

Abstract for ISBT 2011

Analysis of functional activity of a large panel of coagulation factors in fresh and previously frozen plasma treated with the INTERCEPT Blood System

M. Yáñez Izquierdo¹, E. Fernandez Fontecha², M.A. Moya San Pedro¹, S. Prieto Muñoz, Y. Lara Garzon, L. Blanco Peris¹

¹ *Centro de Hemoterapia y Hemodonación de Castilla y León, Spain*

² *Hospital Universitario del Río Hortega (Valladolid), Spain*

Background

The INTERCEPT Blood System™ (IBS) for plasma is a CE mark registered Class III medical device for the pathogen inactivation (PI) of viruses, bacteria, parasites and leukocytes in plasma. Plasma components treated with INTERCEPT have been in routine clinical use in many blood centers in Spain since 2007. PI technology for therapeutic plasma must fulfill several essential requirements: 1) Inactivation of a broad range of pathogens, 2) Preservation of coagulation functions, and 3) Compatibility with routine blood bank operations.

Aims

The aim of this study is to evaluate the plasma quality after INTERCEPT treatment following three processing procedures, 1) freshly collected plasma treated with INTERCEPT and frozen within 8 hours of collection, 2) freshly collected plasma stored overnight, treated with INTERCEPT and frozen within 24 hours of collection, and 3) previously frozen plasma, thawed, treated with INTERCEPT and frozen within 8 hours of thawing.

Methods

For each experimental condition, eight apheresis plasma components (385-650 mL) were collected (Haemonetics, MCS2) and treated with INTERCEPT according to the manufacturer's instructions. Samples were taken before and after INTERCEPT treatment, and after one month of frozen storage at -30°C. Samples were then tested for quality including PT, aPTT, Fibrinogen, factors (F) II, V, VII, VIII, IX, X, XI, XII, antithrombin (AT), protein C, and protein S.

Results

All collections of plasma prior to INTERCEPT treatment met the input requirements of 385-650 mL with $<4 \times 10^6$ RBC/mL. The mean volume of the final INTERCEPT plasma product, residual amotosalen, WBC, RBC and platelet counts met the requirements of European guidelines. Results of plasma clotting time and coagulation factors are presented in Table 1 and 2. The proportion of factor activity retained in INTERCEPT plasma relative to untreated baseline was comparable among the three processing procedures. Immediately after treatment, retention of clotting time and coagulation factors of INTERCEPT plasma were 80-108%, 80-105% and 72-107% for 8 hr, 24 hr and frozen plasma respectively. The mean levels of the most labile F VIII

were 87, 78 and 69 IU/dL for 8 hr, 24 hr and frozen plasma, respectively. Following one month of storage, the factor activities remained within the therapeutic range.

Conclusion

INTERCEPT plasma retained adequate levels of critical plasma coagulation activities. The effect of INTERCEPT treatment on plasma activities is comparable among three procedures. The processing flexibility ensures smooth operation in the blood bank setting while providing a safe and high quality plasma product for transfusion.

Table 1: Functions of IBS-plasma prepared from fresh plasma and frozen within 8hr or 24 hr (n=8)

Assay	8 Hr IBS-Plasma			24 Hr IBS-Plasma		
	untreated	immediately after treatment	after 1 month frozen storage	untreated	immediately after treatment	after 1 month frozen storage
PT (ratio)	1.0 ± 0.1	1.0 ± 0.1	1.0 ± 0.1	1.0 ± 0	1.1 ± 0	1.1 ± 0.1
αPTT (sec)	31 ± 2	32 ± 3	33 ± 3	32 ± 3	33 ± 3	34 ± 2
ATIII (U/dL)	100 ± 6	94 ± 6	92 ± 4	98 ± 8	92 ± 7	91 ± 9
PC (U/dL)	107 ± 19	93 ± 15	91 ± 13	106 ± 17	90 ± 11	90 ± 15
PS (U/dL)	114 ± 22	115 ± 23	101 ± 20	116 ± 16	117 ± 18	102 ± 11
FI (mg/dL)	358 ± 71	308 ± 62	308 ± 77	346 ± 43	278 ± 39	274 ± 39
FII (U/dL)	88 ± 9	88 ± 8	85 ± 8	93 ± 12	85 ± 8	83 ± 9
FV (U/dL)	95 ± 20	93 ± 18	91 ± 18	97 ± 11	90 ± 9	89 ± 9
FVII (U/dL)	96 ± 17	93 ± 14	91 ± 15	85 ± 18	81 ± 16	78 ± 16
FVIII (U/dL)	116 ± 21	98 ± 14	87 ± 12	103 ± 31	83 ± 14	78 ± 14
FIX (U/dL)	120 ± 17	111 ± 17	107 ± 16	114 ± 13	101 ± 13	99 ± 13
FX (U/dL)	84 ± 7	84 ± 8	80 ± 8	95 ± 8	88 ± 7	85 ± 8
FXI (U/dL)	119 ± 25	105 ± 17	96 ± 16	110 ± 14	94 ± 9	97 ± 10
FXII (U/dL)	110 ± 10	118 ± 26	103 ± 14	103 ± 36	81 ± 28†	87 ± 29

† statistically significant differences (p < 0.05) were observed comparing to 8 hr fresh plasma

Table 2: Functions of IBS-plasma prepared from previously frozen plasma (n=8)

Assay	Previous Frozen IBS-Plasma		
	Untreated	Immediately after treatment	After 1 month frozen storage
PT (ratio)	1.0 ± 0.1	1.1 ± 0.1	1.1 ± 0.1
αPTT (sec)	31 ± 1	33 ± 2	34 ± 2
ATIII (U/dL)	98 ± 6	93 ± 7	92 ± 7
PC (U/dL)	107 ± 18	96 ± 23	97 ± 17
PS (U/dL)	113 ± 14	115 ± 14	118 ± 14
FI (mg/dL)	303 ± 29	258 ± 27†	254 ± 30
FII (U/dL)	97 ± 10	87 ± 10	86 ± 8
FV (U/dL)	98 ± 13	94 ± 13	93 ± 10
FVII (U/dL)	93 ± 19	86 ± 19	84 ± 18
FVIII (U/dL)	99 ± 24	72 ± 20†	69 ± 23
FIX (U/dL)	116 ± 18	97 ± 15†	93 ± 21
FX (U/dL)	103 ± 9	93 ± 10	90 ± 10
FXI (U/dL)	104 ± 18	89 ± 15†	86 ± 16
FXII (U/dL)	127 ± 20	104 ± 16	100 ± 14

† statistically significant differences (p < 0.05) were observed comparing to 8 hr fresh plasma

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Authors' email addresses:

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