

The Incidence of CNS Bleeding in Transfusion Dependent Patients Before and After Introduction of Pathogen Inactivated Platelet Components : A Six Year Hemovigilance Survey

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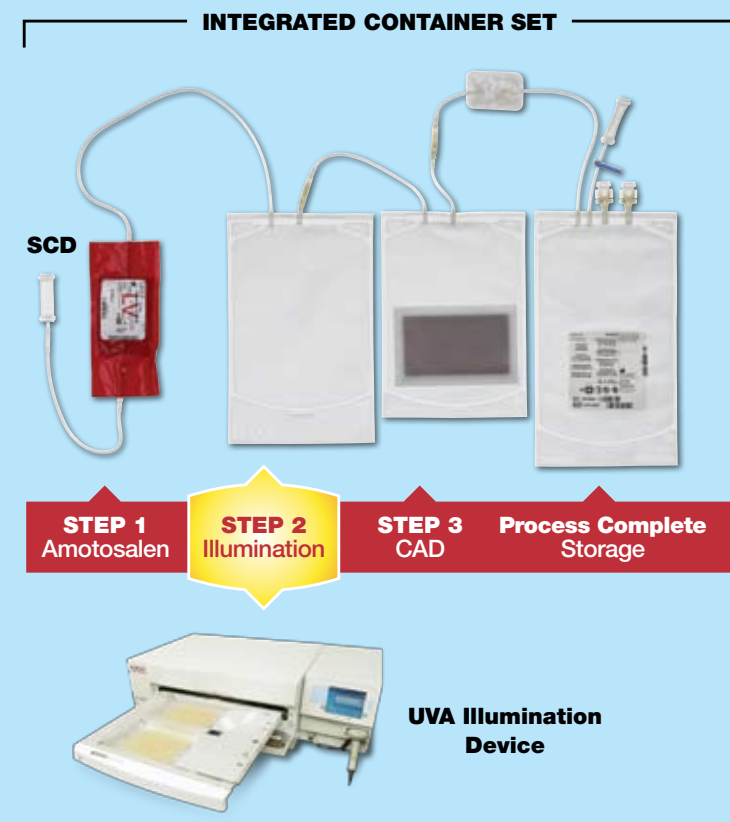


Background

Pathogen inactivated platelet components (PI-PCs) (INTERCEPT Blood System™, Cerus BV, Amersfoort, Netherlands) are used in a large number of transfusion centres throughout Europe. In October 2003, PI-PCs were introduced in routine use in the BTC of Mont-Godinne (Figure 1). INTERCEPT™ treatment of PCs replaced bacterial detection, CMV testing, and gamma irradiation in our center. Comparison of platelet and RBC use by hematology patients requiring chronic platelet support for 3 years before (2000-2003) and 3 years after (2003-2006) introduction of PI demonstrated no change in utilization (Transfusion 2009;49:1412). Central Nervous System (CNS) bleeding, an infrequent serious complication, does not require RBC transfusion, and therefore would not be reflected in RBC component utilization. To determine the impact of PI-PC on CNS bleeding, radiologic examinations were reviewed for the periods before and after implementation of PI-PC.

Figure 1: The INTERCEPT Blood System for Platelets

Using a sterile connecting device (SCD), the platelet container is sterily connected to the INTERCEPT kit. Amotosalen (1) is added by gravity flow and the platelet mixture is illuminated with UVA light (2). Residual amotosalen and its photoproducts in the platelet mixture are reduced to low levels using a compound adsorption device (CAD) (3) before the platelets are transferred to the storage container.



Aims

To assess the impact of PI on CNS bleeding, incidence of CNS bleeding in hematology patients was determined in the 3 years before and 3 years after the introduction of PI-PC.

Methods

Transfusion data for all hematology patients hospitalized and transfused at Mont-Godinne from 2000 – 2006 were analyzed for the two treatment periods as described (Transfusion 2009; 49:1412). Medical records of patients who received platelet components (PCs) were reviewed for radiologic examinations for potential CNS bleeding (CT scan or MNR) within 48 h after each PC transfusion. The reports were reviewed by a neuroradiologist, and classified as negative, positive with other etiologic factors, and positive without etiologic factors for CNS bleeding. CNS bleeding was classified by anatomic site as subdural, subarachnoid, or intraparenchymal. Bleeding incidence in the two treatment periods was compared by exact Chi-square test performed with StatXact software (Cytel, Cambridge, MA).

Results

During the two 3-year observation periods before (conventional PC) and after (PI-PC) introduction of PI at our center, all PCs were stored for up to 5 days prior to transfusions. There were 272 hematology patients hospitalized and transfused at Mont-Godinne in the period before introduction of PI compared to 276 hematology patients in the period after introduction of PI. Unlike the general patient population, hematology patients were intensively transfused due to their underlying diseases. However, introduction of PI had no impact on the usage of PCs (Table 1) and RBC (Table 2) in this patient population. There were no significant differences between the two observation periods in the number of periods of platelet support, days of support, number of platelet transfusions per patient, transfusion/day of support, the total dose of platelets per patient, and platelet dose per day of platelet support (Table 1). Furthermore, there

were no significant differences between the two observation periods with respect to RBC use during periods of platelet support and outside of periods of platelet support (Table 2).

To more specifically define the impact of PI on PC therapy, the subset of hematology patients with potential CNS bleeding were analyzed. Between the two study periods, there were no statistically significant differences in the proportion of patients with CNS bleeding, the proportion of platelet transfusion periods with CNS bleeding, and the incidence of CNS bleeding per 1,000 person-days at risk (p values >0.5). During 3 years before and 3 years after routine implementation of PI-PC there were no differences in utilization of platelet components. Intensively transfused hematology patients exhibited no increased risk of CNS bleeding during periods of platelet transfusion support. (Table 3).

Table 1: Platelet transfusion support for hematology patients before and after adoption of pathogen inactivation treatment of platelet components

Parameter	Conventional PC*	PI-PC*	p Value
Number of patients (n)	272	276	
Periods of platelet support (n)	3.7 (4.6)	4.1 (6.9)	0.40
Duration of support (days)	31.6 (42.6)	33.1 (47.9)	0.70
Transfusions/patient (n)	20.8 (27.1)	24.2 (30.5)	0.17
Transfusions/day of support (n)	0.8 (0.4)	0.8 (0.3)	0.13
Total dose/patient (10 ¹¹)	87.3 (115.4)	88.1 (111.6)	0.93
Dose per day of support (10 ¹¹)	3.2 (1.4)	3.0 (1.3)	0.12

*Data presented as mean (SD).

Table 3: CNS bleeding incidence for hematology patients before and after adoption of pathogen inactivation treatment of platelet components

	Conventional PC	PI-PC	p Value
Hematology patients receiving platelets (n)	272	276	
Patients with CNS imaging within 48 hrs after platelet transfusion (n)	52	45	
Patients with confirmed CNS bleeding (n)	10	11	
Proportion of patients with CNS bleeding (%)	3.7	4.0	> 0.5
Total number of periods of platelet support for haematology patients (n)	1006	1132	
Proportion of platelet transfusion periods with CNS bleeding (%)	1.0	1.0	> 0.5
Total days of platelet support (n)	8593	9312	
Incidence of CNS bleeding per 1,000 person days at risk [95% confidence interval]	1.16 [0.56, 2.14]	1.21 [0.60, 2.16]	> 0.5

Table 2: RBC use by hematology patients during the observation periods, during periods of platelet support, and outside periods of platelet support before and after adoption of pathogen inactivation treatment of platelet components

Parameter	Conventional PC*	PI - PC*	p Value
RBC use during the entire observation period			
Patients (n) [†]	272	276	
RBC units/patient (n)	24.5 (27.1)	26.4 (30.4)	0.43
RBC use during the entire observation period			
Patients (n) [‡]	257	266	
RBC units/patient (n)	25.9 (27.2)	27.4 (30.5)	0.55
RBC use during periods of platelet support			
Patients (n) [§]	222	244	
RBC units/patient (n)	16.4 (19.1)	17.6 (23.3)	0.54
RBC use outside periods of platelet support			
Patients (n)	237	235	
RBC units/patient (n)	12.7 (18.8)	12.7 (19.2)	1.00

* All values expressed as mean (SD).

[†] Patients transfused with platelet components during the observation period.

[‡] Patients transfused with RBC components and platelet components during the entire observation period.

[§] Patients transfused with RBC components during periods of platelet transfusion support.

^{||} Patients transfused with RBC components outside periods of platelet transfusion support.

Conclusions

The introduction of PI-PCs did not result in an increased incidence of CNS bleeding expressed per patient, per period of platelet transfusion support, or the incidence per 1,000 person-days at risk.

References

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