CERVOS MEDICAL

Platelet Rich Plasma (PRP) / Platelet Concentrate (PC) Systems: Preparation Processing Protocols

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Abstract

Purpose

To compare the results obtained using platelet concentrate systems that are based on different underlying blood banking protocols.

Methodology

Complete Blood Count (CBC) performance analysis testing was conducted on 60 consecutive blood donor samples after processing utilizing the CERVOS KEYPRP System compared to the ISTO Magellan PRP System. The same donor blood sample was used for each process to calculate the platelet count per mL in whole blood, platelet concentrate, increase over baseline of platelets in the concentrate compared to whole blood, as well as the platelet percent recovery. The hematocrit of whole blood and the platelet concentrate, and the recovery of white blood cells (WBC) including the WBC cell differential between Agranulocytes (lymphocytes, monocytes) and Granulocytes (neutrophils) were also measured. These results were then compared to previously published results from the same laboratory test center that utilized the same exact same standardized testing methodology for other commercially available systems. All calculations were standardized to conform with guidelines for data submission for FDA, 510(k) clearance.

Results

Point of Care (POC) Platelet Concentrate (PC) Systems are designed to produce a specific biologic based on specific Instructions for Use (IFU) modified or adopted by Blood Banking Protocols. A direct comparison between the CERVOS KEYPRP System and the ISTO Magellan PRP System revealed that CERVOS yielded a higher platelet recovery, a hematocrit of less than 2% as well as significant recovery of Agranulocytes (Lymphocytes and Monocytes) with a minimal recovery of Granulocytes (Neutrophils). A retrospective comparison of published results for various other PC Systems conducted at the laboratory test center demonstrate that CERVOS produces superior results.

Conclusion

The CERVOS KEYPRP System consistently produces higher platelet yield with a minimal hematocrit and a favorable Agranulocyte/Granulocyte Ratio. The system is secure, it is closed to external environment and affords the clinician the ability to customize the various blood fractions as specifically desired.

Introduction

Platelet Concentrate is widely utilized to treat sports-related injuries to minimize disability, time away from work and sport activities. There are numerous commercially available systems on the market to prepare PC in the POC setting. These systems rely on gravity separation typically conducted via centrifugation.[7] Blood banks have developed various methodologies for fractionating blood producing different biologic characteristics. The underlying methodology employed directly impacts the concentration of the biologic produced. However, when using a standardized methodology, a negligible difference between commercially available systems has been reported.

Background

Transfusion medicine practices typically process whole blood by centrifugation for two minutes at approximately 800g to separate plasma and platelets. Plasma and platelet preparation are then sequestered into a second bag using a bag press. The large volume of plasma containing platelets is often referred to in blood banking as Platelet Rich Plasma (PRP). The PRP is then filtered to remove any white blood cells (WBC) to be used for allogeneic transfusion purposes to a patient. Blood products used autologously are typically not filtered to remove WBC. This single spin processing protocol is used by Stryker and Eclipse Systems. An additional centrifugation processing step can be performed at this stage to pellet the platelets to form a platelet concentrate (PC). This second centrifuge processing step is performed by CERVOS, EMCYTE and HARVEST Systems. Apheresis technology can be used to capture a platelet concentrate. A single hard spin protocol is often referred to as a buffy coat method.[7] This technology performs a single long spin and then pushes the separated blood through a series of tubes whereby optics and clamps are deployed to separate the various components. This methodology is performed by the ISTO Magellan and ARTHREX Angel Systems.

Blood Bank defines PC as a biologic that undergoes a two-step centrifugation process with an interim decant step. Clinicians often interchange the terms PC and PRP. A more accurate definition for PRP is a biologic obtained by capturing platelets and plasma after a first soft spin and PC as the biologic obtained by capturing platelets after an interim decant step and a secondary centrifugation step for pelleting the platelets into a concentrate or a concentrate obtained through the buffy coat method and apheresis technology.

Patients and Methods

Institutional review board approval was obtained for this study and the data was submitted as part of a 510(K) submission for regulatory clearance. A total of 60 donors underwent venipuncture to provide the requisite sample for testing for the CERVOS **KEY***PRP* and the ISTO Magellan Systems. A complete blood count (CBC) was performed on whole blood and the PC. These results were then compared to previously published results from the same independent laboratory test center using the same standardized testing methodology for other commercially available systems[3]. All calculations were standardized to conform with FDA guidelines for data submitted for 510(K) Clearance. (Appendix)

Results

The CERVOS **KEY***PRP* and EMCYTE Pure PRP Systems have protocols that closely follow blood banking protocols for preparing a PC; two centrifugation steps and an interim decant step. HARVEST also follows a blood banking protocol for preparing a PC but utilizes an automatic decanting centrifuge for the decant step and then employs a third centrifugation step to optionally reduce the red blood cell content (hematocrit). The ARTHREX System is based on apheresis technology and produced a slightly different biologic. Finally, the STRYKER and ECLIPSE PRP Systems do not make a PC, both make PRP as they both decant all of the plasma and platelets but do not perform a secondary centrifugation step to concentrate the platelets.

Device	Description	Sample	PRP volume	Recovery %	Baseline Increase	Hct	WBC
Cervos PC	Head to head	60	8	78	6	1.8	11.5
Isto Magellan	Head to head	60	7.3	68	5.6	7.8	17.7
Emcyte GS 60	Retrospective	6	7	68	5.9	1.1	10.7
Emcyte GS 30	Retrospective	4	4	72	6.6	3.2	11.3
Harvest Clear	Retrospective	6	7	53	4.5	0.1	1.4
Arthrex Angel	Retrospective	6	7	45	3	2.8	5.9
Stryker	Retrospective	4	6	35	0.7	0	0.8
Eclipse	Retrospective	4	6	30	0.5	0	0.3

Variables in the underlying processing protocol impacts the concentration and ratio of differential white blood cells (WBC). The two-spin processing protocol with an interim decant step each produces a similar composition of WBC. The additional third centrifugation step of the HARVEST System practically eliminates WBC from the concentrate. Apheresis based systems produce WBC counts that are higher than the HARVEST three spin processing protocol and but significantly less than the two-spin manual decant protocol. The single spin, single decant protocol had minimal platelets and WBC. The Percent Recovery (%) and WBC differential of the components for the CERVOS **KEY***PRP (*60mL) is shown below.

	Whole Blood				PRP			
	WBC	LY	MO	GR	WBC	LY	MO	GR
Mean	5.8	1.6	0.4	3.8	11.5	9.3	0.9	1.3
% Recovery					26%	77%	31%	5%

Conclusion

Platelet Rich plasma (PRP) has gained growing popularity in the last decades. To date, results in the literature have been highly variable regarding the success of PC injections[4]. Both Castillo et al. and Mazzocca et al. expressed concerns that it may relate to the underlying heterogeneity of available PC produced by different separation systems, affecting the consistency of reported results [5,6]. Certainly, the method of producing a PC, patient selection, clinician experience, and treatment protocol variations can differ greatly to the point that each clinical study and protocol must stand on its own. The practice of medicine is still as much an art as a science and therefore collecting standardized results across centers of excellence is difficult and expensive. The CERVOS **KEY***PRP S*ystem is customizable to allow for adjusting for various hematocrits, increase over baseline, and PC volume to meet the disparate needs of the patient and clinician.

Appendix

All work reported in this paper was performed at Biosciences Research Associates. The research report dated June 4, 2015, Comparisons of and EmCyte PurePRP 2 2015, Harvest/Terumo APC60 / Clear PRP and Arthrex Angel PRP Products (see section 5.1)[1] and Research Study, Comparison of Emcyte GS 30 PurePRP 2, Emcyte GS 60 PurePRP 2, Arteriocyte MAGELLAN, Stryker REGENKIT kit, and ECLIPSE PRP (see section 4.2)[2] and Equivalence Testing: Ranfac Autologous Platelet Separator vs. Predicate Device, Biosciences Research Associates Cambridge, MA[3] calculated percent recovery and increase over baseline using two different methodologies. Specifically, the first two references were not data submitted to FDA and adjusted the calculations of platelet recovery to reflect the amount of anticoagulant used in order to capture the true efficiency of the device to recover platelets regardless of the dilution factor. Under this methodology, a higher ratio of anti-coagulant to blood that reduces the overall number of platelets in the concentrate will not unfavorably impact the calculation because the additional dilution is subtracted from the formula.[1,2,3] The methodology reported in this paper follows a methodology required for FDA validated testing. The counts reflect the number of platelets aspirated and concentrated in the anti-coagulated samples as a measure of what is delivered to a patient. All amounts were converted to the FDA standard. The calculations are shown below:

		Whole Blood		PRP			
		Baseline Plt	Starting Volume	Plt count	Volume	Percent Recovery	Baseline Increase
Device	Sample N	A	B	C	D	(C*D)/(A*B)	C/A
Cervos PC	60	205	60	1226	8	80%	6.0
Isto Magellan	60	205	60	1145	7.3	68%	5.6
Emcyte GS 60	6	221	60	1293	7	68%	5.9
Emcyte GS 30	4	202	30	1084	4	72%	5.4
Harvest Clear	6	221	60	1003	7	53%	4.5
Arthrex Angel	6	221	60	859	7	45%	3.9
Stryker	4	202	8	98	6	36%	0.5
Eclipse	4	202	8	79	6	29%	0.4

Bibliography

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