Quality Control Evaluation of Methylene Blue Light Treated Plasma.

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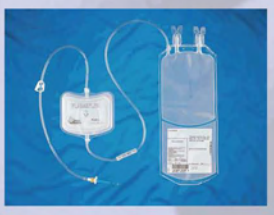
INTRODUCTION

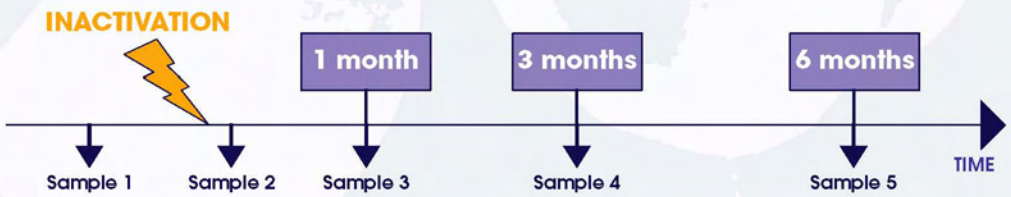
Methylene blue light treated plasma has been used in Spain from 1998. Since then slight variations of the technique have been implemented such as plasma leukoreduction instead of freezing and thawing.
Studies on plasma quality have been published analysing initial methods. We have tested several plasma units to evaluate plasma quality with the current technology.

MATERIAL AND METHODS

Briefly speaking, 450±50 mL whole blood units were collected in automatic scales using top & bottom blood bags.
After collecting, units were cooled with 1.4- butanodiol plates and later stored at 22±2ºC. Then, whole blood was centrifuged at high speed to obtain a concentrate of red blood cells and plasma, while maintaining the buffy coat in the initial blood bag. For plasma inactivation the Springe modified method was used (Theraflex-MB-Plasma system: Macopharma®). Plasma was joined to the MB system by means of sterile docking and, simultaneously, gravity filtered. In batches of four plasma was illuminated for 20 min. Units for storage were frozen after inactivating before 24 hour postdonation. For the study we inactivated 30 plasma units (10 A, 10 O, 5 B and 5 AB). We took several samples: before inactivation (sample1), just after inactivation (sample2), after 1 month of storage at -30ºC (sample3), after 3 months of storage at -30ºC (sample4) and after 6 months of storage at -30ºC (sample5). After each moment samples were stored at -80ºC till the tests were performed.
In every sample we performed the following tests: PT, APTT, FV, FVIII and fibrinogen.



The process of the 5 plasma samples



RESULTS

As published before most affected parameters by the inactivation procedure were fibrinogen and FVIII (18 and 16% respectively decrease from sample 1 to 2). FV was scarcely affected (a 3% decrease from sample 1 to 2). PT an APTT were prolonged only in 2.74 and 5.26% respectively from sample 1 to 2. Results may be seen with more detail in the attached table.

Results of the tests (PT, APTT, Fib, FV and FVIII) for the 5 plasma sample

Sample parameter	(%)↑PT	(%)↑APTT	(%)↓Fib	(%)↓FV	(%)↓FVIII
Δ1-2	2,74	5,26	18,67	3,4	16,9
Δ1-3	6,16	3,85	23,31	5,95	21,04
Δ1-4	7,99	6,23	23,79	13,64	25,62
Δ1-5	13,54	4,6	25,63	14,88	26,39

PT: Prothrombin rate **APTT:** Activated Partial Thromboplastin Time test **Fib:** Fibrinogen
FV: Factor V **FVIII:** Factor VIII

CONCLUSIONS

The Methylene blue inactivation methodology is very easy to use and the plasma factors after inactivation are preserved. However, during storage there is a certain loss of coagulation factors. If the reason for this is related to the treatment or the storage conditions remains to be evaluated.