Published in final edited form as:

J Clin Apher. 2018 October ; 33(5): 580–585. doi:10.1002/jca.21644.

THERAPEUTIC WHITE BLOOD CELL AND PLATELET DEPLETIONS USING THE SPECTRA OPTIA SYSTEM CONTINUOUS MONONUCLEAR CELL PROTOCOL

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Abstract

The Spectra Optia apheresis system® has only recently been approved by the Food and Drug Administration (FDA) for therapeutic white blood cell (WBC) and is not yet approved for platelet depletions. Prior to FDA-approval of the WBC depletion protocol, when our available COBE Spectra apheresis systems were out of service, we successfully performed WBC depletion using a modified Spectra Optia apheresis system Continuous Mononuclear Cell (CMNC) protocol. Using this modified Spectra Optia CMNC protocol, we created institutional protocols for WBC and platelet depletions. We performed 10 WBC depletions in 9 patients and 2 platelet depletions in 2 patients. We compared pre- and post-procedure WBC, platelet count, and hemoglobin to the same data from patients previously treated on the COBE Spectra and found no difference in % WBC and platelet reduction. We also found no significant difference in post-procedural hematocrit decline. Additionally, adverse reactions were not increased. Therefore, we conclude that the Spectra Optia CMNC protocol can be successfully modified for effective WBC and platelet depletions without increase in adverse reactions.

Keywords

COBE Spectra; CMNC protocol; leukapheresis; plateletpheresis

INTRODUCTION

The COBE® Spectra apheresis system (Terumo BCT, Lakewood CO) is being phased out of clinical use and replaced by the Spectra Optia® (Terumo BCT, Lakewood CO).^{1,2} Although approved for both white blood cell (WBC) and platelet depletions in Europe since 2011,³ in the United States (US), the Spectra Optia was not Food and Drug Administration (FDA)-approved for therapeutic WBC depletion until March, 2018⁴ and is not currently (FDA)-

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approved for therapeutic platelet depletions. Therefore, until it is completely phased out of clinical use, the COBE Spectra has been retained for this purpose.⁵

Prior to FDA-approval of the WBC depletion protocol, when an emergent need for white blood cell (WBC) depletion occurred with our COBE Spectras out of service, we successfully performed WBC depletion using the Spectra Optia System Continuous Mononuclear Cell (CMNC) protocol.⁶ Anticipating future similar situations, we used a modified Spectra Optia CMNC protocol to create therapeutic cellular depletion protocols. These protocols are now being used successfully for both platelet and WBC depletions.

PATIENTS AND METHODS

Patient Selection

Starting in August 2016, consecutive patients with symptomatic hyperleukocytosis, regardless of absolute blast count, were treated using a modified CMNC WBC depletion protocol. Additionally, consecutive patients with symptomatic thrombocytosis were treated using a modified CMNC platelet depletion protocol. All patients were considered clinically stable to undergo the procedure.

Procedural Supplies

The following equipment was used: Spectra Optia apheresis system; Spectra Optia System CMNC software; Spectra Optia IDL Tubing Set, IDL Filler; Spectra Optia Collection Preference Tool Colorgram; and Astrotherm Blood Warmer with tubing set. The anticoagulant used was anticoagulant citrate dextrose solution, solution A (ACD-A®; Citra Labs, Braintree MA).

Therapeutic Cellular Depletion Protocol

For both WBC and platelet depletions, target settings were programmed to process 2.0 TBV. For WBC depletions, the ACD-A packing factor was 4.5 with an inlet:AC ratio of 12:1. For platelet depletions, the ACD-A packing factor was 20 with an inlet:AC ratio of 10:1. During the procedure, if clumping was present, the inlet:AC ratio was adjusted accordingly. Replacement fluid decisions were made at the discretion of the providers based on vital signs, acuity, and pre-procedure fluid balance. Volume removal was adjusted so that no more than 1 – 1.5 L was removed in a single procedure. All patients received 1 gram of calcium gluconate running concurrent with the depletion procedure, with additional calcium given as needed for symptomatic hypocalcemia. Additional replacement fluids with normal saline (0.9% Sodium Chloride Injection, USP), separate from the apheresis system, were given, running concurrent with the depletion procedure, as clinically indicated.

To avoid depleting too many red blood cells, the collection preference and collect port were monitored to ensure that the color in the collect line was appropriate. The collection status screen was used to access controls for collection preference and for the collect valve that diverts the collect line to the reservoir. Patients were monitored for adverse events such as paresthesias, hypotension, agitation, and nausea.

Collect Pump Flow Rate Determination

The collect pump flow rate was determined according to the following equations, which were provided to our institution by Terumo BCT (Terumo BCT personal communication):

$$\text{WBC collect pump flow rate} = \text{Inlet flow rate} \times (1 - (1/R)) \times (\text{WBC count}) \times (0.0007)$$

where R is the Inlet:AC ratio.

$$\text{Platelet collect pump flow rate} = \text{Inlet flow rate} \times (1 - (1/R)) \times (\text{Platelet count}) \times (0.0006)$$

where R is the Inlet:AC ratio.

The packing factors and inlet:AC ratios were those recommended by Terumo BCT. To maximize nursing efficiency and eliminate calculation error, we inserted the parameters of the above equations into an Excel® spreadsheet to calculate the flow rates. These calculated flow rates were then used to develop a WBC and platelet depletion pump flow rate table (See Table I). Collect flow rates were adjusted for reduced WBC over time and typically decreased after 1.0 blood volumes were processed. Until our protocol was fully developed, each time a procedure was in progress, initial pump flow rate calculations were confirmed with Terumo BCT Customer Support Center representatives.

Statistical analysis

For WBC depletions, we compared age, pre- and post-depletion WBC counts, percent WBC reduction and periprocedural percent hematocrit and platelet decline with patients previously treated with the COBE Spectra. For platelet depletions, we compared pre- and post-depletion platelet counts, percent platelet reduction, and periprocedural percent hematocrit and WBC decline with patients previously treated with the COBE Spectra. Where more than one WBC or platelet depletion was performed within a hospital encounter, only the first episode was recorded. Data were analyzed using descriptive statistics to summarize patient-level demographics and clinical outcomes. To understand differences between the Spectra Optia and COBE Spectra cohorts, an unpaired t-test was used to compare age, pre- and post-procedural WBC, platelet count and hematocrit, and % WBC and platelet reduction. Due to our small sample size, a test for normality could not be applied. For the platelet depletions, due to the very small sample size, statistical tests could not be applied and simple comparison was used. Statistical analyses were performed using data Analysis software, GraphPad prism® v7.0c (GraphPad Software, Inc., La Jolla, CA).

RESULTS

WBC Depletion Results

Since the initiation of the treatment period, the Spectra Optia modified CMNC WBC depletion protocol has been performed on 9 patients who underwent 10 procedures (see Table II). One patient with AML underwent a second leukapheresis procedure 5 months after his first treatment on the Spectra Optia. A second patient with AML was initially treated with the COBE Spectra and 9 months later received leukapheresis using the Spectra Optia.

In the Spectra Optia group, 4 patients (45%) had acute myeloid leukemia (AML; one patient in this group transformed from a prior diagnosis of CML), 2 had chronic lymphocytic leukemia (CLL; 22%) and 3 had acute lymphocytic leukemia (ALL; 33%). In the comparison COBE Spectra group, 7 patients (70%) had AML (one patient in this group transformed from a prior diagnosis of chronic myelomonocytic leukemia), 3 patients (30%) had ALL (one with a T-cell prolymphocytic leukemia).

Between the groups, there was no statistically significant difference in age (57 ± 16 vs. 58 ± 22 ; $p = 0.99$), pre-treatment WBC (224.0 ± 295.7 vs. $266.9 \pm 117.7 \times 10^9/L$; $p = 0.68$) or post-treatment WBC (147.4 ± 281.2 vs. $136.7 \pm 83.3 \times 10^9/L$; $p = 0.91$). Percent WBC reduction between the groups was comparable (50 ± 18 vs. 49 ± 16 %; $p = 0.95$). There was also no statistically-significant difference in periprocedural percent hematocrit decline (9 ± 10 vs. 11 ± 4 %; $p = 0.54$). Additionally, there was no statistically significant difference in pre- to post-procedure percent platelet decline (22 ± 38 % vs. 31 ± 10 %; $p = 0.49$).

The average leukapheresis product volume in the Spectra Optia group was 805 mL (range 499 – 1217 mL) with an average fluid balance of 193 mL (range 9 – 532 mL). In the COBE Spectra group the average product volume was 1101 mL (range 486 – 1791 mL) with an average fluid balance of 125 mL. There were no statistically significant differences in product volumes and fluid balance between the groups ($p = 0.062$ and 0.25 , respectively). Product volumes and fluid balance for each patient procedure are shown in Table III.

Adverse reactions were similar in both sets of patients and limited to mild citrate reactions. In patients treated on the Spectra Optia CMNC protocol, “mild hypotension” and “tingling lips” were reported in one case each. In patients treated with the COBE Spectra, one patient was reported to have “brief agitation” and a second as having “mild hypotension.” All leukapheresis patients received 1 to 4 grams of calcium gluconate intravenously. Details of intravenous calcium gluconate supplementation are included in Table III.

Platelet Depletion Results

The modified platelet depletion protocol has been performed on 2 patients (see Table II). In the both the Spectra Optia and comparison COBE Spectra groups, 1 patient had essential thrombocytosis (ET) and 1 patient had post-polycythemia vera myelofibrosis (MF).

The ages, pre- and post-platelet counts, and percent platelet decline of both Spectra Optia and COBE Spectra-treated patients are shown in Table II. Pre-treatment hematocrit was 35.8 and 28.9 vs. 31.4 and 45.3%, respectively. Post-treatment hematocrit was 35.1 and 26.8 vs. 31.4 and 42.4%, respectively, with a percent decline of 2 and 7 vs. 24 and 6%, respectively. Pre-treatment WBC was 11.0 and 30.7 vs. 78.5 and $7.3 \times 10^9/L$, respectively, while post-treatment WBC was 8.5 and 25.8 vs. 50.4 and $6.3 \times 10^9/L$, respectively. WBC decline was 23 and 16 vs. 36 and 14% respectively.

There were no adverse reactions reported in either patient group. Both platelet depletion patients received 2 grams of calcium gluconate intravenously during the procedure (See Table III).

DISCUSSION

In this manuscript, we report our experience using the Spectra Optia CMNC protocol for leukocyte and platelet depletions. We found that, when compared to the COBE Spectra, white blood cell and platelet depletions on the Spectra Optia show equivalent percent reduction without increase in adverse reactions. Additionally, we showed that, between the two apheresis systems, the post-procedural decline in the non-targeted cell lines was equivalent.

Our results are consistent with findings in the literature that have demonstrated equivalent therapeutic depletion results between the COBE Spectra and the Spectra Optia;³ Additionally, we found no significant difference in outcome parameters between the two apheresis systems. These findings are consistent with the published literature, which shows that hematocrit and platelet counts exhibit a periprocedural decline that is consistent across apheresis systems and leukapheresis protocols.^{7,8}

The intended software for Spectra Optia leukodepletions, which has not yet become available in the US, is the IDL software. Since it became available in Europe in 2011, the Spectra Optia IDL software has been used successfully.⁹ In 70 granulocyte depletions performed with both the Spectra Optia IDL and COBE Spectra granulocyte depletion (PMN) software, the IDL was shown to produce similar apheresis product neutrophil content ($3.4 \pm 0.2 \times 10^{10}$ vs. $3.6 \pm 0.2 \times 10^{10}$; $p = 0.17$) with lower total blood volume processed (6.5 ± 0.1 vs. 7.0 ± 0.04 ; $p < 0.001$), higher leukapheresis product volume (377.2 ± 11.8 vs. 324.8 ± 8.7 ; $p < 0.001$), and lower platelet percent decline (9.8 ± 1.4 vs. 17.5 ± 1.4 ; $p < 0.001$). In our study, we found no significant difference in percent platelet reduction. The absence of any observable difference in platelet decline likely reflects our small numbers. However, the available data suggests that Spectra Optia WBC depletion-related platelet losses during are, at worst, equivalent to, and at best, better than typically seen with the COBE Spectra.

Where the IDL software is unavailable, the best leukodepletion protocol for use with the Spectra Optia is unknown. A recent case report of one patient treated with 3 different leukodepletion strategies: the Therakos CELLEX buffy coat collection vs. the Spectra Optia CMNC and granulocyte (PMN) protocols found that WBC collection was higher with the PMN protocol (0.59 vs. 1.65 vs. 2.39×10^{10} for the Therakos CELLEX, Spectra Optia CMNC and Spectra Optia PMN protocols, respectively).⁵ Additional studies are needed to determine which Spectra Optia collection protocol is best for therapeutic leukodepletion.

Similarly, with regards to platelet depletion protocols, there is not yet a robust body of evidence for use of the Spectra Optia. One case report demonstrated the safety and feasibility of the Spectra Optia in a pregnant patient with thrombocytosis treated with 5 depletions.¹⁰ Another therapeutic apheresis system that has been successfully used for platelet depletions off-label is the AMICUS Blood Cell Separator.¹¹ Nevertheless, it is important to note that the AMICUS collects platelets internally; therefore, the platform has significant limitations for use in patients with extremely high platelet counts.

Of the available Spectra Optia leukodepletion protocols, we chose the CMNC protocol due to nurse familiarity and availability. Prior to initiation of the leukodepletion protocols, our nurses were already familiar with using the CMNC protocol for mononuclear cell collections. Therefore, developing a protocol based on one that was already familiar to our nurses decreased training time and improved patient safety. In addition to CMNC, other leukodepletion protocols that have been used with the Spectra Optia include the standard leukodepletion (IDL) module, which is not FDA-approved in the US, and the granulocyte (PMN) module, which has been used successfully.⁵

In developing the Spectra Optia therapeutic cellular depletion protocol, our biggest concern was automation of the collect pump flow rate calculations. The mathematical algorithms that calculate Spectra Optia collect pump flow rates for both CMNC and granulocyte (PMN) protocols are not designed for cellular depletions because they are not dependent on patient cell counts. Therefore, when using either the CMNC or PMN protocols, cell count parameters are not entered into the system. However, for our cellular depletion protocols, the patient's pre-procedure WBC or platelet count was necessary to determine the collect pump flow rate. Based on the presenting count, the collect pump flow rate would vary with each procedure. We felt that this variation could introduce procedural error. Therefore, from the onset of protocol development, to minimize error, we determined that pump flow rate calculations would need to be automated. Using the equations provided to us by Terumo BCT, automation of the calculations was done by entering the formulas into an Excel® spreadsheet. Individual parameters were entered and flow rates were calculated. Subsequently, to increase efficiency, we calculated the individual pump flow rates using different pre-WBC and platelet counts and inlet flow rates to develop our reference collect flow rate table (Table I). For simplicity, the starting WBC were listed on the table in increments of 10s and 100s and starting platelet counts in increments of 100s and 1000s. For starting WBC or platelet counts that fell in-between these numbers, nurses were asked to determine the starting parameters by rounding to the nearest number. Additionally, for WBC depletions, because the maximum collect pump flow rate is 10ml/min, we quickly reached the maximum flow rate once WBC exceeded 300. Flow rates of 40-60 mL/min were used initially and, depending on type of vascular access, increased as tolerated.

We found the protocol to be easy to follow. Nevertheless, to enable our nurses to remember all aspects of the procedure necessary for a successful outcome and to keep our patients safe, we developed a list of fast facts (Table IV). Although these fast facts are quick and easy to refer to, they are not considered to be a substitute for reviewing our entire standard operating protocol.

Although similar to other studies that have shown successful depletions with the Spectra Optia,^{3,5} our report demonstrates use of the CMNC protocol, which, until now, has not been examined in therapeutic depletions. Our report is also novel in that the CMNC protocol has been used for therapeutic platelet depletions. Once a platelet depletion protocol is FDA-approved and becomes available for our use, further study will be important to determine whether the platelet depletion protocol yields the same platelet depletion result as our modified CMNC protocol.

The recent FDA-approval in March 2018 of the Spectra Optia for therapeutic WBC depletion is much welcome news in the US apheresis community.⁴ The FDA-approved WBC depletion protocol is already embedded in the current Spectra Optia software; but will not be ready for use until a field service engineer performs the task of turning it “on.” This important step will likely occur after Terumo BCT releases an official “Operator’s Manual.” Once the operator’s manual is released, we anticipate that training for the WBC depletion protocol will be made available to all therapeutic apheresis centers using the Spectra Optia nationally. Based on international experience, we understand that the Spectra Optia WBC depletion protocol includes unique features related to fluid balance and ability to administer replacement fluid through the Optia.³ These features will be important for longer depletion procedures performed to achieve high collection rates. An additional benefit is that the pre-installed WBC depletion protocol uses the same disposable set and centrifuge filler as the CMNC/PMN procedure, an important consideration for inventory control of sets. Pending widespread availability and use of the embedded Spectra Optia WBC depletion protocol, if a patient presents with a need for a therapeutic WBC depletion, our CMNC protocol, described above, should be considered.

CONCLUSION:

We have demonstrated that, when compared to the COBE Spectra, therapeutic WBC and platelet depletions using the above-described, modified Spectra Optia CMNC protocols are both effective and safe. Because the COBE Spectra is being phased out of clinical care, whenever a COBE Spectra is not available for a therapeutic WBC or platelet depletion and until the recently FDA-approved WBC depletion protocol becomes widely available, the Spectra Optia protocol that we have developed should be considered.

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Table I.

WBC and Platelet Depletion Collect Flow Rate Table

WBC Count x 10 ⁹ /L	WBC Depletion AC Ratio = 12:1		Platelet Depletion AC Ratio = 10:1		Collect Flow Rate mL/min
	Inlet flow rate mL/min	Collect Flow Rate mL/min	Platelet Count x 10 ⁹ /L	Inlet flow rate mL/min	
50	50	1.6	700	50	1.9
	60	1.9		60	2.3
	70	2.2		70	2.6
60	50	1.9	800	50	2.2
	60	2.3		60	2.6
	70	2.7		70	3.0
70	50	2.2	900	50	2.4
	60	2.7		60	2.9
	70	3.1		70	3.4
80	50	2.6	1000	50	2.7
	60	3.1		60	3.2
	70	3.6		70	3.8
100	50	3.2	1200	50	3.2
	60	3.9		60	3.9
	70	4.5		70	4.5
200	50	6.4	1500	50	4.1
	60	7.7		60	4.9
	70	9.0		70	5.7
300	50	9.6	1700	50	4.6
	60	10		60	5.5
	70	10		70	6.4
400	50	10	2000	50	5.4
	60	10		60	6.5
	70	10		70	7.6

WBC Depletion AC Ratio = 12:1			Platelet Depletion AC Ratio = 10:1		
WBC Count x 10 ⁹ /L	Inlet flow rate mL/min	Collect Flow Rate mL/min	Platelet Count x 10 ⁹ /L	Inlet flow rate mL/min	Collect Flow Rate mL/min
500	50	10	3000	50	8.1
	60	10		60	9.7
	70	10		70	10

For WBC depletions, the ACD-A packing factor is 4.5. For platelet depletions, the ACD-A packing factor is 20. The maximum Collect Pump flow rate is 10ml/min. WBC = White blood count; AC = anticoagulant.

Table II.
Outcomes for WBC and Platelet depletions on Spectra Optia CMNC Protocol Vs. COBE Spectra

Spectra Optia CMNC WBC Depletion Protocol							COBE Spectra WBC Depletion Protocol						
No.	Age	Sex	Dx	Pre-WBC*	Post-WBC*	% ↓	No.	Age	Sex	Dx	Pre-WBC*	Post-WBC*	% ↓
1	54	F	AML	192.8	75.6	61	1	56	F	ALL	298.6	144.3	52
2	74	F	CLL	105.5	50.0	53	2	86	M	AML	264.0	173.1	34
3	53	F	AML	91.1	55.8	39	3	6	M	ALL	376.8	334	11
4	56	F	AML	113.3	40.0	65	4	58	M	AML	276.6	117.6	57
5	19	F	AML	129.8	67.5	48	5	79	M	AML	128.5	59.1	54
6	69	F	CLL	1057.4	946.3	11	6	59	M	AML	452.6	139.3	69
7 [†]	67	M	ALL	128.9	86.3	33	7	73	M	AML	147.5	81.7	45
8	58	M	ALL	89.3	29.3	67	8	49	M	ALL	403.8	186.0	54
9 [^]	54	M	AML	213.7	71.5	67	9 [^]	54	M	AML	193.0	78.9	59
10 [‡]	67	M	ALL	118.5	51.4	57	10	56	F	AML	127.3	53.4	58
Total Average WBC depletion						50	Total Average WBC depletion						49
Spectra Optia CMNC Platelet Depletion Protocol							COBE Spectra Platelet Depletion Protocol						
No.	Age	Sex	Dx	Pre-PLT*	Post-PLT*	% ↓	Age	Sex	Dx	Pre-PLT*	Post-PLT*	% ↓	
1	47	M	ET	1216	839	31	1	82	M	MF	3054	1402	54
2	56	M	MF	2013	730	64	2	64	M	ET	926	542	41
Total Average platelet depletion						48	Total Average platelet depletion						48

* Platelet and WBC count units are $\times 10^9/L$. PLT = Platelet count; WBC = White blood cell count; CMNC = Continuous Mononuclear Cell; AML = Acute myeloid leukemia; CLL = Chronic lymphocytic leukemia; ALL = Acute lymphocytic leukemia; ET = Essential thrombocytosis; MF = myelofibrosis; Dx = Diagnosis;

↓ = reduction.

[†] Refers to the same patient who underwent a second leukodepletion 5 months after the first.

[^] Refers to the same patient who was initially treated with the COBE Spectra and then underwent a second leukodepletion 9 months later.

Table III.

Product Volumes, Fluid Balance, and Calcium Supplementation

No.	Spectra Optia			Leukodepletions			COBE Spectra		
	Collect Volume (mL)	Fluid Balance (mL)	Calcium (g)	No.	Collect Volume (mL)	Fluid Balance (mL)	Calcium (g)	Fluid Balance (mL)	Calcium (g)
1	774	9	1	1	1279	150	3		
2	944	100	3	2	1289	150	2		
3	499	100	3	3	853	150	1.3		
4	598	100	2	4	1791	150	3		
5	526	NR	2	5	567	0	3		
6	1217	100	4	6	769	150	2		
7 [†]	855	370	1	7	1325	52	1		
8	743	532	1	8	1341	150	2		
9 [^]	1035	100	1	9 [^]	1314	150	2		
10 [†]	855	330	2	10	486	150	2		
Platelet Depletions									
1	329	324	2	1	1353	120	2		
2	1400	13	2	2	360	0	2		

[†] Refers to the same patient who underwent a second leukodepletion 5 months after the first.[^] Refers to the same patient who was initially treated with the COBE Spectra and then underwent a second leukodepletion 9 months later.

Table IV.**Fast Facts Checklist for WBC and Platelet Depletions**

1.	USE IDL kit and IDL plate and prime for CMNC
2.	Process 2 times the TBV (about 3 hours).
3.	Use Run target settings to set packing factor for 4.5 (ACD-A only)
4.	Set collect flow rate using the cell count/inlet flow rate/AC ratio chart posted in protocol
5.	Review on the Collection Status Screen that “Collect in Bag,” NOT the “Return to Patient” mode is active. When “Collect in Bag” mode is active, the collect valve will be open to collect in bag.
6.	Check defaults before starting the procedure. Make sure the procedure is not set to collect extra plasma.
7.	Consider fluid balance and vital signs. During procedure, may need to give separate intravenous fluid infusion
8.	Use the collection preference (CP) function to lighten or darken collect line. To lighten the collect line, increase CP. To darken line, decrease CP. Line should be light salmon, about 3% on colorgram. Establish line color within 10-15 min from start and monitor throughout procedure As buffy coat thins, adjustment may be needed.
9.	Keep a consistent flow rate. Intermittent flow rates prevent buffy coat from being collected.
10.	A large volume of ACD-A is used for depletions. Therefore, check iCa pre-procedure and identify and treat hypocalcemia.