

## ORIGINAL ARTICLE

### Role of Different Types of Anti Androgen in Reduction of Perioperative Bleeding in Transurethral Resection of Prostate for Treatment of Large Size Prostate.

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#### ABSTRACT

**Background:** Perioperative bleeding and excessive fluid absorption are inherent complications of TURP. These complications are related directly to the size although transurethral prostatectomy is still considered the gold standard for operative treatment of benign prostatic hyperplasia, it is not a procedure without morbidity. the prostate is an androgen dependent organ. This study aimed to compare the impact of use vcyproteron acetate versus dutasteride in reduction of perioperative bleeding in transurethral resection of prostate for treatment of large size prostate.

**Methods:** This a randomized controlled trial study was conducted for 6 months on 63 patients, from December 2018 to May 2019, who were admitted to urology department in Zagazig university patients were randomized through a computer randomization into three equal groups.

**Results:** The current study revealed that Control group was statistically significant decrease of HB and HCT post-operative than other two groups and significant less operative time in patients received pre-operative medication than control group with consequence decrease need for transfusion as well as less hospital stay.

**Conclusions:** The pre-operative use of anti-androgen drugs (CPA & dutasteride) in TURP of large size prostate is well tolerated in the properly selected patients and it can help in decreasing the perioperative bleeding and fluid absorption during this surgery also, operative time, hospital stay.

**Keywords:** Transurethral resection of prostate, cyproteron acetate, Dutasteride, Prostate.



#### INTRODUCTION

Benign prostate hyperplasia (BPH) is an age-related and androgen-related phenomenon, and an increasing incidence within an ageing population has been confirmed by many observational studies [1]. Lower urinary tract symptoms (LUTS) due to BPH pose a very common problem for urologists [2]. Although transurethral resection of prostate (TURP) is still considered the gold standard for operative treatment of benign prostatic hyperplasia (BPH), it is not a procedure without morbidity [3]. Perioperative bleeding and excessive fluid absorption are usually on the top of the list of TURP complications, and they are directly related to the size of the gland and technique used [3]. On the other hand, the prostate is a hormonal dependent organ, and it has been shown before that the preoperative reduction of dihydrotestosterone after finasteride

administration is associated with a significant reduction in perioperative bleeding with TURP [4].

Cyproterone acetate and 5 alpha reductase inhibitors their action thought to be mediated by reduction of androgen dependent growth factors that is reflected into a significant decrease in angiogenesis and vascularity of the prostate [5][6].

So, the aim of this study was to compare the impact of use cyproteron acetate versus dutasteride in reduction of perioperative bleeding in transurethral resection of prostate for treatment of large size prostate.

#### METHODS

The randomized controlled trial study was conducted for 6 months on 63 patients, from December 2018 to May 2019, who were admitted to urology department in zagazig university hospitals scheduled for TURP.

**Inclusion criteria:** We included patients with large size BPH (80-100gm weight) who were scheduled for TURP due to Urine retention refractory to medical treatment, Recurrent hematuria, Renal insufficiency secondary to obstruction, Recurrent Urinary tract infection, High IPSS (20-35) and Low Q max <8ml/sec. We choose this size (80-100gm weight), due to the scarcity of studies on Large size prostate 80/100mg, this study specifically studying the outcomes of management in this select group of men. [7].

**Exclusion criteria:** Patients unable or unwilling to give informed consent, Patients with suspicion of prostate cancer as those with abnormal DRE or high PSA level, Hepatic patients with (serum albumin < 3g/dl or prothrombin activity < 75%) or renal impairments (serum creatinine > 1.4 mg/dl), Patient with other bladder or urethral pathologies (i.e patient need secondary procedure), Patient have contraindication for using cyproterone acetate or dutasteride (e.g patients with history thromboembolic disease, chronic depression), patients with blood or coagulation disorders, Patients unfit for surgery ASA comorbidity iii, iv e.g (active hepatitis, uncontrolled HNT, recent MI, CVA, valvular dysfunction sever COPD) and Patient indicated for open surgery e.g large bladder stone or diverticulum.

Written informed consent was obtained from all patients and the study was approved by the research ethical committee of Faculty of Medicine, Zagazig University. The work has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving human.

All patients were subjected to the following:

**Laboratory investigation:** Urine analysis, Coagulation profile, Complete blood count, fasting blood sugar, Renal function tests (urea, creatinine), Liver function tests and serum PSA level (total and free, free to total ratio in some cases when indicated).

**Radiological evaluation:** Including Abdominal – pelvic ultrasound for: Condition of the upper urinary tract, assessment of prostatic size and PVR urine and Concomitant abdominal pathology or organomegaly. Trans-rectal ultrasound was done for better assessment of prostate size and urodynamic study: Uroflow was done pre-operatively for all patients.

**Randomization:** We included 63 patients who were randomized through a computer general block randomization into three equal groups: Group A (n= 21) include 21 Patients who receive. Cyproterone acetate 50 mg two times daily for 2-3 weeks preoperatively [4]. Group B (n= 21)

include 21 patients who receive Dutasteride 0.5mg once daily for 2-3 weeks preoperatively. Group C (n= 21) include 21 patients who were control patients which undergo TURP without pre-operative medication.

The irrigation fluid used was glycine 1.5% at body temperature and maintained 70 cm above the operative table.

**Operative technique : Mauer Mayer technique was used**

**Postoperative data:** All operative data were collected including Hemoglobin was measured in the operative day to assess the blood loss and know patients need blood transfusion or not. Operation time and incidence of time related complication (TURP syndrome). Need for blood transfusion due to excessive operative blood loss. Volume of post operative irrigation fluid. Post operative hospital stay.

Incidence of post operative complication and grading it according to Clavein-dindo grading system [8] for classification of surgical complication as follows:

**Grade I:** Any deviation from the normal post-operative course not requiring surgical, endoscopic or radiological intervention. This includes the need for certain drugs (e.g. antiemetics, antipyretics, analgesics, diuretics and electrolytes), treatment with physiotherapy and wound infections that are opened at the bedside

**Grade II:** Complications requiring drug treatments other than those allowed for Grade I complications; this includes blood transfusion and total parenteral nutrition (TPN)

**Grade III:** Complications requiring surgical, endoscopic or radiological intervention

Grade IIIa - intervention not under general anaesthetic

Grade IIIb - intervention under general anaesthetic

**Grade IV:** Life-threatening complications; this includes CNS complications (e.g. brain haemorrhage, ischaemic stroke, subarachnoid haemorrhage) which require intensive care, but excludes transient ischaemic attacks (TIAs)

Grade IVa -single-organ dysfunction (including dialysis)

Grade IVb - multi-organ dysfunction.

**Grade V:** Death of the patient

**Statistical analysis:** Data were collected, tabulated and analyzed by SPSS 20, software for Windows. The significance level was set at P < 0.05.

## RESULTS

Table (1) showed that there was no statically significant difference among groups regarding IPSS, PSA and prostate size. Table (2) showed that Control group was statistically significant lower regard HB and HCT post operatively than

other two groups with no statistically significant difference between cyproterone and dutasteride groups and all group decreased significantly from pre to post but more in control. Table (3) showed that control group show statically significant associated with Blood transfusion and Grade II clavien-dindo classification of complication. Table (4) showed that Operation time and Hospital stay were statically significant longer in control group than other groups with no statically significant difference between other. Table (5),

showed that there was a mild drug adverse effects distribution among studied group was Dutasteride group significantly associated with fatigue and dizziness, but Cyproterone group significantly associated with fatigue GIT upset

Figure (1) showed that Control group was statically significant higher Post-operative irrigation fluid than other two groups and Dutasteride group was statistically significant higher than Cyproterone group.

**Table (1):** pre operative IPSS , PSA and pre operative prostatic size

	Control group (N=19)	Cyproterone group (N=18)	Dutasteride group (N=19)	F	P
IPSS	24.64±1.94	25.86±1.79	24.4±1.01	3.105	0.056
PSA ng/ml	3.44±0.44	3.39±0.37	3.53±0.36	0.554	0.578
Pre prostate size gm	92.05±5.09	93.61±4.93	92.89±5.59	0.413	0.664

**Table (2):** HB and HCT pre and post-operative distribution among groups

	Control group (N=19)	Cyproterone group (N=18)	Dutasteride group (N=19)	F	P
<b>HB pre g/dl</b>	13.75±1.03	14.03±1.05	14.38±0.99	1.822	0.172
<b>HB post g/dl</b>	*10.87±1.35	13.08±1.37	13.17±1.09	19.485	0.00**
<b>P</b>	0.00**	0.00**	0.00**		
<b>HCT pre %</b>	41.73±2.7	42.03±3.13	43.22±2.94	1.356	0.266
<b>HCT post %</b>	*33.15±3.9	39.17±4.04	39.61±3.26	17.482	0.00**
<b>P</b>	0.00**	0.00**	0.00**		

**Table (3):** Blood transfusion and clavien-dindo grade of complications

			Group			Total	X <sup>2</sup>	P
			Control group	Cyproterone group	Dutasteride group			
<b>Blood transfusion</b>	<b>No</b>	<b>N</b>	<b>15</b>	<b>16</b>	<b>18</b>	<b>44</b>	<b>11.68</b>	<b>0.0041</b>
		<b>%</b>	<b>78.94%</b>	<b>88.9%</b>	<b>94.7%</b>	<b>78.6%</b>		
	<b>Yes</b>	<b>N</b>	<b>4</b>	<b>2</b>	<b>1</b>	<b>12</b>		
		<b>%</b>	<b>21.05%</b>	<b>11.1%</b>	<b>5.3%</b>	<b>21.4%</b>		
<b>Grade</b>	<b>I</b>	<b>N</b>	<b>15</b>	<b>16</b>	<b>17</b>	<b>44</b>	<b>7.32</b>	
		<b>%</b>	<b>78.94%</b>	<b>88.9%</b>	<b>89.5%</b>	<b>78.6%</b>		
	<b>II</b>	<b>N</b>	<b>4</b>	<b>2</b>	<b>2</b>	<b>12</b>		
		<b>%</b>	<b>21.05%</b>	<b>11.1%</b>	<b>10.5%</b>	<b>21.4%</b>		
<b>Total</b>	<b>N</b>	<b>19</b>	<b>18</b>	<b>19</b>	<b>56</b>			
	<b>%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>			

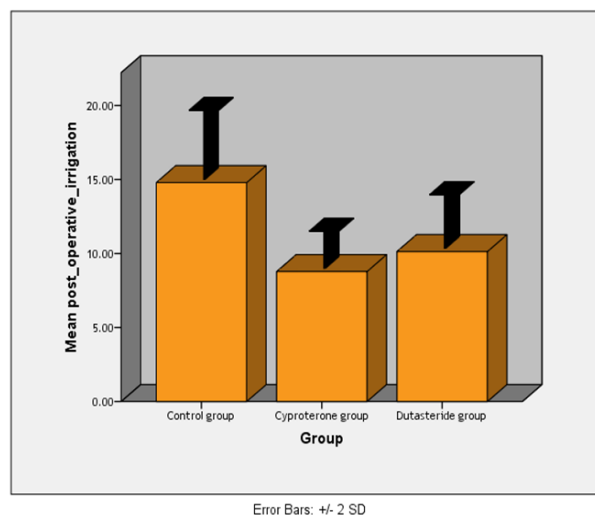
**Table (4):** Operation time and hospital stay among groups

	Control group (N=19)	Cyproterone group (N=18)	Dutasteride group (N=19)	F	P
Operation time (min)	*58.84±5.1	50.16±3.6	49.0±4.1	28.804	0.00**
Hospital stay (day)	*3.15±0.68	1.77±0.62	1.89±0.65	24.888	0.00**

**Table (5):** Drug adverse effect among studied Group

			Group		X <sup>2</sup>	P
			Cyproterone group	Dutasteride group		
<b>Drug adverse effect</b>	<b>No</b>	<b>N</b>	<b>7</b>	<b>9</b>	<b>0.95</b>	<b>0.32</b>
		<b>%</b>	<b>38.9%</b>	<b>47.4%</b>		
	<b>Fatigue and tiredness</b>	<b>N</b>	<b>5</b>	<b>3</b>	<b>3.42</b>	<b>0.06</b>
		<b>%</b>	<b>27.8%</b>	<b>15.8%</b>		
	<b>Decrease Libido</b>	<b>N</b>	<b>1</b>	<b>2</b>	<b>1.66</b>	<b>0.19</b>
		<b>%</b>	<b>5.6%</b>	<b>10.5%</b>		
	<b>Dizziness</b>	<b>N</b>	<b>0</b>	<b>2</b>	<b>8.11</b>	<b>0.004*</b>
		<b>%</b>	<b>0.0%</b>	<b>10.5%</b>		
	<b>Ejaculatory disorder</b>	<b>N</b>	<b>0</b>	<b>1</b>	<b>3.21</b>	<b>0.07</b>
		<b>%</b>	<b>0.0%</b>	<b>5.3%</b>		
	<b>GIT upset</b>	<b>N</b>	<b>4</b>	<b>0</b>	<b>20.04</b>	<b>0.00 **</b>
		<b>%</b>	<b>22.2%</b>	<b>0.0%</b>		
	<b>Headache</b>	<b>N</b>	<b>1</b>	<b>2</b>	<b>1.66</b>	<b>0.19</b>
		<b>%</b>	<b>5.6%</b>	<b>10.5%</b>		
<b>Total</b>		<b>N</b>	<b>18</b>	<b>19</b>		
		<b>%</b>	<b>100.0%</b>	<b>100.0%</b>		

**Figure (1):** Diagram showing post-operative irrigation fluid among groups



**DISCUSSION**

Benign prostate hyperplasia (BPH) are heterogeneous disorders with a wide array of clinical presentations and high prevalence among men [9]. It is a common disease of the ageing male population significantly impact quality of life by causing lower urinary tract symptoms [10]. The incidence of benign prostatic hyperplasia (BPH) is 50-60 % in the 6th decade of life and increases to 80-90% in the 7th and 8th decades of

life [11]. Lower urinary tract symptoms (LUTS) due to BPH pose a very common problem for urologists [2]. Transurethral resection of the prostate (TURP) is considered the gold standard for male lower urinary tract symptoms (LUTS) secondary to benign prostatic hyperplasia (BPH), but is associated with significant morbidity and long-term complications including stricture (7%), surgical revision (6%), significant urinary tract

infection (4%), bleeding requiring blood transfusion (3%), incontinence (3%), transurethral resection syndrome (1%), erectile dysfunction (10%), and ejaculatory dysfunction (65%) [12].

Seeking solution to get an ideal surgical maneuver reaching perfection regarding safety and efficacy, many attempts aiming at minimizing (TURP) bleeding had been carried out. most of this trial depending on the idea of using some drugs that produce a decrease in prostate and attenuating its vasculature (due to androgen deprivation) prior to the procedure [13].

In our study, there was no significant difference between control, CPA and dutasteride groups regarding mean IPSS and mean prostate size.

A similar study conducted by **El-Gamal et al. [4]**, reported that there was no significant difference between the studied groups regarding prostate size was. This can attribute to the tendency of patients to delay the operation as much as possible.

Regarding the operative time of TURP we found the mean operative time was significantly reduced in CPA and dutasteride groups in comparison to control group with no significant difference among two groups, this result similar to **El-Gamal, et al., [4]** after two weeks pre operative treatment with CPA, who reported that operative time was significantly less in CPA group than control group.

Also our result in agreement to that reported by **Kravchick et al. [14]** in their study after the 6-week pre-treatment with dutasteride who reported mean operative time was 50.55 min, 42.65 min in control group and dutasteride group respectively, the results of these studies revealed reduction of prostatic blood flow after short-term of oral therapy with dutasteride ,CPA which is lead to clear operative field throughout the procedures ,due to less time needed for coagulation.

In our study, we assessed operative blood loss by comparing Hemoglobin level and haematocrit value pre and post operative, which revealed marked significant drop in HB level and HCT value in Control group post operative than other two groups with no significant difference between CPA and dutasteride groups, and all group decreased significantly from pre to post but more in control. Our results showed that CPA group was statistically significant less drop in HB and HCT post operative than other two groups , with highly significant p value =0.00\*\*) this observation was in accordance to that reported by **Kim et al.[15]** after dutasteride administrated 2weeks pre operatively who revealed statistically significant difference regarding hemoglobin decrease post operative between control and

dutasteride groups with significant p value  $p=0.011$ ; and similarly **El-Gamal et al. [4]**, who reported that hematocrit value was less decreased in CPA group than control group with statistically significant p value  $p= 0.00^*$ ),this effect explained by its capability to decrease the expression of androgen dependent VEGF and angiogenesis which is significantly reduce microvessel density in prostatic periurethral tissue.

Also our result in agreement with **Woo et al [16]** who reported that pre-operative treatment with dutasteride for two weeks before TURP, Hb and Hct declined less in group 1 (dutasteride) than in group 2 (controls) with statistical significant difference which explained by significant decrease in microvessel density in suburethral portion of prostate after treatment with dutasteride .

A similar finding was also described when finasteride was used before TURP in the studies of **Donohue et al. [17]**, **Özdal et al. [18]** and **Di Tonno et al.[19]**, who reported that the researchers believed that this reduction is likely due to rapid short-term alterations in prostatic blood flow .

Considering the Hospital stay in our study it was significantly longer in control group than CPA and dutasteride groups with no significant difference among two groups, with statistically highly significant in relation to control group, this result was in accordance with **Kim et al. [15]** who revealed significant decrease in hospitalization days after TURP in dutasteride group than control group with statistically significant p value ( $p=0.01$ ), and also in agreement with the study of **El-Gamal et al. [4]** who reported less hospital stay in CPA group with statistically significant p value ( $p=0.001$ ), which was attributed to less postoperative care of TURP including less need for blood transfusion and continuous bladder irrigation and maintenance of a urethral Foley catheter until hematuria ceased and hospitalization , all of which were lower in pre-treatment group related to reduce prostate tissue vascularity.

In our study the need for blood transfusion was less in both CPA and Dutasteride group in comparing to control group, these result in agreement with that reported by **El-Gamal et al. [4]** who need for blood transfusion in CPA and control group, also the study of **Kravchick et al. [14]** who reported no patients in the dutasteride group needed a postoperative blood transfusion, in comparison with transfusions required by 2 patients in the control group, similar result reported in the study of **Kim et al. [15]** who reported that there was no patients in the

dutasteride group needed transfusion after pretreatment with dutasteride.

Regarding post operative fluid irrigation, our study revealed statically significant reduced fluid irrigation after the use of CPA and dutasteride in comparison to control group with high significant difference ( $p= 0.00^{**}$ ) on other hand Dutasteride group was significantly higher than Cyproterone group.

A similar result reported by **Kravchick et al. [14]** who revealed that there was a significant difference regarding post operative fluid irrigation in dutasteride group and control group, also our study in agreement with the study of **Kim et al. [7]** who reported significant decrease in duration of post-operative irrigation in dutasteride group than control group with a significant difference between studied group. Our results also in agreement with the study of **El-Gamal et al. [4]** who demonstrated that fluid irrigation was significantly reduced after the use of CPA with significant difference between studied group.

Our study There was a statically significant association between Blood transfusion and Grade II clavien-dindo classification of complication, also grade Control group was significantly associated with clot retention and blood transfusion.

Although the adverse side effects of these agents are thought to be minimal, the magnitude of adverse effects on sexual function (diminished libido and erectile dysfunction) gynecomastia, depression, and quality of life remains ill-defined [20]. Also, Cyproterone acetate has the advantage of immediate effectiveness, but some side effects are described. These advers effects include loss of libido, erectile dysfunction, cardiovascular and hepatic toxicities [4].

**Conclusions:** The pre-operative use of anti-androgen drugs (CPA & dutasteride) in TURP of large size prostate is well tolerated in the properly selected patients and it can help in decreasing the perioperative bleeding and fluid absorption during this surgery also, operative time, hospital stay.

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#### How to cite

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