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Original Research Article

Comparison of tamsulosin hydrochloride versus tamsulosin hydrochloride and deflazacort in relieving postoperative urinary retention in patients undergoing transurethral resection of prostate: a prospective randomized controlled trial in a tertiary care centre

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ABSTRACT

Background: Benign prostatic hyperplasia (BPH) is common amongst the elderly. Even after transurethral resection of prostate (TURP), retention of urine may persist in some leading to significant morbidity adversely affecting the quality of life. The role of alpha blockers in this situation as a combination is unclear. The present study was conducted to evaluate and compare the efficacy of tamsulosin versus tamsulosin and deflazacort in relieving the postoperative retention of urine following TURP.
Methods: After obtaining ethics approval and written informed consent, 72 patients satisfying the eligibility criteria were included. After TURP, patients with urinary retention following catheter removal were randomized into group A (tamsulosin hydrochloride) and group B (tamsulosin hydrochloride and deflazocort). baseline international prostate symptom score (IPSS) score was done to assess quality of life and findings of radiological investigations were noted. Thereafter, medical therapy was done as per assigned group and postoperative findings were documented and analyzed.
Results: Both the groups were similar in terms of demographic characteristics and baseline characteristics. The relief of symptoms was significantly more in group B along with lower IPSS score and residual volume.
Conclusions: We recommend addition of deflazacort to tamsulosin hydrochloride as medical therapy for the management of postoperative retention of urine (POUR), especially following TURP.

Keywords: Benign prostatic hyperplasia, Deflazacort, Postoperative urinary retention, Transurethral resection of prostate, Tamsulosin hydrochloride

INTRODUCTION

Benign prostatic hyperplasia (BPH) is commonly observed in the elderly population above 50 years of age with an increasing prevalence with age; about 20% to 62% in men beyond 50 years of age.[1] BPH leads to the lower urinary tract symptoms (LUTS), especially in association with bladder outlet obstruction, leading to urinary retention.[2] The persistence of LUTS also seriously compromises the quality of life of the patient.[3,4]

Transurethral resection of prostate (TURP) remains the gold standard for the treatment of BPH.[5-7] It is the most effective surgical procedure for removal of the prostatic

tissue causing obstructive symptoms. However, even after resection of all prostatic tissue, successful resolution of symptoms is not seen in all patients with the persistence of symptoms such as painful micturition, incontinence, and hematuria, which may further aggravate retention of urine. The postoperative retention of urine (POUR) has been attributed to several causes like anesthesia, medications, pain, altering of the normal nervous signalling pathways involved in urination.[8-11] It is of recent view that such patients may benefit from medical therapy, especially with alpha-blocker. However, there are no specified guidelines regarding the dose and duration of usage of medical therapy before the trial without catheter (TWOC).

Therefore, the present pilot study was conducted to compare the effectiveness of medical therapy with alpha-blocker (tamsulosin) alone and in combination with a steroid (tamsulosin with deflazacort) in relieving the retention of urine in patients undergoing TURP.

METHODS

This prospective randomized controlled trial was conducted at department of urology, M.S. Ramaiah Medical College, Bengaluru from January 2018 to January 2023. Patients consenting to participate in the study and who met the inclusion and exclusion criteria as below, were included in the study.

Inclusion criteria

Male patients aged >55 years, with prostate volume 40-60 cc and all patients undergoing bipolar TURP were included.

Exclusion criteria

Patients aged <55 years with residual prostate as confirmed by transrectal ultrasound, patients allergic to any of the study drugs, and patient having active UTI/clot retention of urine were excluded.

All the patients attending outpatient department (OPD) during the study period and diagnosed with BPH and underwent TURP followed by POUR were included in the study after obtaining approval of the institutional ethics committee and voluntary written/informed consent.

Baseline demographic characteristics were noted for all patients. Detailed past and personal histories were recorded. After taking fitness for anaesthesia, patients underwent TURP as per the standard guidelines. Bipolar resectoscope with standard bipolar wire loop was used. Once the resection was completed and haemostasis achieved a 20 Fr Foley's catheter was inserted and irrigation initiated. It was removed after 2 days if the urine was clear. If the patient voided, they were excluded. If the patient did not void, they were re-catheterized and included in the study.

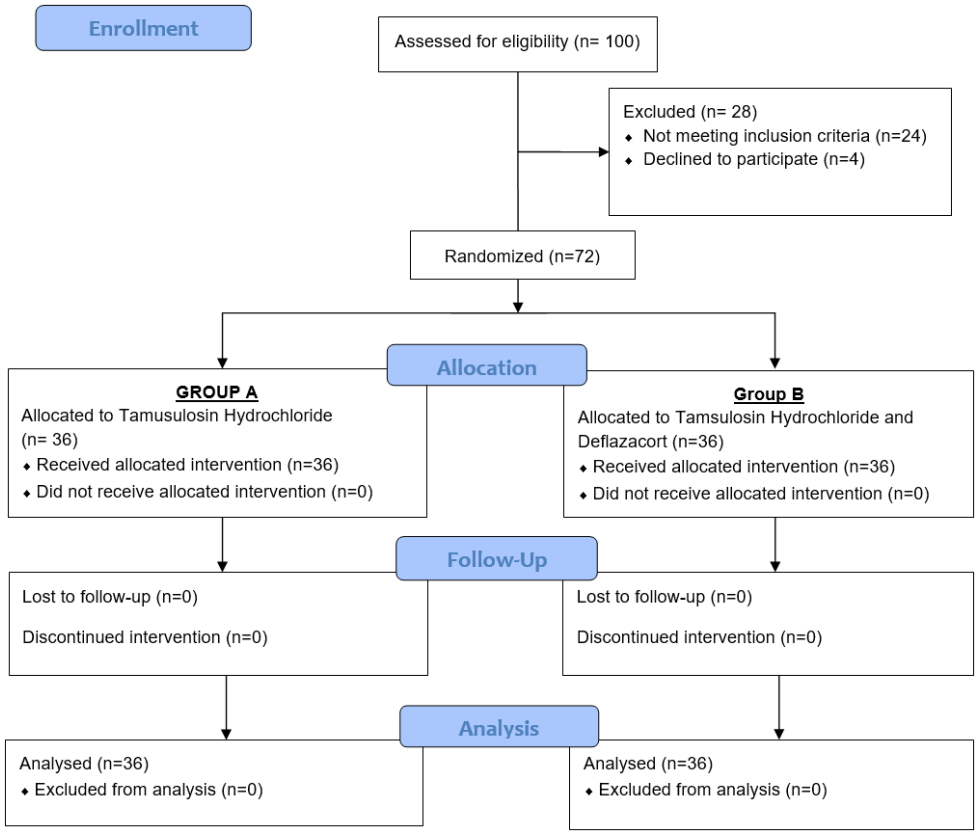

Figure 1: Consolidated standards of reporting trials (CONSORT) 2010 flow diagram.

Preoperatively, international prostate symptom score (IPSS) was used to assess the quality of life in patients of BPH.[12] Abdominal ultrasonography and uroflowmetry were performed. Patients were randomly divided into two groups: group A (tamsulosin hydrochloride 0.4 mg for 5 days) and group B (tamsulosin hydrochloride 0.4 mg + deflazacort 30 mg for 5 days). The consolidated standards of reporting trials (CONSORT) 2010 flow diagram are mentioned in Figure 1.

After 5 days of treatment with either tamsulosin/ tamsulosin and deflazacort, catheter free trial was given and the findings recorded. Radiological and hematological investigations were done and the values were recorded. IPSS was used to assess the symptoms and quality of life. In cases where the patients did not void after the catheter free trial, they were re-catheterized and treated appropriatelyThe data was analyzed using the statistical package for the social sciences (SPSS) software version 22.0. All the qualitative data was expressed as percentages. The p values were assessed by Chi square test (Fischer's exact test was used when more than 20% of the cells had value less than 5). All the quantitative data was expressed as mean±standard deviation. P values were assessed by the student t test. P value of less than 0.05 was considered as "statistically significant" and indicated by "*" in the tables.

RESULTS

A total of 72 patients were included in the study. In the present study, both the groups were similar in terms of demographics and baseline characteristics; p value: more than 0.05 (Table 1).

Table 1: Distribution of baseline characteristics in the study population (n=72).

Parameters	Group A	Group B	P value
Age (years)	67.89±4.51	69.23±5.42	0.324
IPSS score	17.33±2.34	16.78±2.92	0.219
Prostate volume (ml)	52.42±2.12	55.23±2.33	0.313
Residual urine (ml)	235±10.41	245±9.72	0.510
Serum creatinine (µmol/l)	93.92±16.12	90.92±15.54	0.641

All p values are statistically insignificant

Table 2: Distribution of symptoms after medical therapy in the study population (n=72).

Parameters	Group A (%)	Group B (%)	P value
Dysuria	11.11	2.78	0.001*
Increased frequency	11.11	2.78	0.001*
Did not void urine	8.33	0	0.001*

*Indicates statistically significant p value

In the post -treatment period, the persistence of symptoms was significantly less in group B as compared to group A (Table 2). The IPSS score and the residual volume of urine was also significantly less in group B than in group A (Table 3).

Table 3: Distribution of post-treatment findings in the study population (n=72).

Parameters	Group A	Group B	P value
IPSS score	11.99±2.14	8.92±2.46	0.001*
Residual urine (ml)	100.9±13.5	67.33±9.8	0.001*

*Indicates statistically significant p value

DISCUSSION

In the present study, we observed that the two groups were similar in terms of baseline characteristics. After the medical therapy, we observed significant relief of patient's symptoms in the patients of group B (treated with tamsulosin hydrochloride and deflazacort) as compared to group A (tamsulosin hydrochloride). We also observed that there was an improvement in the IPSS in both the groups. The IPSS scores were less after medical therapy in both the groups as compared to the baseline scores. However, on comparison between the groups, we observed that the IPSS scores were significantly less in the patients in group B as compared to group A, indicating significant improvement in the quality of life with tamsulosin and deflazacort as compared to treatment with tamsulosin alone. Similarly, the volume of residual urine was also significantly less in group B as compared to group A.

There is no current consensus regarding the treatment protocol for BPH. Several large multicentric studies have divided views on the surgical and medical management.[13-15] However, TURP is considered the gold standard for surgical management of BPH.[5-7] It has been observed that even after successful resection of the obstructive prostatic segments, POUR due to functional causes is bothersome. Urinary retention is a well-known complication of any urosurgical procedure. It is an emergency condition requiring urgent catheterization. Catheterization may further lead to increased incidence of ascending infection.[16] All these factors ultimately lead to increased morbidity and delay the discharge of the patient.

One of the main causes of this is hypothesized to be the sympathetic overactivity of the autonomic nervous system following surgical procedures. Therefore, alpha-blockers are of value in relieving such retention of urine following urosurgical procedures as they block the receptor activity and relieve the sympathetic overdrive, thereby relaxing the prostatic capsule and smooth muscle of the neck of the urinary bladder and facilitate the voiding of urine.[17,18] There have been studies assessing the efficacy of alpha blockers, especially tamsulosin as it is a selective alpha-adrenergic antagonist. Some studies have found

tamsulosin to be effective in reducing the incidence of POUR while others have uncertain results.[19-22]

Clearly, this indicates that the use of a single drug acting on a particular mechanism or pathway for relieving POUR may not translate into appreciable results in the reduction of POUR. Therefore, there is a room for addition of drugs with a different mechanism of action leading to synergistic effects translating into a clinically significant reduction in the incidence of POUR.

Deflazacort is a synthetic heterocyclic corticosteroid, oxazoline derivative of prednisolone with high efficacy, strong anti-inflammatory activity and good tolerability, repair, muscle proteolysis and immunosuppression.[23] Deflazacort in combination with tamsulosin is used at a much lower dose of 30 mg/day to reduce inflammation and edema particularly in stone disease.[23,24] Same principles is applied with the intention to reduce postoperative edema in patients post TURP.

Limitations

This is a pilot study requiring larger cohorts for further validation of treatment.

CONCLUSION

POUR is a bothersome problem following urological surgeries, particularly TURP, which adversely affects the quality of life of patient. Based on the results of the present pilot study, we recommend addition of deflazacort to tamsulosin hydrochloride as they may have synergistic effect in relieving POUR by acting along different pathways. However, multicentric trials may be needed to establish its efficacy.

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Ethical approval: The study was approved by the Institutional Ethics Committee

REFERENCES

1. Bhat SA, Rather SA, Islam N. An overview of benign prostatic hyperplasia and its appreciation in Greco-Arab (Unani) system of medicine. Asian J Urol. 2022;9(2):109-18.
2. Athanasopoulos A, Chapple C, Fowler C, Gratzke C, Kaplan S, Stief C, et al. The role of antimuscarinics in the management of men with symptoms of overactive bladder associated with concomitant bladder outlet obstruction: an update. Eur Urol. 2011;60(1):94-105.
3. Roehrborn CG. Benign prostatic hyperplasia: an overview. Rev Urol. 2005;7(9):S3-14.
4. Irwin DE, Kopp ZS, Agatep B, Milsom I, Abrams P. Worldwide prevalence estimates of lower urinary tract symptoms, overactive bladder, urinary incontinence and bladder outlet obstruction. BJU Int. 2011;108:1132-8.
5. Ho HS, Yip SK, Lim KB, Fook S, Foo KT, Cheng CW. A prospective randomized study comparing monopolar and bipolar transurethral resection of prostate using transurethral resection in saline (TURIS) system. Eur Urol. 2007;52(2):517-22.
6. Marszalek M, Ponholzer A, Pusman M, Berger I, Madersbacher S. Transurethral resection of the prostate. Eur Urol. 2009;(8):504-12.
7. Marszalek M, Ponholzer A, Pusman M. Transurethral resection of the prostate. Eur Urol. 2009;(l 8):504-12.
8. Darrah DM, Griebling TL, Silverstein JH. Postoperative urinary retention. Anesthesiol Clin. 2009;27(3):465-84.
9. Baldini G, Bagry H, Aprikian A, Carli F. Postoperative urinary retention: anesthetic and perioperative considerations. Anesthesiology. 2009;110(5):1139-57.
10. Elsamra SE, Ellsworth P. Effects of analgesic and anesthetic medications on lower urinary tract function. Urol Nurs 2012;32(2):60-7.
11. Baldini G, Bagry H, Aprikian A, Carli F. Postoperative urinary retention: anesthetic and perioperative considerations. Anesthesiology. 2009;110:1139-57.
12. Johnson TV, Abbasi A, Ehrlich SS, Kleris RS, Owen-Smith A, Raison CL, et al. IPSS quality of life question: a possible indicator of depression among patients with lower urinary tract symptoms. Can J Urol. 2012;19(1):6100-4.
13. Fitzpatrick JM, Desgrandchamps F, Adjali K, Gomez Guerra L, Hong SJ, Reten-World Study Group, et al. Management of acute urinary retention: a worldwide survey of 6074 men with benign prostatic hyperplasia. BJU Int. 2012;109(1):88-95.
14. Teoh JY, Kan CF, Tsui B, Chiu PK, Man CY, Hou SS, et al. Ambulatory care program for patients presenting with acute urinary retention secondary to benign prostatic hyperplasia. Int Urol Nephrol. 2012;44(6):1593-9.
15. Manikandan R, Srirangam SJ, O'Reilly PH, Collins GN. Management of acute urinary retention secondary to benign prostatic hyperplasia in the UK: a national survey. BJU Int. 2004;93(1):84-8.
16. Niël-Weise BS, van den Broek PJ. Urinary catheter policies for short-term bladder drainage in adults. Cochrane Database Syst Rev. 2005;3:CD004203.
17. Schwinn DA, Roehrborn CG. α1-Adrenoceptor subtypes and lower urinary tract symptoms. Int J Urol. 2008;15(3):193-9.
18. Elbadawi A, Hailemariam S, Yalla SV, Resnick NM. Structural basis of geriatric voiding dysfunction. VI. Validation and update of diagnostic criteria in 71 detrusor biopsies. J Urol. 1997;157(5):1802-13.
19. Ghuman A, Dawidek MT, Athwal MS, Kasteel N, Brown CJ, Karimuddin AA, et al. Prophylactic tamsulosin and urinary retention rates following

elective colorectal surgery: a retrospective cohort study. Int J Colorectal Dis. 2022;37:209-14.
20. Li H, Zhang W, Xu G, Wang D, Xu C, Zhang H, et al. Prophylactic tamsulosin can reduce the risk of urinary retention after surgery in male patients: A systematic review and meta-analysis. Front Surg. 2022;9:930707.
21. Rughani A, Cushing D, Lary CW, Cox S, Jumper B, Johnson N, et al. Does tamsulosin decrease postoperative urinary retention in spine surgery? A double-blind, randomized controlled trial. J Neurosurg. 2022;11:1-8.
22. Basheer A, Alsaidi M, Schultz L, Chedid M, Abdulhak M, Seyfried D. Preventive effect of tamsulosin on postoperative urinary retention in neurosurgical patients. Surg Neurol Int. 2017;8:75.
23. Nayak S, Acharjya B. Deflazacort versus other glucocorticoids: a comparison. Indian J Dermatol. 2008;53(4):167-70.
24. Kupeli B, Irkilata L, Gurocak S, Tunc L, Kirac M, Karaoglan U, et al. Does Tamsulosin enhance lower ureteral stone clearance with or without shock wave lithotripsy? Urology. 2004;64(6):1111-5.

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