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Abstract: The objective of this study was to compare the effectiveness of allocated antibiotic treatment to peritonitis in automated peritoneal dialysis (APD) bags without conversion to continuous ambulatory peritoneal dialysis (CAPD), named intervention group or combined APD without antibiotic plus a CAPD to allocate antibiotic for managing peritonitis named control group. We conducted a multicentre non-inferiority randomized, single-blind, clinical trial. Patients with peritonitis were randomly assigned to receive antibiotics (Ceftazidime and Vancomycin) through either APD bags in the night or a CAPD bag in the afternoon. The primary binary outcome was the complete resolution of peritonitis. Data from 64 patients (32 in each group) revealed similar demographic and clinical features. After 15 days, peritonitis resolved in 90.6% of the intervention group and 81.3% of the control group, with no statistically significant difference (p = 0.281). The time from antibiotic initiation to peritonitis resolution was also comparable between the study groups (p = 0.593). Both methods demonstrated similar effectiveness in peritonitis management. This suggests that either antibiotic allocated in APD bags or antibiotic allocated in a CAPD replacement in the afternoon plus APD in the night may be utilized for antibiotic administration in long-term automated peritoneal dialysis patients. Further research could explore additional factors influencing treatment outcomes and optimize peritonitis management.

3. Results

Data from 64 patients were included in the analysis, as two patients in the intervention group were lost to follow-up due to voluntary abandonment of dialytic therapy. Therefore, each study arm comprised 32 patients.

The characteristics of the participants, stratified by the randomly assigned groups, are presented in Table 1. No significant differences were observed between the study arms in terms of demographic data or any of the 17 evaluated comorbid conditions. Additionally, the profile of peritoneal dialysis use, including treatment length and modality, was found to be homogeneous between the study arms.

Table 1. Characteristics of the study groups for selected variables, Mexico 2020 - 2022

Characteristic	Intervention group	Control Group	p
Age (years)	47.4 ± 14.6	51.5 ± 16.9	0.285
Gender			
Female	10 (31.3%)	7 (21.9%)	0.485
Male	22 (68.7%)	25 (78.1%)	
Body Mass Index	26.6 ± 4.9	27.9 ± 6.0	0.676
Erythropoietin, weekly dose (IU)	10,843 ± 5,548	9,437 ± 5,593	0.194
PD, length of (months)	36.0 ± 32.9	30.3 ± 24.8	0.747
APD modality			
CCPD	29 (90.6%)	30 (93.8%)	0.641
INPD	3 (9.4%)	2 (6.3%)	
APD per day, duration (hours)	9.5 ± 0.6	9.6 ± 0.5	0.972
Exchanges per day (number)	5.2 ± 0.8	5.2 ± 0.9	0.954

Isolated pathogen	13 (40.6%)	11 (34.4%)	
No-isolated pathogen	(75%)	(84%)	
Personal history of:			
Tobacco use (yes)	18 (56.3%)	20 (62.5%)	0.611
Alcohol consumption (yes)	22 (68.8%)	24 (75.0%)	0.578
Type 2 diabetes mellitus (yes)	15 (46.9%)	21 (65.6%)	0.131
Diabetic foot (yes)	4 (12.5%)	8 (25.0%)	0.200
Diabetic retinopathy	10 (31.3%)	12 (37.5%)	0.599
Arterial hypertension (yes)	31 (96.9%)	31 (96.9%)	1.000
Ischemic heart disease (yes)	3 (9.4%)	4 (12.5%)	0.120
Stroke (yes)	3 (9.4%)	1 (3.1%)	0.302
Venous thrombosis (yes)	2 (6.3%)	1 (3.1%)	0.554
Hypertriglyceridemia (yes)	19 (55.9%)	15 (46.9%)	0.316
Hypercholesterolemia (yes)	16 (50.0%)	16 (50.0%)	1.000
Hyperuricemia (yes)	9 (28.1%)	8 (25.0%)	0.777
Cataract (yes)	16 (50.0%)	11 (34.4%)	0.206
Anemia (yes)	29 (90.6%)	29 (90.6%)	1.000
Catheter insertion site infection (yes)	8 (25.0%)	6 (18.8%)	0.545
Previous peritonitis episode (yes)	20 (62.5%)	17 (53.1%)	0.448

Abbreviations: APD, automated peritoneal dialysis; IU, international units; PD, peritoneal dialysis; CCPD, continuous cycling peritoneal dialysis; INPD, intermittent nocturnal peritoneal dialysis. The p-values from ji-squared or t-tests are presented, as appropriate.

The prevalence of a previous peritonitis episode was 62.5% (n = 20/32) in the intervention group and 53.1% (n = 17/32) in the control group, with no statistically significant difference (p = 0.448). None of the analyzed individuals received tidal peritoneal dialysis (TPD).

Finally, peritonitis resolution was documented in 90.6% (n = 29/32; 95% confidence interval [CI] 75.0 – 98.0%) of patients who received antibiotics through APD, and in 81.3% (n = 26/32; 95% CI 63.6 – 92.8%) of the control group. These proportions were statistically similar (p = 0.281). The margin of non inferiority analysis was established at 30%, and the result was 9.3%, this limit represents a risk of 0.04, IC(-15.38%-16.38%) power of 99.6%.

The average number of days taken from the commencement of antibiotic treatment to the full resolution of peritonitis was 6.2 ± 2.9 and 5.7 ± 3.3 days for both the intervention and control groups. However, this disparity did not exhibit statistical significance (p = 0.593).

In the analysis of the etiological profile, *E. coli, Staphylococcus epidermidis, Staphylococcus aureus, Pseudomona, Klebsiella pneumoniae, Enterobacter cloacae, and E. coli ESBL*, were the predominant bacterium. In the control group etiological profile was similar to intervention group p 0.23. Notably, the study group exhibited no significant differences in the distribution of identified microorganisms.

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