COMPARATIVE RANDOMIZED STUDY BETWEEN MONOPOLAR AND BIPOLAR TRANSURETHRAL RESECTION OF THE PROSTATE: 1 YEAR FOLLOW UP

Assem Abdelaziz Mahmoud [1], Hussien Abdel hameed Al Daqadossi [1], Mohammed Kamal Saif Elnasr [1], Mohammed Mabrouk Badr[2]

1 Department of urology, Fayoum University, Fayoum, Egypt

2 Department of urology, Alazhar University, Cairo, Egypt

Abstract

Objective: To compare standard monopolar transurethral resection of the prostate (TURP) and bipolar transurethral resection of the prostate for management of benign prostatic hyperplasia (BPH).

Materials and methods: From January 2012 and February 2013, a total of 60 patients with symptomatic benign prostatic hyperplasia who are indicated for surgery were randomized into two groups. The first group was managed by monopolar TURP, and the second group was managed by bipolar TURP. Different clinical parameters, perioperative complications and success rates were compared between both groups. The follow up was done at 1 month, 3months, 6 months and one year after surgical intervention where all patients were subjected to IPSS, uroflowmetry and postvoiding residual urine measurement.

Results: Patient demographic profiles were similar in both groups. Mean resection time and mean weight of resected prostate tissue were comparable for both groups. There was a statistically significant difference in sodium concentration change in the monopolar group (-5.3% change) versus no significant difference in the bipolar group (0.07% change). Two cases of clinically significant TUR syndrome occurred in the monopolar group while none occurred in the bipolar group. There was no significant difference in incidence of intra operative bleeding or blood transfusion between both groups. There was statistically significant improvement in the mean IPSS score, Qmax and PVRU in both groups during the follow up period.

Conclusion: Our study indicates that bipolar TURP is equally as effective as monopolar TURP in the treatment of BPH, but has a more favorable safety profile. The clinical efficacy of bipolar TURP is long-lasting and comparable with M-TURP at 1 year follow up.

Introduction:

Monopolar transurethral resection of the prostate (TURP) is considered the surgical gold standard for benign prostatic obstruction (BPO) due to its well documented long-term efficacy (1). However, TURP complications such as TUR syndrome, bleeding and urethral stricture still occur and, therefore, several technologies have been developed in the last years to minimize the perioperative morbidity of TURP (2). The most significant improvement of TURP was the incorporation of bipolar technology which addresses the main drawback of monopolar TURP, (TUR) syndrome, by allowing resection to be performed in saline. Additionally, there are no new skills with bipolar TURP and, as a result, bipolar TURP is very promising technique (3). As such, we performed this prospective randomized trial to compare the safety profile and clinical efficacy of monopolar and bipolar TURP.

Materials and methods:

From January 2012 and February 2013, a total of 60 patients with symptomatic BPH with indication for surgery were randomized into two equal groups that were managed by either monopolar or bipolar TURP.

The safety end points studied were the occurrence of complications and the changes in the preoperative and immediate postoperative serum sodium (Na+) and hemoglobin (Hb) levels. The efficacy end points that we studied were resection time, weight of resected prostate tissue, and improvement in international prostatic symptom score (IPSS), maximum flow rate (Qmax) and post voiding residual urine (PVRU) over 1 year.

Inclusion criteria were symptomatic BPH that required surgery (due to failed medical therapy or urinary retention) and a TRUS-estimated prostatic weight of 30–100 gm. Exclusion criteria were patient with significant co morbidities, neurogenic bladder, urethral stricture, prostate cancer, bladder stones and chronic renal impairment. The study was approved by our institution's ethics committee, and informed consent was obtained from all patients. The diagnostic evaluation included IPSS, digital rectal examination, complete laboratory tests, abdominal ultrasound, TRUS and uroflowmetry. All operations were performed under spinal anesthesia with glycine 5% solution as the irrigant during monopolar TURP and saline solution as an irrigant during bipolar TURP. All patients were treated postoperatively with continuous bladder irrigation until urine became clear and a full blood count and serum Na

were determined immediately after surgery. Removal of the catheter was done after complete clearance of urine and PVRU was measured to ensure proper emptying before discharge. Any complications as intra operative bleeding, (TUR) syndrome, clot retention were documented. Patients were reassessed at 1 month, 3months, 6 months and one year after surgical intervention by measuring IPSS, maximum flow rate (Qmax) and PVRU.

Monopolar TURP was performed with a 26Fr Karl Storz continuous flow resectoscope and a standard loop electrode for TURP (8 mm diameter, Storz) using the electrosurgical unit (Valleylab Force EZ, Boulder, CO, USA) set at 140 W (cutting mode) and 40 W (coagulation mode). Bipolar resection was performed with a 26Fr Karl Storz continuous flow resectoscope and a Storz bipolar electrode using the electrosurgical device (EMED ES- Vision., EMED, NY, USA) set at 350W (cutting mode) and 120 W (coagulation mode).

The results were analyzed with the use of descriptive statistics paired t test and chi-square test to compare the continuous variables and categoric data. Significant differences were considered at $p < 0.05$ (Statistical Package for the Social Sciences, version 10.1; SPSS Inc, Chicago, IL, USA).

Results:

All cases had histopathology as BPH. As shown in table (1), preoperative patient characteristics were comparable between both groups.

Table (1): preoperative patient data

Variable	Monopolar (n=30)		Bipolar (n=30)		p-value	Sig.
	Mean	SD	Mean	SD		
Age (years)	65.5	8.03	67.8	5.3	0.2	NS
IPSS score	26.9	5.9	28.2	4.1	0.2	NS
PVRU (ml)	237.9	295.8	246.6	186.8	0.9	NS
Qmax(ml/sec)	7.2	10.5	9.3	4.2	0.6	NS
Gland size(gm)	59.2	12.6	61.7	16.4	0.5	NS
Adenoma (gm)	39.7	9.4	41.6	9.9	0.4	NS

NS = nonsignificant.

Perioperative parameters are shown in table (2). There was no statistically significant difference between groups regarding mean resected prostatic weight and operative time or blood transfusion. TUR syndrome occurred in two cases in monopolar group whereas no case developed TUR syndrome in bipolar group.

Table (2): Perioperative patient data

Variables	Monopolar		Bipolar		p-value	Sig.
	Mean	SD	Mean	SD		
Resected prostate weight (gm)	31.8	8.1	33.8	9.4	0.4	NS
Operative time (minute)	71.3	37.6	63	16.8	0.3	NS
	No.	%	No.	%		
Blood transfusion	3	10%	2	6.7%	0.9	NS
TUR syndrome	2	6.6%	0	0%	0.2	NS
Clot retention	3	10%	0	0%	0.2	NS

NS = nonsignificant.

Table (3) summarizes the mean values for hemoglobin and sodium before and immediately after surgery in both groups. In each group, there was a statistically significant difference between preoperative and postoperative hemoglobin (p-value <0.05). In monopolar group, there was statistically significant difference between preoperative and postoperative Na concentration (-5.3% change) while in bipolar group, there was slight increase in postoperative Na (0.07% change) with no statistically significant difference.

Table (3): Mean hemoglobin and sodium values before and immediately after surgery in both groups

		Preoperative Mean ± SD	Postoperative mean ± SD	Change %	P value	Sig.
Monopolar	Hemoglobin (gm/dl)	13.1±1.8	11.7±1.9	-10.7%	<0.001	S
	Sodium (mEq/L)	140.4 ± 3.3	132.9 ± 6.5	-5.3%	<0.001	S
Bipolar	Hemoglobin (gm/dl)	13.2 ± 1.4	12 ± 1.2	-9.1%	<0.001	S
	Sodium (mEq/L)	138.4 ± 4.6	138.5 ± 3.5	0.07%	0.7	NS

NS = nonsignificant, S = significant.

Follow-up (3, 6 and 12 months postoperatively) demonstrated marked and comparable improvement in IPSS, Qmax and PVRU with no statistically significant difference between the two groups and this

improvement was maintained all over the follow up period as shown in figure (1, 2, 3). However, there was higher incidence of irritative symptoms in the monopolar group in the first month leading to significantly higher IPSS score and lower Qmax than the bipolar group.

Figure (1): Mean IPSS

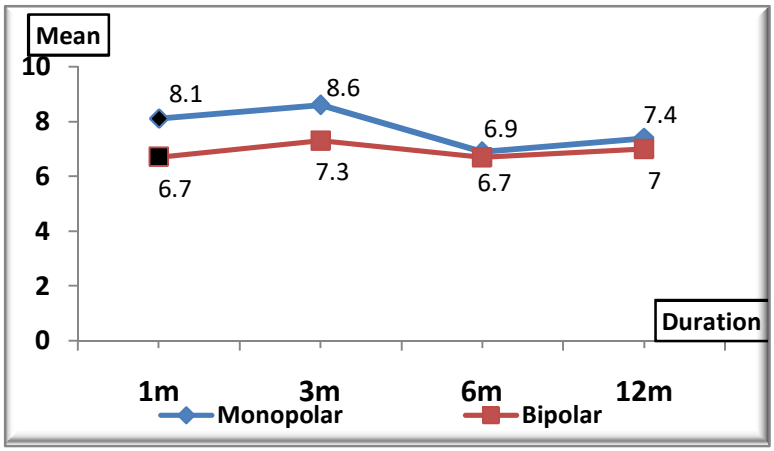


Figure (2): Mean Qmax

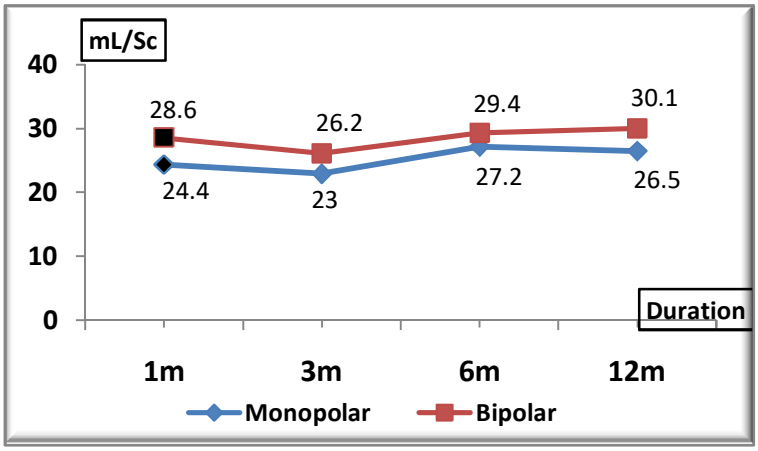
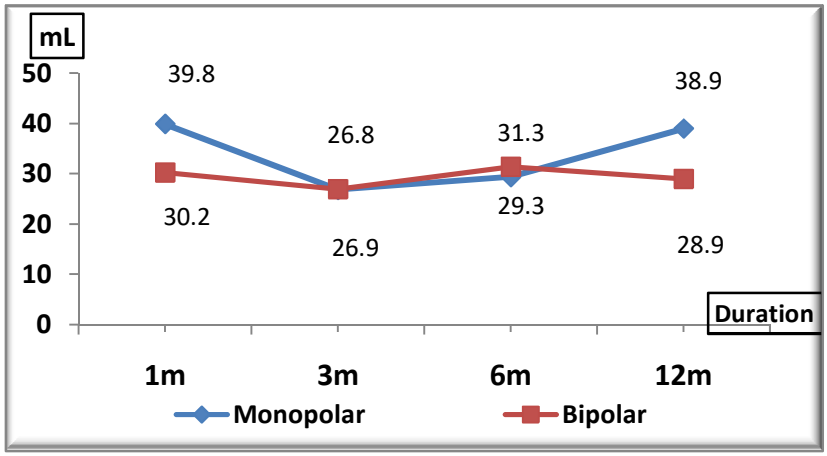


Figure (3): Mean PVRU



Discussion:

Over the past decades, monopolar TURP has evolved as an effective and safe treatment for BPO. Despite low mortality (0.25%), it has the risk of hemorrhage and TUR syndrome. The bipolar system was designed to avoid these complications. By incorporating both the active and return poles on the same electrode, a conductive fluid medium (saline) can be used for the resection instead of the conventional non-conductive irrigation fluid thereby eliminating TUR syndrome (4).

The change in serum Na concentration after TURP has been the most frequently studied item in most trials evaluating the morbidity of monopolar and bipolar TURP because dilutional hyponatremia is the most important criteria of TUR syndrome. The present study demonstrated statistically significant difference in the decrease in sodium concentration between the two groups which is in agreement with other studies (4, 5, 6). Issa et al observed five patients who underwent bipolar TURP with minimal decrease in sodium concentration despite very long operative time (2 hours) and suggested that dilutional hyponatremia would be a historical event in the 21st century (7).

More important finding in this study is the non occurrence of TUR syndrome (0%) in the bipolar group. In the meta-analysis of randomized control trials (RCTs) published by Mamoulakis et al, no case of TUR syndrome occurred in 681 bipolar resections (0%) (8). This observation was supported by Michielsen et al who reviewed the literature on 760 bipolar resections with no single case of TUR syndrome and, therefore, stated that the risk of TUR syndrome is eliminated (6). Although the results in our study didn't translate into significant differences in TUR syndrome rates, as reported in these previous RCTS, our results confirms that bipolar TURP eliminates the danger of TUR syndrome making it a first choice in patients with cardiac disease or large size prostate. Bipolar technology, however, does not prevent fluid absorption, which can cause severe cardiopulmonary failure in cases of large volume uptake; therefore, it should always be kept in mind (9).

The high incidence of TUR syndrome in the monopolar arm of our study (6.6%) compared with the (1 to 3%) reported by Rassweiler et al (2) can be explained by Longer operative time (more than 60% of operations in the monopolar group took more than one hour) which is an important risk factor for TUR syndrome due to increased fluid absorption (6).

Heterogeneous operator experience in this study is also another risk factor.

Bleeding is a major complication of TURP, and it may lead to blood transfusion or clot retention. The haemostatic capacity of the bipolar current has been reported to be superior in ex vivo studies, possibly because of deeper coagulation depths and the 'cut-and-seal' effect (3).

Earlier randomized controlled trials (RCTs) comparing bipolar resection with monopolar TURP demonstrated that blood loss was significantly less in the bipolar group (10, 11). Nevertheless, two recent meta-analyses suggested a similar blood loss for monopolar and bipolar TURP (8, 12). In a recent paper focusing on bleeding complications, the authors also failed to demonstrate an advantage of bipolar technique regarding bleeding (13). These data are confirmed by our study as it failed to show differences in bleeding tendency between the two groups. Hemoglobin levels decreased similarly and clot retention or transfusion rates did not differ significantly. However, the higher incidence of blood transfusion in our study (10% in monopolar group and 6.7% in bipolar group) compared with the reported incidence in the literature (2.9%) (14) can be explained by high incidence of pre operative catheterization (50%) and pre operative UTI infection in our study (60%) which may be responsible for increased bleeding because of a congested gland (2).

In randomized controlled trail studies comparing monopolar and bipolar resection with at least 1-year follow-up, the improvements in IPSS, Q max and PVRU were significant in both groups with no statistical differences in any of the variables measured between the groups (4, 5, 15). Similar to all the previous studies, our study showed marked and comparable improvement in the mean IPSS score [(-69.8%) in monopolar and (-76.2%) in bipolar group], Qmax [(219.4%) in monopolar and (181.7%) in bipolar group], and PVRU [(-83.3%) in monopolar and (-87.8%) in bipolar group], and this improvement was maintained all over the follow up period. However, there was statistically significant difference between monopolar and bipolar groups at 1 month in favor of bipolar technique regarding IPSS score and Qmax. This can be explained by the lower incidence of irritative symptoms in bipolar group which is caused by the lower peak volume of energy in the bipolar technique combined with shallow depth of penetration leading to less thermal damage, decreased granulation tissue formation (16).

Higher incidences of urethral complications with bipolar systems have been occasionally reported. Risk factors were larger resectoscope diameter (11), higher ablative energy (17) and longer procedures (10). Urethral strictures specifically associated with the Olympus bipolar system have been attributed to leakage of electric current through the resectoscope sheath, but this concern has not been verified (4). However, recent studies did not reveal increased incidence of urethral strictures with bipolar techniques (8, 18). In our study, there were no cases of stricture urethra or bladder neck contracture in either group after one year of follow up. This can be explained by strict clinical routines that we followed throughout the study including prophylactic antibiotics, use of narrow instruments and short postoperative catheterization. In addition, to prevent thermal damage to the urethra, we used large amounts of jelly around the sheath in the urethra and always carefully monitored any early exchange of worn loops and discarding of loops with distortion or insulation faults.

The two major limitations of this study are the small number of patients studied and the different levels of experience of the surgeons at our teaching hospitals. These limitations greatly affect the interpretation of our findings. The use of statistics to determine the clinical relevance of our findings is premature at this stage and, therefore, they must be viewed with caution. A larger pool of patients will definitely provide a more accurate picture.

Conclusion:

Bipolar TURP is an efficient method for treating benign prostatic hyperplasia and is comparable to monopolar TURP over a period of one year with the advantage of an improved safety profile. The risk of TUR syndrome is completely eliminated with bipolar TURP and the risk of urethral stricture is not higher with the bipolar technology. The bipolar system is a promising technique to challenge the ‘gold standard’ surgical therapy for BPH and this study contributes to the growing body of evidence that may herald a new era with bipolar TURP as the new gold standard of surgical treatment for clinical BPH.

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