Hemovigilance Surveillance Of Platelet Components Prepared With Pathogen Inactivation Treatment During a Three Year Period.

J P Cazenave, D. Kientz, I. Mendel, H. Isola, and C. Waller.
Etablissement Francais du Sang (EFS) Alsace, Strasbourg, France.

Introduction: EFS Alsace provides labile blood components for 2 million inhabitants of the Alsace region. In mid 2006 pathogen inactivation (PI) treatment of all platelet components (PC) was implemented (Intercept Blood System, Cerus BV, Amersfoort, Netherlands). In compliance with regulations of the nation medicinal agency (Afssaps) quality control and hemovigilance programs were utilized to monitor the quality and safety of platelet components.

Methods: Pooled whole blood buffy coat platelet components (MCP-IA) were produced with use of platelet additive solution (Intersol, Baxter, La Chatre, France) with residual plasma ranging from 32 – 47% by either manual or automated methods (MCP-IA/T) (TACSI, Terumo, Leuven, Belgium) and by apheresis (CPDA-IA) (Haemonetics MCS+, France). All leukoreduced ($\leq 10^6$) components were treated with Intercept (IA) according to manufacturer's directions. Platelet content was determined for all components. Residual amotosalen levels were determined for 1% of components by quantitative HPLC assay. PI was used in place of gamma irradiation and CMV serology without bacterial detection. Clinical response to transfusion was assessed under the Afssaps hemovigilance program (Transfusion 2001; 42: 1356). Adverse reactions to transfusions were compared between EFS-Alsace and national data for the period mid 2006 – mid 2009 using Yates Chi Square with correction for samples with < 5 values.

Results: During 3 years 40,465 PC were monitored for quality control (Table 1) and 42,806 were transfused and evaluated for adverse reactions. Hemovigilance data per 10^6 PC transfused were reported for transfusion transmitted bacterial infection (TTBI), transfusion associated cardiac overload (TACO), TRALI, antibodies to RBC antigens, febrile non-hemolytic reactions and allergic reactions and comparisons were made between IA components in EFS Alsace and national data with conventional PC (Table 2). PC prepared with PI contained sufficient platelet content in conformity with EFS standards and average residual amotosalen levels in compliance with Afssaps standards (mean level < 2.0 μM). Adverse reactions combining all grades (1 -4) were reduced for PI components compared to conventional PLT components.

Conclusions: Platelet components prepared with PI demonstrated acceptable quality control characteristics and reduced adverse reactions over a 3 year observation period.

Table 1: Quality Control Data (Mean ± SD) Reported For Platelet Component Production (2006 – 2009)

Component	Number PC	Platelets (10^{11})	Volume (mL)	Residual Amotosalen (μM)
CPDA-IA	14,644	3.9 ± 0.8	336 ± 22	0.52 ± 0.43
MCP-IA (pool of 6)	21,658	4.6 ± 0.7	313 ± 20	0.27 ± 0.07
MCP-IA/T (pool of 5)	4,163	4.0 ± 0.7	303 ± 16	Not Reported Separately

Table 2: Hemovigilance Data Reported For Transfused Platelet Components (2006 – 2009)

Component	Number PC	Adverse Reactions/ 10^6 PC	P-Value
CPDA-IA EFS Alsace	16,494	2182	< 0.001
CPD National	385,049	6220	
MCP-IA EFS Alsace	26,312	2166	< 0.001
MCP National	117,795	3179	