Advances in Benign Prostatic Hyperplasia Research



Does dutasteride reduce the bleeding in transurethral resection of the prostate in patients on antiplatelet drugs?

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Abstract

Background: The aim of this study was to assess the effect of a 4-week dutasteride treatment on reducing the intraoperative and postoperative bleeding, as well as the amount and duration of irrigation required to clear the urine after transurethral resection of the prostate (TURP) \geq 50 g in men receiving the antiplatelet drug (APD).

Materials and methods: This double-blind randomized clinical trial included patients with a prostate size ≥50 g who were indicated for TURP and were already receiving APD. The study was conducted in the Urology Department of Cairo University over a 12-month period. Routine preoperative laboratory investigations were performed in all patients. Moreover, baseline prostate size, serum prostate-specific antigen level, and International Prostate Symptom Score were estimated. The patients were randomly divided into 2 equal groups (groups A and B). Group A, the dutasteride group, received dutasteride (0.5 mg) once daily for 4 weeks. Group B, the placebo group, received a placebo capsule once daily for 4 weeks. Both groups underwent bipolar TURP. Fifteen patients were excluded from the study; 9 patients from group A and 6 patients from group B, either due to drug intolerability or loss follow-up.

Results: The mean blood loss was insignificant between the 2 groups immediately after and 24 hours after surgery (Δ hemoglobin: 1.41 ± 0.63 g/dL vs. 1.48 ± 0.54 g/dL, 2.12 ± 0.70 g/dL vs. 2.31 ± 0.78 g/dL, respectively, p = 0.631, p = 0.333; Δ hematocrit: 2.97% ± 1.51% vs. 3.16% ± 1.36%, 4.96% ± 1.87% vs. 5.73% ± 4.39%, respectively, p = 0.610, p = 0.380). However, there were significant differences in duration of indwelling urethral catheter (5.10 ± 0.55 days vs. 5.80 ± 1.79 days, p = 0.048), duration of bladder irrigation (13.60 ± 2.85 hours vs. 16.33 ± 6.62 hours, p = 0.044), and the amount of saline used for bladder irrigation (11.03 ± 2.30 L vs. 13.87 ± 6.13 L, p = 0.046) between group A and group B. respectively.

Conclusions: Treatment with dutasteride for 4 weeks before TURP in men receiving APD did not significantly reduce intraoperative or postoperative bleeding after TURP but could significantly reduce the duration of indwelling catheter placement, as well as the duration and amount of saline irrigation.

Keywords: Dutasteride; Transurethral resection of the prostate; Postprostatectomy bleeding; Antiplatelet drugs

1. Introduction

Benign prostatic hyperplasia (BPH) is the most common cause of lower urinary tract symptoms (LUTSs) in older men including symptoms related to storage, voiding, or postmicturition such as frequency, urgency, and nocturia.^[1]

Medications are the first therapeutic line for BPH, but their lack of efficacy together with their side effects lead to an adherence rate below 100% with high rates of patient noncompliance.^[2] Transurethral resection of the prostate (TURP), the gold standard surgical treatment, is often performed in patients with BPH who do not respond to medical treatment. The safety and efficacy of TURP

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have been demonstrated and validated. However, TURP can result in intraoperative and postoperative bleeding, especially in patients receiving antiplatelet or anticoagulation therapy for different indications, which undoubtedly increases the suffering of patients.^[2]

Histological diagnosis of BPH is based on the observation of smooth muscle and epithelial cell proliferation in the transition zone. Dihydrotestosterone is the primary androgen responsible for proliferation in elderly men. It is synthesized from testosterone by type 1 and type 2 5- α -reductases, which are active isoenzymes in the prostate. Dual 5- α -reductase inhibitors (5-ARIs) and α -adrenergic blocking agents (alpha-blockers) have been approved for the treatment of BPH. Five-ARIs inhibit 5-AR and reduce the volume of the prostate over a period of 6 months, and thus can prevent complications of BPH such as acute urinary retention and the need for surgical treatment, and improve patient quality of life by preventing voiding difficulties.

Moreover, 5-ARI treatment decreases the expression of vascular endothelial growth factor and reduced microvessel density in prostatic suburethral tissue, thereby inhibiting angiogenesis. Several studies have examined the effect of 5-ARI on the prostate vascularity. Zaitsu et al.^[3] showed that the artery/arteriole and vein/ venule densities, as well as the area inside the prostate tissue, were reduced upon treatment. In addition, many authors have reported that 5-ARI treatment for 4 weeks before TURP can reduce the

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procedure associated blood loss.^[3] A change in prostatic vascularity, upon treatment, was also observed on Doppler sonography, even for shorter durations (<4 weeks).^[4]

Many patients, indicated for TURP, may receive antiplatelet or anticoagulants therapy for different conditions, such as ischemic heart disease or cerebrovascular disease. These patients could undergo TURP but have an increased risk of bleeding, blood transfusions, and longer hospitalization.^[5] This study was designed to investigate the role of 4 weeks treatment with dutasteride before TURP for men with prostate size \geq 50 g who were receiving antiplatelet drugs (APDs) in reduction of TURP associated bleeding as a primary endpoint. The secondary endpoint was the safety and feasibility of bipolar TURP in patients on APD without discontinuation before or after surgery.

2. Materials and methods

This prospective double-blind randomized study was conducted at the Cairo University Hospital, Cairo, Egypt between August 2021 and August 2022. Based on Martov and Ergakov, power and sample size calculation Software (Version 3.1.2; Vanderbilt University, Nashville, TN, USA) was used to calculate the sample size. Assuming 80% power and a level of significance of 0.05, the minimum sample size was calculated 30 patients in each arm. Written informed consent was obtained from all participants after clear and precise explanation of the indications, possible risks, complications related to the procedure, and the potential benefits of the study.

The participants were randomized, through online blocked randomization, into 2 groups: group A was given dutasteride 0.5 mg capsule once daily, and group B was administrated a placebo once daily; both were administrated for 4 weeks before surgery. A list of 80 patients with their names and numbers were randomly divided into 10 blocks using an online tool. Each block contained 8 patients who received either dutasteride or placebo according to randomization. After finishing the first block list, another randomized block list was created, and this process was repeated until the required sample was recruited.

All patients aged older than 50 years, with prostate size ≥50 g and on APDs, who were indicated for TURP were included in the study. The surgical indications for TURP were BPH complicated by refractory urine retention, recurrent urinary tract infections, refractory gross hematuria, recurrent or large bladder stone, and hydronephrosis due to chronic urine retention or moderate to severe LUTSs (International Prostate Symptom Score [IPSS] ≥8) not responding to medical treatment.

Patients with a prostate size less than 50 g, concomitant urethral stricture, history of a prostate procedure, or prostate cancer before the procedure were excluded from the study. Patients who were already on 5-ARIs before the study were also excluded.

Preoperatively, all patients were assessed through careful history taking, physical examination, and preoperative routine laboratory tests along with serum prostate-specific antigen levels. Urine analysis \pm urine culture was performed for all patients with treatment of active urinary tract infection if present. Prostate size was measured using transrectal ultrasonography, and a transrectal prostate needle biopsy was performed if a prostate cancer was suspected. All participants were referred to a cardiology or neurology specialist before surgery to evaluate their surgical fitness.

Intraoperatively, all patients underwent bipolar TURP in the lithotomy position under regional anesthesia, unless contraindicated, after administration of a prophylactic antibiotic 1 hour before surgery. The mean operative time and volume of the resected prostate (in a graduated beaker) were also measured. All intraoperative complications including volume overload, capsular perforation, bladder injury, and intractable bleeding were monitored and documented. Postoperatively, in addition to the usual follow-up parameters for the immediate postoperative care, hemoglobin (Hb) and hematocrit (HCT) levels were routinely monitored in every patient at 1 hour and 24 hours after surgery. Furthermore, the irrigation fluid time and volume, hospital stay, and indwelling catheter time were measured and documented. All postoperative complications such as clot retention, severe or intractable hematuria, and the need for reoperation along with all postoperative general complications and their way for management have been reported.

All patients were scheduled for follow-up on postoperative day 5–8 and 1 month thereafter. During follow-up, patients underwent urine flowmetry and bladder ultrasonography for postvoid residual urine measurement. Moreover, the IPSS questionnaire was completed by all patients 1 month after the procedure.

The recorded data were analyzed using SPSS Statistics (Version 23.0; IBM Corp, Armonk, NY, USA). Quantitative data were presented as mean \pm standard deviation and ranges. Also, qualitative variables were presented as numbers and percentages. The following tests were performed: an independent samples *t*-test of significance was used when comparing 2 means and Mann-Whitney *U* test for 2-group comparisons of nonparametric data. Qualitative data were compared between groups using the chi-square test and Fisher's exact test instead of the chi-square test only when the expected count in any cell is <5. The confidence interval was set to 95%, and the accepted margin of error was set to 5%. Statistical significance was set at a *p* value <0.05.

3. Results

Two hundred eleven patients were screened, and 80 were eligible for the study and met the prerequisite criteria. During the study, 15 patients were excluded: 9 from group A and the other 6 from group B. Five patients from group A could not tolerate the drug and stopped the treatment in the first week due to different gastrointestinal issues (3 patients with frequent attacks of nausea \pm vomiting, 1 patient with constipation, and 1 with heart burn). An additional 4 patients from group A and 6 patients from group B were also excluded due to missed follow-up. At the end of the study, 65 patients were included, 31 in group A and 34 in group B (Fig. 1).

There was no statistically significant difference between the groups regarding preoperative demographic data in terms of age or preoperative Hb, HCT, international normalized ratio, or prostate-specific antigen values and prostate size (Table 1). The indication for TURP was refractory urine retention in 32 patients (40%), chronic urine retention in 25 patients (31.2%), large or recurrent stone bladder formation in 8 patients (10%), and lower urinary tract symptoms (IPSS ≥8 not respondent to medical treatments) in 15 patients (18.8%). All patients were on acetyl salicylic acid (aspirin 75 mg, 2 tablets once daily), which was not stopped before or after surgery; 23 patients (28.75%) had ischemic heart disease, and 40 patients (50%) had risk factors for thrombosis as obesity with a family history of thrombovascular disease, and the remaining 17 patients (21.25%) had history of previous cerebrovascular events.

Both groups were comparable in terms of mean operative time and average resected prostate volume with no statistically significant differences (Table 2).

There were statistically significant differences in the amount of saline irrigation and the mean time of indwelling catheter insertion, between the groups (Table 2). In contrast, there was no statistically significant difference between the groups regarding the change in postoperative day 0 or day 1 Hb and HCT levels, as well as in



Figure 1. Flowchart demonstrating the consort criteria of our study.

blood transfusion requirements; only 2 patients in group A and 3 patients in group B required blood transfusion (Tables 2, 3).

Unfortunately, 20 patients (9 from group A and 11 from group B) had frequent attacks of fever ($\leq 38.5^{\circ}$ C) with no signs of sepsis, despite considerable perioperative precautions. Most of these patients showed confined small intraprostatic abscesses during prostate resection denoting chronic prostatitis; however, none of these patients required further intervention or intensive care unit admission. In addition, 1 patient in each group had an intraoperative prostatic capsule perforation associated with intractable bleeding for which the procedure was aborted. Both cases were managed conservatively through a 3-way catheter insertion and continuous bladder irrigation for an average of 24 hours.

At follow-up, all patients, who underwent the procedure, could pass urine freely with fair urine flow and insignificant postvoid residual urine in both groups. Regarding the IPSS, there was no substantial difference in the IPSS between the groups in terms of postoperative scores (Table 2).

4. Discussion

Benign prostatic hyperplasia is characterized by an increased proliferation of stromal and acinar cells around the urethra and increased gland angiogenesis. Increased vascularity can result in varying degrees of bleeding during and after TURP. Finasteride is a 5-ARI. It inhibits the conversion of testosterone to dihydrotestosterone and activities of androgen-controlled growth factors, thereby stimulating angiogenesis. Moreover, it lowers the expression of vascular endothelial growth factor, thereby reducing the suburethral microvessel density of the

The preoperative baseline data.							
Preoperative parameters	Total (n = 65)	Group A (n = 31)	Group B (n = 34)	t	р		
Age, yr							
Mean \pm SD	64.70 ± 7.82	64.27 ± 8.04	65.13 ± 7.71	-0.426	0.672		
Range	50-82	50-82	51–78				
Prostate size, g							
Mean \pm SD	81.2 ± 6.04	80.2 ± 7.38	82.2 ± 4.21	1.29	0.202		
Range	55–92	55–92	75–93				
PSA, ng/mL							
Mean ± SD	3.16 ± 1.56	3.34 ± 1.56	2.98 ± 1.56	0.901	0.371		
Range	0.27-6.83	0.61-6.34	0.27-6.83				
INR							
Mean \pm SD	1.08 ± 0.08	1.08 ± 0.08	1.08 ± 0.08	-0.115	0.909		
Range	0.97-1.3	0.98-1.28	0.97-1.3				

INR = international normalized ratio; PSA = prostate-specific antigen.

Table 1

The intraoperative and postoperative parameters.

Interesting and protonousting powerstern	Total (n CE)	Group A (n. 21)	Group D (m. 04)		-
Intraoperative and postoperative parameters	10tal (n = 65)	Group A ($n = 31$)	Group B (n = 34)	ľ	р
Operative time, min					
Mean \pm SD	76.67 ± 10.07	77.00 ± 10.05	76.33 ± 10.25	0.254	0.800
Range	55–95	55-95	60–95		
Resected prostate volume, mL					
Mean \pm SD	81.2 ± 6.04	80.2 ± 7.38	82.2 ± 4.21	-1.29	0.202
Range	48-89	48–89	75–89		
Bladder irrigation after TURP, hr					
Mean \pm SD	14.97 ± 3.33	13.60 ± 2.85	16.33 ± 6.62	-2.08	0.044
Range	9–36	10-21	9–36		
Amount of saline irrigation, L					
Mean \pm SD	12.45 ± 5.44	11.03 ± 2.30	13.87 ± 6.13	-2.07	0.046
Range	6–33	8–17	6–33		
Time of indwelling catheter, d					
Mean \pm SD	5.45 ± 0.54	5.10 ± 0.55	5.80 ± 1.79	-2.05	0.048
Range	5–8	5–8	5–8		
PVR, mL					
Mean \pm SD	11.75 ± 11.18	11.17 ± 10.90	12.33 ± 11.51	-0.055	0.800
Range	0–60	0–40	0–60		
IPSS postoperative 1 month					
Mean \pm SD	5.10 ± 1.61	5.07 ± 1.60	5.13 ± 1.66	-0.159	0.874
Range	2–8	2–8	2–8		
Blood transfusion, n (%)	5 (7.6%)	2 (6.4%)	3 (8.8%)	0.218	0.640

IPSS = International Prostate Symptom Score; PVR = postvoid residual urine; TURP = transurethral resection of the prostate.

prostate.^[6] Therefore, preoperative finasteride treatment may reduce bleeding related to TURP.^[7,8] Dutasteride is believed to achieve results similar to those of finasteride.

The role of 5-ARIs in minimizing TURP-related bleeding has been extensively discussed in the literature and is still a point of debate, as is the course needed to achieve this purpose.^[9] In this study, we assessed the efficacy of a 4-week course for minimizing bleeding. However, intraoperative and postoperative bleeding was not significantly reduced in the treatment group compared with the placebo group; the dutasteride group showed a significant reduction in the time of postoperative bladder irrigation and the duration of indwelling catheterization.

Many authors have concluded that pretreatment with dutasteride could effectively reduce TURP-associated bleeding based on the assessment of prostate vascularity by Doppler ultrasonography before and after treatment or on histopathological examination of the prostate specimens after TURP or in randomized clinical trials. Martov and Ergakov^[10] found a significant reduction in blood loss when dutasteride was administrated >1 month before surgery. Kravchick et al.^[4] found that the vascularity of the prostate, especially in the periurethral area, was reduced after the administrating dutasteride for 6 weeks. Pastore et al.^[11] observed that pretreatment with dutasteride for 6 weeks before TURP reduced surgical bleeding,

Table 3

Hemoglobin and hematocrit changes.

Hb, g/dL	Total (n = 65)	Group A (n = 31)	Group B (n = 34)	t	р	
Preoperative						
Mean ± SD	13.53 ± 1.35	13.51 ± 1.32	13.54 ± 1.41	-0.095	0.925	
Range	10.1–17.1	10.7–15.6	10.1–17.1			
Day 1 postoperative						
Mean ± SD	11.31 ± 1.41	11.39 ± 1.48	11.24 ± 1.35	0.419	0.677	
Range	8.2-13.7	8.2–13.7	8.4–13.7			
Delta change (day 1, pre)						
Mean \pm SD	-2.21 ± 0.74	-2.12 ± 0.70	-2.31 ± 0.78	0.977	0.333	
Range	-3.6 to -0.6	-3.6 to -1.2	-3.4 to-0.6			
HCT, %	Total (n = 65)	Group A (n = 31)	Group B (n = 34)	t	р	
Preoperative						
Mean \pm SD	40.63 ± 3.59	40.62 ± 3.80	40.65 ± 3.44	-0.028	0.977	
Range	32.5-49.1	33.6-47.3	32.5-49.1			
Day 1 postoperative						
Mean \pm SD	35.29 ± 4.04	35.66 ± 3.34	34.91 ± 4.68	0.709	0.481	
Range	26.8-42	28.8-41	26.8-42			
Delta change (day1, pre)						
Mean \pm SD	-5.35 ± 3.37	-4.96 ± 1.87	-5.73 ± 4.39	0.884	0.380	
Range	−15 to −2.3	-12.5 to -2.8	-15 to -2.3			

Hb = hemoglobin; HCT = hematocrit.

prostate volume, and the weight of the resected prostate. Another study found that, after the administration of dutasteride for only 7 days, blood flow to the prostate was reduced as observed by Doppler transrectal prostatic ultrasonography, indicating that vascularity changed during a short treatment time.^[12] Woo et al.^[13] observed that dutasteride treatment for 2 weeks before TURP reduced microvessel density in the suburethral region.

Few recent studies have assessed the safety and feasibility of bipolar TURP in patients undergoing antiplatelet or anticoagulant therapies. Rühle et al.,^[5] studied the outcome of bipolar TURP in patients under ongoing oral anticoagulation (OAC)/APD without stopping or bridging therapy, compared with TURP patients without OAC/APD, and concluded that TURP patients with OAC/APD tended to need slightly longer bladder irrigation (median 24 hours vs. 22 hours, p = 0.06) and longer transurethral catheterization (median 42 hours vs. 24 hours, p = 0.031). In our study, there were various reasons for a longer catheterization time owing to the need for continuous drainage to avoid clot retention in such high-risk patients; some patients had concomitant open cystolithotomy for stone bladder, and 32.2% of our patients were indicated for surgery due to chronic retention for which our local practice was to retain the catheter for longer duration.

In a study conducted by El-Shaer et al.,^[14] bipolar TURP was safe for high-risk patients receiving ongoing OAC/APDs. Although their results match those of our study regarding the feasibility of the procedure, the technique used in their study was bipolar vaporization or enucleation of the prostate rather than bipolar resection, which usually carries a higher risk of bleeding particularly in such patients.

Limitations

Despite the randomized nature of this study, it has several limitations. Prostate vascularity should be assessed pathologically and radiologically to identify the effects of dutasteride on histopathological and radiological findings. Furthermore, more prospective studies should be conducted with a larger number of enrolled patients and a longer follow-up period to emphasize the collection of meaningful data on the feasibility of transurethral bipolar resection of the prostate with ongoing OAC/APDs.

5. Conclusions

A 4-week treatment with dutasteride does not significantly reduce TURP-associated bleeding but could reduce the duration and amount of postoperative bladder irrigation, as well as the duration of urethral catheterization. Moreover, transurethral bipolar resection of the prostate may be a safe procedure even in patients taking APDs.

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Statement of ethics

The Ethical Committee of the Urology Department approved the research, as well as the Research Ethical Committee of the Faculty of Medicine, Cairo University (approval date July 20, 2020; code: MS-190-2020). Written in formed consent was obtained from all participants after clear and precise explanation of the indications, possible risks, complications related to the procedure, and the potential benefits of the study. All procedures performed in this study involving human participants were in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Conflict of interest statement

The authors declare no conflicts of interest.

Author contributions

ES, AHA, AMR: Were the surgeons who performed the procedures; AM, EH: Revised the statistics;

I NAE, AYA: Were responsible for data collection;

AMR: as the corresponding author, wrote the main manuscript text.

Data availability

The datasets generated during and/or analyzed during the current study are not publicly available, but are available from the corresponding author on reasonable request.

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