*5}, Guenter K.H. Auerswald, MD⁶, Arlette Ruiz de Saez^{*7}, Annarita Tagliaferri^{*8}, Angelika Batorova, MD, PhD⁹, Teresa Maria Caimi, MD^{*10}, Ampaiwan Chuansumrit¹¹, Maria Fernanda Lopez Fernandez, MD^{*12}, Marie-Anne Bertrand, MD^{*13}, Elisabeth Verdy, MD^{*14}, Ezio Zanon, MD^{*15}, Lien Abecassis, MD^{*16}, Sophie Aronis^{*17}, Sergio Siragusa, MD¹⁸, Assunta Orecchioni, MD^{*19} and Guglielmo Mariani, MD²⁰

¹ Hematology, Lombardi Comprehensive Cancer Center, Washington DC, DC, USA,

² National Institute of Statistics, Palermo, Italy,

³ Skejby University Hospital, Centre for Haemophilia and Thrombosis, Aarhus, Denmark,

⁴ Laboratory of Hematology, CHU de Montpellier, Montpellier, France,

⁵ Dipartimento di Medicina Clinica e Sperimentale, Centro di Coordinamento regionale per le Emocoagulopatie, Università di Napoli "Federico II" Naples, Italy, Napoli, Italy,

⁶ Klinikum Bremen-Mitte, Bremen, Italy,

⁷ National Haemophilia Centre, Banco Metropolitan de Sangre DC, Caracas, Venezuela, Caracas, Venezuela,

⁸ Ospedale Maggiore, centro emostasi e Cura Emofilia, Parma, Italy,

⁹ National Hemophilia Center, Bratislava, Slovak Republic,

¹⁰ Haematology Unit- Niguarda Hospital "Ca Granda"-Milan, Milano, Italy,

¹¹ Department of Pediatrics, Faculty of Medicine, Ramathibodi Hospital, Mahidol University, Bangkok, Thailand,

¹² Complejo Hospitalario Juan Canalejo, Acoruna, Spain,

¹³ CRTH de Besançon, Besancon, France,

¹⁴ Service d'Hématologie Biologique, Hôpital Tenon, Paris, France,

¹⁵ Centro emofilia di padova-Clinica Medica 2°, Padova, Italy,

¹⁶ Robert Ballanger Hospital, Aulnay Sous Bois, France,

¹⁷ Haemophilia Centre-Haemostasis Unit, Athens, Greece,

¹⁸ Istituto di Ematologia, Policlinico Universitario di Palermo, Palermo, Italy,

¹⁹ Laboratory of Thrombosis and Haemostasis, L'Aquila, Italy,

²⁰ Dipartimento Di Medicina e Sanita' Pubblica, Universita' De L' Aquila, L'Aquila, Italy

Abstract 1262

Introduction: Surgical bleeding is among the most frequent symptoms in Factor VII (FVII) deficient patients: in an analysis by our group, post-surgical bleeding was reported in 24% of cases (Mariani G. et al. *Thromb Haemost* 2005;93:481). A recent retrospective study showed a similar prevalence of surgical bleeding (15%) with a significant relation between this type of bleeding, deep hematomas and a FVIIc coagulant activity (FVIIc) of less than 7% (Benlakal F et al. *J Thromb Haemost* 2011;9:1149). Little is known about prevention of bleeding in 'minor surgical interventions', important tools in modern medicine, bearing not a negligible risk of bleeding, as local hemostasis may not always be punctually achieved.

Aim: Analysis of Replacement Therapy (RT) for minor surgeries in patients with FVII deficiency, prospectively reported in the Seven treatment Evaluation Registry (STER). Clinicaltrials.gov identifier: NCT01269138.

Methods: Analysis of RTs used in 38 minor surgical procedures (34 patients; FVIIc:<1–20%). Minor surgical procedures were defined as suggested by *Kitchens* (Surgery and hemostasis. Textbook of Consultative Hemostasis and Thrombosis. 2007).

Results: Reported interventions included: oral surgery ($n=15$), endoscopic biopsies ($n=7$), catheter insertions ($n=3$), ear-nose-throat and head-neck ($n=5$), mixed type ($n=8$). RT schedules were based on recombinant-activated FVII (rFVIIa; $n=29$), plasma-derived FVII (pdFVII; $n=8$), or Fresh-Frozen-Plasma ($n=1$). One-day RT schedule was employed in 27 procedures, 2–10 days in 11 procedures. Total doses ranged from 7.2–510 $\mu\text{g}/\text{kg}$ (rFVIIa) and 9–300 IU/kg (pdFVII). FFP was given at a total dose of 50 ml/kg (1-day treatment, split into 4 doses of 12.5 ml). Antifibrinolytics were administered together with RT in 16 procedures (11 dental) for a minimum of 1 day to a maximum of 7 days. No bleeding nor thrombotic events occurred; one patient developed an inhibitor

Conclusion: For most of the uncomplicated minor surgery procedures (single dental extractions, catheter insertions, endoscopic biopsies), one-day RT is sufficient with low to medium doses of rFVIIa (median 25 $\mu\text{g}/\text{Kg}/\text{bw}$) or pdFVII (median 18.5 UI/Kg/bw), possibly with more than one administration. In complicated and more elaborate interventions, longer-lasting RT schedules and higher doses may be needed.

Disclosures: No relevant conflicts of interest to declare.