

Study Protocol – Cover Page

Official Study Title:

A Prospective, Randomized Study Comparing the Effect of Alfuzosin, Mirabegron, and Their Combination on DJ Stent-Related Symptoms After RIRS

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COMPARISON OF THE EFFICACY OF ALPHA-BLOCKERS AND MIRABEGRON ON SYMPTOMS ASSOCIATED WITH DJ STENT IMPLANTED AFTER RETROGRADE INTRARENAL SURGERY

ABSTRACT

Introduction: This study aimed to evaluate the efficacy of alfuzosin, mirabegron, and their combination on stone-free rates, residual fragments, stent-related pain, and lower urinary tract symptoms (LUTS) in patients undergoing double-J (DJ) stent placement following retrograde intrarenal surgery (RIRS).

Methods: A prospective, randomized, single-center trial was conducted between February 2022 and December 2023 at Gaziantep University. A total of 103 patients who underwent RIRS for unilateral renal stones (1–2 cm) followed by DJ stenting were enrolled. Patients were randomized into four groups: Group 1 (control, no medication), Group 2 (alfuzosin 10 mg/day), Group 3 (mirabegron 50 mg/day), and Group 4 (alfuzosin + mirabegron). Pain and LUTS were assessed at 30 days postoperatively using the Visual Analog Scale (VAS) and Overactive Bladder-Validated 8 (OAB-V8) form.

Results: The mean age was 43.55 ± 13.93 years. No statistically significant difference was found between groups in stone-free rates, residual stones, pain, or LUTS ($p > 0.05$). Group 2 (alfuzosin) had the lowest mean VAS (1.69 ± 1.52) and OAB-V8 (13.5 ± 7.37) scores, though not statistically

significant when compared to the control group ($p = 0.112$ and $p = 0.592$, respectively). Residual stones were detected in 27.2% of patients, and stone size was a significant predictor ($p = 0.025$).

Conclusion: The use of alfuzosin and mirabegron alone or in combination did not have a significant effect on stone-free rates, procedural pain and LUTS. However, alfuzosin may have potential benefits in both pain control and favorable effects on storage symptoms. Further larger-scale studies are warranted.

Keywords: Retrograde intrarenal surgery, double-J stent, alfuzosin, mirabegron, stent-related symptoms