

EFFECT OF LOW GLUCOSE DEGRADATION PRODUCT (GDP) PERITONEAL DIALYSIS SOLUTION GAMBROSOL TRIO® ON RESIDUAL RENAL FUNCTION IN PATIENTS RECEIVING PERITONEAL DIALYSIS – A Randomized Trial

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Introduction

Residual renal function correlates with mortality and morbidity rates in dialysis-dependent patients. It is also a key contributor to peritoneal dialysis technique success.

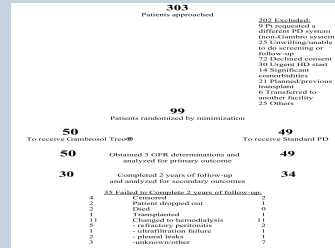
Purpose

We examined whether the use of a biocompatible peritoneal dialysis solution (Gambrosol Trio®) delayed residual renal function decline in incident dialysis patients with GFR

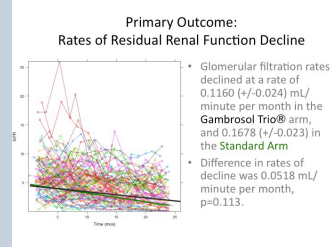
Methods

Patients with glomerular filtration rates of greater than 1 mL/minute were randomized (by minimization to equally distribute variables of centre, CHF and diabetes histories) to receive Gambrosol Trio® (a biocompatible solution with low levels of glucose degradation products) or standard peritoneal dialysis solutions (Baxter solutions) for 2 years. A repeated measures MANCOVA was used to evaluate differences in residual renal function between the two groups for all patients with 3 or more GFR determinations.

Results



| Variable | Gambrosol Trio® | Standard |
|---------------------------------------|------------------|-------------------|
| Female | 12 | 12 |
| Male | 28 | 29 |
| Age (years) (SD) | 59.68 (11.56) | 58.51 (11.60) |
| Original | 38 | 29 |
| Collegium | 2 | 2 |
| Black | 2 | 2 |
| South Asian | 2 | 2 |
| Other | 1 | 1 |
| Number of patients in Hong Kong | 25 | 15 |
| History of Diabetes Mellitus | 25 | 26 |
| History of Congestive Heart Failure | 16 | 20 |
| History of past smoker | 10 | 15 |
| Current of health disease | 1 | 1 |
| Diabetic nephropathy | 12 | 10 |
| Chronic Kidney Disease | 2 | 2 |
| Systolic BP (mmHg) | 4 | 4 |
| Diastolic BP (mmHg) | 2 | 2 |
| Hypertriglyceridemia | 4 | 2 |
| Urine Volume (milliliters per day) | 7,124 (861.335) | 7,126 (1,104.393) |
| Proteinuria (grams per day) | 2.93 (0.41) | 3.40 (0.43) |
| Urine creatinine (millimoles per day) | 4.60 (0.69) | 4.80 (0.64) |
| Urine urea (millimoles per day) | 4.80 (0.77) | 4.32 (0.74) |
| Urea index (millimoles per day) | 1.92 (0.36) | 1.76 (0.34) |
| Hemoglobin (grams/l) | 101.44 (8.33) | 100.10 (7.12) |
| Serum Phosphate (mmol/l) | 1.92 (0.06) | 1.76 (0.06) |
| Serum Albumin (mg/l) | 3.87 (0.88) | 3.37 (0.82) |
| CRP (mg/L) | 9.87 (0.88) | 11.37 (0.86) |
| Weekly Peritoneal Kt/V | 1.40 (0.05) | 1.46 (0.05) |
| Peritoneal EPPV | 6.95 (0.05) | 6.94 (0.05) |
| Dialysis CAI2T (mmol) | 6.82 (0.06) | 6.73 (0.06) |
| Dialysis Bicarbonate (mmol) | 16.82 (0.05) | 16.78 (0.05) |
| Residual BP (mmHg) | 11.50 (1.12) | 11.00 (1.24) |
| Residual HF (mmHg) | 12.30 (1.49) | 14.78 (1.58) |
| Weight (kg) | 62.7184 (2.0910) | 62.87 (2.32) |
| BIA mass by BIA | 24.8461 (1.197) | 23.96 (1.16) |
| Total mass by BIA | 24.8461 (1.197) | 23.96 (1.16) |
| Total mass by BIA | 1.92 (0.06) | 1.76 (0.06) |



Results

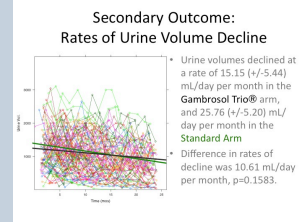


Table 3: Other Secondary Outcomes

| Variable | Gambrosol Trio® | Standard Arm | Significance of Difference |
|---|-----------------|--------------|------------------------------|
| Urea reduction ratio (number of patients) | 4 | 11 | p=0.0518 |
| Urea index (number of patients) | 19 | 17 | p=0.8021 Exact Binomial Test |
| Proteinuria (number of patients) | 55/27=136 | 22/15=147 | p=0.8021 Exact Binomial Test |
| Number of episodes of patients with peritoneal dialysis | 27/10=1.04 | 15/6=0.31 | p=0.0518** |
| Number of patients in treatment group | | | 2 episodes per 100 patients |

Conclusion

Compared with standard peritoneal dialysis solutions, the use of Gambrosol Trio® resulted in clinically, but not statistically, significant slower declines in residual renal function and 24-hour urine volumes.