

Efficacy of DJ Stenting versus Silodosin after Ureteroscopic Lithotripsy for Lower Ureteric Stones: A Prospective Randomized Clinical Trial

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ABSTRACT

Background: A Double J (DJ) stent utilizing following ureteroscopy facilitates the residual fragments passage and provides pain alleviation produced by mucosal swelling & obstruction, despite several complaints of stent related pain postoperatively.

Objective: The current work aimed to compare DJ stenting and Silodosin following ureteroscopy lithotripsy for lower ureteric stones.

Patients and methods: This prospective randomized open label parallel clinical trial was carried out on 70 cases diagnosed with lower ureteric stone 5-18 mm in size and scheduled for ureteroscopic lithotripsy. Cases were randomly allocated into 2 equal groups; group A had a 5 Fr DJ stent to be removed after 3 weeks and group B who get 1 silodosin capsule 8 mg at night preoperatively and for 3 weeks postoperatively. All cases underwent plain X-ray of the kidneys, ureters, and bladder (KUB), ultrasonography, and non-contrast CT of abdomen and pelvis before operation.

Results: Group B had a significantly shorter operative time than group A (21.7 ± 4.65 min vs. 38.6 ± 4.82 min, $P < 0.001$ respectively). Postoperative follow-up of symptoms at days 3, 7, and 15 were insignificantly different between both groups. Group B had a significantly higher stone free rate 24 hours than group A (91.43% vs 68.57%, $P = 0.034$). Group A had a significantly higher need for secondary procedure & residual fragmentation than group B ($P < 0.001$)

Conclusion: Compared to the DJ Stent group, operative time is significantly shorter in cases received silodosin after ureteroscopic laser lithotripsy.

Keywords: DJ Stenting, Silodosin, Ureteroscopic Lithotripsy, Lower Ureteric Stones.

INTRODUCTION

10 - 15 % of whole population is affected by ureteral calculi, and the urolithiasis incidence is elevating over time [1]. It is known that most of these stones pass on their own, with or without expulsive medical treatment and calculus is expelled based on the calculus's size and placement within the ureter. In accordance with these variables, the expulsion rate for calculi < 5 mm ranges from 40 - 98 %, whereas that of calculi the calculi of ≥ 6 mm is between 35 - 50 % [2].

In the presence of stones, and because of presence of α -adrenergic receptors (α -ARs) within ureteral smooth muscles, therefore their contraction results in ureteral colic. The reactive inflammation generated by calculus irritation of the ureteric mucosa creates mucosal swelling, hence enhancing stasis causing obstruction. The lower ureter section involves greatest density of the receptors compared to upper one [3].

70 % of these stones are distal ureteric stones, that are predominantly symptomatic. The ideal choice for distal ureteral stone therapy is determined by stone composition, location, size, clinical variables, surgeon experience & equipment availability [4].

Several studies have demonstrated that semirigid ureteroscopy (URS) lithotripsy is of high success rate for distal ureteric stones treatment despite having various disadvantages that might be hazardous and sometimes problematic [5, 6].

The ureteric calculi therapy is tailored to the patient depending on the need for additional procedures, success rates of various treatment approaches, and the morbidity associated with treatment modality. When

determining the appropriate therapy for ureteric calculi, stone factors (composition, location & burden) and both patient factors (medical comorbidities, coagulation status & body habitus) will be put in consideration [7].

A Double J (DJ) stent utilizing following ureteroscopy facilitates the residual fragments passage and provides pain alleviation produced by mucosal swelling & obstruction, despite several complaints of stent related pain postoperatively. Stent removal is an additional surgical procedure that increases the expense of treatment. Stent related morbidity has been deemed a potential health risk despite their utility [8].

There have been numerous attempts to alleviate these symptoms, but pharmaceutical treatment is the most noninvasive & straightforward alternative. Interestingly, the lower ureter contains an α -ARs abundance, that are responsible for phenylephrine-induced ureteric smooth muscle contraction. While sustaining tonic propulsive contractions, muscle relaxation is provided by the application of a α -blocker that dilates the ureter. Therefore, α -blocker administration reduces intra-ureteric pressure, allowing urine passage. Numerous medications, as anticholinergics, phosphodiesterase inhibitors (PDE5Is), α -blocker & analgesics had been tested to alleviate these symptoms [9, 10].

Silodosin is a highly selective $\alpha 1$ -ARs antagonist utilized for lower urinary tract symptoms (LUTS) treatment. The lower urinary tract smooth muscle cells are densely populated with $\alpha 1$ -ARs, and silodosin induce their relaxation, other investigations have

demonstrated a similar effect. It is documented as a ureteric calculus treatment [11, 12].

We hypothesized that silodosin could replace stenting following ureteroscopic lithotripsy. Using silodosin can prevent morbidity associated with stents and the need for a second operation.

The current work aimed to compare DJ stenting and Silodosin after ureteroscopy lithotripsy for lower ureteric stones.

PATIENTS AND METHODS

This prospective randomized open label parallel clinical trial study included a total of 70 patients aged >18 years, both sexes, diagnosed with lower ureteric stone 5-18 mm in size and scheduled for ureteroscopic lithotripsy, attending at Department of Urology, Benha University Hospitals, Benha. This study was conducted between the period from February 2023 to July 2023.

Exclusion criteria: Cases with neurological disorder, acute pyelonephritis or sepsis signs, history of bladder or prostatic surgery, incomplete stone fragmentation needing secondary procedure, acute or chronic renal insufficiency, a history of ureteral stenting or long-term stenting with regular stent replacement, multiple or bilateral ureteral stones, stones removed totally using a Dormia basket or forceps, intra-operative complications such as ureteric perforation, and cases not available for follow up.

Randomization:

Cases were randomly allocated into 2 equal groups by sealed opaque envelopes and a computer-generated sequence. **Group A (n=35):** a 5 Fr DJ stent was applied, to be eliminated after 3 wks. **Group B (n=35):** received 1 capsule of Silodosin 8 mg in the night preoperatively and for 3 weeks post-operatively.

All cases were subjected to the following: complete history taking (Age, sex, BMI), general examination (blood pressure, heart rate, temperature), physical examination, laboratory investigation CBC, urinalysis with urine culture, renal function tests (serum creatinine, and urea), plain X-ray of the kidneys, ureters, and bladder, ultrasonography, and non-contrast CT of abdomen and pelvis. As the stone's size, the largest dimension was considered.

Ureteroscopic Lithotripsy Technique:

To check the bladder & urethra as well as locate the targeted ureteric orifice, cystourethroscopy was performed under spinal anesthetic after placing the cases in lithotomy posture and. Under fluoroscopic supervision and through the anticipated ureteric orifice, a 0.089 cm (0.035 inch) guidewire was applied until it reached the kidney.

Then, a 6/7.5 F semirigid ureteroscope was inserted into the ureteric orifice so, there was no need for balloon dilation. Then, to access the stone, the ureteroscope was applied into the ureter, and a lithoclast probe was used to disintegrate it. Using a lithotripter, calculi were

totally fragmented. Calculus fragments were not collected.

Following complete fragmentation of the calculus, a 5 Fr DJ stent was inserted in group A cases to be removed after 3 wks., whereas patients in group B patients get 1 silodosin capsule 8 mg at bedtime preoperatively and for 3 weeks postoperatively.

If there was no hydronephrosis or no major stone fragments (0.2 cm), patients were deemed stone-free.

When the body temperature reached 38°C, a diagnosis of fever was considered. Mucosal damage requiring intraoperative ureteric stenting or causing postoperative hematuria was deemed serious.

If cases were symptomatically better, they could be discharged on day one postoperatively, and were followed up for symptom evaluation on 3, 7, & 15 days postoperatively. Additionally, they were asked to report a flank pain, LUTS, hematuria or fever. Each patient's operative time, stone-free rate, re-hospitalization, and need for a second approach were evaluated. On the 21st postoperative day, pelvi-abdominal non-contrast CT was performed to exclude any residual stones in the ureter.

Our primary outcome was presence of residual fragments at 21st days. Our secondary outcome was overall complication, stone free rate determined by non-contrast CT, re-hospitalization.

Sample size calculation

G. power 3.1.9.2 (Universität Kiel, Germany) was used for sample size calculation which was calculated according to non-contrast pelvi-abdominal CT on the 21st postoperative day to search any residual fragments (our primary outcome) which was found in (40%) of DJ Stent group and was found in (10%) of silodosin group according to a previous study. [13] Based on 0.05 α error and 80% power of the study, allocation ration 1:1. To overcome dropout, 6 cases were added (3 cases in each group). Therefore, 70 patients were be allocated.

Ethical consideration:

The trial was performed after approval of Ethical Committee at Urology Department, Benha University Hospital, Benha, Egypt (Approval code: RC 6-2-2023), and Registry No. of the study/trial: NCT05823662. An informed written consent was obtained from the patients. The study protocol conformed to the Helsinki Declaration, the ethical norm of the World Medical Association for human testing.

Statistical analysis

Statistical analysis was performed by SPSS v28 (IBM Inc., Armonk, NY, USA). Chi-square test or Fisher's exact test when appropriate were used for qualitative data which was represented as frequency and percentage (%). Unpaired Student's t-test was used for comparison of quantitative data, which was represented as means (\pm SD). Two-tailed P value <0.05 was the threshold for statistical significance.

RESULTS

In this trial, 97 cases were evaluated for eligibility, 8 cases declined to participate & 19 cases did not match the criteria. 70 cases were randomly allocated into 2 groups (35 cases in each). All allocated patients were followed-up and analyzed statistically. **Figure 1**

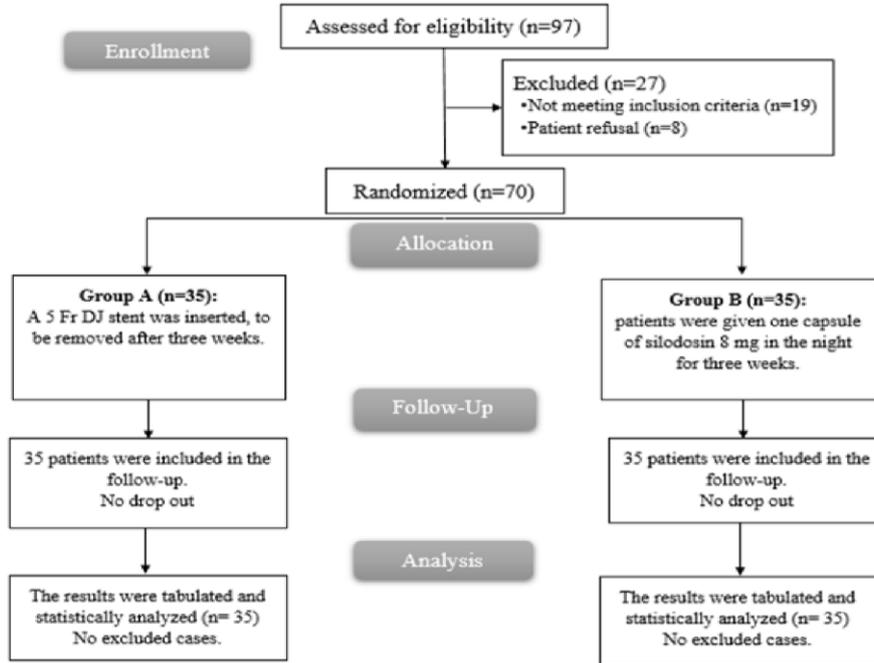


Figure 1: CONSORT flowchart of the enrolled patients

Baseline characteristics (age, sex, & BMI) were comparable between both groups. **Table 1**

Table 1. Baseline characteristics and clinical data between the studied groups

| | | Group A (n = 35) | Group B (n = 35) | P value |
|-------------------------------|---------------|------------------|------------------|---------|
| Age (years) | | 34.5 ± 9.39 | 37.6 ± 9.3 | 0.168 |
| Sex | Male | 23 (65.71%) | 26 (74.29%) | 0.602 |
| | Female | 12 (34.29%) | 9 (25.71%) | |
| BMI (kg/m²) | | 28.9 ± 3.29 | 29.8 ± 3.11 | 0.264 |

Data are presented as mean ± SD or frequency (%). BMI: Body mass index.

The stone characters (side, size and number of patients had radio-opaque calculus) were insignificantly different between both groups. **Table 2**

Table 2. Stone characters between the studied groups

| | | Group A (n = 35) | Group B (n = 35) | P value |
|------------------------------|--------------|------------------|------------------|---------|
| Stone side | Right | 20 (57.14%) | 17 (48.57%) | 0.632 |
| | Left | 15 (42.86%) | 18 (51.43%) | |
| Stone size (mm) | | 10.2 ± 3.08 | 11.4 ± 3.58 | 0.128 |
| Radio-opaque calculus | | 23 (65.71%) | 20 (57.14%) | 0.623 |

Data are presented as mean ± SD or frequency (%). *: statistically significant as P value <0.05

Group B had significantly shorter operative time compared to group A (21.7 ± 4.65 vs. 38.6 ± 4.82 respectively, P <0.001). Number of re-hospitalized patients, immediate emergency visit and need for analgesia were insignificantly different between both groups. **Table 3; Figure 2**

Table 3. Operative or data between the studied groups

| | Group A (n = 35) | Group B (n = 35) | P value |
|----------------------------------|------------------|------------------|---------|
| Operative time (min) | 38.6 ± 4.82 | 21.7 ± 4.65 | <0.001* |
| Re-hospitalized | 2 (5.71%) | 3 (8.57%) | 1.0 |
| Immediate emergency visit | 4 (11.43%) | 7 (20%) | 0.513 |
| Need for analgesia | 2 (5.71%) | 3 (8.57%) | 1.0 |

Data are presented as mean ± SD or frequency (%). *: statistically significant as P value <0.05

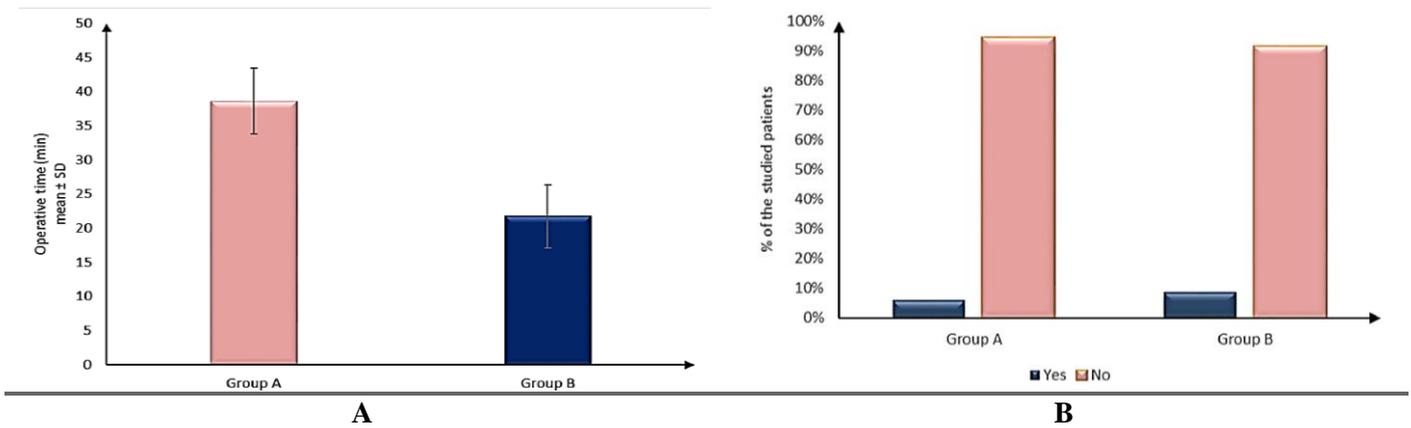


Figure 2: (A) Operative time, and (B) rehospitalization between the studied groups

Post- operatives follow up:

The mean postoperative follow-up of symptoms was 9.23 ± 4.19 days. On day 3 of follow up, 45.71% of group A and 54.29% of group B were asymptomatic. 34.29% of group A and 37.14% of patients in group B had flank pain. LUTS was found in 5.71% of group A and 2.86% of group B. Finally, haematuria occurred in 14.29% of group A and 5.71% of group B. On day 3, clinical symptoms were comparable between treatment modalities.

On day 7 of follow up, 54.29% of group A, and 74.29% of group B were asymptomatic. Flank pain was reported in 28.57% of group A, and 17.14% of group B. LUTS was found in 5.71% of group A and didn't occur to any patient in group B. Haematuria occurred in 11.43% of group A, and only 8.57 % of group B. Clinical symptoms on day 7 were insignificantly different between both groups.

On day 15 of follow up, 80 % of group A and 77.14% of group B were asymptomatic. 11.43% in group A and 5.71% in group B reported flank pain. Fever occurred only in 14.29% of group B but not occur in group A. LUTS was reported only in 2.86% of group A but not reported in group B. Haematuria was present in 5.71% in group A and 2.86% in group B. On day 15, clinical symptoms were insignificantly different between both groups. **Table 4**

Table 4. Postoperative follow-up of symptoms (overall complication) of the studied groups

| | Group A (n = 35) | Group B (n = 35) | P value |
|---------------|------------------|------------------|---------|
| Day 3 | | | |
| Asymptomatic | 16 (45.71%) | 19 (54.29%) | 0.633 |
| Flank pain | 12 (34.29%) | 13 (37.14%) | 0.803 |
| LUTS | 2 (5.71%) | 1 (2.86%) | 1.0 |
| Hematuria | 5 (14.29%) | 2 (5.71%) | 0.428 |
| Day 7 | | | |
| Asymptomatic | 19 (54.29%) | 26 (74.29%) | 0.134 |
| Flank pain | 10 (28.57%) | 6 (17.14%) | 0.393 |
| LUTS | 2 (5.71%) | 0 (0%) | 0.493 |
| Hematuria | 4 (11.43%) | 3 (8.57%) | 1.0 |
| Day 15 | | | |
| Asymptomatic | 28 (80%) | 27 (77.14%) | 0.771 |
| Flank pain | 4 (11.43%) | 2 (5.71%) | 0.673 |
| Fever | 0 (0%) | 5 (14.29%) | 0.054 |
| LUTS | 1 (2.86%) | 0 (0%) | 1.0 |
| Hematuria | 2 (5.71%) | 1 (2.86%) | 1.0 |

Data are presented as frequency (%). LUTS: lower urinary tract symptoms*: statistically significant as P value <0.05

Group B had a significantly higher stone free rate 24 hours than group A (91.43% vs 68.57%, P =0.034), group A had a significantly higher need for secondary procedure & residual fragmentation than group B (P <0.001) where, only 2 patients in group B needed DJ stent insertion. **Table 5; Figure 3**

Table 5. Stone free rate, need for secondary procedure, and residual fragmentation of the studied groups.

| | Group A (n = 35) | Group B (n = 35) | P value |
|------------------------------|------------------|------------------|-------------------|
| Stone free rate 24 hours | 24 (68.57%) | 32 (91.43%) | 0.034* |
| Stone free rate 72 hours | 27 (77.14%) | 33 (94.29%) | 0.084 |
| Need for secondary procedure | 35 (100%) | 2 (6%) | <0.001* |
| Residual fragmentation | 13 (37%) | 2 (6%) | <0.001* |

Data are presented as frequency (%), *: statistically significant as P value <0.05.

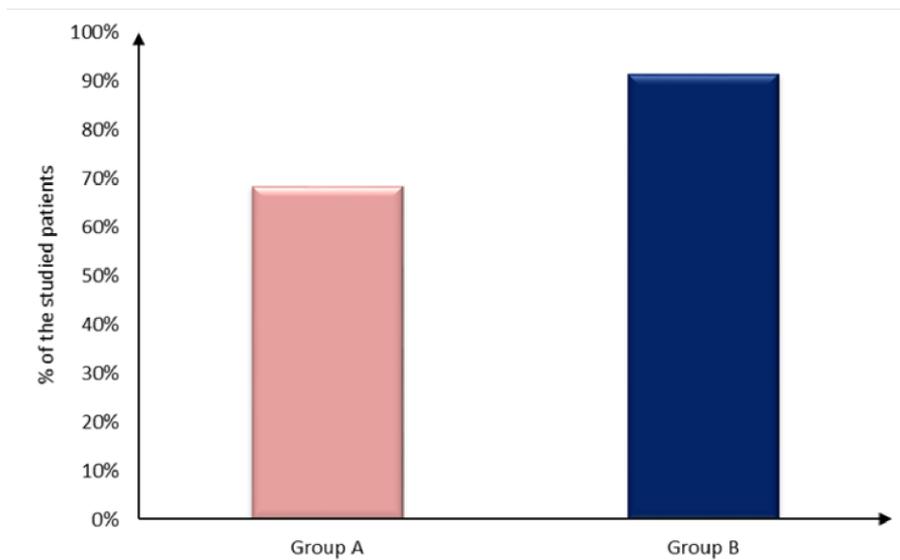


Figure 3: Stone free rate 24 hours between the studied groups.

DISCUSSION

Ureteroscopic lithotripsy is the preferred treatment for distal ureteral calculi. However, it is not risk-free. No standard guidelines available for stents selection for ureteral stones management [12, 14]. This trial was designed for evaluation of the preoperative silodosin effect on the semi-rigid URS efficacy for lower ureteric stones.

In many instances, DJ stenting is performed even after a simple URSL. 63 % of urologists stented patients following URSL as reported by a previous research [15]. Stents have a significant negative influence on patient's life even though stent-related symptoms are a serious concern with their utilization and can occur in most cases. The pathophysiology of these symptoms has been the subject of numerous speculations, but the specific mechanism remains unknown [16-18].

The complications of the stent itself is the most prominent disadvantages of ureteral stenting in the majority of cases. The most prevalent complication caused by the stent are pain and frequency. Additionally, dysuria, urgency, bloody urine, and infection are caused by stents irritation and stimulation of the bladder mucosa. DJ stents are believed to result in ureteric inflammation & swelling, which may have long-lasting consequences. Therefore, it is recommended to utilize just temporary stents. Typical late DJ stent problems as encrustation, migration, hydronephrosis & fragmentation upon removal [19, 20].

Byrne *et al.* [21] discouraged routine DJ stenting after simple URSL. In their evaluation of 60 instances, 38 cases were stented for a mean of 5.2 days whereas 22 cases did not have a stent. There was less flank pain in the stent-free group. Stented patients experienced increased suprapubic pain ($p=0.003$). On day 1, LUTS was comparable between all cases while on day 6, DJ stent group had a significantly higher LUTS. They determined that, if possible, DJ stenting following URSL may be avoided.

In a meta-analysis conducted by Wang *et al.* [17] on treatment of ureteric calculus with or without stent. Pain alleviation & stone elimination were comparable across the stented & non-stented groups. Stenting is significantly more likely to experience infections, haematuria & LUT symptoms.

The compatibility of these stents has been improved via the use of preventative and pharmacological techniques. As a result of increasing stone clearance rate & lowering the expulsion time, literature supports the α -AR blockers effectiveness as medical expulsive treatment for ureteric stones. Recent development of silodosin as a highly selective α_1 -AR blocker [22].

In Bhattar *et al.* [12] study, 335 cases who underwent DJ stenting and developed stent-related complaints within the 1st week were randomly allocated into 8 treatment groups depending on the management protocol. Group A-Silodosin (8 mg OD)+ Solifenacin (10 mg OD)+ Tadalafil (5 mg OD), B - Silodosin 8 mg OD, C - Solifenacin 10 mg OD, D- Tadalafil 5 mg OD, E- Silodosin (8 mg OD) + Solifenacin (10 mg OD), F- Silodosin (8 mg OD)+ Tadalafil (5 mg OD), G- Solifenacin (10 mg OD)+ Tadalafil (5 mg OD) and H- placebo. Diclofenac 50 mg analgesic was given as per necessary and found that silodosin alone was more effective than placebo in lowering SRS.

In our study, group B had a significantly shorter operative time than group A (21.7 ± 4.65 vs. 38.6 ± 4.82 , $P < 0.001$ respectively). Stone side, stone size, number of patients had radio-opaque calculus, number of re-hospitalized patients, Immediate emergency visit and need for analgesia were comparable between both groups.

In accordance with our results, Pai *et al.* [13] examined 60 cases had ureteroscopic lithotripsy (URSL), separated into stented group and non-stented group on silodosin, it was observed that hospital stay and operation time were significantly shorter in

silodosin group than the DJ stent group ($p < 0.009$, < 0.003).

In harmony with our findings, **Mohey et al.** [23] examined 127 adult cases with a single 1 cm distal ureteric stone, reported that silodosin group had significantly shorter surgical time than in the placebo group: 41.61 (4.67), vs. 46.85 (4.6) min. **Aydin et al.** [24] revealed insignificant difference in operative time between the groups studied.

Our findings revealed that postoperative follow-up of symptoms (overall complications) on day 3, 7 and 15 were comparable between both groups which agreed with **Pai et al.** [13]

Silodosin efficacy and safety in ureteral calculi treatment was assessed in previous meta-analysis and systematic review by **Yang et al.** [25] that included 6 RCTs involving 916 participants. In patients receiving straightforward ureteroscopic lithotripsy, they proved that silodosin is safe and efficacious for the treatment of ureteric stones, with a low risk of re-hospitalization and analgesic requirements and less side effects. Small sample size and diverse approaches could explain this disparity.

In the present trial, group B has significantly higher stone free rate 24 hours (91.43% vs 68.57%, $P=0.034$), need for secondary procedure and residual fragmentation compared to group A ($P < 0.001$).

In accordance with our results, **Mohy et al.** [23] study revealed that silodosin group had significantly higher stone-free rate at 24–48 h and after 4 weeks than placebo group (91.94 % vs. 73.85 %, $P = 0.009$, 94.64 % vs. 75.43 %, $P = 0.007$ respectively). This was similar to the rates reported in several trials for distal ureteric stones URS therapy, which vary between 77.5% and 94.6% [26, 27]. The literature reports URS overall complication rates ranging from 9 - 25%. 28 Our study had some limitations. It was a single-center study with a relatively small sample size.

CONCLUSION

Compared to the DJ Stent group, operative time is significantly shorter in cases received silodosin after ureteroscopic laser lithotripsy, with comparable recovery of renal function between both techniques. Although there were no significant differences found in re-hospitalization rates, emergency visits, or symptoms during postoperative follow-up, except for the 24-hour stone-free rates. Therefore, these data imply that DJ stent implantation following uncomplicated URSL may not be required in all cases, and that silodosin may be a suitable substitute for DJ stent after this approach. Further large, multi-centre, randomised trials from additional institutions are required to confirm the silodosin therapy efficacy prior to URS in lower ureteric stones treatment.

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