The Efficacy of Lactulose versus Combination of Ispaghula Husk and Senna in Pre-dialysis Chronic Kidney Disease Patients with Constipations: A Randomized Controlled Trial

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Background: Constipation is a common problem in pre-dialysis chronic kidney disease patients, which leads to a loss of quality of life and increases healthcare costs. Lactulose (duphalac®), ispaghula husk (mucillin®), and senna (senokot®) are useful, but whether lactulose, ispaghula husk and Senna can improve constipation in pre-dialysis chronic kidney disease (CKD) patients are unknown.

Objective: To compare the efficacy of lactulose versus a combination of ispaghula husk and senna to treat constipations in pre-dialysis CKD patients.

Methods: A randomized controlled trial, cross-over study was performed in pre-dialysis CKD patients (GFR < 30 mL/min/1.73 m2) who had constipation (ROME IV). All subjects were randomly assigned to receive either lactulose or combination of ispaghula husk and senna daily for 14 days. After a 7-day washout period, the patients were switched to other substances for another 14 days. Primary outcome was complete spontaneous bowel movement per week, which was assessed by using stool diary after each laxative. Secondary outcome measure was the change of stool appearance by Bristol stool form scale (BSFS).

Results: A total of 23 patients underwent randomization, with 11 patients assigned to receive lactulose and 12 with the combination of ispaghula husk for 14 days. After a 7-day washout period, the patients were switched to other substances. At the end of the study, the mean complete spontaneous bowel movement per week increased in both lactulose with mean ± standard deviation (SD) of 1.25 ± 1.76 (p< 0.003), and the combination of ispaghula husk and senna with 2.45 ± 1.90 (p<.001), respectively. The combination of ispaghula husk and senna led to a significant increase of the mean number of complete spontaneous bowel movement than lactulose 1.05 ± 2.17(p<0.044). The mean ± SD of BSFS at baseline was 3.30 ± 1.36. After the combination of Ispaghula husk and senna, the mean ± SD of BSFS changed to 4.25 ± 1.45 (p =0.021), while after lactulose, the mean ± SD of BSFS changed to 3.95 ± 1.61(p=0.014). There was no significant change in stool appearance after the use of both laxatives 0.3 ± 1.81 (p<0.467).

Conclusion: In pre-dialysis CKD patients, the combination of ispaghula husk and senna is significantly more efficacious for treatment of constipation than lactulose.

Keywords: Chronic kidney disease, Lactulose, Ispaghula husk, Senna, Constipation