

# Effect of Pre-Operative Tamsulosin on Post-Operative Urinary Retention in High Prostatic Risk Patients Undergoing Elective Laparoscopic Hernia Repair in Government Medical College, Alappuzha- A Prospective Observational Study

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## ABSTRACT

### BACKGROUND

After surgery, 1 / 4<sup>th</sup> of patients develop urinary retention. POUR (Post-Operative Urinary Retention) is clinically identifiable urinary bladder post-operatively. POUR occurs more frequently after hernia surgeries (both open and laparoscopic methods), lower urinary tract, perineal, gynaecologic, and anorectal surgeries. tamsulosin, being an alpha-1 receptor blocker, decreases the bladder neck tone and hence increases the efficiency of micturition. We wanted to evaluate tamsulosin in preventing POUR in patients who underwent laparoscopic groin hernioplasty.

### METHODS

From January 2017 through January 2018, a total of 150 males more than 40 years of age who underwent laparoscopic inguinal hernia repair in Government T.D. Medical College were included in this study. In group 1, patients were given 0.4 mg Tamsulosin orally, 2 weeks before surgery and continued postoperatively and group 2 patients were selected from other units in surgery where tamsulosin was not used.

### RESULTS

There are 75 patients in group 1 (tamsulosin) and 75 patients in group 2 (control group). All the patients were male and the mean age in both the groups was almost similar. In tamsulosin group 5 patients (6.7 %), and in control group 14 patients (18.7 %) developed Post-Operative Urinary Retention (POUR). The type and side of hernia, duration of surgery, and post-voiding residual urine volume (PRV) were not effective in causing POUR. There was significantly lower incidence of post-operative urinary retention in Tamsulosin group compared to control group. The age, severity of seven pre-operative urinary symptoms and the prostate volume was statistically significant in patients who developed post-operative urinary retention in both groups.

### CONCLUSIONS

Tamsulosin, before and after surgery, is useful in reducing the incidence of POUR in patients undergoing elective laparoscopic inguinal hernia repair.

### KEYWORDS

Laparoscopic Hernioplasty, Tamsulosin, Urinary Retention, Alpha Adrenergic Antagonist, Post-Operative Urinary Retention (POUR), Post-Voiding Residual Urine Volume (PRV)

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## BACKGROUND

POUR is seen in 1 / 4<sup>th</sup> of patients undergoing hernia surgery in both the sexes and all ages especially in surgeries conducted below the umbilical level.<sup>1</sup> Definition of POUR being difficulty to pass urine in the post-operative settings which is clinically diagnosed with palpable urinary bladder which can be percussed, but, the definition varies widely.<sup>2</sup> This leads to catheterisation, temporary or permanent, recurrent Urinary Tract Infection, which leads to urethral stricture and additional treatments causing financial burden and prolonged or recurrent hospital admissions.<sup>2</sup> After surgery the urinary retention is caused by obstruction and improper neural and detrusor contraction (analgesic use).<sup>3</sup> Alpha adrenergic over activity is also considered as a cause, and, its blockade helps prevent POUR.<sup>4</sup> Tamsulosin acts by relaxing detrusor, easing the tightness at the bladder outlet preventing POUR.<sup>2</sup>

## Objectives

1. To determine the percentage of reduction in post-operative urinary retention with the use of pre-operative use of tamsulosin in high prostatic risk patients undergoing elective laparoscopic hernia repair.
2. To estimate the percentage of significant lower urinary tract symptoms in patients > 40 years undergoing laparoscopic hernia repair, on the basis of International Prostate Symptom Score (IPSS score: Mild 0 - 7, Moderate 8 - 19, Severe 20 - 35).

## METHODS

This observational study was initiated after Institutional Ethical Committee approval of the study, from January 2017 – January 2018 in patients undergoing laparoscopic inguinal hernia repair. Consecutive male patients aged > 40 years who attended General Surgery Outpatient and Inpatient and ER of T.D. Medical College Hospital, Vandanam, Alappuzha, Kerala, India, were included in the study.

## Study Groups

Group 1: The patients were given 0.4 mg of tamsulosin orally, 2 weeks before surgery and continued post operatively who underwent laparoscopic inguinal hernia repair.

Group 2: Patients are selected from other units in surgery where tamsulosin was not used.

## Sample Size

Where,  $Z_{\alpha} = 1.96$  at 5 % level of significance,  
 $p$  = Proportion of the desired variable = 25 % i.e. we expect 25 % of hernioplasty patients will have urinary retention,  
 $q = 100 - p = 75 \%$

Absolute Precision of 10 % is taken

$$n = \frac{Z_{\alpha}^2 \times pq}{e^2} = 72$$

Sample size (n) = 72

75 patients was studied in each group

## Study Variables

Independent variables: Age, sex, comorbidities and pre-operative findings.

Dependent variables: Post-operative urinary retention.

## Inclusion Criteria

Patients > 40 years of age with inguinal hernia who underwent elective laparoscopic hernia repair.

## Exclusion Criteria

1. Age < 40 years
2. Active UTI
3. IPSS < 7
4. Spinal anaesthesia
5. Large hernias with bladder as content
6. Cardiopulmonary or other significant systemic diseases
7. Previous neurological diseases
8. Medications, eg: bethanechole
9. Past history of Kidney Ureter Bladder invasive evaluation
10. Previous urological diseases- stricture of urethra / prostatic cancer
11. Serum Creatinine > 1.6 mg / dl
12. Urinary Incontinence
13. Indwelling Foley's catheter

## Data Collection Tool

Structured data collection proforma.

## Data Collection Procedure

All patients will undergo a thorough clinical and urological evaluation. Patients were given a score using IPSS. Patients with IPSS Score > 7 are considered as high prostatic risk patients and started on tamsulosin 0.4 mg 2 weeks pre-operatively and followed up post-operatively for 24 hours to assess the development of POUR. The other group was taken from surgery units where tamsulosin is not being routinely used.

Post-operative urinary retention (POUR) was identified if:

- Palpable bladder.
- No act of urination in 24 hrs.
- Failed conservative efforts.

Epi Info 7 and Microsoft Excel version 10 was used for data entry and data consolidation. Analysis was carried out with SPSS version 16 and Microsoft Excel version 10. All graphs, tables and charts was made using Microsoft Excel version 10.

## RESULTS

Variables	POUR		Total	P-Value
	Absent	Present		
Age (years)	40-59	36(100%)	0(0.00%)	0.009 <sup>S</sup>
	60-79	34(87.2%)	5(12.8%)	
Type of hernia	Direct	36(90%)	4(10%)	0.418 <sup>NS</sup>
	Indirect	18(100%)	0(0.0%)	
	Direct + Indirect	16(94.1%)	1(5.1)	
Site	Right	29(96.7%)	1(3.3%)	0.638 <sup>NS</sup>
	Left	24(88.9%)	3(11.1%)	
	Right + Left	27(94.4%)	1(5.6%)	
PRV (ml)	<50	37(100%)	0(0.0%)	0.008 <sup>S</sup>
	>50	33(86.8%)	5(13.2%)	
Prostate Volume(cc)	25 - 29	32(100%)	0 (0.0%)	0.009 <sup>S</sup>
	30 - 34	20(95.2%)	1 (4.8%)	
	35 - 39	14(93.3%)	1 (6.7%)	
	40 - 44	4(57.1%)	3 (42.9%)	
Surgery Time(hour)	<1	43(95.6%)	2 (4.4%)	0.357 <sup>NS</sup>
	>1	27(90.0%)	3 (10.0%)	
IPSS	Moderate	62(98.4%)	1 (1.6%)	0.004 <sup>S</sup>
	Severe	8(66.7%)	4 (33.3%)	
Total		70(93.3%)	5 (6.7%)	75

**Table 1. Association between Post-Operative Urinary Retention (POUR) and Study Variables in Tamsulosin Group (1)**

Binary logistic regression was performed | NS → Association is Not Significant, S → Association is Significant at 0.05 level

In tamsulosin group, the prostate volume, PRV, the severity of pre-operative urinary symptoms and advancing age was found to be statistically significant in patients who developed post-operative urinary retention. The number of patients who developed POUR in tamsulosin group was 5 and all the patients had severe pre-operative urinary symptoms and prostate volume in the range of 35 - 44 mL and belonged to the age group 60 - 79 years. Hence, in tamsulosin group, the prostate volume, PRV and pre-operative urinary symptoms ( $p < 0.01$ ) and age ( $p < 0.05$ ) is statistically significant in patient with post-operative urinary retention.

Variables	POUR		Total	P Value
	Absent	Present		
Age (Years)	40 - 59	48(94.1%)	3 (5.9%)	<0.001 <sup>S</sup>
	60 - 79	13(54.2%)	11(45.8%)	
Type of Hernia	Direct	35(83.3%)	7 (16.7%)	0.310 <sup>NS</sup>
	Indirect	21(84.0%)	4 (16.0%)	
	Direct + Indirect	5 (62.5%)	3 (37.5%)	
Site	Right	25(80.6%)	6 (19.4%)	0.815 <sup>NS</sup>
	Left	23(85.2%)	4 (14.8%)	
	Right + Left	13(76.5%)	4 (23.5%)	
PRV (ml)	< 50	37(100.0%)	0 (0.0%)	<0.001 <sup>S</sup>
	> 50	24 (63.2%)	14(36.8%)	
Prostate Volume(cc)	25 - 29	35(100.0%)	0 (0.0%)	<0.001 <sup>S</sup>
	30 - 34	9 (90.0%)	1 (10.0%)	
	35 - 39	15 (75.0%)	5 (25.0%)	
	40 - 44	2 (20.0%)	8 (80.0%)	
Surgery Time (Hour)	< 1	51 (82.3%)	11(17.7%)	0.655 <sup>NS</sup>
	> 1	10 (76.9%)	3 (23.1%)	
IPSS	Moderate	58 (93.5%)	4 (6.5%)	<0.001 <sup>S</sup>
	Severe	3 (23.1%)	10(76.9%)	
Total		61 (81.3%)	14 (18.7%)	75

**Table 2. Association between Post-operative Urinary Retention (POUR) and Study Variables in Control Group (2)**

Binary logistic regression was performed | NS → Association is Not Significant, S → Association is Significant at 0.05 level

In control group (2), 16 patients developed post-operative urinary retention. 14 out of 16 patients were in the age group of 60 - 79. 15 patients with prostate volume in the range 35 - 44 mL had urinary retention. 13 patients who developed urinary retention had severe pre-operative

urinary symptoms. Thus, in control group, age, prostate volume, PRV and the severity of pre-operative urinary symptoms was found to be statistically significant in patients who developed post-operative urinary symptoms after laparoscopic hernia repair.

POUR	Tamsulosin(1) (n = 75)	Control(2) (n = 75)	p - value
Absent	70 (93.3%)	61 (81.3%)	0.034 <sup>S</sup>
Present	5 (6.7%)	14 (18.7%)	

**Table 3. Comparison of Post-operative Urinary Retention between Tamsulosin and Control Groups**

Binary logistic regression was performed | S → Difference is Significant at 0.05 level

5 (6.7%) patients developed Post-Operative Urinary Symptoms in tamsulosin group and 14 (18.7%) patients developed Post-Operative Urinary Symptoms in control group. There was significantly lower incidence of POUR in tamsulosin group compared to control group which is statistically significant ( $p < 0.05$ ).

Age/POUR	Tamsulosin (1)	Control (2)	p-value
40-59 yrs.	Absent 36 (100.0%)	48 (94.1%)	0.070 <sup>NS</sup>
	Present 0 (0.0%)	3 (5.9%)	
60-79 yrs.	Absent 34 (87.2%)	13 (54.2%)	0.005 <sup>S</sup>
	Present 5 (12.8%)	11 (45.8%)	

**Table 4. Age-wise Comparison of Post-operative Urinary Retention between (40-59 and 60-79) Groups**

Binary logistic regression was performed | NS → Difference is Not Significant, S → Difference is Significant at 0.05 level

The Post-Operative Urinary Retention (POUR) in the age group of 60-79 was 5 and 11 in tamsulosin and control group respectively. Hence the incidence of POUR was more in the elderly patients in the age group of 60-79 in both group and it is statistically significant.

## DISCUSSION

The most common immediate post-operative complication of both open and laparoscopic method of hernia repairs is urinary retention.<sup>1</sup> Both spinal anaesthesia and general endotracheal anaesthesia is responsible for the same complications, besides, the other major factor is the site of surgery i.e, groin, presence of Lower Urinary Tract Symptoms or Bladder Outlet Obstruction in patient previously treated or untreated for the same.<sup>1</sup> In anaesthesia the most common cause of Urinary Retention (UR) is General Anaesthesia (GA) and laparoscopic hernioplasties are generally done under GA.<sup>5</sup>

Peter Jensen et al showed (after comparing 72 studies) showed that there is decreased chance of POUR with local anaesthesia when compared to regional and general anaesthesia. Fresh studies on the latest short-acting variants of general and regional anaesthesia is required for further clarification.<sup>6</sup> Other indicators of POUR include pain, narcotic analgesia, and perioperative bladder distention.<sup>7</sup> Initial treatment of urinary retention requires decompression of the bladder with catheterization which is usually for short term.<sup>8</sup> Patients will generally require an overnight admission and trial of normal voiding before discharge. Failure to void normally requires reinsertion of the catheter for up to a week. Chronic requirement of a urinary catheter is rare,

although older patients may require prolonged catheterization.

To assess the symptomatology and grade of the LUTS, there is a scoring system called International Prostate Symptom Score.<sup>2</sup> IPS Score 0 - 7 is mild, IPS Score 8 - 19 is moderate, and IPS Score 20 - 35 is severe.

$\alpha$ -Adrenergic blocking agents reduces the tone of the neck of the urinary bladder and, hence, improving the rate of flow of urine and improves the stream. Alpha receptors are present in the base and neck of bladder.<sup>9</sup> Tamsulosin is a super-selective  $\alpha$ -1a adrenoreceptor antagonist which requires a single daily dosing, low potential for hypotension or interference with concomitant anti-hypertensive therapy and has a rapid action and are effective quickly, and, although the 5  $\alpha$ -reductase inhibitors have fewer side effects, they need to be taken for at least 6 months, and their effect is greatest in patients with large (> 50 g) glands.<sup>10</sup>

In our study, 5 of 75 patients (6.7 %) in the tamsulosin group (1) and 14 of 75 patients (18.7 %) in control group (2) developed post-operative urinary retention following laparoscopic hernia repair. Hence, tamsulosin had a desirable effect in reducing the incidence of urinary retention in male patients more than 60 years of age who underwent laparoscopic inguinal hernioplasty.

In tamsulosin group, the prostate volume and the severity of pre-operative urinary symptoms and advancing age was found to be statistically significant in patients who developed POUR. The number of patients who developed POUR in tamsulosin group was 5 and all the patients had severe pre-operative urinary symptoms and prostate volume in the range of 35 - 44 mL and belonged to the age group 60 - 79 years.

In control group, 16 patients developed POUR. 14 out of 16 patients were in the age group of 60 - 79 years. 15 patients with prostate volume in the range 35 - 44 mL had urinary retention. 13 patients who developed urinary retention had severe pre-operative urinary symptoms, and, hence, they were statistically significant.

In both the groups, age, prostate volume and severity of pre-operative urinary symptoms were statistically significant, in those patients who developed postoperative urinary retention. The side and site of hernia and the post-void urine residual volume had no statistical significance with respect to the incidence of urinary retention.

Madani AH et al studied 80 male patients for hernioplasty in his study. 2.5 % tamsulosin group (I) and 15 % of the control group (II) had urinary retention which was statistically significant ( $p = 0.04$ ).<sup>11</sup> Shaw MK et al showed that the incidence of POUR in high-risk group among tamsulosin users was only 3 (12.5 %) out of 24 patients and among tamsulosin non-users was 10 (41.6 %) out of another 24 patients.<sup>12</sup> In a study by Sivasankaran MV, 350 patients who underwent laparoscopic groin hernioplasty of whom 29 patients developed POUR (8.3 %), old age, BPH and prolonged surgery were independent risk.<sup>13</sup>

Lucas MG et al conducted a study to evaluate the efficacy of tamsulosin compared to placebo for treating catheterized patients with Acute Urinary Retention (AUR) caused by Benign Prostatic Hyperplasia (BPH), by comparing the numbers of patients who voided successfully after removing their catheter. Thirty-four men of 74 taking tamsulosin and

18 out of 75 taking placebo did not require re-catheterization on the day of the trial without catheter (48 % and 26 % respectively,  $p = 0.011$ ).<sup>14</sup> Poylin V et al also suggested the beneficial effects of tamsulosin in preventing POUR.<sup>15</sup> Akkoc A et al showed that, the positive effects of tamsulosin and alfuzosin on POUR were almost same.<sup>16</sup>

## CONCLUSIONS

Pre-operative tamsulosin in laparoscopic hernia repair reduces the incidence of POUR and hence, the need for catheterization. It can be recommended in high prostatic risk male patients more than 60 years of age.

Data sharing statement provided by the authors is available with the full text of this article at jebmh.com.

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