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**THE ROLE OF PERIOPERATIVE TAMSULOSIN IN REDUCING THE INCIDENCE OF POST OPERATIVE URINARY RETENTION IN PATIENTS > 50 YEARS UNDERGOING ELECTIVE OPEN INGUINAL HERNIA REPAIR (LICHENSTEIN'S TENSION FREE REPAIR) UNDER SPINAL ANAESTHESIA.****General Surgery****Dr. Khan Mohd. Qasim***Former resident, Dr Babasaheb Ambedkar Central Railway Hospital, Byculla, Mumbai.
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ABSTRACT

Introduction: Post operative period is a critical period which can include numerous complications either due to surgery or anaesthesia. One of the important preventable complications is post operative urinary retention (POUR). With this background, we conducted a study to investigate the prophylactic effect of tamsulosin, a super-selective alpha-1a adrenergic blocking agent, on the development of urinary retention in men undergoing elective inguinal hernia surgery.

Material and methods: A randomised double blind controlled prospective trial was conducted on the patients undergoing hernia surgery in the department of surgery of tertiary care hospital in Mumbai. The study was carried from June 2015 to March 2017 which included the recruitment of the patients, intervention and follow up. Those patients with history of active or past urinary tract infection, history of use of alpha blockers in the past, history of urological surgery, patients with CKD with dialysis and those with indwelling catheter were excluded from the study. Two groups were randomised into study group and control group. The proportion of catheterisation was studied among both the groups.

Results: The two groups were comparable in terms of age, weight, side and type of hernia. About 15.6% required catheterisation among the placebo group and 2.6% required catheterisation among the study group and this difference was statistically significant ($p < 0.05$). There was no significant difference between the post void volume and prostate size among the two groups ($p > 0.05$).

Conclusions: Tamsulosin started in peri operative period in cases of hernia repair surgery, reduces postoperative morbidity of retention of urine, and chances of invasive intervention i.e. catheterization and in turn the financial burden of catheterization and associated morbidity.

KEYWORDS**INTRODUCTION:**

With an increase in outpatient and fast-track surgical procedures, per urethral catheterization is restricted to fewer procedures and for a limited time. Nowadays hernia repair is considered as day care surgery, but post hernioplasty urinary retention is one of the most significant complications, needing catheterization that lead to delayed discharge from hospital and hazards of catheterization—(13). Both the health and financial costs of retention are considerable, because it can cause urinary tract infections and necessitate catheterization, which can in turn result in urethral strictures, prolonged hospital stays, and additional operations(4,5). Post operative period is a critical period which can include numerous complications either due to surgery or anaesthesia. One of the important preventable complications is post operative urinary retention (POUR). This constitutes about 3 to 25 % of the patients and occurs more frequently after lower urinary tract, perineal, gynaecologic, and anorectal surgeries—(58).

In several clinical studies, alpha-adrenergic blocking agents have been shown to have prophylactic and therapeutic potential on Postoperative urinary retention—(912). The alpha-1 receptor antagonist acts by reducing tone in the bladder outlet, thereby decreasing outflow resistance and facilitating micturition. The aim of this randomized, prospective study is to investigate the prophylactic effect of tamsulosin, a super-selective alpha-1a adrenergic blocking agent, on the development of urinary retention in men undergoing elective inguinal hernia surgery.

MATERIAL AND METHODS:

A randomised double blind controlled prospective trial was conducted in the department of surgery of tertiary care hospital in Mumbai. Male patients who underwent hernia repair surgery were included in the study. The study was carried from June 2015 to March 2017 which included the recruitment of the patients, intervention and follow up. Male patients with age more than 50 years willing to give consent and undergoing lichtenstein tension repair surgery under spinal anaesthesia were included in the study. Those patients with history of active or past urinary tract infection, history of use of alpha blockers in the past, history of urological surgery, patients with CKD with dialysis and those with indwelling catheter were excluded from the study.

Mohammadi Fallah et al(13) conducted a similar study and found that 15% of placebo group required catheterisation and 2.5% of patients with tamsulosin required catheterisation. Using this data, with 5% absolute error and 80% power we calculated the minimum sample size to be 72 in each group. Considering the availability of the cases we actually included 77 study subjects in both the groups. As per US FDA ICH E9 guidelines, double blind procedure was followed here. Doctor and patient were unknown about the treatment. Allocations of patients to two groups were carried out with the help of randomization chart prepared using SAS 9.2 software package. The group to which patient was allotted was concealed in sealed envelopes. After the patient came, the envelope was opened and the patient was allotted to that group (either control or tamsulosin).

All patients had a complete physical examination preoperatively, electrocardiogram, chest X-ray, and baseline blood analysis. In addition, preoperative ultrasonographic investigation for measurement of prostatic volume and post void residual urine volume and to rule out back pressure changes and any bladder outlet obstruction was done. After informed consent, 154 male patients of age >50yrs were divided into two groups randomly by selection of an envelope in the preoperative holding area. In group one (control), the patients were given two doses of placebo orally, 6hrs before surgery and 6 to 12 hrs after surgery. Patients in group two were given 0.4mg of tamsulosin orally in the same manner as the placebo. In all cases, administration of lactated Ringer's solution (1.5 ml/kg/h), started in operating room, continued till postoperative period (np0 i.e. 4-6 hrs). Surgery was performed after the administration of spinal anaesthetic i.e. injection bupivacaine 0.5% heavy 2-3ml. The attending anaesthesiologist choose the same type of anaesthetic agent in same dose to all patient undergoing infra umbilical surgery hernia repair done by Lichtenstein tension free procedure post operatively for pain, injection diclofenac 3cc intramuscular, dosage of analgesia administered was adjusted until patient reported zero to mild pain score on visual analogue scale. Opioids analgesic was not applied to any patient in postoperative period. All patients will closely follow for 24 hours postoperatively, and any voiding difficulties or urinary retention will be recorded. If patient has a palpable bladder, felt discomfort, and fail to pass urine within 24 hours after the operation

despite a sufficient fluid intake and when conservative efforts such as warming the supra pubic region and encouraging the patient to stand up and walk, will be unsuccessful then bladder catheterization done comparing the incidence of postoperative urinary retention in both group.

STATISTICAL ANALYSIS

The data was collected, entered and compiled using Microsoft Excel. The data was analysed using Epi info version 7.2. The qualitative variables were expressed in terms of percentages and the difference between two proportions was tested by fisher's exact or chi square test. The quantitative variables were expressed either in terms of mean and standard deviation or categorised and expressed in terms of percentages. The difference between the two means was tested using student t test. All the analysis was 2 tailed and significance level was set at 0.05.

RESULTS:

We included 77 subjects each in placebo and study group in the present study.

Table 1: Baseline characteristics

Characteristics	Placebo			Study			P value
	Nor/	Mean	%/SD	Nor/	Mean	%/SD	
Age group (in years)							
≤60	27		35.1	26		33.8	0.46
61 to 70	31		40.3	33		42.9	
>70	19		24.7	18		23.4	
Weight	70.03		12.73	72.08		11.87	0.30
Diabetes mellitus							
Present	12		15.6	8		10.4	0.47
Absent	65		84.4	69		89.6	

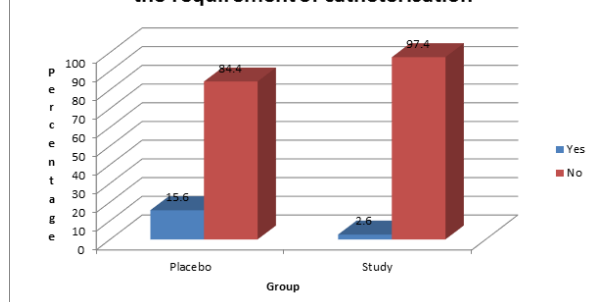
The mean age of the study subjects was 65.16 years and 65.07 years in placebo and study group respectively and this difference was not significant. The mean weight of the study subjects was 70.03 kgs and 72.08 kgs among placebo and study group respectively. About 15.6% of patients in placebo group and 10.4% of the study group had history of diabetes.

Table 2: Hernia characteristics

Characteristics	Placebo			Study			P value
	Nor/	Mean	%/SD	Nor/	Mean	%/SD	
Side of hernia operated							
Left	29		37.7	20		26.0	0.70
Right	48		62.3	57		74.0	
Type of hernia							
Direct	73		94.8	77		100	0.12
Indirect	4		5.2	0		0	

The side of hernia operation was comparable among both the groups. Among the placebo group about 5.2% had indirect hernia and 94.8% had direct hernia. But, among the study group all the hernias were direct hernias.

Chart 3: Distribution of the subjects based on the requirement of catheterisation



About 15.6% required catheterisation among the placebo group and 2.6% required catheterisation among the study group and this difference was statistically significant ($p < 0.05$).

Table 4: Comparison of post void volume and prostate size among the groups

Characteristics	Placebo		Study		P value
	Mean	SD	Mean	SD	
Post void volume	24.48	15.06	24.68	13.81	0.9
Prostate size	34.87	7.86	33.99	7.56	0.5

There was no significant difference between the post void volume and prostate size among the two groups ($p > 0.05$).

DISCUSSION:

Post operative urinary retention is one of the most common complications noticed in the patients undergoing hernia repair surgeries. Bladder catheterisation post operatively will increase the morbidities and the duration of hospital stay of the patient. To prevent this various pharmacological agents have been tried. With this background, we studied the efficacy of tamsulosin among the patients undergoing lichenstein tension hernia repair. The patients were randomised in two groups of which one received the placebo and other received tamsulosin. Both the groups were comparable in terms of age, weight and status of diabetes in the past.

Various pharmacological methods have also been attempted for prevention of POUR. Several authors used phenoxybenzamine, an alpha adrenergic blocker, and found favourable results. Alpha-adrenergic antagonists aid micturition by increasing intravesical pressure and decreasing outflow resistance—(1416). However, phenoxybenzamine is no longer used due to its carcinogenic potential. Tamsulosin, a newer alpha-adrenergic antagonist, has also been found to be effective in reducing the incidence of POUR(11,13).

The study group had lesser proportion of catheterisation when compared to placebo group without affecting the post void volume and prostate size. Similar inferences were inferred by Mohammadi Fallah M et al(13) (15.6% in placebo Vs. 2.6% in tamsulosin group). Madani AH et al(11) conducted a randomised controlled trial on 118 patients receiving tamsulosin and 114 patients were in control or placebo arm. The rates of catheterisation in their study were 5.9% and 21.1% respectively among tamsulosin group and placebo group. Further, they did not notice any serious side effects in the both the groups. Akkoc A and colleagues(10) studied the prophylactic effects of alpha blockers, tamsulosin and alfuzosin on the patients undergoing urologic surgery. The proportion of patients requiring catheterisation was 5% among tamsulosin group, 6.7% in alfuzosin group and 25% in placebo group. Incidence of postoperative retention of urine among 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 as reported by Shaw MK et al(17).

A recent randomised double blind controlled study by Shokrpour M et al(18) inferred that there was a significantly lower incidence of the post operative urinary retention among patients who received tamsulosin. Further, the decrease in urinary flow diameter, mean residual volume and post void volume significantly decreased in tamsulosin group. This was contradictory to our study. Povlin V et al(19) inferred that peri operative use of tamsulosin reduced the chances of retention post operatively among the patients undergoing pelvic surgery. A Cochrane Review by Zeif HJ et al infers that alpha blockers given prior to removal of catheter for acute retention will assist early resumption of micturition of the patients. The study had many aspects which favoured the generalizability of the present research. One of them is the randomisation process, collection of sample and double blinding used in the present study. Only factor interfere with this is that it is a single centre study.

CONCLUSIONS:

The proportions of subjects undergoing catheterisation with tamsulosin group was significantly lower when compared to placebo group. There was no significant difference between the post void volume and prostate size among the two groups. Tamsulosin started in peri operative period in cases of hernia repair surgery, reduces postoperative morbidity of retention of urine, and chances of invasive intervention i.e. catheterization and in turn the financial burden of catheterization and associated morbidity. It can also result in urethral stricture, prolongs or complicates the postoperative recovery phase and hospital stay. Hence, it is recommended the use of tamsulosin drug therapy in peri operative protocol of hernia repair surgery.

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