

LETTER

ROTEM®-guided coagulation factor concentrate therapy in trauma: 2-year experience in Venice, Italy

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Haemostatic therapy for trauma-induced coagulopathy is typically based on administration of allogeneic blood products, although the evidence supporting this approach is poor [1]. Fixed-ratio protocols have been proposed for administering fresh frozen plasma, red blood cells and platelets, but the optimal ratio has not been established and the speed of intervention may be more important [2].

In contrast to fixed-ratio treatment, coagulation factor concentrate therapy guided by point-of-care monitoring allows patients' actual needs to be targeted [3]. Our initial experience with ROTEM® (Tem International GmbH, Munich, Germany) indicated correlation between the clinical condition and extent of coagulopathy, suggesting a need for the early identification and treatment of coagulopathy that ROTEM® enables. Altogether, these factors provided a rationale for implementing ROTEM®-guided therapy for trauma patients in our hospital.

In our experience, this approach is feasible and can replace formula-driven treatment. We found that coagulation factor concentrates (fibrinogen concentrate and prothrombin complex concentrate) correct coagulopathy effectively and rapidly, indicated by normalisation of ROTEM® parameters among bleeding trauma patients (Table 1). European guidelines for managing trauma raised the target fibrinogen concentration to 1.5 to 2 g/l [4], which we find difficult to reach without using fibrinogen concentrate. Without a comparator group, our data are insufficient to show reduced red blood cell transfusion or improvements in morbidity/mortality. However, we did see a progressive reduction in fresh frozen plasma consumption. Another advantage of using a ROTEM®-guided approach is the opportunity to detect hyperfibrinolysis. As reported elsewhere, we found that fulminant hyperfibrinolysis is associated with high mortality. Fulminant hyperfibrinolysis may potentially be considered the last gasp of the coagulation system; it may be a marker not only of severe coagulopathy, but also of

poor clinical outcome. Our experience also suggests that patients with massive bleeding may benefit from immediate, proactive administration of 1 g tranexamic acid followed by 2 to 4 g fibrinogen concentrate, with further doses as soon as ROTEM® results are available.

Fibrinogen concentrate is currently imported in Italy and we use it according to the manufacturer's label. In some countries the product is licensed only for congenital deficiency. However, it is possible to use life-saving drugs for indications beyond the label, providing the physician is convinced that this use is in the patient's best interest; such practice is regulated by health authorities in several countries. High-quality, randomised controlled trials are lacking for both allogeneics and coagulation factor concentrates in trauma, creating a degree of uncertainty with both of these options. Nevertheless, we consider the rationale to be stronger for ROTEM®-guided, concentrate-based therapy.

Competing interests

The authors declare that they have no competing interests.

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Table 1. Details of bleeding trauma patients receiving ROTEM®-guided coagulation factor concentrate treatment

	ROTEM® parameters on arrival				Haemostatic treatment administered in response to initial ROTEM® assessment				ROTEM® parameters following haemostatic treatment					
	EXTEM		FIBTEM		Prothrombin complex concentrate (IU)		Fibrinogen concentrate (g)	Tranexamic acid (g)	Platelet concentrate (U)	CT (seconds)	A10 (mm)	MCF (mm)	FIBTEM	
	ISS on arrival	CT (seconds)	A10 (mm)	MCF (mm)	Prothrombin complex concentrate (IU)	Fibrinogen concentrate (g)	Tranexamic acid (g)	Platelet concentrate (U)	CT (seconds)	A10 (mm)	MCF (mm)	MCF (mm)	Outcome	
1	25	130	31	44	3	2,000	6	2	0	65	42	54	12	Survived
2	25	75	37	48	5	0	2	0	0	N/A	N/A	N/A	N/A	Survived
3	34	59	54	62	10	0	1	0	0	N/A	N/A	N/A	N/A	Survived
4	43	70	35	43	3	0	3	0	0	40	32	34	10	Survived ^a
5	34	95	40	51	7	500	2	0	0	62	42	54	8	Survived ^a
6	25	167	18	29	2	1,000	5	2	2	62	39	50	10	Survived
7	66 ^b	216 ^c	14 ^c	22 ^c	0	1,000	7	2	2	59	38	51	13	Died ^d
8	66 ^b	139 ^c	22 ^c	34 ^c	0	2,000	8	2	2	74	26	38	8	Died ^e
9	34	71	46	56	10	0	3	0	0	61	56	65	14	Survived
10	27	170	20	32	3	1,500	6	2	2	50	39	50	12	Survived
11	45	102	28	37	5	1,500	3	2	1	48	53	63	12	Died ^f
12	36	114	20	29	5	1,500	4	2	1	61	39	48	9	Survived ^a

A10, clot amplitude (firmness) 10 minutes after clotting time (CT); EXTEM, extrinsically activated thromboelastometric test; FIBTEM, thromboelastometric test of fibrin-based clotting; ISS, injury severity score; IU, international units; MCF, maximum clot firmness; N/A, not available. ^aPatient received platelets following the second ROTEM® assessment. ^bProminent hyperfibrinolysis was detected, so aprotinin-controlled thromboelastometric test (APTEM) parameters were initially used to guide treatment. Both patients also received fresh frozen plasma after the second ROTEM® assessment. ^cValue obtained using the APTEM assay. ^dCause of death was multiple organ failure. ^eCause of death was abdominal aortic rupture and unstoppable haemorrhage. ^fCause of death was brain death.