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THE INITIAL CLINICAL EXPERIENCE OF A NEW GENERATION BIPOLAR ELECTROSURGICAL AND MORCELLATOR UNIT FOR BIPOLAR TRANSURETHRAL ENUCLEATION OF THE PROSTATE

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ABSTRACT

Background and Objective

To assess the feasibility and safety of performing bipolar transurethral enucleation of the prostate (BIPO-LEP) with a new generation of bipolar electrosurgical and morcellator system.

Material and Methods

Forty-five consecutive patients scheduled for endoscopic surgery for benign prostatic obstruction were prospectively recruited. BIPOLEP was performed with the use of the third generation Karl Storz AUTOCON III 400 and morcellator unit. All patients had a trial without a catheter on Day-1 after surgery. Demographical, preoperative, intraoperative and follow-up data up to 3 months post-surgery were collected and analyzed.

Results

Between May 2018 and April 2019, 45 consecutive patients underwent BIPOLEP in our institution were prospectively recruited for this study. The mean age was 76 years old. Thirty-four patients (75.6%) were in refractory retention or obstructive uropathy. The mean enucleation efficiency was 1.76 grams per minute of enucleation time (SD = 0.7 gram per minute). The mean bladder irrigation and catheterization times were 5.3 hours and 20.7 hours respectively. Only one patient failed voiding trial on Day-1 after surgery. The postoperative Day-1 discharge rate was 73.3% (n = 33). The median length of hospital stay was 1 day. No patient required clot evacuation or blood transfusion. Seven patients (15.6%) were readmitted within thirty days postoperatively for complications, due to hematuria (8.9%, n = 4) and febrile urinary tract infection (6.7%, n = 3). Nevertheless, none was readmitted for acute urinary retention.

Conclusion

The use of a new generation of bipolar electrosurgical and morcellator unit for BIPOLEP was safe and the majority could be discharged without catheter within one day after surgery.

Key Words: Benign Prostatic Hyperplasia, Bipolar Enucleation of Prostate

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Benign prostatic obstruction (BPO) may be addressed endoscopically by resection, enucleation, vaporization, or a combination of these techniques using a wide variety of energy modalities. The traditional gold standard treatment is transurethral resection of the prostate (TURP). However, in TURP, the removal of prostatic tissue is commenced from the luminal part and does not follow the anatomical plane. Therefore, it may increase the risk of bleeding from the resected raw surface in both intra- and postoperative periods. Enucleation is a mimicked to traditional open prostatectomy, where surgery is commenced from the surgical plane between the adenomas residing in the transitional and peripheral zone. As a result, the blood supply to the main obstructing prostatic tissue will be controlled first, leaving behind a relatively devascularized prostatic tissue for subsequent resection or morcellation, which in turn would help to decrease perioperative bleeding. This together with the potential of more complete removal of obstructing prostatic tissue is the potential benefit of enucleation over traditional TURP. As a result, enucleation has emerged as a new standard treatment enlarged prostates with a size of 80 mL or above.¹

Currently, there were many reports on the usage of bipolar transurethral enucleation of the prostate (BIPOLEP) in different series with satisfactory outcomes^{2–12} (Table 1). However, most of these studies still reported prolonged postoperative irrigation time, catheter time and also hospital stay. While some of these might be related to the difference in clinical practises in different centres, it might also be related to the less than ideal hemostasis by the current endoscopic system and hence longer irrigation and catheter time was required. All these would inevitably increase workload to staffs and hospitals, as well as affect the recovery of the patients. Enhanced Recovery After Surgery (ERAS) protocol was an important topic in the surgical field, ¹³ which has proven beneficial to patients, staffs and also hospital management. Therefore,

TABLE 1 Summary of Different Series of Bipolar Enucleation of Prostate (BIPOLEP)

	Number of patients	Mean prostate tissue resected *	Mean Irrigation time*	Mean Catherization time*	Mean Discharge time*
Geavlete B et al. 2013 ²	80	98.7 gm	1.2 days	1.6 days	2.5 days
Giulianelli R et al. 2015 ³	50	Median 50 gm	90 % patients > 24 hrs	24% patients > 36 hrs	22% patients > 48 hrs
Kawamura Y et al. 2015 ⁴	30	39.1 gm	N/A	2.6 days	N/A
Wei Y et al. 2016 ⁵	270	43.2 gm	32.56 hrs	N/A	4 days
Abou-Taleb A et al. 2017 ⁶	245	63.8 gm	N/A	12.7hrs	21.3 hrs
Mu X et al. 2017 7	39	68.1 gm	N/A	110 hrs	5.82 days
Hirasawa Y et al. 2017 ⁸	603	30.5 gm	N/A	3.9 days	only 3 patients stayed overnight
Xu P et al. 2018 9	52	54.2 gm	18.4hrs	40 hrs	66.7 hrs
Li K et al. 2018 10	42	72.5 gm	21.1 hrs	48.8 hrs	N/A
Zou Z et al. 2018 11	57	37.2 gm	20.6 hrs	43.0 hrs	4 days
Chiruvella M et al. 2018 12	103	Median 39 gm	N/A	3 days	N/A
Our series	45	58.7gm	5.3 hrs	20.7 hrs	Median 1 day

^{*} Mean value would be used unless otherwise specified.

N/A – data not available.

further improvement in surgical technology would be helpful to improve not only the safety of surgery but also contribute to the success of ERAS development in urology.

The latest Karl Storz AUTOCON III 400 (Karl Storz Endoscope, Tuttlingen, Germany) and morcellator system, with up to 400 W power output and a thicker resection loop (0.4 mm), had the potential to provide better hemostasis during surgery. We hypothesized this improvement in hemostasis might allow early cessation of bladder irrigation and catheter removal after BIPOLEP, and hence earlier discharge of patients from hospital. Therefore, we would like to perform a prospective study to assess the feasibility and safety of early catheter removal in BIPOLEP with this new generation of bipolar electrosurgical and morcellator units in our population.

METHODS

Study Setting

This was a single-centre prospective study conducted in a secondary referral centre. Informed consent approval of all involved patients was obtained. Ethics approval was also obtained from the institutional review board before the study.

INCLUSION AND EXCLUSION CRITERIA

Forty-five consecutive patients with a clinical diagnosis of BPO and were scheduled to undergo transurethral prostatic surgery were identified and recruited for the study. Patients with anticoagulants, prior TURP, urethral stricture, active urinary tract infection, prostate cancer, neurogenic bladder, small prostates (preoperative sizing less than 30 grams) and those who could not give informed consent were excluded.

Preoperative Assessment

After obtaining informed consent, demographical characteristics were collected. All eligible patients were evaluated by digital rectal examination, urinalysis, prostate sizing by transabdominal ultrasound, uroflowmetry (if not on a urethral catheter), laboratory studies including hemoglobin, sodium and prostate-specific antigen (PSA) levels. Patients with an elevated PSA were offered prostate biopsies to rule out prostate cancer before the operation. Urine culture would be

collected before surgery to ensure there was no active infection in the patients.

Operative Technique

Preoperative Preparation

All operations were performed under spinal anesthesia in the Lloyd-Davis position. Sterile normal saline was used for irrigation with the bag elevated to about 80 cm above patient level. Single dose of prophylactic antibiotic, 160 mg intravenous gentamicin if normal renal function or 1.2 gm intravenous co-amoxiclav was given before the operation, irrespective of patients with or without the urethral catheter.

Operative Approach

The standard operative technique employed was first described by Prof CX Liu at Zhujiang Hospital of Southern Medical University in Guangzhou. 14 Enucleation was performed in a retrograde fashion starting from cutting the mucosa of the prostatic apex, separating it from the external urethral sphincter, to avoid urinary incontinence after the operation. With the proximal verumontanum serving as the landmark between the adenoma and the external urethral sphincter, a blunt incision was made with the beak of the resectoscope to expose the pseudocapsule. The pseudocapsule was the surgical plane between the adenomas residing in the transitional and peripheral zone. Blunt dissection was carried forward in a clockwise and counter-clockwise motion to detach the adenomas from the pseudocapsule. The cranial extent of the dissection was reached when the circular fibres of the bladder neck were exposed, and the procedure was repeated on the contralateral side. After enucleation, the devascularized adenoma might be removed by piecemeal resection or detached into the bladder for morcellation. If resection was chosen, the adenoma was left attached to the bladder neck at the 7 o'clock position via a narrow stalk. The prostatic tissue collected was weighed and sent for histopathological examination.

Equipment

The electrosurgical unit (ESU) used in the current study was the third generation Karl Storz AUTOCON III 400 (Karl Storz Endoscope, Tuttlingen, Germany) and the thick resection loop system. (Figure 1) ESU used radiofrequency energy to avoid neuromuscular

FIG. 1 The AUTOCON III 400 (Karl Storz Endoscope, Tuttlingen, Germany) and the thick resection loop system.





stimulation. The key advantage of Bipolar ESU was the permission of tissue cutting in normal saline, which has been shown to reduce the risk of dilutional hyponatremia and transurethral resection syndrome associated with glycine. The cutting waveform could achieve a high voltage for producing an electrical arc from the active electrode to the tissue surface. The coagulation waveform differed from that used for cutting by being damped and pulsed to increase peak voltage for deeper tissue penetration. There were five modes of this new Storz ESU for transurethral prostate surgery, three using the cutting waveform and two using the coagulation waveform, which was different from the older generation. (Table 2) Different modes had different effect settings based on the peak voltage or power level achieved. The default mode for general usage was Mode-2. The wider choice of setting allowed surgeons to select specific energy settings according to the clinical situation. For example, if dissection or hemostasis of the prostatic fossa was difficult, a higher effect setting might be used at the discretion of the operating surgeon. If there were residual adenomas attached to the prostatic fossa after enucleation, the operating surgeon could switch to the button electrode to vaporize these adenomas. The potential advantages of this unit included the high-power output (up to 400 W), which could significantly improve the efficiency and effectiveness of the cutting and coagulating effects than the older generations' bipolar instruments. It also eliminated the Fire up delay effect, which could provide a better intraoperative and postoperative bleeding control. The resectoscope could either be fitted with a loop electrode for resection, or a button electrode for vaporization. The loop used in the current study was thick loop measuring 4 mm which provided excellent hemostasis property, especially good for enucleation.

After enucleation, the morcellator system (Figure 2) enabled fast and efficient comminution of prostate tissue. Continue removal of comminuted tissue during morcellation provided an undisturbed endoscopic view. A major advantage of the system was that the S-PILOT® vacuum control unit and the UNIMAT®30 suction pump could both be used with exiting central suction system, which might present a cost-effective solution.

Post-procedural Management

After completion of surgery, a 22-Fr three-way urethral catheter was inserted. No catheter traction was applied. Irrigation would be resumed if effluent

TABLE 2 The Comparison of the Two Generations of Electrosurgical Unit, AUTOCON II and AUTOCON III Modes

	4	AUTOCON II 400	0		A	AUTOCON III 400	0	
	Cutting		Coagulation	Cutting			Coagulation	
Mode	Saline C-cut	Top Cut	Saline Coagulation	Bipolar resection	Bipolar resection C-cut	Bipolar vaporization	Bipolar resection	Bipolar vaporization
Electrode	Loop	Loop	Гоор	Loop	Гоор	Button	Loop	Button
Power output at rated load resistance	370W + 8% or -20%	10-300W	200W ± 20%	250W	1-200W	300-400W	125-350W	250W
Max HF peak 640Vp voltage	640Vp	950Vp	190Vp	650-750Vp	1.4-1.6kVp	350-450Vp	190Vp	190-500Vp
Number of effects	8	8	8	5	6	3	4	3

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FIG. 2 Morcellator system with S-PILOT® vacuum control unit and the UNIMAT®30 suction pump.



fluid was heavily bloodstain after cessation of irrigation. Hemoglobin and sodium levels were rechecked immediately after surgery. The urethral catheter was removed at 9 am on postoperative day one. The patient was encouraged to ambulate and void. Post-void residual urine (PVRU) was monitored.

Discharge Criteria

The patient could be discharged on postoperative day one if (1) PVRU was less than 200 mL for two consecutive measurements, (2) afebrile and (3) no significant hematuria. Voiding efficiency was calculated as the quotient of voided volume and pre-micturition volume, wherein the pre-micturition volume was the sum of the voided volume and PVRU.

Statistical Methods

All outcome measurements were analyzed with an intention-to-treat principle. Independent samples t-test was used for parametric continuous variables; Mann-Whitney U test was used for non-parametric continuous variables; chi-square test was used for categorical variables. A *p*-value less than 0.05 was considered to be statistically significant. All statistical analysis was performed using SPSS version 23.0 (Armonk, NY: IBM Corp.).

Results

Demographics

Between May 2018 and April 2019, 45 patients fulfilled the inclusion and exclusion criteria were recruited for this study. The average age was 76 years

old. Amongst these patients, 34 patients (75.5%) were in secondary to the retention of urine or obstructive uropathy (Table 3). The mean duration of urethral catheter indwelling time was 42 days (SD = 27 days). A total of 11 patients (24.5%) did not have a urethral catheter before the operation. The preoperative mean flow rate, PVRU, and IPSS score were 8.2 mL/s, 89 mL and 26 respectively.

All patients were classified as ASA grade II. There were 12 (26.7%) patients on oral acetylsalicylic acid 80 mg daily, which were not stopped in the perioperative period. Patients who were on other anticoagulants were excluded. One patient had hemophilia B, requiring Factor IX transfusion perioperatively.

The Operation

The median preoperative prostate volume was 98.9 mL (SD = 51.0 mL, range: 37 - 231 mL). The mean enucleation time was 33.3 minutes (SD = 13.1 minutes, range: 12-65 minutes). The mean weight of

TABLE 3 Indications for Surgery in Our Cohort

Indications	Number of patients (%)
Refractory retention or obstructive uropathy	34 (75.5%)
Recurrent hematuria due to benign prostate hyperplasia	4 (8.9%)
Bladder stone secondary to benign prostate obstruction	7 (15.6%)

the resected prostate was 58.7 grams (SD = 29.4 grams, range: 21-206 grams). The adenoma was morcellated in 80% of cases (n = 36) and resected piecemeal in the rest. The mean enucleation efficiency was 1.76 grams per minute of enucleation time (SD = 0.7 gram per minute).

Postoperative Course

The mean bladder irrigation and catheterization times were 5.3 hours and 20.7 hours respectively. There was no significant difference between preoperative and postoperative sodium levels ($138 \pm 2 \, \text{mmol/L}$ vs 139 \pm 3 mmol/L, p = 0.36). However, there was a minor drop in hemoglobin level by an average of 0.71g/dL ($13.1 \pm 1.5 \, \text{g/dL}$ vs $12.4 \pm 1.5 \, \text{g/dL}$, 95% CI, 0.39 to 1.03). Nevertheless, no transfusion was required. All except one patient failed voiding trial on Day-1 after surgery, who could successfully wean off urethral catheter on Day-3 after surgery.

Discharge

The postoperative day one discharge rate was 73.3% (n = 33). Median length of hospital stay was 1 day. The reasons for prolonged hospital stay included, persistent hematuria after cessation of bladder irrigation (n = 3), failed to void on postoperative day-1 (n=1), febrile urinary tract infection requiring oral antibiotic (n=3, one patient's post-surgery urine culture grew Pseudomonas), development of paroxysmal fast atrial fibrillation (n=1) and non-medical reasons (n=4). (Table 4)

Readmission

Seven patients (15.6%) had an unplanned readmission within thirty days postoperatively for complications related to BIPOLEP. The most common reason for readmission was hematuria (8.9%,

TABLE 4 Reasons for Prolonged Hospital Stay

Reasons for a prolonged hospital stay	Number of patients (%)
Persistent hematuria	3 (6.7)
Febrile urinary tract infection	3 (6.7)
Fast atrial fibrillation	1 (2.2)
Failed to void on postoperative day-1	1 (2.2)
Non-medical reason	4 (8.9)

n = 4) and febrile urinary tract infection requiring oral antibiotics (6.7%, n = 3, one patient's post-surgery urine culture grew *Escherichia coli*). None required clot evacuation or blood transfusion. There was no readmission for acute urinary retention.

Complications

A total of 12 patients developed postoperative complications within 30 days after surgery, and 2 complications were Clavien-Dindo grade II. (Table 5) Apart from hematuria and UTI, one patient developed arrhythmia requiring antiarrhythmic therapy and one patient developed deep venous thrombosis requiring anticoagulation in the postoperative period.

Follow-up

At three months follow-up, the mean Qmax was 18.5 mL/s (SD = 11.8 mL/s), and the mean PVRU was 45.5 mL (SD = 48.8mL). A total of 2 patients complained of stress urinary incontinence requiring up to 2 pads per day at 3-month follow-up. After practising pelvic floor exercise, 1 patient recovered while another one has improved stress urinary incontinence, requiring 1 pad per day at 1-year follow-up.

DISCUSSION

The study participants were representative of the elderly male population with moderate-to-severely enlarged prostates suffering from complications of BPO. This population frequently suffered from medical comorbidities and had polypharmacy. Their physiology was brittle and perioperative anesthetic and surgical complications were commonplace. This case series

TABLE 5 Complications by Clavien-Dindo Classification (no Grade III to V Complication in the Series)

Complication grades		Number of patients (%)
Grade I	Hematuria requiring rehospitalization	4 (8.9%)
Grade II	Urinary tract infection requiring oral antibiotic therapy Arrhythmia requiring antiarrhythmic therapy Thromboembolic event requiring anticoagulation	6 (13.3%) 1 (2.2%) 1 (2.2%)

demonstrated that BIPOLEP was a safe and effective procedure. As compared to previous studies, ^{2–12} our series had shorter bladder irrigation time, earlier catheter removal and discharge, and also zero blood transfusion Even there was some readmission due to secondary hemorrhage, they were self-limiting and none of our patients suffered from postoperative urinary retention. This result supported our hypothesis that the new machine has good hemostasis effect and lead to an improvement in clinical outcomes.

Currently, there were no head-to-head comparisons between different bipolar electrosurgical units in the literature. They were primarily evaluated based on the quality and consistency with which the desired tissue effect was achieved. Parameters that determined the tissue effect achieved include generator waveform, active electrode size, configuration, voltage and power generated, tissue impedance, electrode excursion speed, and tissue contact pressure. In many regards, the third generation Storz ESU was an improvement over the second-generation system and other electrosurgical units. Firstly, in contrast to quasi-bipolar ESUs, this was a true bipolar system in which current flew exclusively between the active and passive electrode without flowing through the sheath of the resectoscope, theoretically reducing the risk of urethral stricture and bladder neck contracture. 15 Secondly, the maximum voltage output for cutting was significantly increased over 1 kVp to overcome the delay in the onset of bipolar cutting in older generation systems. Thirdly, the maximum power output for coagulation was increased from 200 W to 400 W, which theoretically increased the depth of tissue penetration and resulted in more secure hemostasis after initial tissue sloughing. Last but not least, a thick loop was well suited for enucleation as it was more durable and retained its shape even after prolonged transurethral manipulation, in addition to facilitating simultaneous cutting and coagulation.¹⁶

One large BIPOLEP study was published in 2017 by Hirasawa et al.⁸ There were 603 consecutive patients included for analysis. Patients were discharged with a catheter and asked to return for a trial of weaning four days postoperatively; only 3 patients (0.49%) required readmission. However, the mean resected prostate weight was only 35.5 g, which was lower compared

to our series (58.7 g). Review of the vast body of literature on BIPOLEP showed that there was significant variation in the duration of catheterization, length of stay, readmission rate, complication rate depending on institutional practice and surgeon experience.^{2–12} The experience of our study might be able to help to encourage earlier trials without the urethral catheter and discharge after BIPOLEP.

The rate of postoperative urinary tract infection in this cohort was higher (13.3%) compared with the typical figure of 5% in most other studies. The prolonged indwelling catheterization for refractory retention before surgery might account for higher postoperative urinary tract infection. Fortunately, all these patients were recovered with oral antibiotic therapy.

The short-stay protocol in this study was conceived from the Enhanced Recovery After Surgery (ERAS) protocol currently in use for rectal and urological pelvic operations. Henrik Kehlet firstly pioneered the concept in the 1990s with the idea to standardize and optimize perioperative management practice to reduce variability in outcome across European colorectal centres.¹³ Implementing ERAS protocols has been shown to shorten hospital stay, reduce cost, and reduce morbidity and mortality. Even though the severity of surgical stress from endoscopic prostatic operations was considered minute, the physiological milieu in frail elderly men might be deceptively tenuous. Even minor surgical stress might tip the balance. Early catheter removal and cessation of bladder irrigation permitted early mobilization and discharge from the hospital environment. This might alleviate the impact of the operation on their functional capacity and early return to normal life. Akin to ERAS protocol, implementing the short stay protocol in the current study required multidisciplinary input, counselling and attitude change towards dogmatic perioperative practice. Certainly, the improvement of surgical technique and equipment would also contribute by providing safer postoperative course and contribute to the success of ERAS in our protocol.

The limitations of the study included single centre data only. In the future, larger study and preferably randomized study would be required to assess the benefit over other models. Also, BIPOLEP was not as mainstreamed as Holmium enucleation of the prostate (HOLEP). In our centre, we also performed HOLEP. Our experience believed that apart from a shorter learning curve in mastering BIPOLEP than HOLEP, both clinical outcomes were similar. However, we did not compare the clinical data between BIPOLEP and HOLEP in this study. Future evaluation between BIPOLEP and HOLEP was necessary to choose a better surgical option for patients with BPO.

CONCLUSION

The use of the new generation of bipolar electrosurgical and morcellator units for BIPOLEP could allow early catheter removal and discharge, with no compromised surgical safety. This would help to improve the overall care of these patients.

DECLARATION

All authors had no conflict of interest to disclose and had full access to the data, contributed to the study, approved the final version for publication, and took responsibility for its accuracy and integrity. There was no financial support for the research.

THE ROLE OF THE AUTHORS IN CONTRIBUTING TO THE MANUSCRIPT

- (1) Concept or design Ka Lun LO, Kevin LIM, Chi Fai NG.
- (2) Acquisition of data Ka Lun LO, Kevin LIM, David LEUNG.
- (3) Analysis or interpretation of data Ka Lun LO, Kevin LIM, Siu Fai MA, David LEUNG, Chi Fai NG.
- (4) Drafting of the manuscript Ka Lun LO, Kevin LIM, Chi Fai NG.
- (5) Critical revision for important intellectual content All authors.

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