HAEMAPHERESIS VIGILANCE: FIRST RESULTS OF AN INTERNATIONAL INTERNET-BASED SYSTEM TO ASSESS DONOR COMPLICATIONS DURING OR AFTER HAEMAPHERESIS PROCEDURES

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Purpose

To assess donor- and/or apheresis-complications related to preparative haemaphereses: a simple, safe, and effective international Internet-based system has been developed: http://haemapheresisvigilance.eu

Methods

All complications (e. g. venous access and circulation problems, citrate toxicity, donor compliance and some technical complications), are assessed with respect to preparative plasmapheresis, platelet apheresis, leukapheresis (blood stem cells, granulocytes, monocytes), red cell apheresis and multicomponent apheresis from healthy donors. The complications are evaluated according to the International Haemovigilance Network Standards. To avoid operator-specific interindividual variability the grading for mild, moderate or severe undesired events are based on the operator's interventions rather than on the operator's subjective estimation of the severity of the complication. An automatic evaluation program will allow comparing the centre-specific complication rate with corresponding rates of other centres from the same institution as well as with a national benchmark. The system is supported by the German Society for Transfusion Medicine and Immunohaematology (DGTI).

Results and Discussion

Currently, 20 centres (Austria, n=1, Germany, n=15 and Switzerland, n=4) use the system. For data assessment two HTML pages are availabe: one page that collects donor variables (e. g. gender, body weight, blood volume) and offers clickable submenues to assess technical characteristics of the planned apheresis procedure (e. g. platelet apheresis, see Fig. 1). The second page is designed for collecting specific information about the complication and its severity (Fig. 2a / 2b). The upper part of this HTLM page records discontinuations and the consequences of this event for the donor (e.g. red cell losses), the set and product logistics (e. g. available products despite discontinuation; Fig. 2a). The middle and lower part of this page include clickable submenues that summarize specific complications (e. g. venous access problems, citrate toxicity, circulation reactions, donor compliance, Fig. 2a) and assess the severity of the complication by an underlying automatical algorithm that combines donor symptoms and medical staff interventions to control the complication. These masks are supported by an entry-control and by an automated evaluation system that is visible for center related authorized personnel only, see here preparative platelet aphereses, January through November, 2012, Fig. 2b).

From January 23, 2012 to December 31, 2012 a total of 4.630 reactions have been recorded to the system. The distribution to different apheresis techniques was 54% for plasmaphereses, 40% for plateletphereses, 5% for stem cell aphereses, other aphereses (granulocytes, lymphocytes, monocytes) ≤1%. The registered undesired events consisted of venous access problems (n=2533; 54.7%), citrate toxicity (n=744; 16.1%), circulation reactions (n=508; 11.0%), donor compliance problems (n=727; 15.7%), technical (apheresis machine or apheresis disposable related) problems (n=453, 9.8%) and combined events comprising at least two events simultaneously (e. g. venous access problem plus circulation reaction, n=416; 9.0%). The reactions were graded as mild 83.6%, moderate 14.7% or severe 1.7%. However, severe reactions associated with hospital stays, injuries lasting one year or more or death were never observed.

Conclusions

This Internet based platform provides a simple, safe and useful tool to assess and to evaluate all relevant complications associated with preparative haemapheresis procedures.

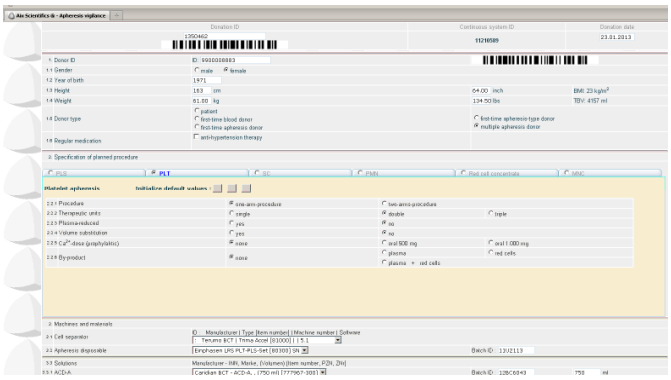

Figure 1 Donor and Procedure related Data (e.g. platelet apheresis)

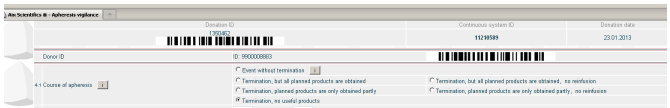

Figure 2a Discontinuation, unsuccessful phlebotomy at Hannover Medical School

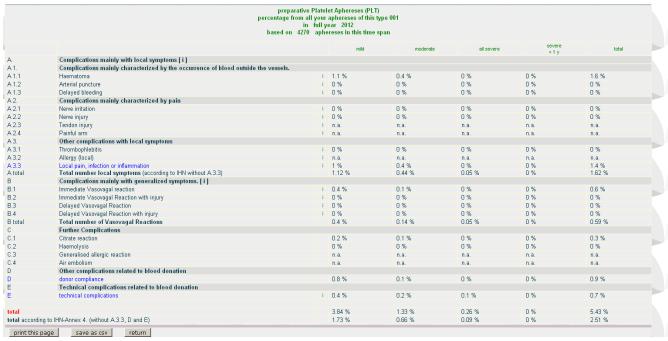

Figure 2b Evaluation according to IHN Standard, here platelet aphereses, collected from 01/2012 – 11/2012.

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