

**Original article:**

## **Preventive role of Tamsulosin on post-operative urinary retention: A randomized placebo controlled study**

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### **ABSTRACT**

**Background:** As we have progressed over time, prophylactic use of Tamsulosin has shown significant effect on the postoperative urinary retention (POUR) after perineal, anorectal and inguinal surgeries. This study was conducted to evaluate the preventive role of tamsulosin on postoperative urinary retention.

**Material and Methods:** This case control randomized study was conducted on eighty patients with forty patients in each group selected on basis of random sampling method who met the inclusion criteria over a period of one year. One group received tamsulosin and the other group received placebo. All the patients were followed for 24 hours and results were compared.

**Results:** Tamsulosin significantly reduced the incidence of postoperative urinary retention.

**Conclusion:** The preoperative role of Tamsulosin in patients undergoing perineal, anorectal and inguinal hernia surgeries under spinal anaesthesia significantly reduces the incidence of post-operative urinary retention and improves the quality of life in early stages of post-operative rehabilitation and also decreases the duration of hospital stay.

**Keywords:** Post-operative urinary retention and Tamsulosin.

### **Introduction:**

Urinary retention (UR) is a severe impairment of voiding which can be acute or chronic. Increased sympathetic activity resulting from surgery may be a contributing factor <sup>[1]</sup>. Acute urinary retention is a painful bladder distension, which usually presents as an emergency and is often seen in postoperative patients. Chronic urinary retention (CUR) is a painless bladder distension leading to overflow dribbling and risk of impaired upper urinary tract function. Postoperative urinary retention (POUR) has generally been defined as the inability to pass urine voluntarily with concomitant urge, in the presence of a palpable or percussable bladder after surgery, but the definition varies widely <sup>[2]</sup>. POUR is a common and potentially serious morbidity with a reported incidence of 3 to 25%. POUR occurs in patients of both sexes, all age groups and after all types of surgical procedures, seen more frequently after lower urinary tract, perineal, gynecological and anorectal surgeries. Injury to the pelvic nerves, pain evoked reflex and increase in the tone of the internal sphincter explains the high incidence of POUR in patients undergoing anorectal surgery. The widely varying reported incidence of POUR reflects differences in patient

characteristics, the lack of uniform defining criteria and the multifactorial etiology of POUR including age, gender, inadequate perioperative fluids, type of anesthesia and type of surgery. Several contributing mechanisms leading to POUR have been suggested which include traumatic instrumentation, bladder over-distention, diminished awareness of bladder sensation, decreased bladder contractility, increased outlet resistance, decreased micturition reflex activity, nociceptive inhibitory reflex and preexistent outlet pathology. Alpha-receptors are located in the trigonum and in the urethra. The adrenergic stimulation of  $\alpha_{1A}$ -receptors leads to an increase in the bladder closure while its inhibition leads to a reduction of bladder closure, Alpha-blockers have been found useful in cases of POUR. Tamsulosin, a benzenesulfonamide, is an  $\alpha_{1A}$  receptor antagonist with some selectivity for  $\alpha_{1D}$  subtypes compared to  $\alpha_{1B}$ . Tamsulosin is well absorbed and has a half life of 10-12 hours. Tamsulosin may be administered at a 0.4mg starting dose; a dose of 0.8mg ultimately will be more efficacious in some patients. Postsynaptic  $\alpha_{1A}$ -blockade leads to smooth muscle relaxation of the prostate, bladder neck and the urethra. There are only few studies emphasizing on the preventive role of Tamsulosin in postoperative urinary retention, it was proposed to take up this study in postgraduate department of Surgery, ASCOMS, Jammu.

#### **Material and Methods:**

A randomized Placebo controlled study was conducted in the Department of General Surgery, Acharya Shri Chander College of Medical Sciences and Hospital, Sidhra, Jammu from November 2016 to October 2017. 80 patients were taken in the study group with 40 patients in each group selected on the basis of Random sampling method fulfilling the eligibility criteria. Group A received Tab Tamsulosin 0.4mg 8-10 hrs preoperatively and 8-10 hrs postoperatively, Group B received placebo in the similar way. The medication was given to both the groups by a Staff nurse. Patients were asked to empty their bladder prior to surgery. In all patients intravenous fluids (1.5ml/kg/hr) were administered in the operating room before anaesthesia and patients were kept nil per oral with intravenous fluids for 4-6 hrs. All patients were anesthetized by spinal route.

In the intraoperative and postoperative periods Tramadol was used as an analgesic followed by Diclofenac for pain control. All the patients were followed for 24 hrs postoperatively, any difficulty in voiding or urinary retention was recorded and the occurrence of POUR was compared between the two groups.

Following parameters were assessed over 24hrs, failure to pass urine within 24hrs, Suprapubic Discomfort, Palpable Suprapubic Mass, Incidence of catheterisation postoperatively. A 14-French nelaton catheter was placed to decompress the bladder in patients who were not able to urinate 12 hours after surgery.

The cases which were studied included patients of either sex, age 18-70yrs, patients posted for perineal, Anorectal (Hemorrhoidectomy, Fistula surgery, Lateral sphincterectomy, Incisional drainage of perianal abscess) and Inguinal hernia surgeries. Patients with active urinary tract infection, neurological disorders, Urinary calculi or stricture, benign hypertrophy of prostate, medications that could affect voiding function such as cholinergic drugs, urogenital malignancies, previous urological surgeries, indwelling catheter, history of urinary incontinence and serum creatinine greater than 1.6 mg/dl were excluded.

**Statistical Methods:** The recorded data was compiled and entered in a spreadsheet (Microsoft Excel) and then exported to data editor of SPSS Version 20.0 (SPSS Inc., Chicago, Illinois, USA). Continuous variables were summarized as Mean $\pm$ SD and categorical variables were expressed as frequencies and percentages. Graphically the

data was presented by bar diagrams. The Student’s independent t-test and ANOVA were employed to analyze the statistical differences in parametric data. Chi-square or Fisher’s exact test, whichever appropriate, was applied for categorical data. A P-value of less than 0.05 was considered statistically significant.

**Results:**

Patients admitted in the department of surgery for perineal, anorectal and inguinal hernia surgeries were enrolled in the study after fulfilling the eligibility criteria. The patients were allocated to two groups of 40 patients each on the basis of random sampling method. The patients were evaluated and a detailed general physical and systemic examination was conducted prior to the surgery.

**Table 1: Age distribution of study patients among two groups**

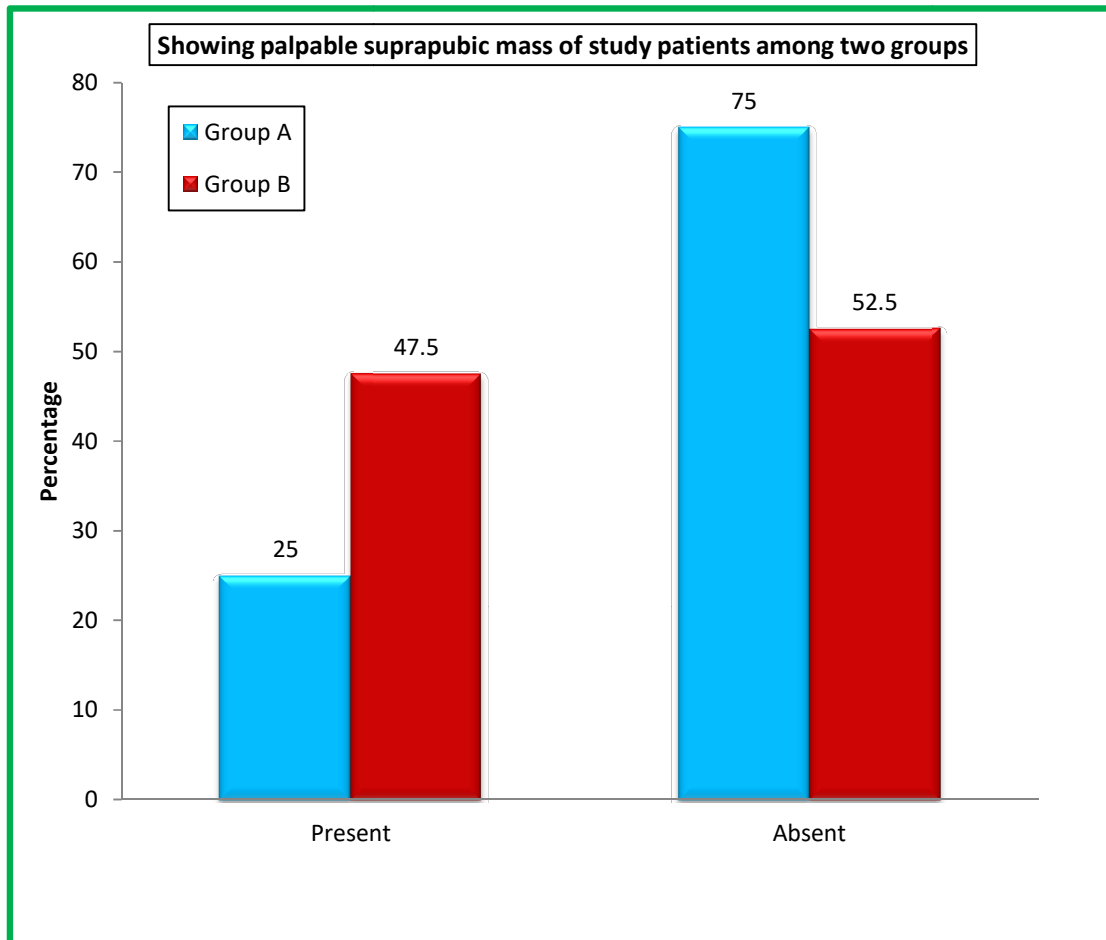
Age (years)	Group A [n=40]		Group B [n=40]		P-value
	No.	%age	No.	%age	
15-29	5	12.5	7	17.5	0.949
30-44	16	40.0	14	35.0	
45-59	15	37.5	14	35.0	
≥ 60	4	10.0	5	12.5	
Mean±SD	42.9±12.54		43.2±12.07		

The patients included in group A and group B were in range of 18-70 years. Majority of the patients were in the range of 30-60 years in both groups (Table 1). The study comprised of 80% males and 20% females in group A and 75% males and 25% females in group B. The youngest patient in the study was 19 years and oldest was 68 years. The mean length of hospital stay was lesser in group A (2.31 days) compared to group B (2.50 days).

**Table 2: Type of surgery among two groups**

Type of Surgery	Group A		Group B	
	No.	%age	No.	%age
Open Haemorrhoidectomy	18	45.0	18	45.0
Stapler Haemorrhoidectomy	1	2.5	0	0.0
Open Hernioplasty	11	27.5	9	22.5
Varicocelelectomy	3	7.5	0	0.0
Fistulectomy	3	7.5	3	7.5
Lateral Sphincterotomy	1	2.5	0	0.0
Anal growth Biopsy	1	2.5	0	0.0
Jabouley's Procedure	1	2.5	3	7.5
Perianal abscess drainage	1	2.5	7	17.5
Total	40	100	40	100

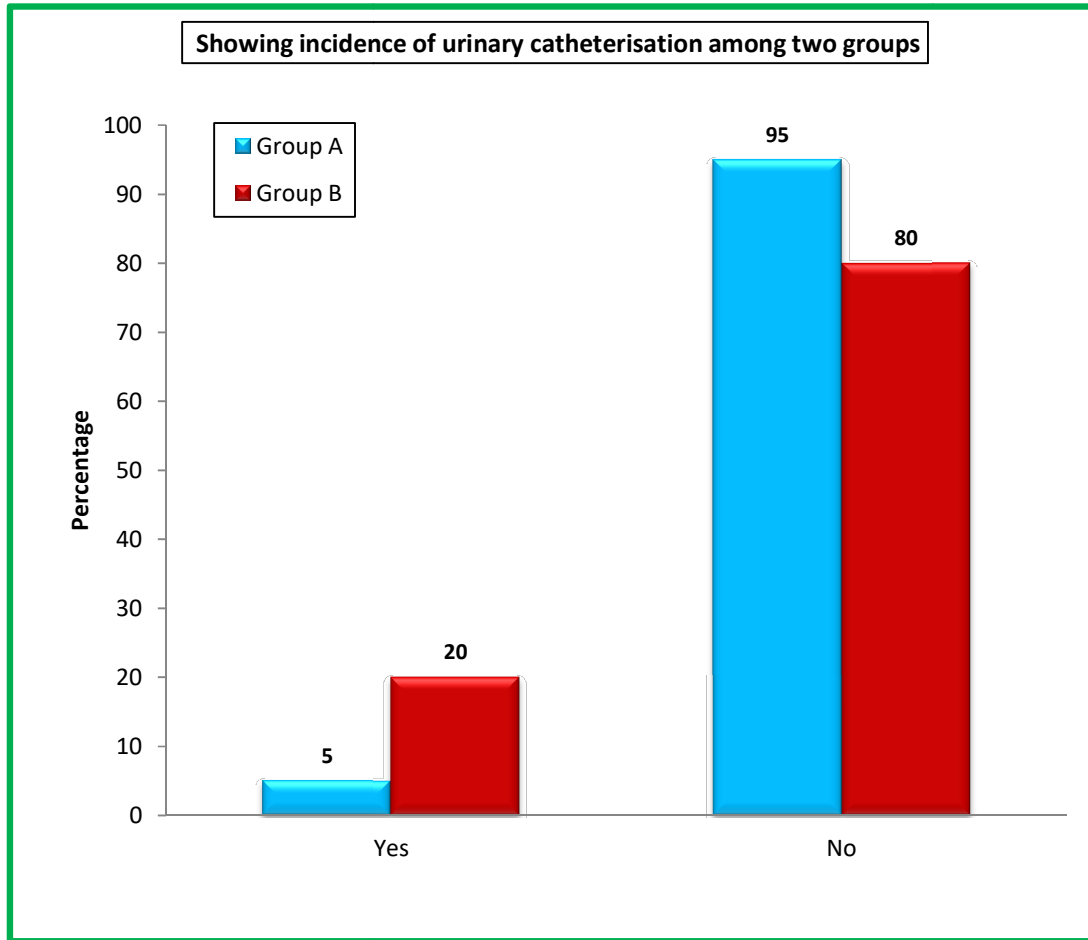
In group A, Palpable suprapubic mass was present in 10 patients (25%) and in 19 patients (48%) of group B. This was statistically significant ( $p=0.036$ ). In group A, Suprapubic discomfort was present in 15 patients (38%) and 21 patients (53%) in group B which was statistically insignificant.



**Table 3: Showing spontaneous passage of urine among two groups**

Spontaneous passage of urine	Group A		Group B		P-value
	No.	%age	No.	%age	
Yes	38	95	32	80	0.043*
No	2	5	8	20	
Total	40	100	40	100	

In group A, 70% patients failed to pass urine 0-2 hours postoperatively, 30% failed to urinate 2-4 hours postop, 25% failed to urinate 4-6 hours and 5% failed to urinate 6-8 hours. In group B, 90% patients failed to pass urine between 0-2hours postop, 75% patients failed to urinate 2-4 hours, 48% failed to urinate 4-6 hours postop, 20% failed to urinate 6-8 hours postop and 8% patients failed to urinate 8-10 hours postop. The statistical difference of failure to urinate between 2-4 hrs and 4-6 hrs was significant in two groups ( $p=0.002$  and  $p=0.036$  respectively).



In group A, 38 patients (95%) passed urine spontaneously compared to group B in which only 32 patients (80%) passed spontaneously (Table 3). This difference was statistically significant ( $p=0.043$ ). The incidence of catheterization in patients included in group A and group B was 2(5%) and 8(20%) respectively. This was statistically significant ( $p=0.043$ ).

**Discussion:**

Urinary retention is a common complication after any surgical procedure. The incidence of POUR varies according to the type of surgery and is commonly seen in perineal, anorectal and inguinal surgeries. Although the incidence of POUR in general surgical population is around 3.8% [3]. The incidence of POUR after anorectal surgery ranges between 1% and 52% with an average of 18% [4][5][6] and the incidence of urinary retention after hernia surgery ranges from 0.2 to 30% [7]. Injury to the pelvic nerves, pain evoked reflex and increase in the tone of the internal sphincter explains the high incidence of POUR in these patients.

Accordingly, in light of previous studies, it was generally assumed that POUR increases with age, the risk increasing by 2.4-2.8 times in patients over 50 years of age [8]. Therefore, efforts should be made to prevent POUR especially

in men at high risk for the condition. The development of POUR is multifactorial. These include the direct effects of anesthetic agents on the bladder, traumatic instrumentation, pelvic dissection, overzealous intravenous hydration resulting in bladder distension, diminished awareness of bladder sensation, increased outlet resistance, immobilization after the procedure, postoperative pain (nociceptive inhibitory reflex), use of narcotics for analgesia, type of anesthesia, type of surgery, patient age and sex<sup>[9]</sup>.

Many different methods have been tried to prevent this complication, including the use of Para sympathomimetic agents, use of alpha-adrenergic blockers, use of anxiolytic agents, restriction of perioperative fluid intake, avoidance of anal packing, sitz baths, use of local anesthesia and use of short-acting anesthesia.

Some precautions such as limitation of fluid intake, early mobilization, warm compresses to the suprapubic area and the use of short-acting local or spinal anesthesia have been reported to prevent this complication<sup>[10][11]</sup>.

We took up this study to assess the preventive role of tamsulosin in POUR in perineal, anorectal and hernia surgeries. In our study, 80 patients were randomly and equally divided into two groups of 40 patients each, after matching inclusion parameters. In one group of patients, tamsulosin was given 8-10 hours preoperatively and 8-10 hours postoperatively, in the other group placebo was given in similar manner.

Mean age in our study was  $42.9 \pm 12.54$  in group A and  $43.2 \pm 12.07$  years in group B with male predominance in both the groups 80% and 75% respectively. All the patients between 18 and 70yrs were included. Majority of the patients were in the range of 30-60 years in both groups. The youngest patient in the study was 19 years old and oldest was 68 years old. The number of males and females in group A were 32 and 8 respectively and in group B were 30 and 10 respectively. Some studies have reported higher incidence of POUR in men compared with women<sup>[12]</sup> but in other studies there isn't significant difference between men and women<sup>[9]</sup>. In our study, in group A two patients were catheterized and in group B eight patients POUR was predominantly found in male patients.

In a randomized prospective study of perioperative fluid restriction in anorectal surgery, Bailey and Ferguson were able to reduce urinary retention from 14.9% to 3.5%. Similarly Salvati, et al.<sup>[13]</sup> studied decrease in the incidence of urinary retention and catheterization on fluid restriction.

In our study, intravenous fluids were restricted to 1.5ml/kg/hr administered in the operating room before anesthesia. All the patients were operated under spinal anesthesia.

These multifactorial precautions helped to decrease the incidence of POUR. The palpable suprapubic mass was present in 10 patients and 19 patients in group A and group B respectively which was statistically significant. In group A, 28 patients failed to pass urine between 0-2 hours postoperatively, 16 patients failed to urinate between 2-4 hours, 10 patients failed to urinate between 4-6 hours and 2 patients failed to urinate between 6-8 hours postoperatively. In group B, 36 patients failed to pass urine between 0-2 hours postoperatively, 30 patients failed to urinate between 2-4 hours postoperatively, 19 patients between 4-6 hours postoperatively, 8 patients failed to urinate between 6-8 hours and 3 patients failed to urinate between 8-10 hours postoperatively. The statistical difference was significant 2-4 hours and 4-6 hour ( $p=0.002$  and  $p=0.036$  respectively). In group A, 38 patients passed urine spontaneously as compared to group B in which only 32 patients passed urine spontaneously, which was in accordance with studies conducted by M M Fallah, et al.<sup>[2]</sup> and AH Madani, et al.<sup>[14]</sup>.



The pain in the perineal area can stimulate the alpha-receptors in the bladder neck and proximal urethra, thereby increasing urethral resistance and bladder outlet tone. The end result is that attempts to void encounter increased output resistance<sup>[15]</sup>. In our study, the suprapubic discomfort was observed in 15 patients in group A and 21 patients in group B. Pain control during intraoperative and postoperative periods was achieved by injectable tramadol and diclofenac.

Jensen, et al<sup>[16]</sup> studied the incidences of POUR following inguinal herniorrhaphies performed under local anesthesia, regional anesthesia and general anesthesia were 0.37%, 2.4% and 3.0% respectively. The investigators concluded that the type of anesthesia significantly influenced the risk of POUR. In our study, all the patients were operated under spinal anesthesia which reduced the incidence of POUR significantly.

Goldman G, et al.<sup>[7]</sup> performed a randomized, placebo-controlled trial on 102 men older than 60 years undergoing hernioplasty who were randomly assigned to receive phenoxybenzamine or a control. POUR developed in 26% of men in the control group and none in men who received phenoxybenzamine.

Gonullu NN, et al.<sup>[1]</sup> demonstrated that the incidence of urinary retention after herniorrhaphy was 25% in the placebo group, of whom 13.8% required catheterization. By contrast, 10.8% in the prazosin group developed urinary retention, of whom 3.5% required catheterization.

Tamsulosin is a superselective adrenoceptor antagonist (alpha-1a). Its preventive effect has been studied in few studies with very less literature. Patel R, et al.<sup>[17]</sup> investigated the potential efficacy of alpha-blockers for facilitating early removal of the urinary catheter following radical prostatectomy. A consecutive group of 250 men undergoing radical prostatectomy received tamsulosin, 0.4 mg, 3 days before a cystography planned for postoperative day 8. Tamsulosin was administered for an additional 4 days following the catheter removal. The incidence of POUR in the men who received tamsulosin was only 2.6% compared with 10% in the control group.

Mohammad reza M Fallah, et al.<sup>[2]</sup> conducted a study on a total number of 80 males who underwent elective inguinal herniorrhaphy and were randomly distributed into two groups: placebo group and tamsulosin group which were given 6 hours preoperatively and 6-12 hours postoperatively to the patients. In placebo group, 6 patients were catheterized and in tamsulosin group only one patient was catheterized. Thus, showing the effects of tamsulosin in reducing the incidence of POUR from 15% to 2.5%. Similarly, MM Ahmed, et al.<sup>[18]</sup> studied effects of tamsulosin on postoperative urinary retention in 626 patients undergoing anorectal surgeries and found a decrease in the incidence of POUR from 18% to 2.5%.

In our study, 2 out of 40 patients (5%) in the group A developed urinary retention. In the group B, 8 out of 40 patients (20%) had urinary retention and required catheterization. The incidence of suprapubic palpable mass was significantly (p-value= 0.036) more in group B than group A (group A: 25% and group B: 47.5%). The difference was statistically significant. The range of hospital stay in group A and group B was 2-3 days. The mean of hospital stay in group A and group B was 2.31 days and 2.50 days respectively.

In our study, the incidence of acute urinary retention was significantly high in placebo group as compared to tamsulosin group. Tamsulosin helped in decreasing the incidence of POUR from 20% to 5% (p value=0.43). It is therefore, concluded that the usage of Tab. Tamsulosin 0.4mg in patients undergoing anorectal, perineal and inguinal hernia surgeries prevents POUR which thus improves quality of life postoperatively.

**Conclusion:**

The preoperative role of tamsulosin 0.4mg in patients undergoing perineal, anorectal and inguinal hernia surgeries under spinal anesthesia significantly reduces the incidence of post-operative urinary retention. It was hence seen to improve the quality of life in early stages of post-operative rehabilitation and also decreases the duration of hospital stay.

Therefore, it is recommended to use tamsulosin preoperatively in patients undergoing perineal, anorectal and inguinal hernial surgeries to reduce the incidence of post-operative urinary retention and catheterization.

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