



CD34 collection with Spectra Optia

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Blood and Beyond



Agenda

- Background / Aim
- Methods and Materials
- Results
- Conclusions
- Discussions

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Background



- Tot medio 2014



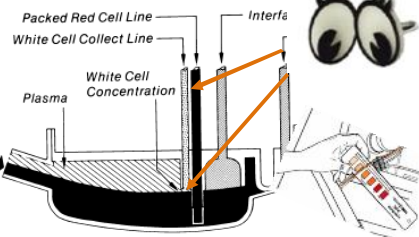
Background



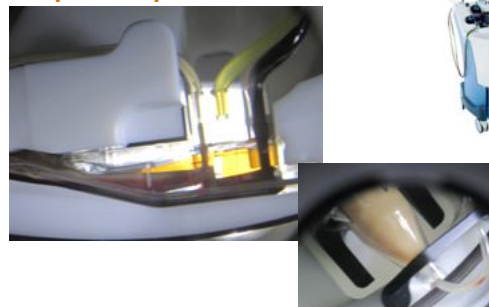
- Vanaf medio 2014

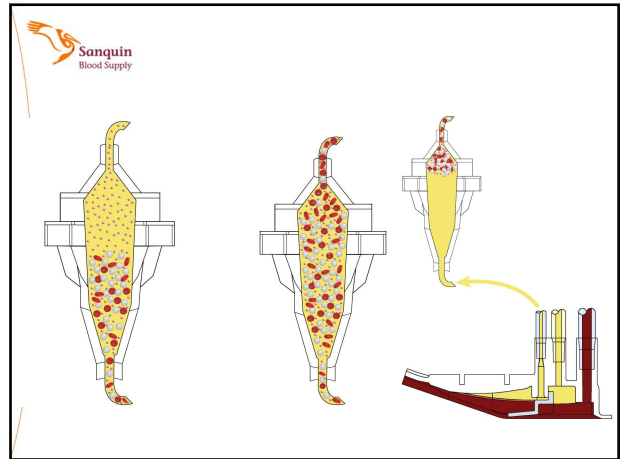
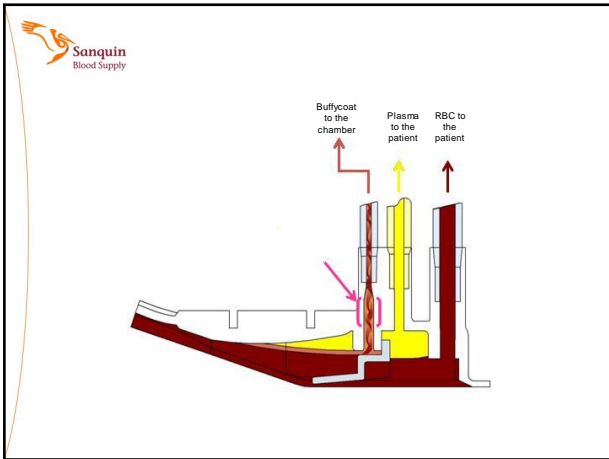


Cobe Spectra



Spectra Optia





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Qualification

- Design qualification (DQ)
- Installation qualification (IQ)
- Operational qualification (OQ)
- Process / Performance qualification (PQ)

APPROVED

REJECTED

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Aim of the study

- Validation of the Spectra Optia in collection of CD34 +ve cells.
- Comparison with
 - Data CD34 +ve cell collection with Cobe Spectra
 - Data from literature

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Methods / Materials

- CD34 +ve cell collection procedures with Spectra Optia (Feb – Dec 2013)
- Autologous donors
- Comparison with
 - Data CD34 +ve cell collection with Cobe Spectra
 - Data from literature

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Methods / Materials

<u>Donors/Patients</u>	<u>Procedure</u>	<u>Product</u>
• TBV	• Time	• Volume
• Hb pre/post	• TBV processed	• Hb
• Hct pre post	• Side effects	• Hct
• Plt pre/post	• CE ₁	• WBC
• WBC pre		• CD34
• CD34 pre		• Plt
		• RBC

$$CE_1 \geq \frac{CD34_{product}}{(CD34_{pre}) * (\text{Processed volume} - AC \text{ volume})} \times 100$$

Results

Donors / Patients

- 45 procedures in 33 patients (14 ♀, 19 ♂)

• MM	19
• NHL	8
• AML	2
• CML	4
• TBV	
• Female patients	4182 (3077-5401)
• Male patients	5404 (4769-5953)

Results

Donors / Patients

•Precount	•Postcount	•Delta
•Hct 0.32 (0.22-0.41)	•Hct 0.29 (0.23-0.38)	•Hct 0.02 (-0.04-0.06)
•Plt 146 (22-604)	•Plt 111 (10-456)	•Plt 40 (-24-148)
•WBC 14.2 (1.3-45.8)	•WBC 14.8 (1.4-41.0)	•WBC -0.6 (-12.9-5.9)
•CD34 53.0 (10.0-176.0)		
		•Plt % 27% (7%-47%)

Results

Procedure

• Time	258	(155-316)
• Cycles	10	(4-18)
• PV	12,101	(6,444-16,485)
• ACD-A	1,068	(622-1,505)
• ACD-A (patient)	1,045	(585-1,456)
• CE ₁	56%	(33-86%)
• Technical problem 1 (flow problems)		
• Side effects		
• 1/45	preventive Ca support	
• 3/45	light citrate reaction	
• 13/45	mild citrate reaction	
• 1/45	headache	

Results

Product

• Volume (mL)	185	(72-324)
• CD34 cells (x10 ⁶ /kg)	4.43	(0.70-13.30)
• Plt (x10 ⁹ /L)	1,106	(59-4,790)
• WBC (x10 ⁹ /L)	206	(11-1,260)
• RBC (x10 ¹² /L)	0.30	(0.02-0.60)
• Hb (mmol/L)	0.9	(0-1.0)
• Hct (L/L)	0.07	(0.01-0.09)

Results (overall)

• Side effects	→ no difference compared to Cobe Spectra literature: 37-40% → this study: 27%
• Plt loss	
• CD34 cells	→ no difference compared to Cobe Spectra Cobe Spectra 41% (p<0.0001)
• CE	in range with literature
• Productvolume	→ no difference compared to Cobe Spectra
• Hct product	literature: 0.015 L/L → this study 0.07 L/L
• Procedure time	Cobe Spectra 177 minutes (p<0.0001)
• Viability	no difference compared to Cobe Spectra

Conclusions

- Spectra Optia is valid for collection of CD34 +ve cells in autologous donors.
- Spectra Optia significant higher CE compared to Cobe Spectra.
- Spectra Optia significant higher procedure time compared to Cobe Spectra.
- Spectra Optia significant lower platelet loss in donor/patient
- No difference in side effect frequency between Spectra Optia and Cobe Spectra.