Two-year Follow-up in Bipolar Transurethral Enucleation and Resection of the Prostate in Comparison with Bipolar Transurethral Resection of the Prostate in Treatment of Large Prostates. Randomized Controlled Trial

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OBJECTIVE To assess the safety and long-term efficacy of bipolar transurethral enucleation and resection of the prostate (B-TUERP) in the treatment of enlarged prostate in comparison with bipolar transurethral resection of the prostate (B-TURP).

MATERIALS AND METHODS From June 2015 to March 2019, a total of 240 patients with enlarged prostates of more than 80 gm were randomized into 2 groups, each containing 120 patients. Patients in group A were subjected to B-TUERP while those in group B underwent B-TURP. The perioperative data and postoperative outcomes followed at 1, 6, and 24 months after surgery at which points they were analyzed, and a comparison made between the 2 groups.

RESULTS There were no significant differences in the preoperative parameters of the 2 groups. Comparing with B-TURP, B-TUERP had longer operative time (105.09 ± 31.08 vs 61.09 ± 29.28 min), more resected prostatic tissue (50.41 ± 13.07 vs41.12 ± 8.91 g) and had less hemoglobin drop (1.5 vs 2g/dL). In addition, indwelling catheter time, postoperative bladder irrigation duration, and hospital stay were significantly shorter in the B-TUERP group than in the B-TURP group. At 24 month after the procedure, patients with B-TUERP achieved better results of International Prostate Symptom Score (6 vs 7 $P = .008$), quality of life (1 vs 2, $P = .243$), maximal flow rate (24.9 ± 5.74 vs 20.09 ± 3.27mL/sec, $P = .034$), post-voiding residual urine volume (18.64 ± 3.28 vs 24.74 ± 4.02 mL, $P = .001$), and residual prostate volume (18.64 ± 3.28 vs 20.74 ± 4.02 mL, $P < .001$). On the other hand, there were no significant differences in postoperative complications between both groups.

CONCLUSION B-TUERP is a more effective modality in the treatment of enlarged prostate compared to B-TURP with almost no variation in safety. UROLOGY 133: 192–198, 2019. © 2019 Elsevier Inc.

Abbreviations: *TURPL, transurethral resection of prostate; B-TUERP, bipolar transurethral enucleation and resection of the prostate; B-TURP, bipolar transurethral resection of the prostate; M-TURP, monopolar TURP; BPH, benign prostatic hyperplasia; LUTS, lower urinary tract symptoms; I-PSS, International Prostate Symptom Score; QOL, quality of life; TPSA, total prostate specific antigen; PVRU, post-voiding residual urine volume; Q max, maximal flow rate*

Conflicts of Interest: *The authors declare no conflict of interest.*

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Benign prostatic hyperplasia (BPH) may lead to a wide spectrum of urinary voiding problems, which can significantly affect the quality of life for old men.[1] There are different treatment options for BPH, including watchful waiting, drug therapy, and surgery, surgery being the most effective treatment option for BPH.[2] The monopolar transurethral resection of the prostate (M-TURP) is thus far considered the gold standard intervention for the treatment of BPH.[3] The morbidity rate associated with M-TURP is still high and varies from 18%

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and 26%. Furthermore, the M-TURP mortality rate is about 1%.[4]

Many minimally invasive modalities have been attempted to overcome these complications. One of the technical modifications of TURP is the bipolar transurethral resection of the prostate (B-TURP) which enabled urologists to use sodium chloride solution as an irrigation fluid to overcome the risk of TUR syndrome occurrence.[3] Another advantage of B-TURP is that it leads to less volume overload than M-TURP, although the volume of the resected prostate and the operative time do not differ significantly between the 2 procedures. The morbidity of B-TURP nonetheless is still considered high. For that, bipolar transurethral enucleation and resection of the prostate (B-TUERP) has been recently developed for treating BPH. The crux of the idea behind B-TUERP is that it depends on removing the prostatic tissue along the surgical capsule as in open prostatectomy, but in a minimally invasive manner.[5]

To our knowledge, there is limited published data comparing enucleation of the prostate with resection. The aim of our study was to assess the safety and efficacy of B-TUERP in comparison with B-TURP in treating BPH patients.

PATIENTS AND METHODS

This randomized prospective study was carried out at a single tertiary care hospital from June 2015 to March 2019. The inclusion criteria was as follows: patients aged between 50 and 80 years old with prostate sizes of more than 80 gm by transrectal ultrasound and severe lower urinary tract symptoms (LUTS) (International Prostate Symptom Score [IPSS] >20 and maximal flow rate [Qmax] < 10 mL/sec) refractory to medical treatment with alpha blockers. Patients known to have neurogenic bladder, prostate cancer, urethral stricture, or who have had previous prostate surgery were excluded.

Sample size was calculated using PASS program, setting the type-1 error (α) at 0.05 and the power (1-β) at 0.8. Results from a previous study (kan et al, 2014) showed that the mean 12-months postoperative Qmax among B-TUREP patients was 19.5 ± 8.67 vs 15.1 ± 11.11 for the B-TURP group. Calculations based on these values produced a sample size of 85 cases per group. The sample rose to 102 cases per group after taking in consideration a 20% drop-out rate.[6]

A total of 300 patients with LUTS as a result of BPH were assessed for eligibility to enter the study. Sixty patients were excluded for different reasons. For not meeting inclusion criteria, 15 patients were excluded while 29 refused to participate and 16 did not enter the study for other reasons as shown in Figure 1. The remaining 240 patients were randomly divided using the closed envelope method into 2 equal groups; group A underwent B-TUERP and group B underwent B-TURP.

All patients gave their consent to be included in this study after having been provided an explanation of the study procedures and the follow-up course. The study was approved by the Ethics Committee of Ain Shams University.

We assessed the efficacy of the procedure through operative time, resected prostatic tissue weight, catheterization time, and hospital stay, IPSS, Qol assessment, residual prostate volume, uroflowmetry (Qmax), and post-voiding residual urine volume (PVRU) as well as safety by TUR syndrome, hemoglobin decrease, and transfusion rate, urethral stricture and urinary incontinence. The primary end point was to investigate the safety of the B-TURP compared to TUERP. The secondary end point was to evaluate the efficacy of both approaches.

- *Operative procedure:* All the patients were operated by the same surgical team. Prophylactic antibiotics were given during anesthesia. Spinal anesthesia was used for all patients. The patients were placed in the lithotomy position and diagnostic rethra-cystoscopy was done before the procedure. Both (B-TUERP) and (B-TURP) were performed with normal saline as an irrigation fluid.

Both B-TUERP and B-TURP were done using a high frequency generator (ESG-400; Olympus, Tokyo, Japan). The cutting power was set at 200 W and the coagulation power was set at 120 W. A 26-Fr Olympus continuous flow resectoscope was used.

- In B-TUERP, enucleation was performed with the same technique described by Kim et al[7] First making 2 lateral incisions at 5 and 7 o'clock positions starting from the bladder neck to the prostatic apex using the mushroom loop and deepened to the level of the surgical capsule. Then, the 2 incisions were connected transversely. Retrograde blunt dissection, utilizing the beak of the resectoscope and the loop, was used to separate the median lobe of the prostatic bed pushing it towards the bladder. Simultaneously, any bleeding vessels were controlled. The median lobe was left suspended by a small stalk for the purpose of easy, rapid, and safe resection in a bloodless manner using the cutting loop. Then, enucleation of the 2 lateral lobes was done in the same manner by making a longitudinal incision starting at a12 o'clock position extending from the bladder neck to the prostatic apex. The incision was deepened to the level of capsular fibers to separate the 2 lateral lobes from each other. This enabled us to manage each lobe individually in a retrograde fashion starting at the apex and sweeping it back into the bladder by the resectoscope tip till it reached the level of bladder neck. While it was still attached by a small pedicle to the bladder, the lobe was safely and rapidly cut into pieces (chips) using the cutting loop. Prostatic chips were removed from the field using Ellic evacuator (chips were sent for histopathological examination). At the end of the procedure, any residual adenomatous tissues in the prostatic bed were ablated by the mushroom loop.
- In B-TURP, the procedure starts by resection of the median lobe from the bladder neck to the prostatic apex using the cutting loop then resection of the lateral lobes.

Triple silicon Foley catheter 22 fr was inserted and the balloon inflated by 40-80 cc normal saline depending on the size of the prostate upon which continuous urinary bladder irrigation begins by normal saline until the wash becomes clear.

- *Outcome measures:*

We compared the 2 groups with respect to operative time, intraoperative irrigation fluid volume, resected prostatic tissue weight, postoperative bladder irrigation duration, urinary catheter indwelling time, postoperative length of hospital stay, and any perioperative complications, including bleeding requiring

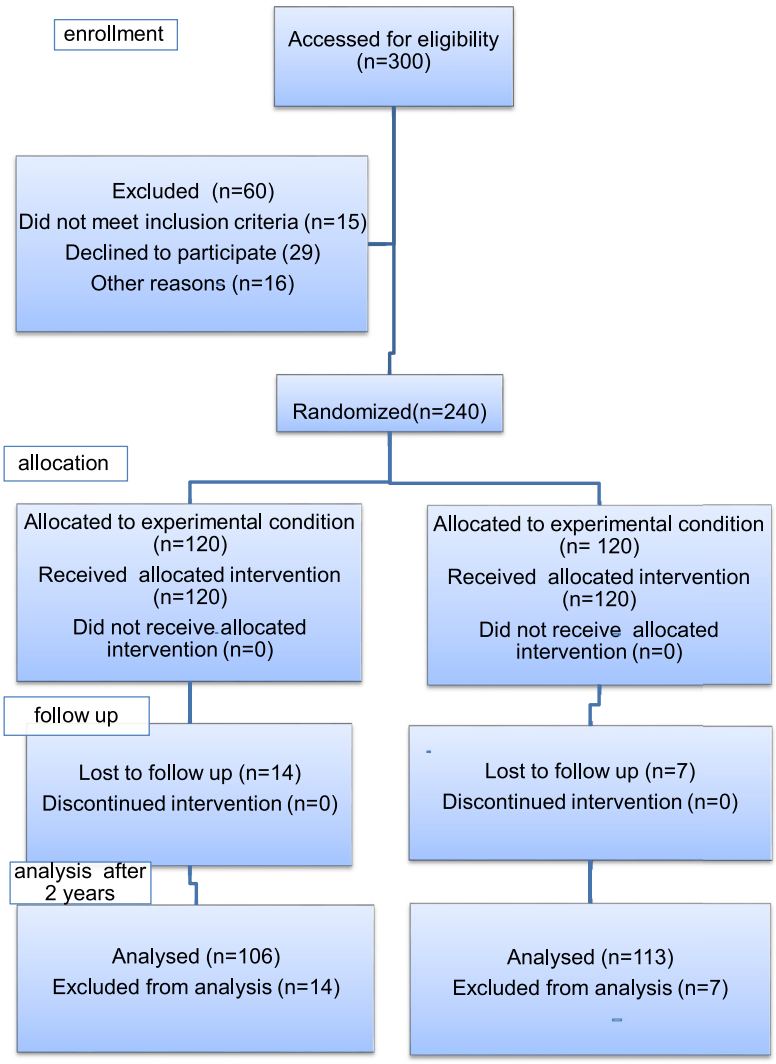


Figure 1. Consort flow chart. (Color version available online.)

blood transfusion, TUR syndrome, urethral stricture, and urinary incontinence. Serum hemoglobin and serum sodium were assessed preoperatively and on the first day postoperatively.

The patients were evaluated at the 1st, 6th, and 24th month. The preoperative and postoperative values of IPSS, Qol assessment, total prostate specific antigen (TPSA), residual prostate volume, uroflowmetry (Qmax), and PVRU were recorded and compared.

■ *Statistical Analysis:*

The collected data was revised, coded, tabulated, and introduced to a PC using Statistical package for Social Science (SPSS 21). Kolmogorov–Smirnov's test was used to evaluate normal distribution of continuous data. All results are presented as mean and SD values or as median and interquartile range according to the distribution of data. Categorical results are presented as numbers of cases and percentages. Continuous variables were compared using Student *t*test or Mann–Whitney *U* test, depending on the distribution of data. *P* value <.05 was considered statistically significant and *P*value <.001 was considered highly statistically significant.

RESULTS

There is no statistical difference between the 2 groups regarding preoperative parameters; both groups had comparable preoperative values for age, IPSS, QOL, TPSA, prostate volume, Qmax, and PVRU. See Table 1.

With regards to the perioperative data, there was a significant difference between both groups in operative time and intraoperative irrigation fluid volume, which were higher in the B-TUERP than in the B-TURP group (105.09 ± 31.08 and 18.86 ± 3.44 vs 61.09 ± 29.28 and 14.78 ± 3.33). Also, the weight of the resected tissue was significantly higher in the B-TUERP group in relation to B-TURP group (50.41 ± 13.07 vs 41.12 ± 8.91) ($P \leq .001$). On the other hand, indwelling catheter time, postoperative bladder irrigation duration, and hospital stay were significantly shorter in the B-TUERP group than in the B-TURP group. See Table 2.

Regarding treatment efficacy, there was significant difference in all follow-up parameters in favor of the B-TUERP procedure except that after 6 month, there was no significant difference in the Qmax and TPSA, and after 24 months, the Qol score ($P = .243$) between the 2 groups was not significantly different (Table 2 and Fig. 2). Although these parameters were statistically significant they are clinically insignificant.

Table 1. Baseline preoperative parameters of the included patients

	B-TUERP Group Mean ± SD Median (IQR)	B-TURP Group Mean ± SD Median (IQR)	*P* Value
No. of cases	120	120	–
Age (y)	66.41 ± 6.38	64.81 ± 5.73	.053
IPSS	29 (27-32)	30 (29-32)	.277
Qol	5 (4-5)	5 (4-6)	.756
TPSA (ng/mL)	3.36 ± 2.03	3.55 ± 1.88	.454
Prostate volume (mL)	105.3 ± 20.26	112.7 ± 23.15	.250
Qmax (mL/s)	6.5 ± 1.69	6.91 ± 1.65	.077
PVRU (mL)	303.76 ± 158.58	289.30 ± 170.68	.599

Abbreviations: B-TUERP, bipolar transurethral enucleation and resection of the prostate; IPSS, international prostate symptom score; PVRU, post-voiding residual urine volume; TPSA, total prostate specific antigen.

With reference to perioperative and postoperative complications, there was significant difference between both groups on the issue of drop in hemoglobin level; it was 2 g/dL in the B-TURP group and 1.5 g/dL in B-TUERP ($P \leq .001$). On the other side, there was no statistically significant difference in the postoperative sodium change between the 2 groups ($P = .59$). None of the patients in the groups developed TUR syndrome. Five (4.16%) and 6 (5%) of patients who underwent B-TUERP and B-TURP respectively had bleeding, requiring blood transfusion (all of them had a prostate size of more than 70 gm). After a year of follow-up, only 1 (0.9%) patient in the B-TUERP had urethral stricture and none in the patients of the B-TURP group. Two (1.9%) and 3 (2.7%) of the patients who underwent B-TUERP and B-TURP respectively developed urinary incontinence. Overall, there was no significant difference in the incidence of complications in the 2 groups. See Table 2.

DISCUSSION

BPH is a common disease in aging men, resulting in cumbersome LUTS.[8]

TURP is still the mainstream line of management for relieving outlet obstruction in men with BPE, when medical therapy fails, due its fast, postoperative recovery and low mortality.[2,9] On the other hand, M-TURP is associated with a complication rate ranging between 7% and 43% and a mortality rate around 0.2%.[10]

Bipolar resection has challenged monopolar TURP, the gold standard of BPE treatment, boosting its safety profile by using saline as irrigation fluid.[11] Nowadays, B-TURP has been advocated as an alternative to monopolar TURP.[12]

Ideal TURP should involve accurate, complete removal of the adenoma. However, when performing traditional TURP, it is difficult to accurately judge the boundary between outer and inner glands and the depth of excision. This often results in excessive resection which may induce capsular perforation, or result in insufficient removal of the adenoma.[13]

Transurethral resection can achieve the removal of about 53% of the total prostate volume only.[14] Resected adenomas have been reported to recur in at least 15% of cases in long follow-up that required repeat surgical intervention. This may be due to incomplete removal of these obstructing prostatic adenomas rather than recurrent of denomas after adequate resection.[15]

Also, when the volume of the prostate gland is large, for example, significantly above the level of the verumontanum, the surgeon often does not cut enough prostatic tissue at the apex due to serious concern over damaging the urethral sphincter and causing incontinence.[16]

TUERP is a technique that replicates the open enucleation of prostatic adenomas in an endoscopic fashion, combining the benefits of complete removal of adenoma in a minimally invasive approach.[17]

With regards to its efficacy, in our study, B-TUREP achieved a better outcome in: IPSS, Qol, residual prostate volume, Qmax, and PVRU. This is mainly attributed to the more complete removal of the adenoma. This statistically significant outcome was in agreement with the results of Kan et al, who reported that patients with bipolar enucleation had better IPSS (6.4 vs 11.6, $P = .032$), QOL (1.7 vs 2.6, $P = .040$), and peak flow rate (19.5 vs 15.1 mL/s, $P = .019$) but that the residual prostate volume had no significant difference between the 2 groups. They attributed this to the method they used to measure prostate size. Moreover, they reported no significant difference in the PVRU between the 2 group.[6] Also, Wei et al found out that there were significantly better postoperative IPSS and Qmax in the B-TUERP group than in the B-TURP group ($P < .05$ for both) but the postoperative QoL score and PVRU were similar ($P > .05$).[5] This data agreed with meta-analysis from Ahyai when comparing laser enucleation of the prostate with the resection technique.[18] On the other hand, while Liao and Yu, Zhang et al, and Luo et al noticed no significant difference between the 2 groups in IPSS, QOL, Qmax PVRU during follow-up, Zhang et al reported that the PVRU was better in the B-TUERP group (13.8 +/−19.5 vs 25.2 +/−18.7 mL; $P < .01$).[19,20,21] Zhu et al reported no significant difference in the early 2-year postoperative but in longtime follow-up the results were significantly better in the enucleation group.[22]

In our study, the operative time for the B-TUERP was significantly longer than the B-TURP which may be attributed to that B-TUERP is a newer technique with difficult learning curve. You may need at least 50 case to get familiar with this technique. Kan et al reported a

Table 2. Perioperative and postoperative parameters in the 2 groups

	Group		
	B-TUERP Mean ± SD	B-TURP Mean ± SD	*P* Value
Operative time (min)	105.09 ± 31.08	61.09 ± 29.28	<.001
Catheter time (h)	43.89 ± 8.62	54.03 ± 6.08	<.001
Postoperative irrigation time (h)	10.36 ± 3.58	18.91 ± 4.21	<.001
Intraoperative irrigation fluid volume (L)	18.86 ± 3.44	14.78 ± 3.33	<.001
Weight of resected tissue (gm)	50.41 ± 13.07	41.12 ± 8.91	<.001
Hospital stay (h)	52.53 ± 5.17	60.41 ± 6.13	<.001
Postoperative assessment after 1, 6, and 24 mo			
	Group		
	B-TUERP Mean ± SD Median (IQR)	B-TURP Mean ± SD Median (IQR)	*P* Value
IPSS			
1 mo	15 (10-18)	19 (15 -22)	<.001
6 mo	12 (9-15)	13 (10-21)	.002
24 mo	6 (3-9)	7 (7-8)	.009
QoI			
1 mo	2.5 (1-4)	3 (2-4)	.011
6 mo	2 (1-3)	2.5 (2-4)	<.001
24 mo	1 (0-2)	2 (1-2)	.243
Qmax			
1 mo	19 ± 4.34	15.42 ± 4.42	<.001
6 mo	22 ± 6.23	18.96 ± 6.50	.764
24 mo	24.9 ± 5.74	20.09 ± 3.27	.034
PVRU			
1 mo	22.06 ± 9.92	32.63 ± 9.07	<.001
6 mo	19.43 ± 1.23	22.72 ± 2.84	.022
24 mo	18.64 ± 3.28	24.74 ± 4.02	.001
TPSA			
1 mo	1.79 ± 0.91	2.17 ± 0.60	<.001
6 mo	1.43 ± 0.64	1.55±.0.60	.158
24 mo	0.49 ± 0.500	0.87 ±.0.50	.001
Residual prostate volume			
1 mo	26.47 ± 11	34.78 ± 5.15	<.001
6 mo	19.8 ± 4.18	22.24 ± 4.37	<.001
24 mo	18.64 ± 3.28	20.74 ± 4.02	<.001

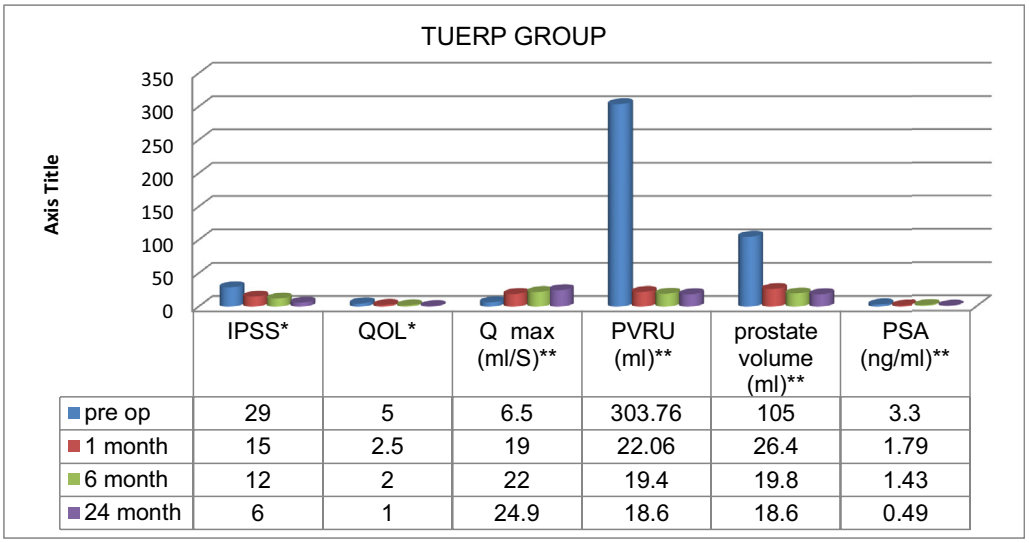
Complications of the 2 groups

		Group				
		B-TUERP		B-TURP		*P* Value
Change in sodium (mmol/L) Median (IQR)		1 (2-4)		1 (0-2)		.59
Change in haemoglobin (g/dL) median (IQR)		1.5 (0.9-2.5)		2 (1.3-3.3)		<.001
Blood transfusion	No	115	95.83%	114	95%	.758
	Yes	5	4.16%	6	5%	
Urethral stricture	No	105	99.1%	113	100.0%	.484
	Yes	1	0.9%	0	0.0%	

Abbreviations: B-TUERP, bipolar transurethral enucleation and resection of the prostate; IPSS, international prostate symptom score; PVRU, post-voiding residual urine volume; TPSA, total prostate specific antigen.

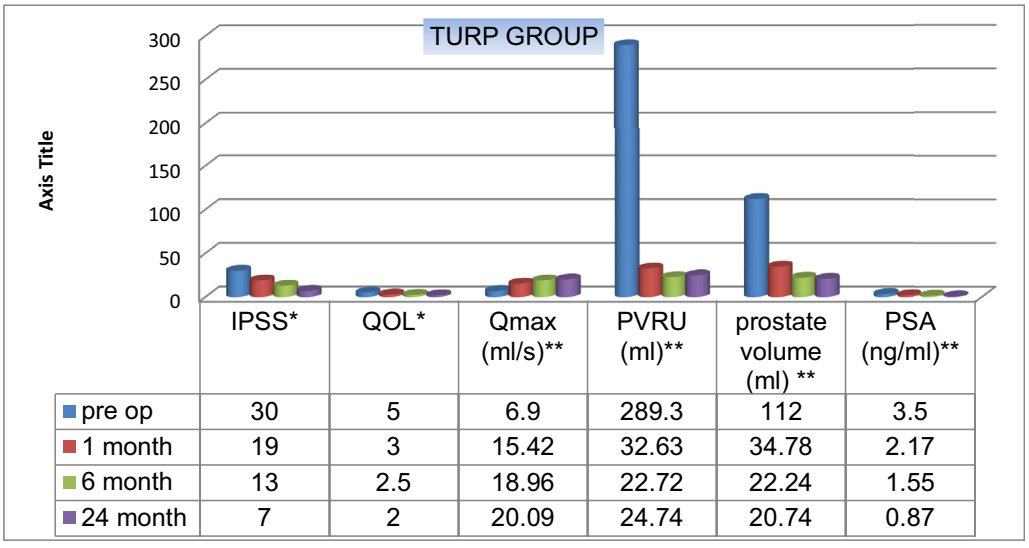
significant longer operative time in the enucleation group (156 vs 87 min, $P = .000$).[6] On the other hand, Wei et al reported that B-TUERP required significantly shorter time than the B-TURP (73.37 ± 19.99 vs 83.77 ± 20.89 min, $P < .001$). Also, Zhang et al found that the operative time was shorter in the B-TUERP technique (42.3 ± 5.4 vs 65.8 ± 29.3 min, $P < .01$).[5,20] Luo et al recorded that enucleation of the prostate had longer operative time for prostate volume <60 mL(56.1 ± 14.6 vs 41.3 ± 9.6 min; $P < .001$), but shorter operative time for prostate volume >60 mL (75.6 ± 12.3 vs 88.7 ± 14.3 minutes; $P < .001$).[21] Zhu et al and Liao and Yu reported no statistically different between both groups with regards to the operative time.[22,19]

In our study, B-TUERP resulted in a greater volume of prostatic tissue removal than the B-TURP. This can be explained by the fact that the adenoma is removed along the surgical capsule in the B-TUERP technique. This is consistent with Kan et al, who noted more prostate tissue resected in the bipolar enucleation group (61.4 vs 45.7 g, $P = .000$).[6] Also Zhu et al, Wei et al, and Zhang et al reported that the weight of resected prostatic tissue was significantly greater in the B-TUERP group.[22,5,20] On the other hand Liao and Yu, and Lou et al, reported that there



	IPSS*	QOL*	Q max (ml/S)**	PVRU (ml)**	prostate volume (ml)**	PSA (ng/ml)**
pre op	29	5	6.5	303.76	105	3.3
1 month	15	2.5	19	22.06	26.4	1.79
6 month	12	2	22	19.4	19.8	1.43
24 month	6	1	24.9	18.6	18.6	0.49

(A) * median , ** mean



	IPSS*	QOL*	Qmax (ml/s)**	PVRU (ml)**	prostate volume (ml) **	PSA (ng/ml)**
pre op	30	5	6.9	289.3	112	3.5
1 month	19	3	15.42	32.63	34.78	2.17
6 month	13	2.5	18.96	22.72	22.24	1.55
24 month	7	2	20.09	24.74	20.74	0.87

(B) * median , **mean

Figure 2. Treatment efficacy over 2 years (A) TUERP group, (B) TURP group. (Color version available online.)

were no significant differences in resected tissue weight between the 2 group.[19,21]

Due to excellent hemostasis in B-TUERP, as the bleeding is controlled once the adenoma is lifted off the surgical capsule while in B-TURP these blood vessels cause repeated bleeding episodes as they are repeatedly cut during the procedure until the surgical capsule is reached, the indwelling catheter time, postoperative bladder irrigation duration, and hospital stay were shorter in B-TUERP, which is in agreement with the results of Wei et al and Zhu et al.[22] However, Liao and Yu and Luo et al noted that there was no significant difference in postoperative catheterization time and postoperative hospital stay.[19,21] Also, Kan et al found that there was no significant difference in hospital stay between the 2 procedures.[6]

Excessive intraoperative absorption of irrigation fluid may lead to TUR syndrome, and the use of saline for irrigation can reduce this risk.[23] In our study, change in sodium level wasn't statistically different between the 2 groups and none of our patients developed TUR syndrome. The data corresponded with the results of Kan et al and Luo et al.[6,21] On the other side, Wei et al reported that no TUR syndrome was developed but there was significant lower incidences of hyponatremia in the B-TUERP group ($P = .139$) and explained this by citing longer operative time and greater intraoperative blood loss associated with the B-TURP procedure.[5]

Again due to excellent hemostasis in B-TUERP, the decrease in hemoglobin level was significantly lower in B-TUERP. However, the need for blood transfusion was not

significantly different between the 2 group. This in agreement with Luo et al who reported significantly less blood loss in the enucleation group especially for prostate volume >60 mL (167.6 ± 44.4 vs 225.7 ± 49.5 mL; $P < .001$).[21] Also Wei et al and Zhu et al reported that the blood loss and blood transfusion was significantly lower in the B-TUERP group.[5,22] At the same time Liao and Yu and Liu et al, reported less blood loss in the enucleation group.[19,16] On the other hand, Kan et al reported more hemoglobin drop (1.8 vs 1.1 g/dL, $P = .006$) in the enucleation group but this drop was clinically insignificant with no difference in the overall transfusion requirement. They cited this as due to longer operative time.[6]

With regard the long-term complications such as "urethral stricture and urine incontinence," our study found no significant different between the 2 groups. This is in agreement with Zhu et al, Kan et al, and Luo et al.[22,6,21] Conversely, Wei et al reported a higher incidence of overall postoperative complications in the bipolar group but no difference in both groups in urinary incontinence after 3 months, as well as urethral stricture and bladder neck contracture.[5]

The main limitation of our study was the relatively short follow-up course and the inability to measure intraoperative blood loss. So, further studies with longer follow-up are needed to assess the durability of the enucleation technique.

CONCLUSION

When placed in comparison with B-TURP, bipolar enucleation is a safe and more effective approach in the treatment of BPH.

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