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Novel apheresis device removes platelets and platelet aggregates: a postmarketing surveillance study

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Background: Subgroup analyses within two big recent sham-controlled trials using Adacolumn® granulocyte and monocyte adsorption apheresis (GMCAP) showed clearly better response and remission rates for the GMCAP group in ulcerative colitis (UC) patients with higher disease activity. Platelet abnormalities and secondary thrombocytosis are clinical features of UC and may be involved in the pathogenesis of UC. The number of platelets correlates with disease severity. Recently, we could demonstrate that the novel Immunopure® adsorber strongly removes platelets, monocytes and granulocytes and exhibits a good safety profile. The aim of this post-marketing surveillance study was to evaluate the influence of the Immunopure® device on platelet activation markers and platelet aggregates in patients with active UC.

Methods: Six patients with moderately to severely active UC (clinical activity index (CAI) according to Rachmilewitz 6–10) received 5 apheresis sessions at weekly intervals with a treatment time of 60 min each. Flow cytometry and ELISA (sP-Selectin, sCD40L) were performed during the 1st, 3rd and 5th treatment session at different time points from blood samples of the column inflow and outflow. Blood from 8 healthy volunteers served as controls.

Results: 67% of the patients were in remission, while 83% showed a clinical response after the treatments using the CAI according to Rachmilewitz. Flow cytometry revealed a strong decrease in CD10+ granulocytes (to 48%), CD14+ monocytes (to 29%) and proinflammatory CD14+CD16+ monocytes (to 48%), while T cells remained unchanged. A strong intra-treatment reduction of platelets (to 31%) was accompanied by a reduction of platelet aggregates to about 30%. The platelet activation was significantly increased after the treatment as was reflected by increased numbers of CD63 and P-selectin positive platelets and increased concentrations of sCD40L and sP-Selectin (only during the 3rd session) in the plasma. There were no inter-treatment changes. Compared with healthy volunteers, patients with UC had significantly higher platelet numbers and higher numbers of of platelet monocyte and platelet granulocyte complexes.

Conclusions: Immunopure® treatments improved disease activity. In addition to monocytes and granulocytes Immunopure® is able to adsorb platelets, platelet aggregates and proinflammatory CD14+CD16+ monocytes. Since UC is associated with abnormalities of platelet number and function, their reduction by apheresis may be associated with disease improvement.

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