CAN SILODOSIN REPLACE THE STENT IN POST URETEROSCOPIC LITHOTRIPSY PATIENTS: INITIAL REPORT OF 20 PATIENTS EACH
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ABSTRACT: INTRODUCTION: Routinely we insert stent after Ureteroscopic lithotripsy, can silodosin be used instead of stent after ureteroscopic lithotripsy in order to avoid stent related morbidity. OBJECTIVE: This study compares efficacy of silodosin with stent to prevent stent related morbidity in post URSL patients. MATERIALS AND METHODS: From August 2013 to July 2014, 40 consecutive patients with 5 to 18 mm ureteral stones undergoing URS using pneumatic lithotripsy were alternatively grouped into each group. Group 1 (20 patients) stent removed after 2 week, and group 2 (20 patients) silodosin 8mg given daily night for 2 weeks. After discharge patients were asked to report either immediately if they develop flank pain and fever or on post-operative day 3, 7, and 15. RESULTS: The two groups were comparable in relation with the duration of stent and silodosin therapy, 3 out of 20 patients in whom silodosin was given had flank pain which subsided with analgesics. CONCLUSION: This study demonstrates that silodosin can be used safely instead of stent in an uncomplicated URSL but, needs large scale multicentric randomized control trials. KEYWORDS: Silodosin, Stent, Post URSL.

INTRODUCTION: Routinely we insert stent after Ureteroscopic lithotripsy as the placement of a Double-J stent helps to avoid the complications of pain and infection that can result from ureteral edema.

But Stenting can cause discomfort1,2 to the patients, presence of intraureteral stent carries risk of bacterial colonization and subsequent urinary tract infection3 and encrustation.4 In addition to these, presence of intraureteral stents induces vesico-ureteral reflux specifically with high bladder pressure during voiding,5 and there is need for stent removal as an additional procedure.

Silodosin is a selective α-1 receptor (1A, 1B, 1D) antagonist with documented use in urology in the management of LUTS in BPH6 and also in spontaneous expulsion of distal ureteric stones7. So we wanted to know if silodosin can be used instead of stenting to serve the same purpose.

OBJECTIVE: This study compares efficacy of silodosin with stent to prevent stent related morbidity in post URSL patients.

MATERIALS AND METHODS: From August 2013 to July 2014, 40 patients with age group from 20 years to 40 years, both male and female, solitary lower ureteral stones without renal stone, the stone size ranges from 5 to 18 mm were included in the study.

Exclusion Criteria:
- Female patients who are pregnant or breast feeding the babies.
- Patients with febrile urinary tract infection or severe hydronephrosis or hypotension.
Patients with severe hepatic dysfunction (e.g. hepatic failure, hepatic cirrhosis, icterus, hepatoma).
Patients who have taken α-blocker before enrolling into the study.
Patients with multiple ureteral calculi.
Patients whose urinary tracts are anatomically deformed or stenosed.
Patients who underwent invasive operations on their ureters before.
Patients who are enrolled in other studies.
Patients with comorbidities.
Stone size more than 18mm.
Patients with renal stones.

URS done using 6/7.5 Wolf ureteroscope. None of the patients required balloon dilatation. The stones were fragmented with pneumatic lithotripsy. The total stone clearance was achieved. At the end of the procedure no 5Fr DJ stent inserted alternatively.

They were grouped into two groups alternatively. Group 1 included 20 patients in whom stent inserted for 2 weeks, Group 2 included 20 patients in whom tab silodosin 8mg given daily at night for 2 weeks. After discharge patients were asked to report either immediately if they develop flank pain and fever or on post-operative day 3, 7, and 15.

RESULTS: The two groups were comparable in relation with the duration of stent and silodosin therapy, 3 out of 20 patients in whom silodosin was given had flank pain which subsided with analgesics.

Age, sex and ureteral stone size distribution of Patients (Table 1): There was no statistically significant difference between the two interventional groups with respect to age and sex distribution of study patients.

Similarly there was no statistically significant difference with respect to size of calculi among the patients of two interventional groups.

Outcome variables of two intervention Groups (Table 2, Graph 1): In both intervention groups the outcome variables measured are onset of flank pain, haematuria, LUTS. There was no statistically significant difference with respect to onset of flank pain after the procedure, similarly there was no event of haematuria and LUTS in both the groups.

DISCUSSION: Many studies have been done to evaluate morbidities associated with intraureteral stents and its preventive measures in the past. But no study has been done using silodosin instead of stent in post ureteroscopic lithotripsy in order to avoid stent related morbidity.

Complication of intraureteral stents are categorized in to intraoperative, early postoperative and late postoperative. Intraoperative are ureteral injury (mucosal injury), false passage and perforation. Early postoperative are haematuria, irritative voiding symptoms, flank pain, stent migration. Late postoperative are urinary tract infection, stent encrustation, stent fragmentation and forgotten stent.
\( \alpha_1 \)-adrenergic receptors are members of the \( G_q \) protein-coupled receptor superfamily. These alpha-1 receptor are present in ureter (they are present throughout the ureter but high density in distal ureter), bladder neck, smooth muscles of prostatic capsule.

And these receptors are also present in blood vessels including major vessels, bronchioles, and uterus in women.

Alpha 1 receptors are three types -1A, 1B, 1D. Silodosin is a alpha-1A adrenoceptor antagonist with high uroselectivity. It acts by dilatation of smooth muscles of the distal ureter, bladder neck and prostate. Because of its high affinity for the alpha-1A receptors, it causes practically no orthostatic hypotension (in contrast to other alpha blocker). On the other hand this high selectivity causes retrograde ejaculation which accounts for 22.3%.

In our study sexually active males who were selected for silodosin group instructed to expect retrograde ejaculation and it will subside when the drug is withheld. All patients were comfortable with retrograde ejaculation.

The cost of the stent and the stent removal approximate amount is very much higher than the cost of the silodosin. So silodosin is comparable to stent in relation to its cost effectiveness, saves patient time and patient is totally devoid of stent related morbidity.

**CONCLUSION:** This study is the first of its type and marks a new perspective, beginning of use of silodosin instead of stent in an uncomplicated post ureteroscopic lithotripsy patient for lower ureteric calculi, however further large scale multicentric randomized trials are needed to validate and authenticate the study.

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|                          | Intervention Group -1 n=20 | Intervention Group -2 n=20 | P value |
|--------------------------|-----------------------------|-----------------------------|---------|
| **Age**                  | 20-29 yrs 04                | 20-29 yrs 03                | 0.703   |
|                          | 30-39 yrs 10                | 30-39 yrs 10                | 0.763   |
|                          | > 40 yrs 06                 | > 40 yrs 07                 | >0.99   |
| **Sex**                  | M 14                        | M 11                        | 0.352   |
|                          | F 06                        | F 9                         |         |
| **Size of the Calculi**  | 05-09 mm 04                 | 05-09 mm 05                 | 0.725   |
|                          | 10-14 mm 14                 | 10-14 mm 12                 | 0.530   |
|                          | 15-18 mm 02                 | 15-18 mm 03                 | 0.670   |

Table 1: Age, sex and ureteral stone size distribution of patients

| Outcome Variables     | Intervention Group -1 | Intervention Group -2 | P value |
|-----------------------|------------------------|------------------------|---------|
| **Pain**              | Yes                    | 00                     | 03      | 0.2308* |
|                       | No                     | 20                     | 17      |         |
| **Haematuria**        | Yes                    | 0                      | 0       | -       |
|                       | No                     | 20                     | 20      |         |
| **LUTS**              | Yes                    | 0                      | 0       | -       |
|                       | No                     | 20                     | 20      |         |

Table 2: Outcome variables of two intervention groups
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