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Research Article

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Comparison Between Tamsulosin and Oxybutynin in Relieving Ureteral Stent Related Symptoms

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Abstract

One handred cases with unilateral ureteral stent insertion were randomized into four groups; given placebo (25 patients), Oxybutynin 5mg once daily (25 patients), Tamsulosin 0.4mg once daily (25 patients) or combination respectively. All patients received the drugs for three weeks and completed the symptom questionnaire and quality of life questionnaire one week after stent insertion and one week after stent removal. There was no significant difference in the efficacy between Tamsulosin and Oxybutynin in relieving urgency (9 patients, 9 patients respectively), frequency (7 patients, 9 patients respectively) and dysuria (11 patients, 9 patients respectively) with the superiority of combination therapy (12 patients, 16 patients, 17 patients respectively)(P-values: 0.01, 0.001, 0.001 respectively). For relieving abdominal pain, Tamsulosin was more efficacious than Oxybutynin (8 patients versus 5 patients) with the superiority of the combination therapy (12 patients) (P-value: 0.001). For relieving hematuria, Tamsulosin and combination therapy were comparable and both superior to Oxybutynin with a P-value 0.001. For improving quality of life, both Tamsulosin and Oxybutynin were comparable (9 patients, 9 patients) with superiority of combination therapy (15 patients) with a P-value 0.001.

Keywords: Tamsulosin Drug, Oxybutynin Drug, D-J Stent, Laparoscopic Operations and Symptoms of Laparoscopic Operations.

Introduction

The use of ureteral stents in surgery was described as early as the 19th century [1]. The first urologist to access the ureter endoscopically was Dr. James Brown at Johns Hopkins Hospital in 1893 [2]. Zimskind, however, in 1967 was the first to describe the cystoscopic placement of indwelling ureteral stents for obstructed ureters [3]. At that time, stents were very prone to migration and device expulsion, which deterred widespread adoption. The first "double-J" (DJ) or double pigtail stent was developed almost simultaneously by Finney and Hepperlen [4]. After this novel advance, the use of DJ stents increased dramatically in urology departments worldwide, which had a tremendous positive impact on endourologic surgery and patient care. Today, ureteral stents are of fundamental importance to any urologic practice. Currently used stents are commonly composed of polyurethane, silicone, or proprietary copolymers such as Silitek (Surgitek, Medical Engineering Company, Racine, WI), C-Flex (Cook Medical, Bloomington, IN), Percuflex (Boston Scientific, Marlborough, MA), or Tecoflex (PNN Medical, Kvistgaard, Denmark). New metallic stents composed of a unique continuous unfenestrated coil of nonmagnetic alloy have proved to be safe and effective for patients with extrinsic compression of the ureter and offer longer indwelling times (3.5 to 11 months) [5]. Ureteral stents play a major role in a wide range of situations where urinary drainage is needed. Urgent indications include cases of obstructive pyelonephritis and intolerable acute renal colic [18] Safety indications following endoscopic procedures include ureteral edema or perforation, steinstrasse [7]. Relative indications would still include stone burden larger than 2 cm undergoing extracorporeal shockwave lithotripsy, pregnancy, long-standing impacted stone, recent history of urinary tract infection or sepsis, stent to passive dilate the ureter and/or ureteral orifice, prolonged endoscopic operative time (over 45 minutes) and any patient with imminent post-operative plans such as a second-look ureteroscopy [8]. Hematuria, urgency, frequency, dysuria, and both bladder and flank pain are the most prevalent symptoms related to indwelling ureteral stents. The authors reported quality of life to be influenced in 80% of stented patients [9]. Sexual dysfunction has been reported in 42% to 82% of male patients and 30% to 86% of female patients with an indwelling ureteral stent [10]. A prospective cohort study reported that approximately one third of patients required early removal of ureteral stents because of stent discomfort [11]. The pathophysiologic explanation for such stent-related symptoms is not yet fully understood. Irritation of the bladder mucosa and especially the trigone by the distal portion of the stent, reflux of urine, and smooth muscle spasm are thought to contribute to stent-related symptoms [12]. Vesicoureteral reflux as measured on cystoureterogram has been reported in 56% to 62% of stented patients [13]. Fluoroscopic imaging in patients with an indwelling stent revealed positional changes of the stent in relation to standing,

sitting, and bending, which may explain why physical activity can influence stent discomfort [14]. Positioning the proximal coil in the upper pole of the kidney in contrast to in the renal pelvis appears to be better tolerated by stented patients [15]. Several authors have reported that stents crossing the midline of the bladder have a significant and deleterious influence on associated discomfort. Appropriate stent position with the distal coil not crossing over the midline of the bladder appeared to have more effect on stent-related symptoms than α-blockers or anticholinergics in a prospective RCT [16]. Choosing the appropriate stent length may therefore aid in ameliorating stent symptoms [17].

Patient and Methods

This study was conducted as a comparative study from first of March 2016 to the first of January 2017, at Rizgary Teaching Hospital in Erbil city/Kurdistan region/Iraq. Total of one hundred patients (15-44 years) who underwent JJ-ureteral stent placement following Ureteroscopy had been enrolled in the study and prospectively randomized into four groups. Patients in group 1 (19 males and 6 females) (mean age 33.40 years) received placebo for three weeks, patients in group 2 (12 males and 13 females) (mean age 31.48 years) received Oxybutynin 5mg once daily for three weeks, patients in group 3 (17 males and 8 females) (mean age 32.76) received Tamsulosin 0.4mg once daily for three weeks and patients in group 4 (16 males and 9 females) (mean age 27.96) received combination of Oxybutynin and Tamsulosin for three weeks. All patients completed the symptom questionnaire (hematuria, urgency, frequency, dysuria, and abdominal pain) and the quality of life questionnaire one week after stent insertion and one week after stent removal.

Inclusion Criteria:

(1) All Patients 15 to 45 years of age
(2) Patients of both sex (male and female)
(3) Patients undergoing retrograde double-J ureteral stent placement.

Exclusion Criteria:

(1) Age<15 years and <45 years.
(2) Patients refusing to participate in the study.
(3) Patients, who are known allergic to Tamsulosin or Oxybutynin.
(4) History of previous ureteral stenting due to false perception of symptoms.
(5) Patients with bilateral double J stenting, because of aggravation of lower urinary tract symptoms due to increased trigonal stimulation.
(6) Bladder pathology like diagnosed bladder tumour.
(7) Benign prostatic hyperplasia related LUTS.
(8) History of interstitial cystitis, chronic cystitis, or chronic prostatitis.
(9) Urinary tract infection.

After stenting, all patients were prescribed ciprofloxacin 500mg twice daily for 10 days to prevent urinary tract infections.The same JJ-stent design was inserted for all patients, the stent size was 4.7-5 Fr., and the length was adjusted by body height.All patients were stone-free at the completion of the procedure and the JJ-stent correct position was confirmed by a KUB film.

Statistical Analysis

Data were analyzed using the Statistical Package for Social Sciences (SPSS, version 22). Chi square test of association was used to compare between proportions. Student's t test was used to compare between means of two groups. A p value of ≤ 0.05 was considered statistically significant.

Approval and Ethical Consideration

This study was approved by each of; the local thesis committee, Iraqi Ministry of Health, Council of Arab Board of Heath Specialization and Rizgary Teaching Hospital administration. The purpose and procedure of the study were explained to all participants and were give the right to participate or not, verbal consent was taken with reassurance that interpret gained will be kept confidentially and not to be used for other than the research object.

Results

A total of 100 patients were enrolled in the study and randomly distributed into 4 groups:

- Group 1: 25 patients received placebo (19 males and 6 females).
- Group 2: 25 patients received Oxybutynin (12 males and 13 females).
- Group 2: 25 patients received Tamsulosin (17 males and 8 females).
- Group 3: 25 patients received combination of Tamsulosin and Oxybutynin (16 males and 9 females).

Figure 1 and Figure 2 show distribution of participants by gender and marrital state respectively which show that most of the patients are married males.

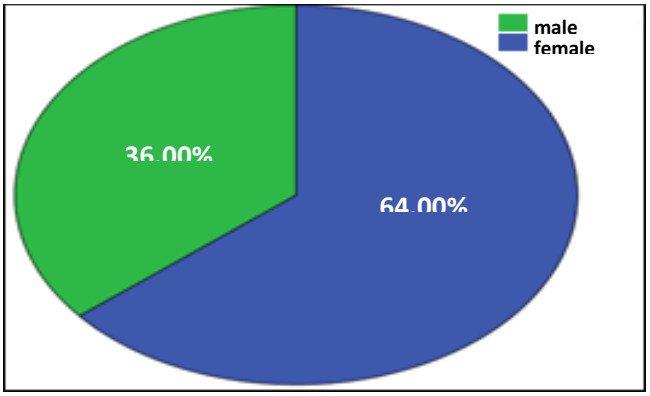

Figure 1: Distribution of participants by gender.

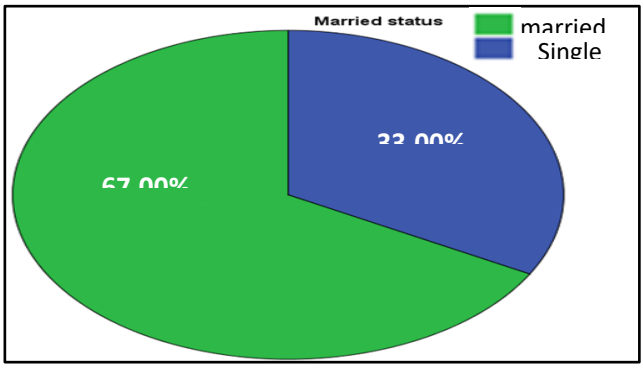

Figure 2: Distribution of participants by marital state.

Table 1 shows that the mean age of participants for the 4 study groups with the mean age of all participants of 31.40 years with the P-value of 0.02 which is significant.

Groups	N	Mean	Std. Deviation	P-value	ANOVA
Placebo	25	33.40	6.99	-	-
Oxybtynin	25	31.48	6.46	-	-
Tamsulosin	25	32.76	6.07	0.02	Significant
Combined	25	27.96	7.47	-	-
Total	100	31.40	6.99	-	-

Table 1: Age of different study groups.

Table 2 shows the association between study groups and gender with the P-value of 0.21 and table 3 shows the association between study groups and marital state with the P-value of 0.66 and both were not significant.

Study groups	Sex		Total
	Male	Female	
Placebo	19 76%	6 24%	25 100%
Oxybutynin	12 48%	13 52%	25 100%
Tamsulosin	17 68%	8 32%	25 100%
Combined	16 64%	9 36%	25 100%
Total	64 64%	36 36%	100 100%

Table 2: Association between study groups and gender (P: 0.21).

Study groups	Marital status		Total
	Single	Married	
Placebo	6 24%	19 76%	25 100%
Oxybutynin	10 40%	15 60%	25 100%
Tamsulosin	8 32%	17 68%	25 100%
Combined	9 36%	16 64%	25 100%
Total	33 33%	67 67%	100 100%

Table 3: Association between study groups and marital status (P: 0.66).

Tables 4,5,6,7,8 and 9 show the association between study groups and urgency, freguency, dysuria, abdominal pain, hematuria and quality of life respectively, with significant P-values in all of them as shown in the tables.

Study groups	Urgency				Total
	No	Mild	Moderate	Severe	
Placebo	0 0.0%	16 64.0%	9 36.0%	0 0.0%	25 100.0%
Oxybutynin	9 36.0%	6 24.0%	8 32.0%	2 8.0%	25 100.0%
Tamsulosin	9 36.0%	7 28.0%	7 28.0%	2 8.0%	25 100.0%
Combined	12 48.0%	8 32.0%	4 16.0%	1 4.0%	25 100.0%
Total	30 30.0%	37 37.0%	28 28.0%	5 5.0%	100 100.0%

Table 4: Association between study groups and urgency (P: 0.01).

Study groups	Frequency				Total
	No	Mild	Moderate	Severe	
Placebo	1 4.0%	12 48.0%	10 40.0%	2 8.0%	25 100.0%
Oxybutynin	7 28.0%	13 52.0%	5 20.0%	0 0.0%	25 100.0%
Tamsulosin	9 36.0%	12 48.0%	4 16.0%	0 0.0%	25 100.0%
Combined	16 64.0%	6 24.0%	3 12.0%	0 0.0%	25 100.0%
Total	33 33.0%	43 43.0%	22 22.0%	2 2.0%	100 100.0%

Table 5: Association between study groups and frequency (P: 0.001).

Study groups	Dysuria			Total
	No	Mild	Moderate	
Placebo	3 12.0%	11 44.0%	11 44.0%	25 100.0%
Oxybutynin	11 44.0%	10 40.0%	4 16.0%	25 100.0%
Tamsulosin	9 36.0%	16 64.0%	0 0.0%	25 100.0%
Combined	17 68.0%	8 32.0%	0 0.0%	25 100.0%
Total	40 40.0%	45 45.0%	15 15.0%	100 100.0%

Table 6: Association between study groups and dysuria (P: < 0.001).

Study groups	Abdominal pain			Total
	No	Mild	Moderate	
Placebo	0 0.0%	15 60.0%	10 40.0%	25 100.0%
Oxybutynin	5 20.0%	17 68.0%	3 12.0%	25 100.0%
Tamsulosin	8 32.0%	15 60.0%	2 8.0%	25 100.0%
Combined	12 48.0%	13 52.0%	0 0.0%	25 100.0%
Total	25 25.0%	60 60.0%	15 15.0%	100 100.0%

Table 7: Association between study groups and abdominal pain (P:<0.001).

Study groups	Hematuria			Total
	No	Mild	Moderate	
Placebo	2 8.0%	14 56.0%	9 36.0%	25 100.0%
Oxybutynin	10 40.0%	11 44.0%	4 16.0%	25 100.0%
Tamsulosin	20 80.0%	5 20.0%	0 0.0%	25 100.0%
Combined	20 80.0%	5 20.0%	0 0.0%	25 100.0%
Total	52 52.0%	35 35.0%	13 13.0%	100 100.0%

Table 8: Association between study groups and hematuria (P:<0.001).

Study groups	Quality of life				Total
	Delighted	Mostly satisfied	Mostly unsatisfied	Terrible	
Placebo	1 4%	8 32%	6 24%	10 40%	25 100%
Oxybutynin	9 36%	2 8%	10 40%	4 16%	25 100%
Tamsulosin	9 36%	9 36%	7 28%	0 0%	25 100%
Combined	15 60%	9 36%	1 4%	0 0%	25 100%
Total	34 34%	28 28%	24 24%	14 14%	100 100%

Table 9: Association between study groups and quality of life (P:<0.001).

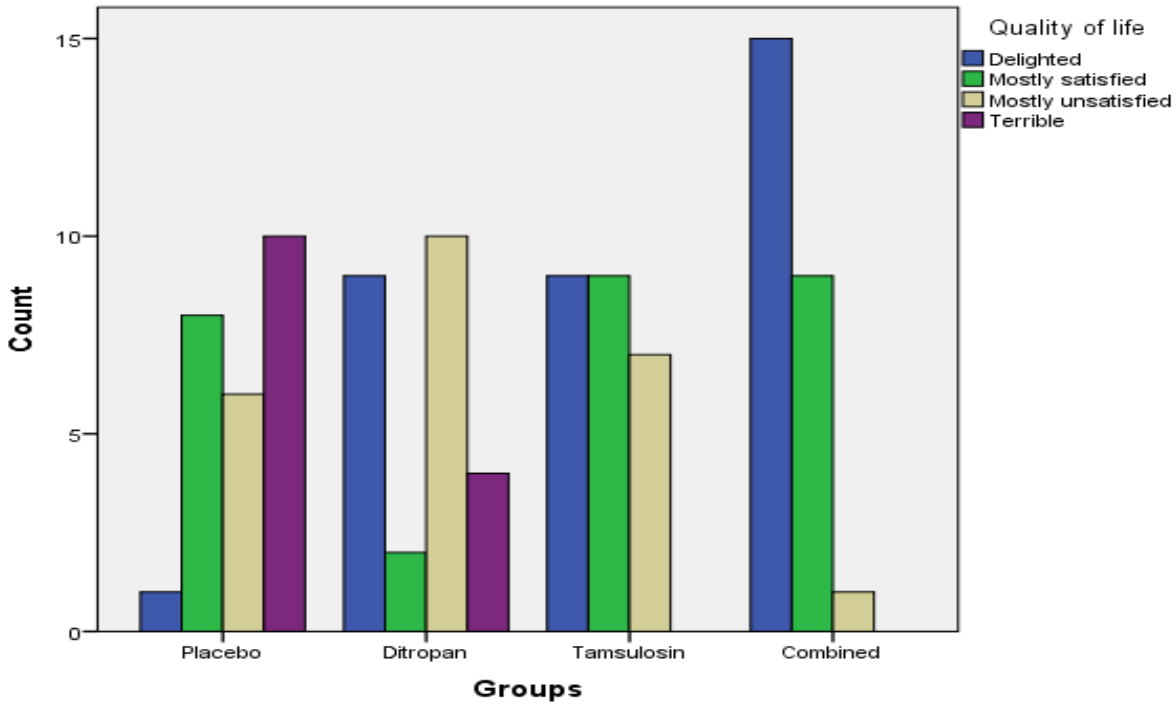

Figure 3: Association between study groups and quality of life.

Discussion

Despite widespread use of ureteral stent in urologic surgeries, it is associated with morbidities including urinary symptoms, pain and impact on patient QoL [19]. The etiologies of stent--related symptoms are not fully understood and it is thought that involuntary bladder contraction caused by trigone irritation contributes to urinary bothersome. In addition, increased bladder outlet resistance and pressure during micturition result in urine reflux to the kidneys, which contribute to stent-related flank pain [20].

Alpha-blockers relieve flank pain by decreasing the muscle tone of the ureter, bladder trigone and prostatic urethra by blocking the alpha-adrenergic receptors and thus reducing bladder outlet resistance and pressure during micturition [21]. In addition, alpha blockers by decreasing muscle spasm and intrarenal urinary reflux may explain the ability to relieve flank pain [22]. Moreover, anticholinergics decrease bladder overactivity and contraction by mediating the muscarinic receptors, thereby reducing urinary symptoms [21].

In our study, it is proven that there is difference in lowering abdominal pain in the patients who are received Tamsulosin versus who were retained on placebo. This is consistent with the study done by Wang et al who reported that Tamsulosin improved urinary symptoms and flank pain during voiding [23]. Beddingfield et al. also concluded in their study that Alfuzosin 10 mg daily improved flank pain [24]. Similarly, Aggarwal et al. concluded that Tamsulosin was effective in relieving urinary symptoms, body pain, general health, and work performance as compared to placebo. Improvement in general health and work performance can be explained by decreased urinary and body pain symptom score [22].

On the other hand, Tamsulosin was superior to Oxybutynin in relieving abdominal pain in our study. This may be explained by the association of flank pain with urine reflux from bladder to kidney, especially the voiding phase (25). This is consistant with the study done by Zhou et al. whom reported that Antimuscarinic agents at clinically recommended doses have little effect on voiding contractions (26).

As shown in our study, there was no statistically significant difference between Tamsulosin and Oxybutynin in relieving urinary symptoms (urgency, frequency and dysuria). These results are consistent with those reported by Park et al. who studied the effect of alfuzosin and tolterodine for the treatment of Dj stent related symptoms. Similar to our results, there was no statistically significant difference in all domains between alfuzosin and tolterodine groups [27]. Lee et al. studied the role of solifenacin in placebo controlled randomized study and found it to be effective in relieving urinary symptoms [28]. This can be explained by that mechanical stimulus coming from bladder D-j stent coil and local trigone sensitivity could contribute to urinary frequency and urgency [29]. Zhou et al. mentioned that improvement of urinary frequency and urgency by Alpha-blockers might be because of blocking the α1 adrenoreceptors of the bladder trigone [26]. On the other hand, because muscarinic receptors mediated the involuntary bladder contraction caused by trigone irritation, antimuscarinics have been thought to block muscarinic receptors on the efferent fibers supplying the detrusor muscle and reduce the ability of contraction and were considered first-line treatment for patients

with overactive bladder [30].

Both Tamsulosin and Oxybutynin had comparable effect on QOL in our study and this is consistant with the study conducted by Zhou et al. who concluded that both alpha-blockers and antimuscarinics were shown to improve the QoL [26].

Tamsulosin and solifenacin are effective drug for stent relate symptoms [31]. Assuming that both alpha and cholinergic receptors have a role to play in genesis of DJ-stent related symptoms, studies have been done comparing combination with monotherapy, proving combination to be better than monotherapy [32].

Our study showed that combination therapy improved irritative urinary symptoms, abdominal pain and QoL and this is consistant with the study done by Avila et al. [33]. In addition, Lim et al reported that combination therapy of tamsulosin and solifenacin is more effective than monotherapy [21]. Meanwhile, the study done by Liu et al. concluded that combination of tamsulosin and solifenacin can take effect faster and improve the stent related symptoms better than monotherapy in the first few days. After that, combination and monotherapy relieve the stent related symptoms equally [34]. So, for long term using, patients with stent related symptoms may get comparable benefits from both combination therapy and monotherapy. This is not consistant with our study and this may be explained by that our questionnaire is only seven days after insertion while theirs was on days 1,2,3,4,5,6,10, and 14 post Dj-stent insertion.

Conclusion

The administration of Tamsulosin and Oxybutynin markedly improve the the irritative symptoms commonly associated with a D-j stent and QoL. Tamsulosin was more efficacious than Oxybutynin in respect to sexual function and abdominal pain relieve. The combination therapy was more efficacious than monotherapy in relieving the irritative symptoms and abdominal pain and in improving the sexual function and QoL.

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