INTRODUCTION

Adsorptive cytapheresis techniques, which selectively remove leukocytes from the peripheral blood, have been recognized as safe and effective treatment strategies for immunological diseases such as inflammatory bowel disease (IBD), rheumatoid arthritis, and other 1-3. Currently, two extracorporeal blood perfusion systems are commercially available: Adacolumn® is using cellulose acetate beads preferably adsorbing granulocytes, monocytes, platelets but only a small fraction of lymphocytes. The Cellsorba® apheresis system consists of a column filled with polyethyleneglycolate fibers and captures lymphocytes, granulocytes, monocytes, and platelets (35% decrease). An increase in peripheral platelets has been recognized as a common feature during the active phase of IBD, and high platelet numbers correlate with disease severity. Interestingly, the reduction of activated platelets has been shown to be a possible early predictor for a successful outcome after leukocytapheresis 4,5. Therefore, the development of new adsorber materials further decreasing activated platelets as well as the number of leukocytes would be an interesting approach for the treatment of patients with IBD. Here, our aim was to evaluate the safety, tolerability and clinical efficacy of the novel adsorptive type cytapheresis module Immunopure® which particularly captures platelets in patients with active ulcerative colitis (UC).

RESULTS

PATIENTS AND METHODS

Demographic data:

10 patients (6 male, 4 female, mean age: 47.1 years, minimum age: 25 years, maximum age: 73 years) with moderately to severely active UC, defined by Clinical Activity Index (CAI according to Rachmilewitz4, 6-10), who have failed to achieve long-term remission with steroids and/or immunosuppressants or who were complicated or intolerant to steroids and/or immunosuppressants were recruited.

Study design:

- 5 treatment sessions at weekly intervals (week 1-5) with a treatment duration of 60 min
- Blood flow of 30mL/min, anticoagulation by standard heparin
- Safety analyses: laboratory parameters and vital signs
- Disease activity: evaluated by assessing the CAI (baseline, week 6 and week 10) as well as the Endoscopic Index (baseline, week 10). Clinical remission in UC is defined as a CAI score of 4 or less. Clinical response is defined as CAI drop ≥ 3 or CAI ≤ 4.

The Immunopure® (Nikkiso, Japan) device has been specifically designed to be used in a simple hemoperfusion setting for the removal of activated granulocytes, monocytes and platelets. The device is a gamma-ray sterilized single use (disposable) module filled with amorphous polylysate resin beads of 1.0 mm diameter. The total volume is 350 ml. The void volume of the device is 130 ml.

### CONCLUSIONS

The apheresis treatments with Immunopure® columns assured a high degree of safety. 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 were essentially stable during the apheresis sessions.
- The tolerability of the apheresis treatments with the Immunopure® device was well to very well.
- The clinical efficacy appears to be very good. The response rates are in full concordance with response rates reported for other adsorptive cytapheresis devices (Adacolumn®; Cellsorba®) in patients suffering from active ulcerative colitis.
- Controlled studies are needed to further elucidate the efficacy of the new device.

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REFERENCES