One Year Clinical Experience with Mini-Pool Solvent/Detergent-filtered Plasma

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Background and Aim

A CE-marked medical device allowing the implementation of solvent-detergent and filtration (S/D-F) treatment of plasma has been developed [1]. Plasma is S/D-treated in a bag system and subjected to oil extraction, followed by adsorption and sterilizing filtrations (F).

Aims: Evaluate the tolerance, clinical efficacy and safety of this S/D-F plasma in patients with liver diseases or requiring therapeutic plasma exchange.

Methods

- IRB approval was obtained from Shabrawishi hospital and patients provided informed consent
- S/D-F plasma was transfused to15 patients (a) with FV, FX or FVII deficiency for treatment of their bleeding episodes, or (b) end-stage liver disease with coagulopathy, or (c) for therapeutic plasma exchanges (TTP or cytotoxic renal antibodies removal), or (d) INR correction due to over dose of oral anticoagulants.
- Evaluation of clinical outcome was based on correction of global hemostasis tests (PT and aPTT), control of specific coagulation factors, control of bleeding episodes and report of any adverse events.

Results

- Coagulopathies: 10 ml/Kg bw led to good correction of global hemostasis tests and deficient coagulation factors in patients with hereditary FV and FX deficiency (Fig 1)
- End-stage liver disease with coagulopathy: first transfusion with 320 ml of S/D-F plasma followed by 320 ml of normal FFP 12 hrs after led to correction of PT and aPTT receiving S/D-F not significantly different from that with standard FFP (Fig 2)
- Plasma exchange: good correction by replacement of defective plasma by an equal volume of S/D-F plasma in Guillain-Barré and TTP patients and by replacement by 50% of the volume as 5% saline albumin and 50% of S/D-F plasma in patient with renal cytotoxic antibodies. Patient with renal cytotoxic antibody has completed 12 sessions of therapeutic plasma exchange to ensure a reduction of cytotoxic antibodies and the antibodies were reduced to 30% of starting cytotoxic renal antibodies.(Table 2)
- Correction of INR in patients with anticoagulant overdose was efficient.
- No adverse events in any patients, except one with high INR (moderate allergic reaction at her second S/D-F plasma transfusion).

Fig 1: FV, FX, and FVII level after 10 ml S/D-F/kg bw in deficient patients

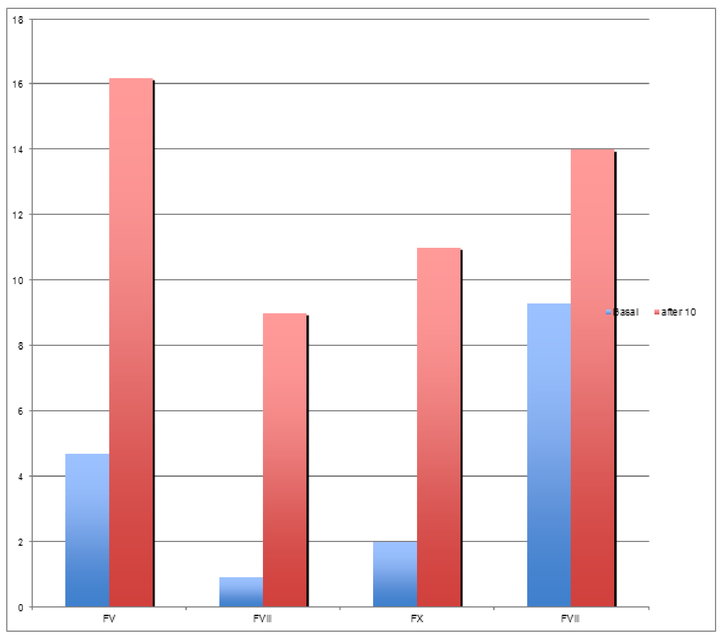

Table 1: Infusion of 320 ml S/D-F plasma followed by 320 ml FFP 12 hrs later in patients with end-stage liver disease with coagulopathy. PT and aPTT improvement was significant with both plasmas. No significant change in fibrinogen.

Patient code	Vol. infused	PT sec		aPTT sec		Fibrinogen mg/dl		Wt	Age	Puls	Temp	Adverse events
		Basal line	After infusn	Basal line	After infusn	Basal line	after infusn					
1	320ml SD-plasma	28.4	23.7	74	57	49	76	80	80	70	37	nil
2	320ml SD-plasma	19.1	18.2	54.7	53	119	135	65	62	80	36	nil
3	320ml SD-plasma	17.4	16.7	45.6	42.1	120	99	98	56	82	37	nil
4	320ml SD-plasma	21.9	19.6	71.5	65	107	125	70	40	88	37	nil
5	320ml SD-plasma	20.1	18	101	90	174	185	76	48	78	37	nil
6	320ml SD-plasma	16.3	14.5	45.2	39	273	290	75	52	80	36.5	nil
7	320ml SD-plasma	18.3	15	60.4	54	299	310	77	54	85	37	nil
Mean		**20.2**	**18.0**	**64.6**	**57.2**	**163**	**174.3**	**77.3**	**56**	**80.4**	**36.8**	
1	320ml FFP	28.4	23.2	74	ND	49	82	80	80	70	37	nil
2	320ml FFP	19.1	18.9	54.7	58.8	119	94	65	62	80	36	nil
3	320ml FFP	16.6	14.7	42.9	40.8	89	106	98	56	82	37	nil
4	320ml FFP	21.9	19.5	71.5	66	107	120	70	40	88	37	nil
5	320ml FFP	20	17.9	99	90	176	188	76	48	78	37	nil
6	320ml FFP	16	14.2	44	38	275	285	75	52	80	36.5	nil
7	320 ml FFP	18	14	59	53	300	315	77	52	80	36.5	nil
Mean		**20**	**17.5**	**63.6**	**57.8**	**159.3**	**170**	**77.3**	**56**	**79.7**	**36.7**	

Table 2: Therapeutic plasma exchange using S/D-F plasma.

GB: Guillain-Barré

RF: renal failure due to cytotoxic antibodies

Patient	Age	Sex	Weight Kg	Diagnosis	No. Exchange	Vol Exchange	Frequency	5% Alb	S/D-F Plasma	Total vol.	Adv events	outcome
1	44	M	78	GB	3	2 L	every other day	0	2 L	6 L	Nil	improved muscle power
2	28	F	74	RF	9	2 L	every other day	1 L	1 L	9 L	Nil	70% reduction Abs
3	58	M	90	GB	5	3 L	every other day	1.5 L	1.5 L	7.5 L	Nil	Improved muscle power
4	27	F	60	TTP	5	2 L	every day	0	2 L	10 L	Nil	recovery

Conclusions

Clinical experience with the S/D-F plasma in different pathologies strongly suggests that it is both efficient and safe, and is well tolerated.

Reference

1 El-Ekiaby M, Sayed MA, Caron C, Burnouf S, El-Sharkawy N, Goubran H, Radosevich M, Goudemand J, Blum D, de Melo L, Soulie V, Adam J, Burnouf T: Solvent-detergent filtered (S/D-F) fresh frozen plasma and cryoprecipitate minipools prepared in a newly designed integral disposable processing bag system. Transfus Med. 2010;**20**: 48-61.

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