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P244

Prospective open-label pilot study to evaluate the safety, tolerability and efficacy of a novel adsorptive type cytapheresis module in patients with moderately to severely active ulcerative colitis

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Aim: To evaluate safety, tolerability and clinical efficacy of a novel adsorptive type cytapheresis module in patients with active ulcerative colitis (UC).
Materials and Methods: 10 patients with active UC (defined by Clinical Activity Index (CAI) according to Rachmilewitz: 6–10), who have failed to achieve long-term remission with steroids and/or immunosuppressants or who were contraindicated or intolerant to steroids and/or immunosuppressants were recruited. The new Immunopure® adsorber (Nikkiso, Japan) has been specifically designed to remove activated granulocytes, monocytes and platelets from the peripheral blood. Cytapheresis treatments were performed weekly for five consecutive weeks using the investigational device in a simple hemoperfusion setting with a treatment duration of 60 min (blood flow 30 ml/min). The safety of the device was analyzed by laboratory parameters and vital signs. Disease activity was evaluated by assessing the CAI (baseline, week 6 and week 10) as well as the Endoscopic Index (baseline, week 10).
Results: All of the 10 patients finished the study according to the suggested protocol. All measured safety parameters remained substantially unchanged, both during intra-treatment and inter-treatment periods. Vital parameters such as blood pressure, heart rate and body temperature remained essentially stable during the apheresis sessions. Performance data showed that especially platelets (to 20%), monocytes (to 34%) and neutrophil granulocytes (to 53%) were effectively reduced during the cytapheresis treatments. Remission of the disease was achieved in 8 out of 10 patients (80%) at week 10. Clinical remission was accompanied by the reduction of endoscopic index in 4 out of 9 patients (44%) who gave consent to endoscopic examination.
Conclusion: During this pilot trial the novel semi-selective device Immunopure® has been shown to be safe, well tolerable and clinically efficient in patients with active UC. Response rates and cell reduction rates were comparable to already established cytapheresis techniques. Controlled studies are needed to further elucidate the efficacy of the new device.

P246

Technical performance of a novel adsorptive type cytapheresis module in patients with moderately to severely active ulcerative colitis

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Aim: To evaluate the technical performance and biocompatibility of a novel cytapheresis module in patients with active ulcerative colitis (UC).
Materials and Methods: 10 patients with moderately to severely active UC, defined by Clinical Activity Index (CAI according to Rachmilewitz: 6–10), who have failed to achieve long-term remission with steroids and/or immunosuppressants or who were contraindicated or intolerant to steroids and/or immunosuppressants were recruited. The investigational device was an adsorptive type cytapheresis device (Immunopure®, Nikkiso, Japan) that has been specifically designed to be used in a simple hemoperfusion setting for the removal of activated granulocytes, monocytes and platelets. All patients were scheduled to receive 5 apheresis sessions at weekly intervals (week 1–5) with a treatment duration of 60 min (blood flow of 30 ml/min, anticoagulation by standard heparin). Technical performance was investigated by repeated measurements of cellular blood counts, complement factor C3a as well as different cell surface markers by flow cytometry.
Results: Cellular blood counts showed that platelets (to 20%), monocytes (to 34%) and neutrophil granulocytes (to 53%) were effectively reduced during the treatment at the column outlet. In contrast, lymphocytes were only moderately depleted (to 94%), while red blood cells were not influenced by the device. Flow cytometry data revealed significant reductions of CD10+ granulocytes, CD14+ monocytes, CD62L+ cells, CD11b+ cells, CD3+HLADR+ cells, while there was only little impact on CD3+CD4+, CD3+CD8+ cells. CD42b+CD63+ activated platelets were significantly increased especially in the column outflow. CD4+CD25+FoxP3+ cells were increased after 15 min in the outflow, but decreased at the end of the treatment.
Levels of complement factor C3a were not significantly increased suggesting a high biocompatibility of the column material. This is also reflected by a slight decrease of CD62L mean channel fluorescence and a relative low increase of CD11b mean channel fluorescence.
Conclusion: During this pilot trial with 10 active UC patients the novel semi-selective device Immunopure® has been shown to be highly biocompatible and technically effective. Notably, the material is characterized by high removal capacities for platelets, granulocytes and monocytes.

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