

## Haemovigilance of Transfusions with Platelets Treated with INTERCEPT Blood system™ Using an Active Haemovigilance Programme – Data from Slovenia.

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### Background

The INTERCEPT Blood System utilizes amotosalen and UVA light for the inactivation of pathogens and leukocytes in platelet components. This CE marked technology has been introduced into routine practice of the Blood Transfusion Centre of Slovenia in 2008. In addition to our national haemovigilance (HV) programme, we are since the beginning of 2009 participating in the INTERCEPT™ HV programme, an active haemovigilance programme for the notification of platelet transfusion adverse effects in order to ensure the clinical surveillance of new blood component.

### Objective

An objective of this study was to determine the transfusion safety of INTERCEPT treated platelet components as well as to evaluate the feasibility and quality of this active HV programme.

### Methods

In our open label observational study we used an internet-based electronic data capture system (EDCS) to collect data on a real time basis which accommodates data collection at multiple sites over extended periods of time. In the study we analyzed the clinical outcome of transfusions with INTERCEPT treated platelets to hematology-oncology patients from April 2009 until to date. All adverse events were reported and graded according to the International Haemovigilance Network (IHN) definitions. The collected data were statistically analysed using the EDCS system.

### Results

We have enrolled 80 hematology-oncology patients (47 (59%) male and 33 (41%) female) in the study. Their average age was 54,1 years (median = 54,0; range 19 - 87 years). Seventy-five patients were treated on the non-invasive care unit, 3 were outpatients and for two patients data are not available. The most frequent diagnoses of the enrolled hematology-oncology patients were: acute myelogenous leukaemia in 36 (45%) patients; plasmacytoma in 24 (30 %) patients; acute lymphocytic leukaemia in 6 (7,5%) patients; Non-Hodgkin's Lymphoma in 4 (5%) patients and other diagnoses in 10 (12.5%) patients. Forty-six patients (57,5%) had a history of previous transfusion.

In total the patients received a total of 466 units of INTERCEPT treated platelets. More than half of the units (290; 62,4%) were pooled buffy-coat platelets and 175 units (37.6%) were apheresis platelets. Quality control was performed on 69 (24%) pooled buffy-coat PLT units that contained  $368,0 \times 10^9$  (median) PLTs per unit (range 253,1 - 523,2) and on 30 (17%) apheresis PLT units that contained  $306,7 \times 10^9$  (median) PLTs per unit (range 247,9 – 391,6). The mean number of transfused units of platelets per patient was 5.82 with a range from 1 to 27 units. Only 1 (0,2%) acute transfusion reaction was reported which was a generalised urticaria that vanished after appropriate antihistaminic therapy. There were no reports from the clinic on diminished bleeding control or lower efficacy of transfused PLTs. No death, or episodes of TRALI, or TA-GVHD due to transfusion of INTERCEPT treated platelets were reported.

The collected data were subsequently followed and compared with the reports of others involved in the haemovigilance programme.

### Conclusion

In the study 99,8% of INTERCEPT treated platelet transfusions were without reported adverse effects. An INTERCEPT haemovigilance programme with the EDCS is an excellent tool for the reporting and evaluation of data on adverse events.