Safety of Amotosalen/UVA (INTERCEPT) Platelet Components in France over 9 Years, Including 2 Years As the National Standard of Care

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Background

France implemented pathogen reduction (PR) using the amotosalen/UVA INTERCEPT® Blood System for 100% of the national platelet component (PC) supply in November 2017. The conversion to universal PR followed 7 years in which PR PCs accounted for 4-11% of PCs issued annually in France.

Aims

To compare transfusion reaction (TR) rates associated with platelet component (PC) transfusions and blood component use in two sequential time periods in France (2010-2014 and 2015-2019), including the first 2 years of nationwide pathogen reduction (PR) adoption.

Methods

Blood component use and TR rates were manually extracted from French health authority (ANSM) annual hemovigilance (HV) reports for 2010-19. T-tests were performed on the 5 most common TRs in two discrete 4-year periods (2010-14 [P1], 2015-19 [P2]). Chi-square tests assessed annual changes.

Results

Transfusion-transmitted bacterial infections (TTBI) were reported for conventional PCs yearly between 2010-17 (2-9 cases/year). No confirmed or unexpected TTBI were associated with PR PCs during the full study period. Overall TR rates in PC declined from 526 (2010) to 359 (2019) per 100,000 PCs issued. Allergic TRs, alloimmunization, febrile nonhemolytic TRs (FNHTR), immunologic incompatibility and PC refractoriness were (in decreasing frequency) the most common TRs (93% of all TRs per year on average). No statistically significant increases were reported for any TRs during the whole study period, despite significant single-year increases for alloimmunization (2012) and FNHTR (2013) in P1. No significant year-on-year increases occurred for any TRs in P2; however, significant reductions in immunologic incompatibility and alloimmunization were observed in 2016-2017 and 2017-18, respectively (**Figure 1**). Reductions in overall TR trends accelerated in 2018-2019 following the national adoption of INTERCEPT PCs. PC and RBC use increased 17.8% and 3.1%, respectively from 2010-19, but average annual growth slowed for both components between P1 and P2: From 2.4% to 1.7%/year (PC) and from 0.9% to 0.1%/year (RBC). The number of apheresis units issued per year declined from 2014 to 2019. During this period the number of pooled buffy coat (BC)-derived PCs issued per year increased following major changes in production practices implemented in 2018 (**Figure 2**). The average number of BCs included in each pool was reduced from 5 BC per "single dose" unit to 8 BC per "double dose" unit, with reduction in the mean PC dose from ~4.0 to ~3.2 x10^{11} platelets. Annual trends in the proportions of BC-PC and apheresis PC did not change with the national adoption of INTERCEPT PC. Likewise, the overall number of RBCs issued and blood components transfused per patient remained stable in P2.

Figure 2: Platelet Distribution in France, 2010- 2019

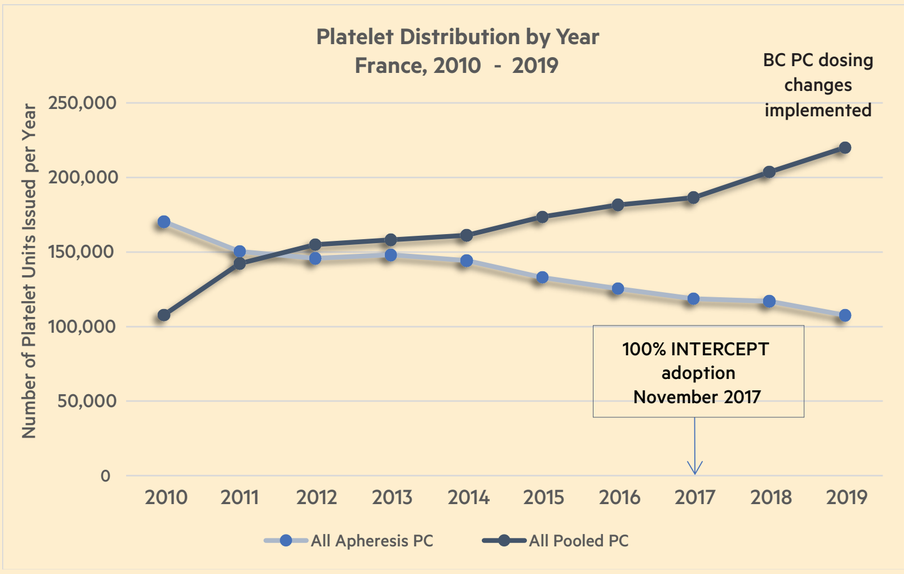
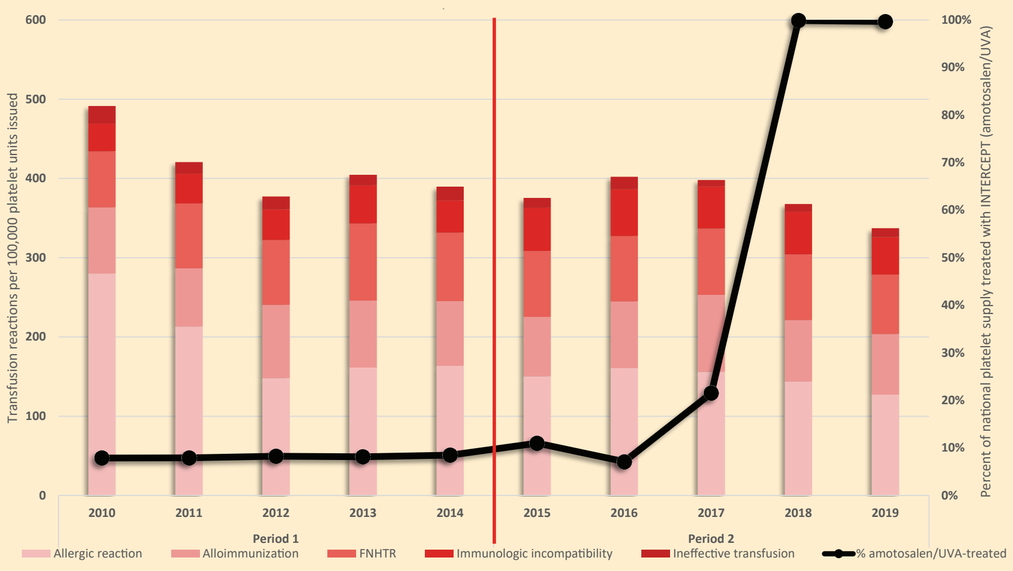


Figure 1: Evolution of Top 5 Most Common Transfusion Reaction Rates Per 100,000 Platelets Issued and Overall Use of INTERCEPT Platelets, France, 2010-2019



Conclusions

France is the largest user of amotosalen/UVA platelet components in Europe, where INTERCEPT PCs account for more than 25% of the PCs transfused in EU member states. National HV data from France show:

- Progressive improvements in PC safety since 2010, including no incidents of TTBI in PR PCs and a trend toward fewer TRs overall.
- Stable RBC and PC use following universal adoption of INTERCEPT PCs despite increases in BC-derived PC use due to changes in national pooling and reduced dosing standards.

HV data from a large country with a well-established hemovigilance program, a diverse patient population and advanced healthcare system are a robust source of clinical data to track safety during a scale-up to PR PCs as the national standard of care.

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