

The Clinical Usefulness of Novel Biocompatible Peritoneal Dialysis Fluids (PDFs) with Neutral pH and Low Glucose Degradation Product (GDP) Concentration-Balance

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Objectives : The recent studies have been focused on the impact of PDFs exposure and the relationship to changes in the peritoneal membrane's dialytic function. This relationship may be associated, either to a direct effect of glucose itself, or to GDP formed during heat sterilization of the solutions. We performed a randomized, prospective study to investigate the impact of novel biocompatible PDFs with neutral pH, low GDP concentration (Balance[®], Fresenius Medical Care, St.Wendel, Germany, Balance group) compared with conventional PDFs (Standard group) on peritoneal solute and fluid transport characteristics as well as on other biochemical and clinical parameters.

Methods : 104 clinically stable patients maintained on CAPD for more than 6 months in Severance Hospital were enrolled. After being randomized into Balance group or Standard group (Balance group: Standard group=51:53), subjects undertook blood and effluent sampling, PET and adequacy evaluation at 0, 4, 8, 12 and 24 month visit.

Results : Actual D/P cr values tend to be stable in Balance group compared to Standard group (0 month: 0.67 ± 0.11 vs. 0.67 ± 0.10 , 4 months: 0.66 ± 0.10 vs. 0.65 ± 0.10 , 8 months: 0.67 ± 0.10 vs. 0.66 ± 0.11 , 12 months: 0.66 ± 0.10 vs. 0.66 ± 0.11 , 24 months: 0.67 ± 0.11 vs. 0.70 ± 0.09). Δ D/P Cr (% changes from the baseline values) also tend to be stable in Balance group whereas those of Standard group were increasing with time, but did not reveal significant differences between the two groups. The peritoneal ultrafiltration (mL/g dextrose load) was significantly higher in Balance group compared to Standard group at all follow-up visits (4 months: 9.1 ± 4.3 vs. 6.0 ± 3.0 , 8 months: 8.3 ± 3.4 vs. 6.0 ± 3.0 , 12 months: 8.9 ± 3.3 vs. 6.1 ± 3.3 , 24 months: 8.1 ± 5.1 vs. 6.9 ± 4.3 mL/dextrose g, $p < 0.05$). Peritoneal Kt/V urea and total weekly Kt/V urea at 4 months in Balance group showed significantly higher values than those of Standard group (1.9 ± 0.4 vs. 1.7 ± 0.3 , 2.0 ± 0.4 vs. 1.8 ± 0.3 , $p < 0.05$). The residual renal function tends to be stable in Balance group compared to Standard group, though there was no significant difference between the two groups. Effluent CA125 levels in Balance group were significantly higher than those in Standard group at all follow-up visits during the 24 months follow-up period (4 months: 37.8 ± 20.8 vs. 22.0 ± 9.5 , 8 months: 41.2 ± 20.3 vs. 25.9 ± 11.3 , 12 months: 40.4 ± 21.4 vs. 28.6 ± 13.1 , 24 months: 42.1 ± 22.8 vs. 33.2 ± 12.8 U/mL, $p < 0.05$).

Conclusion : This study suggested that the use of novel biocompatible PDFs with neutral pH and low GDP may contribute not only to the improvement of the peritoneal ultrafiltration and the increase in peritoneal effluent CA125, a marker of peritoneal membrane integrity but also possibly to the preservation of residual renal function in PD patients.