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Effectiveness of Pomegranate Juice Powder on Renal Damage in Patients with Diabetic Nephropathy: A Double-Blinded Randomized Clinical Trial

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ABSTRACT

Introduction: Diabetic nephropathy as a progressive disease affects more than 40 % of diabetic patients and is the second leading cause of death in this population. Current medications, including ACEI inhibitors, ARB, Statin, and Calcitriol, represent limitations both in terms of maximum efficacy and adverse effects, including electrolyte imbalance. Animal studies exist regarding the nephroprotective effects of *Punica granatum* extract. The present study aimed to assess the safety and efficacy of pomegranate in patients with diabetic nephropathy.

Methods and Materials: Freeze-dried pomegranate juice powder was purchased from Shaanxi Tianxingjian Co, China (Batch number: LXSL140203). Twenty-five patients in the drug group with 24-hour urine protein ≥ 1 gram received four capsules of pomegranate (each 500 mg ± 5) daily for 8 weeks, while 25 patients in the placebo group received identical-looking capsules similarly. All patients received maximum tolerated doses of ACEI inhibitors/ARB and Statin for the last 6 months before entering the study. FBS, serum creatinine, BUN, AST, ALT, Total cholesterol, HDL, LDL, urine microalbumin, and 24-hour urine protein were measured at baseline and the end of the fourth and eighth weeks. The results were statistically evaluated using IBM SPSS Statistics Version 20.

Results: There were no remarkable statistical differences between the investigated parameters between the drug and the placebo group at baseline. Among all the investigated parameters, urine microalbumin and 24-hour urine protein reduced significantly (P-value 0.001) in the drug group after 4 and 8 weeks compared with the drug group baseline and in comparison to the placebo group at all intervals. Other parameters represent no differences in any of the groups. None of the groups reported adverse reactions during the study interval.

Conclusion and Discussion: Previous studies suggest that pomegranate's phenolic and flavonoid content possesses anti-inflammatory properties by inhibiting IL-1, IL-6, IL-8, TNF-α, and TGF-β. This is the first clinical trial study investigating the efficacy of pomegranate in diabetic nephropathy, suggesting a promising role for this formulation as a supplement for patients receiving standard treatment since it remarkably reduced the leading indicators of diabetic nephropathy known as urine microalbumin and 24-hour urine protein.

Keywords: Clinical trial, Diabetic nephropathies, Pomegranate

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