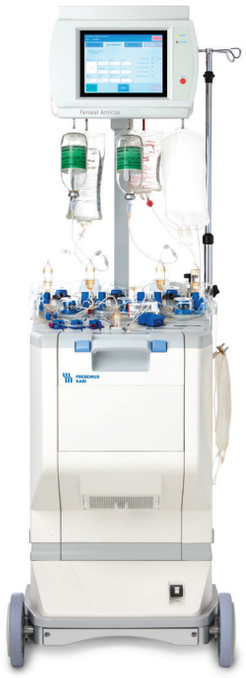
Patient study:

A multicenter, randomized, nonblinded, cross-over paired evaluation of Amicus and COBE Spectra



Fenwal Amicus

Therapeutic apheresis and cell collection

THERAPEUTIC PLASMA

Study Parameters

- 30 patients were enrolled with the following diagnoses: multiple sclerosis (11), chronic inflammatory demyelinating polyradiculopathy (4), hyperviscosity (3), renal transplantation (2), myasthenia gravis (2) thrombotic thrombocytopenic purpura (2), focus segmental glomerulosclerosis (2), Lambert-Eaton myasthenic syndrome (1), pemphigus vulgaris (1), neuromyelitis optica (1), myeloma cast neuropathy (1)

Key Outcomes

- The primary objective of the study was to compare the plasma removal efficiency (PRE) of Fenwal Amicus and COBE Spectra
- The secondary objectives compared:
  - Platelet content in waste plasma
  - Plasma hemoglobin (Hb) concentration in waste plasma
  - Changes in markers in coagulation and complement activation
  - Fluid balance accuracy
  - Procedure time
- Also measured:
  - Anticoagulant to the patient
- There were no serious or unanticipated adverse events reported

Notes

- There were no clinically significant differences seen between Fenwal Amicus and COBE Spectra in a number of laboratory measurements including complement activation, coagulation cascade activation and hematologic variables

Source: Winters JL et al. A multicenter evaluation of a new therapeutic plasma exchange procedure. Transfusion. 2013 Dec; 53(12):3269-78.

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TABLE 1

Amicus delivered high plasma removal efficiency which resulted in less AC to the patient.

PATIENT	Amicus n=30 Mean ± SD	Cobe Spectra n=30 Mean ± SD	P-value
Weight (kg)	91.6 ± 20.0	91.2 ± 19.4	0.52
Height (cm)	174 ± 12	174 ± 12	
Blood Volume (mL)	5329 ± 1039	5314 ± 1030	0.52
Preprocedure Hct (%)	36 ± 5	36 ± 6	0.88

PROCEDURE	Amicus n=30 Mean ± SD	Cobe Spectra n=30 Mean ± SD	P-value
Procedure Time (min)†	103.9 ± 30.8	110.5 ± 27.1	<0.001‡
WB Volume Processed (mL)§	7159 ± 1908	7730 ± 1858	<0.0001‡
AC Used (mL)	577 ± 164	598 ± 144	0.0004‡
Volume Processed-AC (mL)	6583 ± 1745	7132 ± 1714	<0.0001‡
Plasma Processed (mL)	4257 ± 1151	4578 ± 1012	<0.001‡
Plasma Removed (mL)	3459 ± 840	3448 ± 849	0.70‡
Plasma Collect Rate (mL/min)†	34.2 ± 6.8	31.8 ± 6.1	0.00056

RESULTS	Amicus n=30 Mean ± SD	Cobe Spectra n=30 Mean ± SD	P-value
PRE (%)	81.9 ± 7.6	75.2 ± 6.3	<0.00001
Replacement Fluid to Patient (mL)	3438 ± 830	3524 ± 838	0.0422
AC to Patient (mL)	126 ± 86	144 ± 53	0.008‡
Fluid Balance Accuracy (%)	99.8 ± 0.2	98.8 ± 1.8	<0.0001‡
Waste Plasma Free Hb (mg/dL)†	0.51 ± 0.62	0.80 ± 2.05	0.91‡
Waste Plasma PLT (x10^{10})‖	3.59 ± 2.07	3.66 ± 2.83	0.39‡
Platelet CE1 (%)‖	11.10 ± 4.2	11.23 ± 4.6	0.64

† Only 29 pairs were available for evaluation.
‡ Wilcoxon signed-rank test used to compute p value for nonparametric data. Paired t test used for all other p values.
§ Whole blood volume processed.
‖ Only 26 pairs were available for evaluation.

Note: Reinfusion volume of approximately 200mLs was not included in fluid balance for COBE Spectra.

Source: Winters JL et al. A multicenter evaluation of a new therapeutics plasma exchange procedure. Transfusion 2013;53:3269-3278.

Plasma Removal Efficiency (PRE)% $= 100 \left(\frac{\text{Vol. Patient plasma removed}}{\text{Vol. Total plasma processed}} \right)$

Platelet CE1% $= \frac{\text{Platelets collected}}{\text{Avg. (pre and post) platelet concentration X (Vol. WB processed – Vol. AC used)}}$

Refer to the Amicus Separator operator's manual for the full list of warnings and cautions associated with the use of the Amicus device.

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