

Comparative Study of Polyethylene Plasma Separator Sterilized by Ethylene Oxide and Gamma Rays

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Introduction

We studied plasmapheresis using a polyethylene plasma separator, OP-05W (wet-type), with gamma-ray sterilization, newly developed by Asahi Medical Co., Ltd. as well as a commercially available separator OP-05 (dry-type) with EOG sterilization in order to clinically evaluate the operational performance capacity of plasma component separation and effects on plasma proteins.

Subjects and Methods

A total of nine patients, including five with familial hypercholesterolemia (FH), three with malignant rheumatoid arthritis and one with Berger disease, were treated. As for plasmapheresis, LDL-apheresis with a dextran sulfate cellulose bees column (DSC-LA) was used for the treatment of four of the FH patients and double filtration plasmapheresis (DFPP) was used for treatment of the other diseases. The flow rate of blood and plasma were 80 to 130 ml/min and 20 to 44 ml/min, respectively. The average volumes of plasma processed were 4.3 and 4.1 L, and the time needed for treatment was 149 and 145 minutes, respectively, for OP-05W and OP-05.

Results

Trans Membrane Pressure (TMP)

The average TMP during treatment with OP-05W was 10 mmHg or less for all procedures. However, TMP during treatment with OP-05 was increased in three

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of the nine procedures; and the plasma flow rate had to be reduced in two of these three procedures.

Sieving coefficient (SC)

The SC for total protein, albumin, Ig-G, Ig-A, Ig-M and total cholesterol were between 0.94 and 1.0, being high for both separators. There were no significant differences between the two separators (Fig. 1).

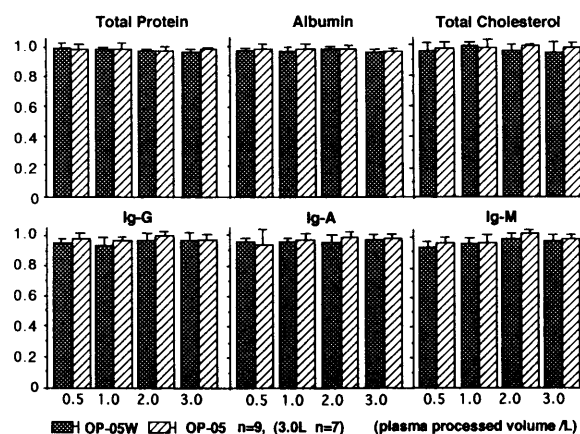


Fig. 1 Sieving Coefficients of Plasma Components

Changes in bradykinin levels

Bradykinin levels in the inlet side of the plasma separator (point A) and in the separated plasma (point B) were 26 pg/ml and less on average, being consistently low in all procedures with OP-05W. On the other hand, the bradykinin level at point A was 23.8 pg/ml or less, being relatively low with OP-05; the bradykinin level at point B was 29 - 40 pg/ml, showing a tendency of slight increase, but returned to 18.0 pg/ml after the treatment was over (Fig. 2).

Granulocyte elastase

Before the initiation of plasmapheresis with OP-05W and OP-05, granulocyte elastase

activities were slightly high at 75.5 and 87.5 $\mu\text{g/L}$, respectively, but no significant difference was observed in any other procedures (Fig. 3).

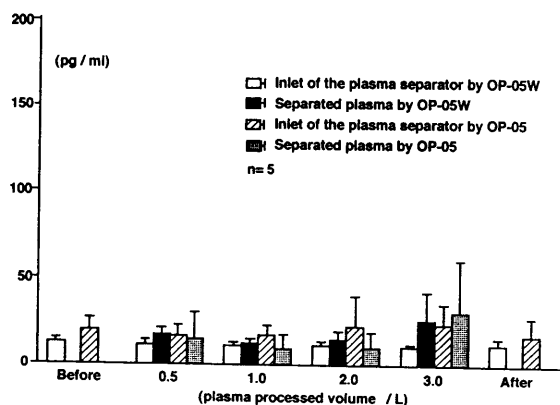


Fig. 2 Bradykinin Level of Patients Treated by OP-05W and OP-05 (DFPP)

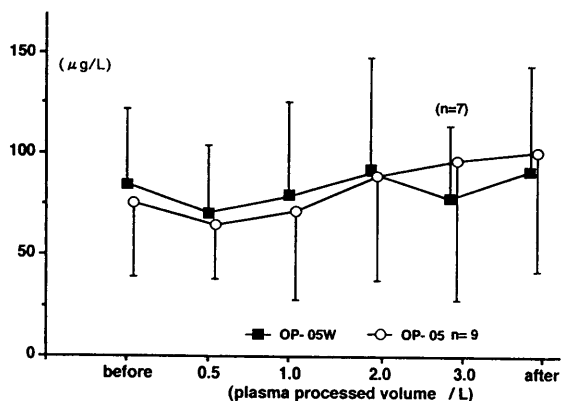


Fig. 3 Comparison of Granulocyte Elastase between OP-05W and OP-05

Adverse effects

No adverse effects attributable to either OP-05W or OP-05 plasma separators were noted on this occasion.

Discussion

The OP-05W was filled with physiological saline and the preparation for operation was easy after sufficient air removal. Accordingly, little air remained in the hollow fibers to keep the effective area wide and small pores open, resulting in low and consistent TMP during the treatment. However, the SCs for OP-05W and OP-05 during the treatment showed no significant difference between the two separators in the

permeability of plasma components. Judging from the experience of using OP-05, OP-05W is also considered to have equal usefulness for plasmapheresis therapy. When an angiotensin converting enzyme inhibitor (ACE-I) was administered during the DSC-LA procedure, anaphylactoid reaction was reported to occur. This phenomenon is considered to occur due to the activation of bradykinin by dextran sulfate and the inactivation of kininase by ACE-I.¹⁾ In this study, no patient received ACE-I and no patient showed high bradykinin levels in DFPP using either OP-05 or OP-05W. Granulocyte elastase is a neutral serine protease released from neutrophils when they are activated or when they are lysed. It is relatively nonspecific in target tissue, so it also impairs normal tissue and is considered to be involved in the etiology and progress of disease such as inflammation caused by inflammatory diseases, rheumatoid arthritis and atherosclerosis. Therefore, granulocyte elastase levels in patient Åfsera were high before treatment, but did not increase during treatment. This suggests that plasmapheresis with OP-05 and OP-05W hardly activates granulocyte elastase, although Joachim Bohler et al.²⁾ reported the activation of granulocyte elastase using OP-05.

Conclusion

The OP-05W has stable operational performance and high permeability, and has little influence on bradykinin and granulocyte elastase levels. It can be considered to be a clinically useful plasma separator.

References

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