

Comparative study to evaluate effect of tamsulosin and Solifenacin on DJ stent related symptoms.

Dr. Devendra singh pawar¹, Dr Ashok Kumar², Dr. Shobha Benjwal³, Dr Seema Mittal⁴, Dr Jatin Lal⁵, Dr. Atul Khandelwal⁶, Dr Lokendra Kumar Yadav², Dr Vikas Verma²

¹Professor, Department Of Urology, Pt BD Sharma PGIMS, Rohtak.

²Department Of Urology, Pt BD Sharma PGIMS, Rohtak

³Associate Professor, Department Of Rachna Sharer, MSM Institute Of Ayurveda, Khanpur Kalan, Sonapat.

⁴Assistant Professor (Microbiology), BPS Khanpur Medical College(W), Sonapat

⁵Professor, Department Of Anaesthesia, Pt BD Sharma PGIMS, Rohtak.

⁶Assistant Professor, Department Of Urology, BPS Khanpur Medical College(W), Sonapat

Introduction: Double J (DJ) stents are probably commonest foreign material placed in human body for various urological indication and like any foreign body are not complication free. Common discomfort are pain, lower urinary tract symptoms (LUTS), infection, encrustation, displacement etc. Various measures had been proposed for these symptoms. But for pain and LUTS alpha blocker and anticholinergic drugs are most commonly used drugs after painkillers. We studied effect of tamsulosin and solifenacin on stented patients.

Material and method: A total of 180 patients were included in study with sixty in three groups. Group A was given tamsulosin 0.4 mg HS, group B given Tab solifenacin 5 mg hs and group C given tab multivitamin hs. These were post operative patients and were evaluated for IPSS and VAS score. Result were analysed later on for by ANOVA one way test.

Results: All the three groups are comparable in terms of age, sex and stone size. There is significant decrease in international prostate symptom score (IPSS) and visual analog scale (VAS) score in group A and B with significant p value. In group no significant decrease in p value occurs in IPSS and Pain score in group C. The decrease in IPSS is significant among three group as well with in same group at 7 and 14 day for group A and B.

Conclusion: DJ stenting is fairly common procedure done in urology and is not complication free. Stented patients need some kind of medication to allay discomfort. Tamsulosin and solifenacin are effective drug for stent related symptoms.

Keywords: Tamsulosin, Solifenacin, DJ stent.

I. Introduction

Ureteral stents are the most common prosthetic devices used by urologists. Ureteral stents are mostly used in obstructive uropathy, promote ureteral healing after surgery, and to help with ureteral identification during complex surgical procedure. Ureteral stent placement is not complication free. Some degree of morbidity in the form of generalized urinary discomfort is complained by the majority of patients. The ideal stent has yet to be discovered.

Stent discomfort vary from patient to patient but is found to affect majority of patients. most common complication of stent are incomplete emptying, urgency, frequency, dysuria, flank & suprapubic pain.⁽¹⁻³⁾

Some etiologies have been for these complications includes mechanical irritation of the bladder trigone, urine renal reflux from bladder resulting obstruction, bacterial colonization of stent, stent positioning as well as size of stent and design strategies for managing stent complications include accurate stent indications, pre stenting maneuvers, stent length, design and use of medications (4).

Few studies had been conducted in literature to study effect of various drugs to relieve these symptoms. These drugs used are intravesical chemical agents, alfusin, tolteradine, oxybutynin, tamsulosin. (5-9) We had selected tamsulosin and solifenacin to compare and evaluate in patient with stent in situ to relieve stent related discomfort.

II. Method

This study was conducted in urology department of Pt. BD Sharma PGIMS Rohtak in the year 2015-16 to study the effect of drugs solifenacin and tamsulosin to relieve stent related complications.

After taking well informed consent all the patients undergoing stenting postoperatively during this period were randomized to either receive tamsulosin, solifenacin or placebo and were followed for a period of two weeks at day 1, 7 and 14 as per IPSS Score and VAS (visual analog scale) pain score with .

Our inclusion criterion was all patients undergoing stenting during surgical processes PCNL and URS .

The exclusion criteria included indwelling ureteral stent over the past 3 months, a history of pelvic or gynecologic surgery, transurethral resection of the prostate or a bladder tumor, chronic consumption of alpha- - blocker and/or anticholinergic, recent or recurrent urinary tract infection, benign prostate hyperplasia, prostatitis, prostate cancer, bladder outlet obstruction, diabetes and pregnancy.

All patients undergoing urs were operated with either wolf or Olympus ureteroscope and lithotripsy done with EMS lithoclast. PCNL was done with 22F sheeth and 17F storz nephroscope were either tubed or tubeless.

Patient were randomized with card method and ratio is kept at 1:1:1. It was a single blind study with only patient were blinded which drug they are receiving . Drug were removed from packet and was given to patient. Placebo in form of multivitamin tablets were given. All the three drug were advised to take at night time, same set of advise regarding complication was given in the form of handout to each and every patients. Group A was given tamsulosin 0.4 mg HS, group B given Tab solifenacin 5 mg hs and group C given tab multivitamin hs

III. Results

A total of 210 patients who met inclusion criterion and consented for study were included in the study for the period between 2014 -2016. Out of 210 , thirty patients were excluded from study due to various reasons, removal of stent due to severe side effects before two weeks, loss of follow up,did not take medicine, drug side effects etc. Number of patients leaving group A was 5 mostly due to four non compliance and one due to side effects. Seven patient left group 4 due to non compliance and three because of side effects and eighteen patients left group C tweleve due to removal of stones because of side effects and six due to non compliance.

A total of 180 patients were enrolled in study and ratio is kept at 1:1:1 with 60 patients in each group. They were comparable in terms of age, sex ration, type of surgery and stane size. (table1,2,3)

	group a	group b	group c
Male	38	40	37
Female	22	20	23
Urs	28	27	30
Pcnl	32	33	30

Table 1: distribution of patients in groups.

Age groups	Group A	Group B	Group C
0-20 years	5	4	3
21-45 years	45	40	48
> 45 years	10	16	9

Table 2: Age wise distribution of patients.

	A	B	C	p value
Mean age	33.25±9.05	34±10.25	30.12±9.85	0.45
Mean stone size	15.25±8.75	18.25±10.15	16.38±12.25	0.15
Male	38	40	37	0.95
IPSS day1	8.75±3.25	9.25±2.95	9.38±3.32	0.39
IPSS day 7	6.35±3.12	7.02±2.36	12.65±4.02	0.01
Ips day 14	6.25±2.12	6.85±3.75	11.35±4.35	0.02
p value	0.03	0.04	0.56	
Pain score VAS day 1	5.62±1.23	6.02±2.23	6.15±1.54	0.36
VAS day 7	3.23±1.02	4.02±1.65	5.25±2.02	0.04
VAS day 14	2.02±0.85	3.01±1.07	4.25±1.85	0.07
p value	0.04	0.03	0.15	

Table 3: Comparative analysis of IPSS and VAS score in stented patients

Side effect	Group A	Group B	Group C
Orthostatic hypertension	5	2	1
Headache	3	1	2
Dry mouth	1	5	2

Table 4 : Side effect profile of patients.

All the three groups are comparable in terms of age, sex and stone size. There is no significant difference in baseline IPSS and pain score among three group with p value of 0.39 and 0.36 respectively.

There is significant decrease in IPSS and vas score in group A and B with significant p value. In group no significant decrease in p value occurs in IPSS and Pain score in group C. The decrease in IPSS is significant among three group as well with in same group at 7 and 14 day for group A and B. (table 3)
Both the drugs had few side effects and well tolerated. (table 4)

IV. Discussion

DJ stents are one of the most common prosthetic devices used in modern medicine which are indwelling and left in situ for various reasons. These are also common reason for discomfort, pain, infection and other side effects. Some study shows stent related discomfort affect 80 % of patients. Our study shows IPSS of around 10 and VAS of 6 at day 1 which is well above bothersome symptoms.^(2,3)

Precise cause for such discomfort is not fully known but various theories has been put forward for this. Based on these theories various drugs has been tried in past to control various symptoms. Intravesical instillation. alpha blockers, bladder relaxants , pain killers are typical drugs used for these symptoms, we used tamsulosin and solifenacin for these symptoms.⁽⁵⁾

Some investigators used alpha-blockers including alfuzosin and terazosin on stent-related discomforts. Kuyumcuoglu et al. concluded that stent discomforts does not change even after administering alpha blocker. They proposed new strategy by using new stent design and other modification to control symptoms. But, a recently published study has showed that new stents did not improve stent-related symptoms . Our study and the two meta-analyses recently published shows that alpha-blockers can effectively relieve stent-related symptoms.^(7,10-14)

One of the proposed mechanism of stent related discomfort is irritation of trigone and bladder with stent tail. Anticholinergic drugs may allay such symptoms by bladder relaxant effect. Lim et al. have demonstrated a reduction in the total IPSS in patients receiving solifenacin compared with those receiving no medication. Our study also shows such effect of solifenacin on IPSS on stent related side effects.⁽¹⁵⁾

In study of damiano et al showed that alpha blocker significantly decrease flank pain by causing ureteral relaxation. Our study also shows similar results.⁽⁹⁾

In study of tehranchi et al in Iran also showed significant decrease in pain and IPSS by alpha blocker and bladder relaxant in patient with stent after PCNL and trans urethral lithotripsy. Our study shows similar decrease in morbidity of stent.⁽¹⁶⁾

In contradiction to this data, Norris, et al. published data of small number of patients but well conducted doubleblind study comparing ER oxybutynin, phenazopyridine, and placebo in patients who had a stent place after ureteroscopy. Assessment tools included were questionnaire for stent symptoms, visual analog scale scores, and requirement of narcotic medications. Results did not show differences for flank pain, suprapubic pain, urinary frequency, urgency, dysuria, narcotic usage, or hematuria (except for phenazopyridine versus placebo on Day 2). But our study used solifenacin and tamsulosin and showed significant differences.⁽¹⁷⁾

There are few shortcoming of our study. Our study did not take in to account surgical complication and symptoms related to that. Only post surgical patients were included other patient not included in this study. A fourth group with combined use of both drugs may be added to further elucidate effect of drugs.

V. Conclusion

DJ stenting is fairly common procedure done in urology and is not complication free. Stented patients need some kind of medication to allay discomfort. Tamsulosin and solifenacin are effective drug for stent related symptoms.

References

- [1]. Chew BH, Knudsen BH and Denstedt D. The use of stents in contemporary urology. *Curr Opin Urol* 2004;14:111-5.
- [2]. Byrne RR, Auge BK, Kourambas J, et al. Routine ureteral stenting is not necessary after ureteroscopy and ureteropyeloscopy: a randomized trial. *J Endourol* 2002;16:9-13.
- [3]. Joshi HB, Okeke A, News N, Keeley FX Jr, Timoney AG. Characterization of urinary symptoms in patients with ureteral stents. *Urology* 2002;59:511-9.
- [4]. Miyaoka R, Monga M. Ureteral stent discomfort: Etiology and management. *Indian J Urol* 2009;25:455-60
- [5]. Beiko DT, Watterson JD, Knudsen BE, Nott L, Pautler SE, Brock GB, et al. Double-blind Randomized Control Trial Assessing the Safety and Efficacy of Intravesical Agents for Ureteral Stent Symptoms after Extracorporeal Shockwave Lithotripsy. *J Endourol* 2004;18:723-30.
- [6]. Deliveliotis C, Chrisofos M, Gougousis E, Papatsoris A, Dellis A, Varkarakis IM. Is there a role for alpha 1-blockers in treating double-J stent-related symptoms? *Urology* 2006;67:35-9.
- [7]. Beddingfield R, Pedro RN, Hinck B, Kreidberg C, Feia K, Monga M. Alfuzosin to Relieve Ureteral Stent Discomfort: A Prospective, Randomized, Placebo Controlled Study. *J Urol* 2009;181:170-6.
- [8]. Park SC, Seo IY, Jeong HJ, Oh SJ, Rim JS, Jeong YB. The effect of alfuzosin and tolterodine in treating double-J stent-related symptoms. *J Urol* 2008;179:289.
- [9]. Damiano R, Autorino R, De Sio M, Giacobbe A, Palumbo IM, D'Armiento M. Effect of Tamsulosin in Preventing Ureteral Stent-Related Morbidity: A Prospective Study. *J Endourol* 2008;22:651-5.

- [10]. Mokhtari G, Shakiba M, Ghodsi S, Farzan A, Heidari Nejad S, Esmaili S: Effect of terazosin on lower urinary tract symptoms and pain due to double-J stent: a double-blind placebocontrolled randomized clinical trial. *Urol Int.* 2011; 87: 19-22.
- [11]. Kuyumcuoglu U, Eryildirim B, Tuncer M, Faydaci G, Tarhan F, Ozgöl A: Effectiveness of medical treatment in overcoming the ureteral double-J stent related symptoms. *Can Urol Assoc J.* 2012; 6: E234-7.
- [12]. Davenport K, Kumar V, Collins J, Melotti R, Timoney AG, Keeley FX Jr: New ureteral stent design does not improve patient quality of life: a randomized, controlled trial. *J Urol.* 2011; 185: 175-8.
- [13]. Lamb AD, Vowler SL, Johnston R, Dunn N, Wiseman OJ: Meta-analysis showing the beneficial effect of α -blockers on ureteric stent discomfort. *BJU Int.* 2011; 108: 1894-902.
- [14]. Yakoubi R, Lemdani M, Monga M, Villers A, Koenig P: Is there a role for α -blockers in ureteral stent related symptoms? A systematic review and meta-analysis. *J Urol.* 2011; 186: 928-34.
- [15]. Lim KT, Kim YT, Lee TY, Park SY: Effects of tamsulosin, solifenacin, and combination therapy for the treatment of ureteral stent related discomforts. *Korean J Urol.* 2011; 52: 485-8.
- [16]. Tehranchi A, Rezaei Y, Khalkhali H, Rezaei M. Effects of Terazosin and Tolterodine on Ureteral Stent Related Symptoms: A Double-Blind Placebo-Controlled Randomized Clinical Trial. *Int Braz J Urol.* 2013; 39: 832-40
- [17]. Norris RD, Sur RL, Springhart WP, Marguet CG, Mathias BJ, Pietrow PK, et al. A Prospective, Randomized, Double-blinded, placebo-controlled comparison of extended release oxybutynin versus phenazopyridine for the management of postoperative ureteral stent discomfort. *Urology* 2008; 71:792