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Benign Prostatic Hyperplasia: Enucleation versus Resection Using Plasmakinetic Energy: A Prospective Randomized Study at Zagazig University Hospital

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ABSTRACT

Background: Transuretheral resection of the prostate (TURP) has been the gold standard endoscopic treatment for bladder outlet obstruction (BOO) secondary to benign prostatic hyperplasia (BPH). New technologies have been developed to minimize the morbidity of TURP. Recently, the Gyrus Plasma Kinetic (PK) System is the first bipolar device used in urological practice, as a new modality in treatment of BPH.

Objective: To evaluate the efficacy and safety of plasmakinetic enucleation compared to plasmakinetic resection of the prostate in the management of BOO induced by BPH. **Patients and Methods:** This study was conducted on 58 volunteers from Department of Urology, Faculty of Medicine, Zagazig University between January 2018, and January 2020. Patients were randomized to either plasmakinetic enucleation of the prostate (PKEP) group or plasmakinetic resection of the prostate (PKRP) group. All patients were indicated for surgical treatment (prostate size ≥ 60 g and ≤ 120 g). **Results**: There were no statistically significant differences between the two groups preoperatively. PKEP resulted in a greater volume of prostatic tissue removal than the PKRP. Tissue retrieved/total operative time in PKEP group was greater than in PKRP group (0.69 gm/min vs 0.67 gm/min respectively). The mean indwelling uretheral catheter time was shorter in PKEP group (34.7 ±4.40 hrs.) than in PKRP (48.79 ±4.31 hrs.). Regarding postoperative complication (early and late), there were no statistically significant differences between the two groups.

Conclusions: We concluded that regarding, surgical safety and efficacy PKEP is comparable to PKRP for prostates (60-120 ml). Either PKEP or PKRP can be on an equal footing to TURP as an endoscopic management of BPH.

Keywords: BOO, BPH, PKEP, PKRP, TURP, Urinary tract.

INTRODUCTION

Benign prostatic hyperplasia (BPH) is a common urologic disorder that affects 33.5% of men aged 60 to 70 years**.** About 75% of men >50 years of age have symptoms due to BPH, and 20–30% of men reaching 80 years of age require surgical intervention for the management of BPH**.** BPH can result in lower urinary tract symptoms (LUTS). There are many types of therapy available for patients with BPH including watchful waiting, medical management, endoscopic treatment and open surgery. Transurethral resection of the prostate (TURP) has been the gold standard endoscopic treatment for BOO secondary to BPH and is considered to be safe and effective **[1].**

In recent decades monopolar TURP morbidity has continuously decreased. The perioperative complications as clots' retention (2 vs 5%), blood transfusion (0.4 vs 7.1%), urinary tract infection (1.7 vs 8.2%), urinary retention (3 vs 9%) and capsular perforation (6.2 vs 17.3%) were significantly decreased in recent M-TURP studies compared to the earlier series. On the other hand, late-term complications such as bladder neck contracture (BNC) (3.8 vs 4.7%) and urethral stricture (3.8 vs 4.1%) remained stable **[2].**

Among the most important recent innovation was the introduction of holmium laser enucleation of the prostate (HoLEP). Since its inception in 1996, HoLEP has been rigorously studied and has demonstrated long-term clinical improvement and a low rate of complications**.** Despite proven efficacy, HoLEP has not become widely used because of the perceived steep learning curve and the costs associated with high power holmium laser systems **[3]**.

In the era of minimally invasive treatment, various new technologies have been developed to minimize the morbidity of TURP. Recently, the Gyrus PlasmaKinetic (PK) System is the first bipolar device used in urological practice, as a new modality in treatment of benign prostatic hyperplasia**.** The transurethral plasmakinetic resection of the prostate (PKRP) provides a new minimally invasive surgical option for treatment of BPH. In this technology, high frequency current runs between an active and passive electrode, converting the irrigation solution (electroconductive solution) into a plasma layer energy that disintegrates tissue on contact **[4].** Compared with conventional TURP, PKRP has been accepted as a safer and more effective therapy for BOO induced by BPH**.** The PKRP technique has been further refined by the development of PK technology that allows enucleation of the prostate. Plasma kinetic enucleation of the prostate (PKEP) is technically feasible and a safe procedure **[5].**In the present study, we aimed to evaluate the efficacy and safety of plasmakinetic enucleation compared to plasmakinetic resection of the prostate in the management of BOO induced by BPH.

PATIENTS AND METHODS

This study was carried out at Department of Urology, Faculty of Medicine, Zagazig University

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between January 2018, and January 2020. A randomized Clinical trial was carried out using computer generated random table in 1:1 ratio.

Inclusion criteria: Any patients scheduled for TURP due to BPH: (failure of medical treatment for BPH or patients with refractory urinary retention, recurrent urinary tract infection, recurrent hematuria..., etc.) with the following criteria: IPSS > 8, Qmax ≤ 15 with voided urine volume >150 ml, PVR urine ≤ 200 ml. Prostatic volume ≥ 60 gm as measured by transrectal ultrasound (TRUS) and ≤ 120 gm.

Exclusion criteria: Patients unfit for anesthesia. Severe skeletal deformity (scoliosis.., etc.), Uncorrectable coagulopathy, Prostatic volume < 60 gm and >120 gm as measured by TRUS. Patient with urethral stricture. Patients with bladder pathology (Bladder stone, bladder mass). Patients with history of urethral or prostatic surgery. Suspected malignant disease of lower urinary tract (cancer prostate). Patient with neurogenic bladder dysfunction.

Subjects and Grouping: The study included a total number of 58 subjects. Studied subjects were divided randomly according to treatment procedure into two groups: 29 patients who were treated with Bipolar (Plasmakinetic) enucleation of the prostate (PKEP) and 29 patients who were treated with Bipolar (Plasmakinetic) resection of the prostate (PKRP).

Operational Design:

A- Preoperative evaluation:

- All the patients were subjected to complete clinical evaluation with special emphasis on: 1- History taking (previous prostatic, urethral surgery or medical disease (pulmonary or cardiac diseases)) with special attention to recurrent urinary infection, retention, bleeding disorders, and anticoagulant therapy. 2- Voiding symptoms and quality of life (QoL) were graded according to the IPSS and its QoL assessment index. 3- Physical examination and local examination included Digital Rectal examination (DRE).
- Radiological investigation: Pelvi-abdominal ultrasound to assess PVR urine and assessment of kidneys and bladder. Transrectal ultrasound (TRUS) for accurate estimation of the prostate size and full scanning of prostate, rectum, and bladder base.
- Special investigations: Uroflowmetry study to determine flow time, pattern of voiding and voided volume.

B- Operative steps:

- Anesthesia: for both groups, procedure was performed with the patient under spinal or epidural anesthesia according to anesthesiologist evaluation. Prophylactic antibiotic: was taken within 60 min before starting the procedure. The patient was placed in lithotomy position. Using magnified image on video monitor. Blood transfusion was initiated when serum hemoglobin (Hb) was <8 g/dL or symptoms of acute blood loss were apparent. All endoscopic interventions were performed by the same senior surgeon who had extensive experience in BPH minimally invasive surgery.
- Operative technique: Urethra-cystoscopy was performed for evaluation of the urethra, prostate, ureteral orifices and bladder. Urethral dilation using serial urethral sounds with copious amounts of lubricating jell. Insertion of 26 fr continuous flow resectoscope with saline irrigation and plasmakinetic device. Irrigation by normal saline solution (0.9% NaCl) at height about 60 cm from the operating table.
- Regarding prostatectomy technique: Bipolar transurethral enucleation of the prostate (Group A): done by using **the 'mushroom' technique**. Bipolar resection of the prostate (Group B): done by using **The Mauermayer technique**.

C- Postoperative care:

- The patient was monitored by experienced recovery room staff for initial postoperative period. Pulse, blood pressure, oxygen saturation, irrigation inflow and outflow volumes, degree of hematuria, body temperature and abdominal examination were recorded. The specimen was measured then prepared was sent for histopathological examination. Saline Irrigation continued until the catheter drainage became clear. The catheter was removed 48 hours after stoppage of irrigation. The patient discharged for follow up at outpatient clinic with recommendation of quinolones for one week. The patient was instructed to avoid straining, constipation and to come back after 1week to receive the result of histopathology. Follow up visits were scheduled at 1, 3, 6 months, and one year.

Ethical consent:

An approval of the study was obtained from Zagazig University Academic and Ethical Committee. Every patient signed an informed written consent for acceptance of the operation and participation in the study. This work has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.

Statistic analysis

Data were imported into Statistical Package for the Social Sciences (SPSS version 20.0) software for analysis. According to the type of data; qualitative were represented as number and percentage and quantitative were represented by mean ± standard deviation (SD), and range. Difference and association of qualitative variable were calculated by Chi square test (X^2) and Fisher exact test. Differences between quantitative independent data were calculated by t test and paired data by paired t test. P value was set at <0.05 for significant results and <0.001 for high significant result.

RESULTS

This table (1) shows that there was no statistically significant difference between both groups regarding demographic and clinical data.

Table (1): Demographic Characteristics of the studied groups

Variable			Group I Enucleation (n=29)		Group II Resection (n=29)		P
Age in years (Mean ± SD) Range			66.38 ± 3.45 58 - 73		65.86 ± 3.14 61 - 71		0.55
BMI: (Mean ± SD) Range			29.44 ± 3.84 24 - 35		29.18±3.15 23 - 34		0.78
Variable			**No**	**%**	**No**	**%**	**P**
Comorbidity	No	Total	13	44.8	12	41.4	0.80
	Yes	Total	16	55.2	17	58.6	
		DM	7	24.1	8	27.6	
		HPT	7	24.1	6	20.7	
		Other	2	6.9	3	10.3	
Smoking	No		20	69	22	75.9	0.56
	Yes		9	31	7	24.1	

SD: Standard deviation,

Table 2 shows that there was no statistically significant difference between studied groups regarding clinical presentation. The most common presentation was voiding symptoms not responding to medical treatment.

Table (2): Clinical presentation among the studied groups

Clinical presentation	Group I Enucleation (n=29)		Group II Resection (n=29)		P
	No	**%**	**No**	**%**	
Refractory urine Retention	7	24.1	7	24.1	0.94
Recurrent Hematuria	5	17.2	6	20.7	
Voiding symptoms	17	58.6	16	55.2	

This table shows that the mean operative time for PKRP group was statistically significantly lower than that for PKEP group. The mean weight of retrieved tissue and weight of retrieved tissue / operative time for PKEP were significantly higher than that for PKRP group. However, mean volume of intraoperative irrigation fluid was significantly lower in PKRP group than that of PKEP group. There was a statistical significant increase in duration of postoperative uretheral catheterization and hospital stay among PKRP group compared to PKEP group (table 3).

Table (3): Operative data, intraoperative complications and perioperative data among the studied groups

Variable	Group I Enucleation (n=29)		Group II Resection (n=29)		P
Operative data					
Operative time (min), (Mean ± SD)	84.97±5		81.76±4.75		0.02*
Tissue removed (gm), (Mean ± SD)	60.34±8.1		55.34±5.87		0.009*
Weight of tissue / time (gm/min) (Mean ± SD)	0.69±0.09		0.67±0.06		0.02*
Volume of irrigation (L), (Mean ± SD)	35.1±2.56		33.4±2.82		0.004*
Intraoperative complications					
Blood transfusion	1	3.4	2	6.9	0.64
Capsular perforation	2	6.9	1	3.4	
Anesthesia complication	2	6.9	1	3.4	
Perioperative data					
Irrigation (L), Mean ± SD	5.11±0.48		5.13±0.47		0.87
Duration of catheterization (hours), Mean ± SD	34.7±4.40		48.79±4.31		<0.001**
Hospital stays (hours). Mean ± SD	38.31±3.87		52.55±3.74		<0.001**

SD: Standard deviation, *: Significant (P<0.05), **: Highly significant (P<0.001)

There was no statistically significant difference in perioperative hemoglobin changes in both groups meanwhile; there was a statistical significance drop in Hb level postoperatively in both groups, being more in PKRP group compared to PKEP group.

Table (4): Perioperative Hb level change among the studied groups

Variable		Group I Enucleation (n=29)	Group II Resection (n=29)	P
Pre Hb (gm/dl)	Mean ± SD	13.54±0.74	13.52±0.7	0.94
Post Hb (gm/dl))	Mean ± SD	11.7±0.37	10.73±0.36	**<0.001****
P		<0.001**	0.03*	
Drop	Mean ± SD	1.82±0.90	2.79±0.88	**<0.001****
Drop	**%**	**13.59%**	**20.64%**	

SD: Standard deviation, **: Highly significant (P<0.001)

Regarding differences between pre- and postoperative readings there was a highly statistical significance decrease in IPSS at (1, 3, 6 and 12 months) postoperatively compared to basal in both groups (Table 5).

Table (5): IPSS change among the studied groups

IPSS		Group I Enucleation (n=27)	Group II Resection (n=28)	P
Pre-operative	**Mean ± SD**	26.54±4.31	26.78±4.41	0.84
Post 1 month	**Mean ± SD**	5.62±0.70	5.82±0.79	0.33
Post 3 months	**Mean ± SD**	6.62±1.44	7.04±1.6	0.32
Post 6 months	**Mean ± SD**	6.35±1.35	6.52±1.28	0.64
Post 12 months	**Mean ± SD**	5.69±0.88	5.78±0.93	0.73
P		<0.001**	<0.001**	
P (post-hoc test)		<0.001**[1] <0.001**[2] <0.001**[3] <0.001**[4]	<0.001**[1] <0.001**[2] <0.001**[3] <0.001**[4]	
Improvement at one year	Mean ± SD	20.85±4.27	21.0±4.22	0.90
% Of improvement at one year	%	78.56%	78.42%	

SD: Standard deviation P1: Basal versus 1 month, P2: Basal versus 3 months, P3: Basal versus 6 months, P4: Basal versus 12 months, **: Highly significant (P<0.001).

There was statistically high significant improvement in IIEF-5 within each individual group on follow up (Table 6).

Table (6): Comparison between the studied groups regarding IIEF-5

	Enucleation group (N=27)	Resection group (N=28)	P
	Mean ± SD	**Mean ± SD**	
Preoperatively	13.64 ± 4.37	14.7± 4.58	0.358
3 months postop.	13.69 ± 2.99	15.3 ± 3.76	0.775
6 months postop.	16.69 ± 2.99	16.2 ± 2.48	0.17
12 months postop.	16.8 ± 2.44	17.09 ± 3.34	0.776
P	<0.001**	<0.001**	
% Improvement at 1 year	23.16 %	16.25 %	0.308

**: Highly significant (P<0.001).

This table shows that the mean ±SD at 3, 6 and 12 months was (1.23±0.43 vs. 1.26±0.45), (1.31±0.47 vs 1.33±0.48) and (1.27±0.45 vs. 1.33±0.48) for PKEP and PKRP groups respectively as shown in table 9. There was no statistical significance difference between the two groups in QoL basal or post-operative at any time of follow up. Regarding differences between pre and post-operative readings there was a highly statistical significance decrease in QoL at (1, 3, 6 and 12 months) compared to basal in both groups.

Table (7): QoL change among the studied groups

QOL		Group I Enucleation (n=27)	Group II Resection (n=28)	P
Preoperative	Mean ± SD	4.31±0.74	4.22±0.80	0.69
Post 3 months	Mean ± SD	1.23±0.43	1.26±0.45	0.81
Post 6 months	Mean ± SD	1.31±0.47	1.33±0.48	0.85
Post 12 months	Mean ± SD	1.27±0.45	1.33±0.48	0.62
P		**<0.001****	**<0.001****	
P (post-hoc test)		**<0.001**1** **<0.001**2** **<0.001**3**	**<0.001**1** **<0.001**2** **<0.001**3**	
Improvement at one year	Mean ± SD	3.04±0.82	2.89±0.93	0.54
% Improvement at one year	%	70.53%	68.48%	

SD: Standard deviation P1: Basal versus 3 months, P2: Basal versus 6 months, P3: Basal versus 12 months,
**: Highly significant (P<0.001)

DISCUSSION

BPH can result in lower urinary tract symptoms (LUTS). There are many types of therapy available for treatment of symptomatic BPH including watchful waiting, medical management, Endoscopic treatment and open surgery [(6)].

Open prostatectomy is effective in managing adenoma larger than 80 gm. However, the role of open prostatectomy is decreased due to its increased morbidity and invasiveness compared to newer endoscopic modalities in management of symptomatic BPH [(7)].

Compared with PKRP, PKEP is safe and effective method for the treatment of BPH more than 80 ml, but PKEP has the advantages of complete gland resection, precise surgery, shorter operation time, less bleeding, high safety during operation, and fewer postoperative complications. PKEP is effective for treating all prostates regardless of volume, it is more efficient for the large ones [(8)]. **Luo *et al.*** [(9)] found no differences in functional outcomes in patients undergoing PKEP according to prostate volume (< or > 60 mL).

European Association of Urology (EAU) guidelines recommend both PKEP and HoLEP as first-line treatment option for larger (> 80 mL) prostates. To note, some authors suggested that PKEP is associated with lower costs [(10)]. With mushroom technique, we can fragment the enucleated lobe without need for morcellator for prostatic tissue retrieval. Although this process without morcellation may take more time, the whole lobes of the prostate still can be fragmented into pieces very rapidly and bloodlessly using the conventional PK cutting loop [(6)]. No morcellation was performed in all described techniques, except for **Geavlete *et al.*** [(11)]**.** Notably, morcellation is a fundamental step during HoLEP, whereas this is not the case for b-EEP. Indeed, the instrument features allow resecting the adenoma using the instrument loop with decrease costs and morbidity of using morcellator [(12)].

In this study, the safety, and the efficacy of PKEP were compared with PKRP and our results were compared to similar previous studies.

In our study the mean preoperative prostate volume by TRUS was 90.31 ± 11.28 ml. and 89.45 ± 10.66 ml. for PKEP and PKRP groups, respectively. The mean weight of prostatic tissue retrieved by PKEP and PKRP was 60.34 gm ± 8.1 (66.81% of preoperative prostate volume) and 55.34 gm ± 5.87 (61.86% of preoperative prostate volume) respectively with more tissue yield in PKEP group.

In our study, PKEP resulted in a greater volume of prostatic tissue removal than the PKRP. This can be explained by the fact that the adenoma is removed along the surgical capsule in the PKEP technique. This is consistent with **Kan *et al.*** [(13)], who noted more prostate tissue retrieved in the bipolar enucleation group (61.4 vs 45.7 g). Also **Wei *et al.***, and **Zhu *et al.***, reported that the weight of resected prostatic tissue was significantly greater in the B-TUERP group [(14,15)]. On the other hand **Liao and Yu**[(6)]**, and Luo *et al.*** [(9)]**,** reported that there were no significant differences in retrieved tissue between the 2 groups.

Regarding mean operative time, in our study, it was 84.97±5 min. in PKEP group and 81.76 min. in PKRP group with more tissue yield in PKEP group 60.34 gm ± 8.1 vs 55.34 gm ± 5.87 in PKRP group. Tissue retrieved/total operative time) was 0.69 gm/min in PKEP group vs 0.67 gm/min in PKRP group. **Hirasawa *et al.*** [(1)] reported more tissue retrieved/operative time in PKEP group 0.54 gm/min vs 0.45 gm /min for PKRP group. Also, **Liao and Yu**[(6)] reported more tissue retrieved /operative time as it was 0.71 gm/min for PKEP group and 0.61 gm/min for PKRP group**,** which are comparable to our results.

In our study, the mean indwelling uretheral catheter time was shorter in PKEP group (34.7 ±4.40 hrs.) than in PKRP (48.79 ±4.31 hrs.). Hospital stay was shorter in PKEP group (38.31±3.87 hrs.) than in PKRP group (52.55±3.74 hrs.). This is attributed to good hemostasis in PKEP procedure. **Samir *et al.* [16]** reported that, the mean indwelling uretheral catheter time was shorter in PKEP group (43.89 ±8.62 hrs.) than in PKRP (54.03 ±6.08 hrs.). Hospital stay was shorter in PKEP group (52.53±5.17 hrs.) than in PKRP group (60.41±6.13 hrs.), which are comparable to our results.

Hirasawa *et al.* [1] reported shorter catheter time in PKEP group (44.9 hrs.) than PKRP group (64.6 hrs.). Also, hospital stay was shorter in PKEP group (68.9 hrs.) than in PKRP group (88.6 hrs.) which are comparable to our results.

Again, due to excellent hemostasis in PKEP group, the decrease in hemoglobin level was significantly lower in PKEP group 1.82 ± 0.90 gm vs 2.79 ± 0.88 gm in PKRP group. However, the need for blood transfusion was not significantly different between the 2 groups, one case in PKEP group vs two cases in PKRP group. This in agreement with **Luo *et al.* [9]** 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 < 0.001). Also **Wei *et al.* [14] and Zhu *et al.* [15]** reported that the blood loss and blood transfusion was significantly lower in the B-TUERP group. On the other hand, **Kan *et al.* [13]** reported more hemoglobin drop (1.8 vs 1.1 g/dL, P = 0.006) 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.

In our study follow up visits were scheduled at 1, 3, 6 and 12 months for patients enrolled in the study for IPSS, assessment of QoL. Both PKEP and PKRP had high significant improvement in these parameters with no significant differences between them. **Luo *et al.* [9]** reported that no significant differences between the PKEP and PKRP groups in IPSS and QoL, which are in agreement with our study**. Liao and Yu[6]** reported that there was significant improvement from baseline in terms of IPSS, QoL and PVRU volume values in both PKEP and PKRP groups with no significant difference was found between them, which is in agreement with our study**.**

Regarding IIEF-5, there was significant improvement in both studied groups at one year follow-up (23.16 % for enucleation group and 16.25 %for resection group), with no significant difference between both groups.

Treatment for BPH can improve Erectile Function (EF) concomitantly with LUTS improvement. However, surgical intervention for BPH may harm EF due to erectile nerve and vascular injury along with psychological factors [17]. **Xu *et al.* [18],** reported improvement in IIEF-5 for patients undergoing BPEP at 24 months of follow-up, which is in agreement with our results. **Jiang *et al.* [8]** found that the postoperative ILEF-5 scores in both groups (PKEP and PKRP) were conspicuously lower after surgery, but there was no significant difference in the postoperative ILEF-5 score and the incidence of ED between the 2 groups. This may be because prostate glands with a volume larger than 80 ml have more severe compression of the erectile nerve outside the capsule, which leads to chronic ischemia of the erectile nerve and affects the erectile function of BPH patients, this in contrast with our results.

In our study, all the cases were performed by one surgeon to avoid the effect of the difference in the experience of operators. On the other hand, the main limitation of this study is the short-term follow up. A long-term follow up is mandatory to confirm our results for the comparable efficacy and safety of both techniques.

CONCLUSION

The results of our study suggest regarding, surgical safety and efficacy PKEP is comparable to PKRP for prostates (60-120 ml). Either PKEP or PKRP can be on an equal footing to TURP as an endoscopic management of BPH. We experienced more preference to PKEP as we are more familiar with instruments used in PKEP.

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