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Original Article

Preventive effect of tamsulosin on postoperative urinary retention in neurosurgical patients

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Abstract

Background: Postoperative urinary retention (POUR) is common in neurosurgical patients. The use of alpha-blockade therapy, such as tamsulosin, has benefited many patients with a history of obstructive uropathy by decreasing lower urinary tract symptoms such as distension, infections, and stricture formation, as well as the incidence of POUR. For this study, we targeted patients who had undergone spinal surgery to examine the prophylactic effects of tamsulosin. Increased understanding of this therapy will assist in minimizing the morbidity of spinal surgery.

Methods: We enrolled 95 male patients undergoing spine surgery in a double-blind, randomized, placebo-controlled trial. Patients were randomly assigned to receive either preoperative tamsulosin (N = 49) or a placebo (N = 46) and then followed-up prospectively for the development of POUR after removal of an indwelling urinary catheter (IUC). They were also followed-up for the incidence of IUC reinsertions.

Results: The rate of developing POUR was similar in both the groups. Of the 49 patients given tamsulosin, 16 (36%) developed POUR compared to 13 (28%) from the control group ($P = 0.455$). In the control group, 5 (11%) patients had IUC re-inserted postoperatively, whereas 7 (14%) patients in the tamsulosin group had IUC re-inserted postoperatively ($P = 0.616$). In patients suffering from axial-type symptoms (i.e., mechanical back pain), 63% who received tamsulosin and 18% from the control group ($P = 0.048$) developed POUR.

Conclusion: Overall, there was no statistically significant difference in the rates of developing POUR among patients in either group. POUR is caused by a variety of factors, and further studies are needed to shed light on its etiology.

Key Words: Adrenergic alpha-antagonists, indwelling urinary catheter, neurosurgery, postoperative urinary retention, tamsulosin, urinary retention

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INTRODUCTION

Postoperative urinary retention (POUR) has been defined as the inability to void despite a full bladder.[27,25] Catheterization can cause significant pain, bladder discomfort, anxiety, and increased cost, resulting in prolonged hospital stays.[8,22.24,30] It has been reported that a single significant episode of bladder distention can lead to weakened bladder collagen fibers, resulting in chronic impairment of bladder emptying capacity or even atony.[2,6]

Advances in pharmacology, specifically the institution of selective alpha-blockers (e.g., tamsulosin), have provided feasible, noninvasive interventions in the treatment of benign prostatic hyperplasia (BPH).[23,31] In our clinical experience, male patients undergoing spinal surgery, regardless of age, have a significant incidence of POUR, resulting in delayed discharge from the hospital and additional testing and procedures.

The purpose of our study was to determine if pharmacological intervention using tamsulosin, administered perioperatively, would reduce the incidence of POUR in men undergoing elective spinal surgery.

MATERIALS AND METHODS

Study design and participants

This was a double-blind, randomized, placebo-controlled trial carried out from April 2012 to January 2013. Ninety-five male neurosurgical patients undergoing spine surgery in our hospital were randomly assigned to receive preoperative tamsulosin (Flomax®) and then followed up prospectively for the development of POUR. This study was approved by the Henry Ford Hospital Institutional Review Board (IRB # 6893).

The study was introduced to eligible male patients between the ages of 18 and 80 who presented to the Neurosurgery Department Clinic of Henry Ford Hospital for elective spinal surgery. Patients were excluded from the study if they met any of the criteria in Table 1. Our rationale for enrolling male patients only was that tamsulosin has been approved by the Food and Drug Administration (FDA) for use in male patients as it exerts its therapeutic effects by relaxing the smooth muscles in the prostate. Furthermore, diagnosed or undiagnosed BPH could be a contributing cause in relatively high-risk males.[23] Those with a creatinine level >2.5 were excluded. Tamsulosin is metabolized mainly via the liver, therefore, liver function was also assessed. All participants underwent ultrasonographic investigation or bladder scanning in the clinic to measure residual urine [Table 2].

Randomization, masking, and data collection

Patients who enrolled were then randomly assigned to either tamsulosin or placebo pills using a computer-generated randomization list, which was stratified by age (<50, 50–64, and 65+ years). Patients and study assessors were masked to the treatment allocation. Medication (0.4 mg of tamsulosin or placebo) was administered orally 48 h before the surgery and the night before surgery. On the day of the surgery, patients were monitored by the project team while in hospital as well as upon discharge. The amount of postoperative urinary volume was monitored using the standard bladder ultrasound until post-void residual of <250 ml was reached. Patients were continued on medication/placebo every night while inpatient until the Foley placed during surgery was removed, typically on postoperative day 1. Medication/placebo was discontinued if no Foley was placed during surgery. No patients were sent home on the medication/placebo postoperatively. In all cases, intravenous fluids were administered in the operating room before the anesthetic was given and continued postoperatively until the day after surgery (12–18 h).

Patients were placed on a pain-control pump (PCA) of either morphine or Dilaudid postoperatively and subsequently weaned to oral narcotics on postoperative day 1. Patients' charts were reviewed and total narcotics dosage and benzodiazepine doses were calculated. All patients were followed during their postoperative stay for any voiding difficulties, and urinary retention was recorded.

Definition of postoperative urinary retention

POUR, as per the hospital protocol, was defined as an initial post-void residual (PVR) greater than 250 ml using bladder ultrasonography (BVI 3000, Verathon) 6 h after the removal of IUCs inserted during surgery. Straight catheterization was performed for patients with PVR greater than 250 ml every 6 h. For patients with the third PVR greater than 250 ml, IUCs were reinserted. Patients were then discharged and instructed to return to the urology clinic in 5–7 days for follow-up. Subsequently, patients' records were reviewed for multiple variables [Tables 3-5]. The total amount of narcotic use was calculated and converted into morphine equianalgesic dose (MED). Total benzodiazepine intake was collected and also considered in our analyses.

RESULTS

The incidence of POUR in all patients was 32% (i.e., based on our definition of first PVR greater than 250 ml). The rate of developing POUR was similar in the placebo and treatment groups, with 16 patients (36%) in the tamsulosin group developing POUR compared to 13 patients (28%) from the placebo group ($P = 0.455$). The rates of Foley reinsertion were also comparable for the two treatment groups (14% for tamsulosin vs 11% for placebo, $P = 0.616$). No differences were observed between the two groups for length of stay (LOS) ($P = 0.755$)

Table 1: Inclusion and exclusion criteria used for patients enrolled in the study

Inclusion criteria	Exclusion criteria
1. Male gender 2. Age 18 to 80 3. English-speaking 4. Able to provide informed consent 5. Scheduled to undergo an elective spine surgery with a planned postoperative inpatient stay of at least 1 night	1. Being on Flomax within the last one month 2. Patients with history of moderate to severe orthostatic hypotension or presence of orthostatic hypotension at the time of eligibility screening 3. Patients who make less than 200 ml/day of urine preoperatively (i.e. end-stage renal disease, renal failure) 4. Patients with allergy to tamsulosin or severe sulfonamides hypersensitivity 5. Patients who have chronic urinary catheterization 6. Patients with alternative voiding pathways or pre-existing indwelling urinary catheter, suprapubic catheter or urostomy 7. Patients who will be admitted to the intensive care unit 8. Patients with history of symptomatic hypotension. Patients will be excluded in clinic if they have a systolic blood pressure <90 9. History of severe heart failure or major cardiovascular event within the previous 6 months 10. Patients with current ALT or AST >1000, or Crt >2.5 during their clinic visits 11. Patients who are actively taking medications that may interact with Flomax 12. Younger than age 18 13. Non-English speaking 14. Lacking capacity to provide informed consent

Table 2: Demographic and past medical history information

Variable	Response	Tamsulosin (*n*=49)	Placebo (*n*=46)	*P*
Age	Mean±SD	57.7±15.1	57.0±13.9	0.800
	Median (range)	60 (18 to 86)	56.5 (23 to 84)	
Race	African American	8 (16%)	10 (22%)	0.463
	White	38 (78%)	30 (65%)	
	Hispanic	0 (0%)	1 (2%)	
	Other	3 (6%)	5 (11%)	
Currently employed	Yes	20 (41%)	17 (37%)	0.700
Education	College - Completed	20 (41%)	17 (37%)	0.985
	College - Some	12 (24%)	12 (26%)	
	High School	14 (29%)	14 (30%)	
	Less Than High School	3 (6%)	3 (7%)	
Treated History of BPH	Yes	5 (10%)	8 (17%)	0.308
Past urologic surgery	Yes	4 (8%)	4 (9%)	0.926
Past cancer dx	Yes	2 (4%)	4 (9%)	0.356
History of diabetes	Yes	8 (16%)	8 (17%)	0.890
Narcotic intake	Less than 6 months	18 (37%)	16 (35%)	0.491
	More than 6 months	16 (33%)	11 (24%)	
	Never	15 (31%)	19 (41%)	
Sexually active In Last 3 months	Yes	31 (63%)	26 (57%)	0.503
Patient BMI	Mean±SD	30.0±6.1	29.7±3.9	0.762
	Median (Range)	29.6 (16.5 to 47)	29.2 (22.8 to 40.8)	

and discharge disposition ($P = 0.394$). For those with predominantly axial back pain, using tamsulosin postoperatively resulted in POUR in 63% versus 18% of patients receiving placebo ($P = 0.048$).

DISCUSSION

POUR is a well-established and commonly encountered problem across all surgical specialties (frequency of 5% to 75%), but has not been studied extensively in spinal neurosurgical patients.[3,7,11,13] Boulis *et al.* reported a 39.1% incidence or POUR in 503 spine patients.[5] McLain *et al.* and Jellish *et al.* reported a 23% and 22.9% incidence of POUR, respectively, in lumbar spine surgery.[10,17] In our previous study, the overall incidence of POUR after spine surgery was 39.4%.[2] Many factors may contribute to POUR, including old age, male gender, and preexisting urologic symptoms to be associated with the development of POUR.[20,21,25-29] Certain medications, such as beta blockers and anticholinergic agents, also contribute to POUR.[4,6] In our study, only male gender and spine surgery were strongly linked to POUR.

Table 3: Data collected from patients during surgery and hospitalization

Variable	Response	Tamsulosin (*n*=49)	Placebo (*n*=46)	*P*
Length of surgery, hours	Mean±SD	3.6±1.9	3.6±1.9	0.818
	Median (range)	3.1 (1.7 to 11.85)	3.0 (1.5 to 9.35)	
Surgery type	Cervical	23 (47%)	18 (39%)	0.742
	Lumbar	24 (49%)	26 (57%)	
	Thoracic	2 (4%)	2 (4%)	
EBL	Mean±SD	144.2±220.3	134.0±279.8	0.266
	Median (range)	62.5 (5 to 1200)	50 (5 to 1800)	
Ins	Mean±SD	1949.0±913.3	1936.4±1075.9	0.779
	Median (range)	1800 (800 to 5000)	1800 (90 to 5000)	
Urine output	Mean±SD	329.1±278.8	249.3±177.4	0.241
	Median (range)	300 (0 to 1500)	245 (0 to 710)	
Foley Inserted	Yes	43 (88%)	38 (83%)	0.479
Foley Length of Time (hours)	Mean±SD	24.9±14.2	23.6±10.3	0.876
	Median (range)	21.8 (4.5 to 78.5)	22.1 (7.7 to 57.2)	
Total pain medication (MEDD)	Mean±SD	94.9±123.9	81.0±84.4	0.93
	Median (range)	59 (9 to 628.25)	59 (2 to 499.6)	
Mean pain score during hospitalization (scale 0 to 10)	Mean±SD	3.9±2.0	3.8±1.9	0.73
	Median (range)	4 (0.1 to 7.6)	3.6 (0.8 to 8.0)	
Total benzodiazepine intake	Mean±SD	20.5±29.1	17.7±18.1	0.827
	Median (range)	10 (0 to 115)	15 (0 to 20)	

Table 4: Presurgical clinical data collected from all study patients

Variable	Response	Tamsulosin (*n*=49)	Placebo (*n*=46)	*P*
Myelopathy	Yes	15 (31%)	10 (22%)	0.326
T2 Signal	Yes	15 (48%)	7 (28%)	0.120
Clinic Sx Type	Axial	9 (18%)	11 (24%)	0.788
	Combined	14 (29%)	13 (28%)	
	Radicular	26 (53%)	22 (48%)	
POUR History	Yes	6 (12%)	5 (11%)	0.834
Pain level in clinic	Mean±SD	6.7±2.1	6.3±2.2	0.295
	Median (range)	7 (1 to 10)	6 (1 to 10)	
IPSS in Clinic	Mean±SD	5.5±5.5	6.3±5.7	0.454
	Median (range)	4 (0 to 23)	5 (0 to 21)	
Clinic PVR	Mean±SD	45.2±75.0	37.7±55.8	0.513
	Median (range)	13 (0 to 392)	12 (0 to 202)	
Clinic UA	Negative	46 (98%)	38 (93%)	0.243
	Questionable	1 (2%)	3 (7%)	
Clinic Glucose Level	Mean±SD	107.8±55.0	92.5±23.6	0.420
	Median (range)	91 (64 to 339)	87.5 (55 to 182)	
Home Rx Antihistamine	Yes	4 (8%)	3 (7%)	0.760
Home Rx Beta blocker	Yes	9 (18%)	12 (26%)	0.365
Home Rx NSAID	Yes	28 (57%)	24 (52%)	0.627

Tamsulosin was first developed in Japan and marketed in 1996 under the trade name Flomax®.[23] It is a potent selective alpha-1 receptor antagonist. Specifically, it has preferential selectivity for the alpha-1A adrenergic antagonist (α1A) receptor in the prostate versus the alpha-1B adrenergic antagonist (α1B) receptor in the blood vessels.[14] It decreases the peristaltic movements in the ureter, the amplitude of detrusor contractions, the urethral opening pressure, and the frequency of micturition. Studies have validated its effectiveness in the symptomatic treatment of BPH.[9,19] By selectively binding to the alpha-1A receptors in the bladder neck and the prostate, it causes relaxation of the smooth musculature, which in turn results in less resistance to urinary flow.

We are aware of only four randomized trials that assessed the effectiveness of tamsulosin administered perioperatively to prevent POUR, however, none involved spine surgery.[1,9,15,16,18,20] Mohammadi-Fallah

Table 5: Subgroup statistical analysis comparing POUR with several variables between the tamsulosin and placebo groups

Subgroups	Tamsulosin# POUR/Total# (%)	Placebo# POUR/Total# (%)	*P*
Age			
<60	5/23 (22%)	8/27 (30%)	0.526
≥60	11/22 (50%)	5/19 (26%)	0.121
Race			
White	15/34 (44%)	11/30 (37%)	0.544
Non-white	1/11 (9%)	2/16 (13%)	0.781
BMI			
<30	10/26 (38%)	7/25 (28%)	0.428
≥30	6/19 (32%)	6/21 (29%)	0.835
Surgery time			
<3 hours	9/21 (43%)	4/23 (17%)	0.064
≥3 hours	7/24 (29%)	9/23 (39%)	0.471
Type of surgery			
Cervical/thoracic	7/22 (32%)	4/20 (20%)	0.384
Lumbar	9/23 (39%)	9/26 (35%)	0.743
Narcotic intake			
<6 months	6/18 (33%)	2/16 (13%)	0.152
>6 months	5/14 (36%)	4/11 (36%)	0.973
Never	5/13 (38%)	7/19 (37%)	0.926
Hx of diabetes			
Yes	4/7 (57%)	1/8 (13%)	0.067
No	12/38 (32%)	12/38 (32%)	>0.99
Myelopathy			
Yes	3/14 (21%)	2/10 (20%)	0.932
No	13/31 (42%)	11/36 (31%)	0.332
Clinic sx type			
Axial	5/8 (63%)	2/11 (18%)	0.048
Combined	2/14 (14%)	4/13 (31%)	0.303
Radicular	9/23 (39%)	7/22 (32%)	0.608

et al. followed 80 males who underwent elective inguinal herniorrhaphy.[18] Patients were randomly assigned to receive two doses of placebo orally, 6 h before surgery and 6 to 12 h after surgery (controls), versus the treatment group who received 0.4 mg tamsulosin orally; 15% of the patients in the control group developed POUR compared to only 2.5% in the treatment group ($P = 0.04$).[18]

Madani *et al*. followed 232 male patients aged 18 to 50 years of age undergoing varicocelectomy, inguinal herniorrhaphy, and scrotal surgery.[16] They were randomized to receive either three doses of 0.4 mg tamsulosin (N = 118) or placebo (N = 114). POUR developed in 5.9% of the patients receiving tamsulosin versus 21.1% for control patients ($P = 0.001$). Ahmad *et al*. studied 626 patients undergoing benign anorectal conditions; 313 patients received tamsulosin and 313 received placebo/controls.[25] Of the control group, 56 (17.9%) developed POUR compared to 8 (2.5%) patients from the tamsulosin group. In the fourth study, Jang *et al*. found that tamsulosin had no effect on the rate of POUR.[19] There were 94 patients with rectal cancer who were randomly assigned to tamsulosin (0.2 mg/day orally for 7 days) (N = 47) or the control group (N = 47); POUR occurred in 23.4 vs. 21.3 %, respectively; $P = 0.804$).

The etiology of urinary retention following spine surgery is likely neurological manipulation.[10,12,15] Although the benefits of tamsulosin therapy have been demonstrated in those with BPH, there have been no studies to demonstrate the efficacy of this therapy for urinary retention in the neurosurgical patient. Nevertheless, many patients without underlying BPH may benefit from alpha-blockage, particularly those who have had manipulation of the neurogenic supply to the bladder and urethra secondary to recent spinal surgery. Studies have shown that male gender, preoperative urinary symptoms, diabetes mellitus, large amounts of intravenous fluid administered perioperatively, and postoperative pain are independent risk factors for POUR.[2,20,29]

We previously found a trend of increased retention following cervicothoracic surgeries compared with lumbar surgeries, which may be due to damaged spinal cord fibers,

however, the type of surgery had little to no bearing on the development of POUR in the tamsulosin and placebo groups.[2] In addition, longer LOS is positively correlated with POUR.[4] Balderi *et al*. found that patients who developed POUR had a median LOS of 7 days compared with 6 days without POUR ($P = 0.007$).[4] In this study, patients with POUR had significantly longer LOS compared to those without (4.1 vs. 2.5 days, $P = 0.018$). However, we found no statistically significant difference in LOS between those receiving perioperative tamsulosin and those receiving placebo (3.5 vs. 2.8 days, $P = 0.755$). This was expected as the rate of developing POUR was similar in both groups.

Finally, it is widely believed that the use of pain medications contributes to the development of POUR.[12,19] This was not the case in our study as there was no difference in the amount of narcotic analgesics used by both groups. Not only did patients have similar use of narcotics ($P = 0.93$) but they also had similar pain scores ($P = 0.73$). Thus, narcotic use had no bearing on the incidence of POUR.

CONCLUSION

Despite largely negative study results, tamsulosin has shown promise when used in other specialties as well as positive trends in certain patient subgroups. Further and larger clinical trials are needed to investigate the effectiveness of such medications in patients undergoing spinal surgery.

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Conflicts of interest
There are no conflicts of interest.

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