ORIGINAL ARTICLE

MANAGING DJ STENT RELATED SYMPTOMS- TAMSULOSIN VS OXYBUTYNIN VS THEIR COMBINATION

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Background: Double J (DJ) stent insertion is a vital procedure in urology, used for urinary diversion, drainage, or support during reconstruction. Common indications include urolithiasis, ureteral strictures, pyeloplasty, or other reconstructive surgeries. Despite its benefits, DJ stenting often leads to stent-related symptoms due to its nature as a foreign object. These symptoms are evaluated using the Ureteral Stent Symptom Questionnaire (USSQ). Various medications, such as alpha blockers and antimuscarinics, have been used to mitigate these effects. This study compares the efficacy and side effects of Tamsulosin (alpha blocker), Oxybutynin (antimuscarinic), their combination, and conservative measures. **Methods:** A total of 216 patients undergoing unilateral 4.7 Fr DJ stenting for urolithiasis or reconstructive procedures were enrolled and divided into four groups (n=54 each): Group A (Oxybutynin), B (Tamsulosin), C (combination), and D (conservative). Patients under 18, with positive urine cultures, bilateral stents, or who declined participation were excluded. Symptom scores were recorded at 1st and 4th postoperative weeks using USSQ. **Results:** Combination therapy showed the best symptom control at week 1 (83.3%), while Tamsulosin alone was less effective initially (52.3%, p=0.001). At week 4, Oxybutynin and Tamsulosin groups had similar scores (mean: 39 vs. 40.4). Conservative management resulted in higher symptom scores; 5.5% of these patients required further intervention. Patients with constipation, positive cultures, or those treated for urolithiasis reported worse symptoms across all groups. **Conclusion:** Combination therapy with Tamsulosin and Oxybutynin offers superior relief from DJ stent-related symptoms compared to monotherapy or conservative approaches.

Keywords: DJ stent; Endourology; Stent related symptoms; Alpha blockers; Anticholinergics

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INTRODUCTION

Insertion of a Double J stent is an essential part of urological practice, which is used as a diversion, for drainage purposes, or as an aid in reconstruction. Common procedures requiring stenting are procedures for urolithiasis, narrow ureters, pyeloplasty or ureteral reconstruction.[1] DJ stents are made of polyurethane or silicon, and as a foreign body, tend to trigger irritative effects at the trigone of the bladder and cause DJ stent-related symptoms. The size and material of the stent also impact the symptoms. Literature reveals that larger calibre stents cause more symptoms.[2]

Symptoms include pain in the flank or suprapubic region, strangury, haematuria, dysuria, burning micturition, or onset of urinary tract infections with fever. Stents are also noted to interfere with sexual activities and also affect the activities of daily life.[3] The DJ stents, if left for longer duration, tend to get encrusted and become a source of UTI as bacteria tend to form a biofilm on the stent's surface and are difficult to eradicate. If medical treatment fails, stent removal is then the preferred management, even before the intended duration.[3]

Patients suffering from these symptoms have a significant negative impact on their quality of life, about 92% of the stented individuals suffer bothersome symptoms, and these are managed via multiple measures.[4] Conservative options, such as avoiding constipation, timely voiding and adequate hydration cause a significant relief as well as serve as preventive options.[5] Medical therapy includes the addition of antimuscarinic, alpha blocker, calcium channel blocker, or phosphodiesterase inhibitor on regular or as per need basis to deal with the symptoms.[6] These symptoms are quantified using the standard (USSQ) Ureteral Stent Symptom Questionnaire. This questionnaire comprises of 6 major headings

comprising of 35 symptoms. The components include urinary symptoms, body pain, general health, work performance, sexual health, and additional problems.[7] The standardized questionnaire is also translated into multiple languages for better understanding and for bias prevention.

MATERIAL AND METHODS

This was a prospective randomized comparative study. 216 patients were enrolled in the study who underwent various sorts of procedures requiring DJ stenting, 4.7 Fr DJ stent of the same material (polyurethane with hydrophilic coating) was inserted to prevent bias. DJ stents were inserted in either retrograde or antegrade manner over a 0.0032 guidewire with the help of endoscopic and fluoroscopic guidance. Patients included were aged above 18 years (18–63 years).

Patients were grouped into 4 groups with 54 patients in each group through computerized randomization. Group A patients received Oxybutynin 5 mg once a day, Group B was advised Tamsulosin 0.4 mg HS, Group C was advised Oxybutynin and Tamsulosin in combination while Group D was managed conservatively with timed voiding, adequate hydration, and stool softeners. Patients receiving Oxybutynin were also evaluated for post void residual volume before prescribing the medication. Patients less than 18 years, with bilateral stents and receiving a stent other than 4.7 Fr in size were excluded from the study.

Patients were followed at 1st and 4th week post operatively and were asked to fill the USSQ. Scoring was done by 5-point Lickert Scale. (Table 1). Scores from 35 to 75 were taken as mild, scores from 76 to 115 were deemed moderate while any score above 116 was considered to be in severe category (Table 2). At 1st week, Patients requesting for change of treatment, were recommended the addition or replacement with another drug, and were excluded from the study. Scores were calculated and all the data along with patients' demographics, procedure type, urine cultures and status of constipation along with other variables were recorded. Data was analyzed by SPSS v23.0. For continuous variables such as age, gender and stone size, mean and standard deviation was used while for categorical variables, frequency and percentages were used. The assessment of difference between two mean values was performed with the help of chi-square test keeping the *p*-value of ≤0.05 as significant.

RESULTS

One hundred and fifty-four (71.2%) of the patients were male, while the rest were female. Mean BMI was 26.1 kg/m^2 with a deviation of 6.002. 28 (12.9%) patients presented with fever, while 13 (6.02%) of the patients had positive cultures which were treated before intervention. 167 (77.3%) of the patients underwent URS with laser or pneumatic lithoclast, while 19 (8.7%) of the patients underwent PCNL. 10 (4.6%) each underwent Laparoscopic Pyeloplasty and RIRS, while 6 (2.7%) underwent pre-stenting. Four (1.85%) underwent Laparoscopic partial nephrectomy.

Group A (Oxybutynin group) showed good compliance along with higher scores from the first week. 12 (22.2%) patients were in the mild category, 24 (44.5%) patients were in the moderate category and 14 (26.1%) were in the severe category, with a mean score of 132.4. These patients were preoperatively assessed for post void residual volume. At 4th week, the mean score was around 39.

The second group (B), which was prescribed Tamsulosin, showed 11 (21.1%) patients in mild category, 12 (22.2%) patients were in moderate category and 28 (52.3%) patients were of severe category. These patients showed adequate control from the start with a mean score of 111.3 that further reduced to 40.4 at 4th week. None of the patients reported any side effects or intolerance and once nightly administration was easy to comply.

The combination group (group C), showed significantly lower scores from 1st week with a mean score of 40.8 that further reduced to 37.8 at 4th week. Once a day Oxybutynin along with once nightly Tamsulosin was prescribed. None of these patients were in severe category.

Group D that was managed conservatively showed severe scores from 1st week with a mean score of more than 162. 3 (5.5%) patients did ask for addition of medication due to bothersome symptoms and found it harder to comply. (*p*-value = 0.023) (Table 3)

Higher scores were observed in patients with constipation (*p*-value 0.012), patients undergoing urolithiasis procedure (*p*-value 0.04) and patients who had positive cultures at presentation (*p*-value 0.04). 2.7% (n=6) of the patients had positive cultures after the insertion of DJ, only one of them presented with febrile UTI requiring intravenous antibiotics.

Table-1

Ureteral Stent Symtpoms Score (USSQ)
1= not present, 2=mild, 3= bothersome, 4= moderate, 5= severe

SECTIONS	ITEMS	SCORE				
Urinary Symptoms	Weak stream	1	2	3	4	5
	Intermittent	1	2	3	4	5
	Incomplete emptying	1	2	3	4	5
	Straining	1	2	3	4	5
	Frequency	1	2	3	4	5
	Urgency	1	2	3	4	5
	Nocturia	1	2	3	4	5
	Dysuria	1	2	3	4	5
	Hematuria	1	2	3	4	5
	Urge Incontinence	1	2	3	4	5
	Impact quality of life	1	2	3	4	5
Pain	Loin/flank region	1	2	3	4	5
	Hypochondrium/lumbar region	1	2	3	4	5
	Groin	1	2	3	4	5
	Bladder region	1	2	3	4	5
	External genitalia	1	2	3	4	5
	Affected by physical activity	1	2	3	4	5
	Pain in voiding	1	2	3	4	5
	Pain in kidney area at voiding	1	2	3	4	5
General Health	Physical symptoms	1	2	3	4	5
	Vitality (feeling tired)	1	2	3	4	5
	Psychosocial impact (calm & peaceful)	1	2	3	4	5
	Dependence (Need extra help)	1	2	3	4	5
	Social life enjoyment	1	2	3	4	5
	Physical activity	1	2	3	4	5
Work Performance	Failure	1	2	3	4	5
	Miss work	1	2	3	4	5
	Reduced work hours	1	2	3	4	5
	Difficulty in concentration	1	2	3	4	5
	Difficulty in punctuality	1	2	3	4	5
	Functional limitation	1	2	3	4	5
Sexual Matters	Quality of work	1	2	3	4	5
	Pain during sex	1	2	3	4	5
	Overall satisfaction	1	2	3	4	5
	Complete sexual dysfunction	1	2	3	4	5

Table-2

Score	Severity
<36	No Symptoms
36-75	Mild
76-115	Moderate
>116	Severe

Table-3

1st Week	Nil	Mild	Moderate	Severe	*p*-value
Group A	7.4% N=4	22.2% N= 12	44.5% N=24	26.1% N=14	**<0.005**
Group B	5.5% N=3	21.1% N=11	22.2% N=12	52.3% N=28	
Group C	83.3% N=45	16.7% N=9	0%	0%	
Group D	0%	16.7% N=9	75.4% N=41	7.1% N=4	

DISCUSSION

Extensive work has been done on this topic throughout the world with different groups of medication. The introduction of combination drugs in a single tablet has made it more patient-friendly to overcome this bothersome scenario with better compliance.

Balaji AR *et al* in their study titled A Study to Compare the Safety and Efficacy of Solifenacin, Tamsulosin and Tadalafil in Relieving Double-J Stent Related Symptoms compared three drugs in managing DJ related symptoms. Their prospective randomized controlled study targeted to compare the efficacy of the three drugs in treating ureteral stent-related symptoms (SRS). 146 patients were studied and divided into four groups, receiving Placebo, Solifenacin, Tamsulosin, or Tadalafil for three weeks. Their results suggested that Tadalafil could be a promising option for managing SRS in terms of sexual function, while Solifenacin remains preferable for LUTS associated with ureteral stents.[8] In contrast to this study, we did not use a PDIE5 inhibitor like Tadalafil and also used a combination therapy in our patients but these investigators were not inclined towards combination therapy, and an antimuscarinic (Solifenacin) proved to alleviate DJSS just like Oxybutynin in our study. Role of Alpha blockers have already been established in the prevention of these SRS.[9,10] so is the established role of antimuscarinics.[11, 12] Newer agents with combination regimes are being introduced for managing SRS.[13]

Like our study, Maldonado-Avila M *et al*, in the study titled Efficacy of Tamsulosin, Oxybutynin, and their combination in the control of double-j stent-related lower urinary tract symptoms, addressed to assess the efficacy of tamsulosin, oxybutynin, and a combined therapy involving both medications in dealing with these symptoms. Fifty-one patients were divided into three groups; each prescribed a specific drug regimen for a duration of three weeks. The results revealed that the combination therapy featuring tamsulosin and oxybutynin yielded notable improvements in irritative symptoms, work performance, and sexual matters like in our sudy. Furthermore, the lack of reported side effects enhances the appeal of this combination therapy as a well-tolerated intervention.[14] The results are in agreement with our study.

Antimuscarinics other than oxybutynin were also evaluated in other studies. The study by Sivalingam S *et al*, involved 80 randomized patients, with 44 in the combination therapy group (tamsulosin 0.4 mg and tolterodine early release 4 mg) and 36 in the monotherapy group (tamsulosin 0.4 mg and placebo). Results indicated that combination therapy did not significantly correct urinary symptoms, body pain, or quality of life compared to tamsulosin alone. Tamsulosin was superior to the combination, suggesting poor role of Tolterodine in this regard.[15] This study did compare a combination of an alpha blocker with an antimuscarinic but Tolteradine did not prove to be a good companion to Tamsulosin and Tamsulosin montherapy took the lead.

The role of beta 3 agonist is already established in treating overactive bladder and it is also being evaluated in the treatment of DJ stent related symptoms in the study by Jaworski P *et al* Mirabegron as effective as oxybutynin for ureteral stent symptoms. Patients who underwent urolithiasis treatment and received a double J stent were assigned to two groups: Group O, administered oxybutynin 5 mg/day, and Group M, receiving mirabegron 50 mg/day. The Ureteral Stent Symptoms Questionnaire (USSQ) was applied on the 3rd, 6th, and 15th postoperative days. Analysis indicated that USSQ scores did not significantly differ between the oxybutynin and mirabegron groups across the three postoperative days (p>0.05). Remarkably, subjects receiving oxybutynin showed lower scores for urinary symptoms and body pain. In conclusion, both mirabegron and oxybutynin established equivalent efficacy in relieving ureteral stent symptoms, and certain stent-related symptoms seemed to diminish over time, emphasizing the potential effectiveness of both medications in managing discomfort associated with ureteral stents.[16]

Furthermore, thorough work is being done through the world in managing the stent related symptoms to improve the patient's quality of life. The need of single- tablet administration at cheaper cost should be considered. There is also inconclusive literature regarding size and material of the stent placed. Some studies suggest that longer length and larger caliber of the stent causes more symptoms while other studies contradict this statement. Crossing of midline of the distal end of the stent also remains an independent factor of causing bladder pain and hematuria[17]. Uniformity of stent size in our study excludes this bias but potential to research on this fact remains open. Similarly, stent material is another inconclusive cause of stent related symptoms as silicon "soft" stents are thought to cause lesser irritative symptoms as compared to non-silicon ones.[18]

As much as stent related factors are involved in bothering the patients, patient related factors play a major role too. Kati *et al* concluded that the stent symptoms are also affected by colonization of the patient's urine as they evaluated one hundred and thirty-five subjects in their study. The distal end of the DJ stent was sent for culture after DJ removal. Candida species was the most frequent colonizer, and both the encrustation rate as well as symptoms were higher in colonizers versus the non-colonizers.[19]

Keeping in mind such extrinsic and intrinsic factors for DJ stent related symptoms, one should proceed intellectually regarding the choice of stent

placement and the drugs required to manage the symptoms to make the patient's life easier. Furthermore, adequate hydration, avoiding constipation and timely voiding should be counselled clearly to the patient.

CONCLUSION

Combination therapy proved superior to monotherapy in controlling DJ stent related symptoms from day one while tamsulosin alone took longer time to control the DJ stent symptoms.

Recommendation:

Combination of an alpha blocker along with antimuscarinic should be considered as an effective option to manage bothersome DJ stent related symptoms.

Limitation:

This is a single center study with limited participants and only two drugs. More drugs and their combinations can be compared at multi-institutional level to conclude results with more weightage.

AUTHORS' CONTRIBUTION

UR: Objective, write-up, primary investigator. SS: Subject specialist, final approval. AM: Data collection, data analysis. MO: Data collection, data interpretation. AK: Write-up, results presentation. ME: Ethical consideration, subject enrolment.

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