Single Donor Platelet Concentrates (SDPC) collected from Volunteer Apheresis Donors (VAD) in an Environment of Increasing Economical and Regulatory Pressures – Impact on the Blood Center's SDPC supply

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ABSTRACT / SUMMARY

New regulatory requirements, limited availability of Volunteer Apheresis Donors (VAD) and increasing demands of Single Donor Platelet Concentrates (SDPC) will have impact on the blood center's platelet (PLT) supply. We investigated the performances of three currently applied apheresis devices in our blood center for collection of SDPCs (Amicus, n = 270; Cobe/Spectra, n = 84; MCS3p, n = 158). Additionally, we surveyed device related adverse events (DERA) and donor related adverse events (DORA) by questionnaire. We show that technically advanced apheresis devices such as Amicus and Cobe/Spectra produce SDPCs with constant PLT content from VADs with broad range of PLT precounts. 91% and 60% of SDPCs collected by Amicus and Cobe/Spectra resp. fulfill the required product specification by the Swiss Red Cross (SRC, >2.7 x 10^{11} PLT/U). In contrast, SDPCs collected by MCS3p using similar apheresis conditions, fulfill the SRC criteria in 32% of collections only. Amicus allows to benefit best from high PLT count of VAD and may be most suitable to collect double SDPCs. DERAs occur more frequently with technically advanced apheresis devices and require optimal support by the device provider. DORAs are mainly associated with ACD infusion and easily handled by administration of calcium-gluconate or modification of separation parameters. To comply with future SDPC needs, it will be important to apply most efficient apheresis devices, that allow to minimize collection time (CT) and to collect double SDPCs from suitable VADs in reasonable CT. To further increase PLT yields priming of VADs with thrombopoietin may become a future approach.

- *Volunteer Apheresis Donors (VAD)*
  Preselected VADs
  PLT precount ≥200 x 10^9/L on 3 previous PLT collections
  Collection sites
  Blood Center Limmattal – Amicus, Cobe
  (Suburb area of Zürich)
  Blood Center Zürich – MCS3p
  (Midtown area of Zürich)
- *Cell counts*
  Sysmex K-1000
- *Survey of adverse events by questionnaire* (Figure 1)

Figure 1

Donor Related Adverse Event (DORA)	Device Related Adverse Event (DERA)
☐ ACD Toxity (Presthesia Cramps)	☐ Durty Kit
☐ Allergy (Urticaria, Flush)	☐ Leaking Kit
☐ Hypotension	☐ Cuff Pressure
☐ Hypertension	☐ Centrifuge Lid
☐ Tachycardia	☐ Overpressure
☐ Bradycardia	☐ Air Sensor
☐ Dyspnoea	☐ Blocked Pumps
☐ Thorax Pain	☐ Humidity Alarm
☐ Back Pain	☐ PRP Separation Device
☐ Headache	☐ Kit Fixation Frame
☐ Dizziness	☐ Umbilicus Rupture
☐ Agitation	☐ Return
☐ Somnolence	☐ ACD/WB Ratio
☐ Needle Displacement	☐ Technical Support required
☐ Lipemia	

Intervention			
	Procedure	☐ con't	☐ interrupted
	Kit Exchange	☐ yes	☐ no
	Ca-Gluconate administered	☐ yes	☐ no

- *Analysis and Statistics*
  Mean values ± Standard Deviation (SD)
  Data analysis using precount PLT cohorts of 50'000
  Comparative statistics applying student's t-test and X^2-test where appropriate

RESULTS

1. *Characteristics of VADs donating SDPCs on 3 different apheresis devices* (Table 1)

Table 1

	Amicus	Cobe/Spectra	MCS3p
N	270	84	158
Sex (%) m/f	41/59	25/75	72/28
Weight (kg) ± SD	70±12	69±13	70±9
Hct (%) ± SD	42±4	41±3	45±3
PLT (x10^9/L) ± SD Range Median	260±46 171–460 254	280±39 204–376 274	243±46 158–345 241

2. *Performance of apheresis devices*
A. *Summary of consecutive apheresis procedures* (Table 2)

Table 2

	Amicus	Cobe/Spectra	MCS3p
Preset Target Parameter			
PLT Yield (x 10^{11})	3.2	2.7	–
Collection Cycles	–	–	5 (≈60 min)
Apheresis Results			
Number of Procedures	270	84	158
PLT Yield (x 10^{11})	3.4±0.5	2.8±0.4	2.5±0.6
% of SDPC >2.7 x 10^{11} PLT*	91	60	32
Collection Time (min)	59±11	65±9	64±6

* Minimal PLT content of SDPC as required by Swiss Red Cross (SRC)

Using our currently applied apheresis regimen, all three apheresis devices require similar CTs (60 to 70 min). However, SDPCs with >2.7 x 10^{11} PLT/U were collected in 91%, 60% and 32% of procedures performed with Amicus, Cobe and MCS3p resp. (Table 2)

B. *PLT Yield and PLT precount* (Figure 2A – 2C)

Figure 2A: Amicus

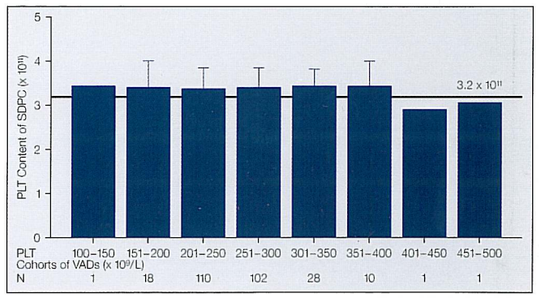


Figure 2B: Cobe/Spectra

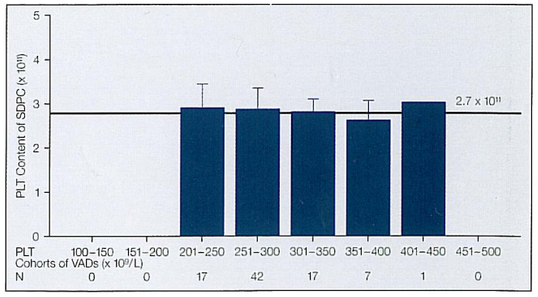
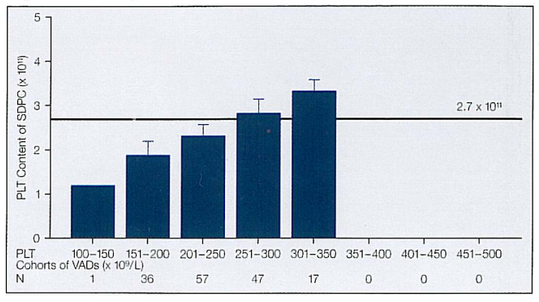


Figure 2C: MCS3p



C. *Collection Time and PLT precount* (Figure 3A – 3C)

Figure 3A: Amicus

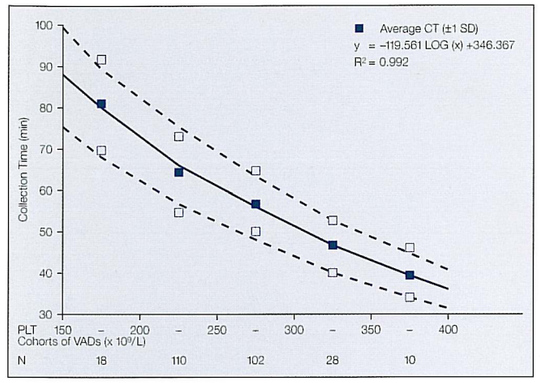


Figure 3B: Cobe/Spectra

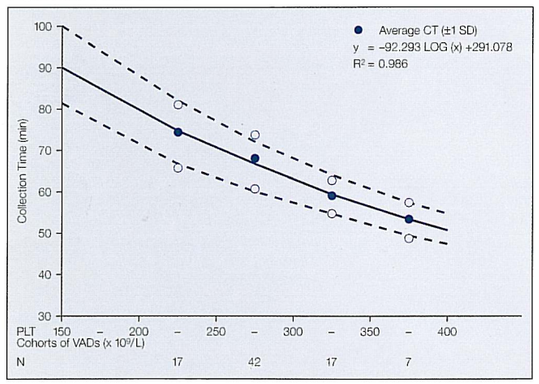
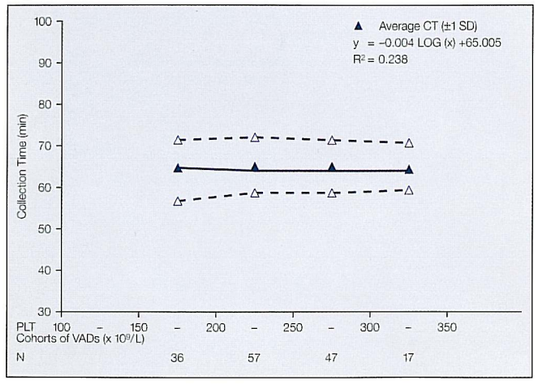


Figure 3C: MCS3p

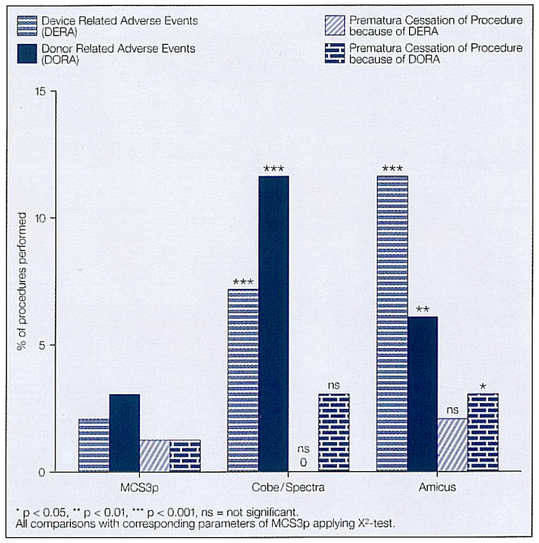


Amicus and Cobe/Spectra provide SDPCs with constant PLT content according to preset target yield (3.2 x 10^{11} PLT/U for Amicus and 2.7 x 10^{11} PLT/U for Cobe/Spectra resp.). In contrast, MCS3p produces SDPCs with steadily increasing PLT content depending on PLT precount of VAD. Using our collection regimen, VADs donating on MCS3p need to have PLT precount >250 x 10^9 PLT/L in order to provide satisfactory SDPCs by SRC criteria (Figure 2A – 2C).

Amicus and Cobe/Spectra revealed good correlation between PLT precount and CT (R^2Amicus = 0.992 and R^2Cobe = 0.986, resp.). However, Amicus collects faster (in average 10 to 15 min) and more efficient (larger slope of regression) as compared with Cobe/Spectra. Since MCS3p is cycle- (time) triggered, there is no modification of CT by PLT precount (Figure 3A – 3C).

3. *Biocompatibility of apheresis devices*
A. *Frequency of DERAs and DORAs* (Figure 4)

Figure 4:



* p < 0.05, ** p < 0.01, *** p < 0.001, ns = not significant.
All comparisons with corresponding parameters of MCS3p applying X^2-test.

B. *Highest ranked DERAs and DORAs (% of procedures performed),* (Table 3)

Table 3:

Device	DERA	DORA
Amicus	Centrifuge lid (17%)	Needle displaced (32%)
	Umbilicus rupture (13%)	ACD toxicity (28%)
Cobe	Return pressure (57%)	ACD toxicity (43%)
	ACD/WB Ratio (21%)	Needle displaced (17%)
MCS3p	Overpressure (29%)	ACD toxicity (24%)
	Leaking kit (23%)	Lipemia (24%)

Technically advanced devices (Amicus, Cobe) generate more DERAs and DORAs. DERAs often require technical support by the device provider. DORAs are mainly ACD related and require administration of Ca-gluconate and/or modification of collection parameters.

CONCLUSION

1. Growing needs for SDPCs, restricted availability of VADs and stringent product standards have become major determinants for SDPC supply of the blood center.
2. Technically advanced devices for collection will be required to comply with modern determinants of SDPC supply.
3. New approaches such as collection of double SDPCs, shortening of apheresis interval and/or priming of VADs with thrombopoietin may become strategies to secure future SDPC supply.

LITERATURE

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