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Bipolar vaporization of the prostate may cause higher complication rates compared to bipolar loop resection: a randomized prospective trial

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Abstract

Introduction Transurethral resection of the prostate (TURP) by resection loop or vaporization button is becoming a standard of care due to its better safety profile (less bleeding and less incidence of TUR syndrome). However, there are published data showing bipolar vaporization may be associated with increased late complications. In this study, we compared results of bipolar TURP using the resection loop versus vaporization button for treatment of benign prostatic hyperplasia (BPH) to determine the relative safety profile.

Patients and methods Between January 2013 and March 2014, 89 patients with BPH were randomized to surgical intervention either by Olympus (Gyrus) Bipolar loop TURP or Olympus (Gyrus) Bipolar button vaporization. Inclusion criteria were; BPH with Q-max < 10 ml/s, IPSS > 18 and prostate volume > 40 g. All patients were evaluated preoperatively and at 1, 3 and 9 months. Evaluation included IPSS, uroflowmetry, prostate volume by ultrasound. Clavien complications and operative time were recorded. Statistical analysis was done using Statistical Package of Social Science (SPSS) version 17 software.

Results 44 patients were included in bipolar TURP and 45 patients in vaporization arm. Preoperative mean prostate volume (59 g versus 58 g, $p = 0.52$) and mean IPSS (19 versus 20, $p = 0.38$) were equivalent in both groups. Vaporization was associated with a significant increase in operative time (mean of 81 ± 15 min range 40–110 versus 55 ± 10 min range 30–70 min, $p < 0.001$), less blood loss (0.8% versus 2.0% drop in hemoglobin, $p < 0.001$) but increased postoperative urinary frequency (80% versus 50%, $p < 0.001$), hematuria with clots up to 4 weeks post surgery (20% versus 2%, $p < 0.001$) and postoperative urethral stricture (11% versus 0%, $p < 0.001$). Both techniques improved urine flow with Q-max (17 ml/s versus 18 ml/s $p = 0.22$). Prostate volume (32 g versus 31 g, $p = 0.31$) and IPSS (6 versus 5, $p = 0.22$), were comparable in both treatment arms.

Conclusions Bipolar vaporization of the prostate, despite being a technically robust, speedy and with less intraoperative bleeding, appears to be associated with increased postoperative irritative symptoms, increased late-onset postoperative bleeding and high urethral stricture rates.

Keywords Bipolar vaporization · Prostate · Bipolar loop resection · Prospective trial

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Introduction

Benign prostatic enlargement (BPE) is a progressive disease affecting older males and represents a common problem for aging men [1]. It can lead to lower urinary tract symptoms (LUTS) and affects quality of life [2]. Although monopolar transurethral resection of the prostate (TURP) is considered the endoscopic gold standard for the surgical removal of symptomatic BPE, newer technologies including bipolar resection and bipolar electro-vaporization techniques are increasingly used [3–10]. These bipolar TURP procedures have similar or superior performance characteristics to monopolar TURP [10–13] and adding the benefits of fewer perioperative complications (less blood loss, earlier removal of the catheter and saline irrigation allows more time for removal of large adenoma with negligible risk of TUR syndrome) [14–20].

Bipolar transurethral resection of prostate technology uses high frequency energy to create a vapor layer of plasma which contains energy-charged particles that induce tissue disintegration through molecular dissociation. As the active and return electrodes are placed on the same axis of the resectoscope, high current densities are achieved locally and distant negative effects reduced [21]. This technology provides an advantage over the monopolar system in which the energy current passes through the patient's body, from the active electrode, placed on the resectoscope, toward the return plate placed on the patient's leg, with several disadvantages such as heating of deeper tissue, nerve or muscle stimulation, and possible malfunction of the cardiac pacemaker [22].

Although these are commonly performed procedures, there is little data reporting the relative performance characteristics of bipolar loop resection compared to bipolar vaporization. While bipolar vaporization seems to be slightly less speedy than bipolar resection, vaporization technique is associated with almost no intraoperative bleeding. We endeavored to compare these two approaches, hypothesizing that they would have equivalent performance characteristics.

Patients and methods

This prospective randomized study was done between January 2013 and March 2014, patients with moderate to severe LUTS due to BPE were included in this study. Simple randomization was used to divide patients into two groups (simple randomization, one case vaporization and one patient resection consecutively). Group 1 included patients who underwent bipolar TURP using Olympus Gyrus Bipolar Loop and Group 2 included patients who underwent bipolar plasma vaporization using Olympus Gyrus Button Vaporization system. Inclusion criteria were: BPH with Q-max < 10 ml/s, IPSS > 18 and prostate volume > 40 g. Exclusion criteria were active urinary tract infection, coagulopathy, neurogenic bladder, prostate volume above 80 g, PSA above 4 ng/ml or abnormal DRE, previous urethral stricture or urethral surgery, presence of bladder stones or renal impairment. All patients were evaluated preoperatively by history, IPSS and quality of life (QoL) questionnaire, physical examination, laboratory investigations, uroflowmetry test with residual urine (RU), transrectal ultrasound (TRUS) and pelvi-abdominal ultrasound. All patients were followed up at 1, 3, and 9 months postoperatively by IPSS, uroflowmetry and TRUS. Operative time was recorded. All complications in perioperative period were recorded and classified according to modified Clavien system [23].

Informed written consent was taken from all participants and study protocol was approved from Local ethical committee. All procedures were performed by single surgeon under spinal anesthesia. Surgical protocol starts with urethral dilation up to size 26 French before insertion of the resectoscope. 24 French resectoscope was used in both groups. The procedure was performed via continuous irrigation system using normal saline. The Olympus bipolar generator was set to coagulation at 150 W and cutting at 270 W, doing the standard technique of bipolar resection and vaporization in both groups. At the end of the procedure triple way Foley's catheter, 20 French was placed for 24–48 h postoperatively in all patients, and irrigation with saline was continued till urine became clear. Data were collected, tabulated and statistically analyzed using Statistical Package of Social Science (SPSS) version 17 software. Suitable statistical techniques were computed (frequencies, mean, standard deviation and range).

Results

The study included 44 patients in bipolar TURP group, and 45 in bipolar vaporization group (Table 1). No patient has history of urine retention requiring indwelling

Table 1 Pre-operative variables

Variables (mean ± standard deviation)	Loop resection (Group I)	Vaporization (Group II)	*p* value
Number of patients	44	45	NA
Age (years)	52.2 ± 11.9	51.7 ± 11.2	0.3
Q-max pre-op (ml/s)	8.1 ± 7.7	9.01 ± 4.1	0.22
Prostate volume (g)	58.2 ± 12.5	59.4 ± 13.9	0.52
IPSS	19.9 ± 1.4	19.1 ± 1.2	0.38

catheterization preoperatively. There was no significant age difference in both groups [mean age in group-1 (52.2) and in group-2 (51.7), $p = 0.25$]. Preoperative prostate volume was similar in both groups (59 g versus 58 g, $p = 0.52$), and similarly IPSS showed insignificant difference (19 versus 20, $p = 0.38$). Vaporization was associated with significant increase in operative time [81.4 ± 15.3 min, range (40–110), versus 55.5 ± 9.8 min, range (30–70), $p < 0.001$], less blood loss (0.8% compared to 2% drop in hemoglobin, $p < 0.001$) but increased postoperative urinary frequency (80% versus 50%, $p < 0.001$), hematuria with clots as long as 4 weeks after surgery (20% versus 2%, $p < 0.001$) and postoperative urethral stricture (11% versus 0%, $p = <0.001$) (Table 1). Postoperatively both techniques improved Q-max (17 ml/s versus 18 ml/s, $p = 0.22$), postoperative prostate volume measured by TRUS (32 g versus 31 g, $p = 0.31$) and IPSS (6 versus 5, $p = 0.22$) equivalently. There was no significant difference between the two groups regarding improvement in postoperative IPSS, Q-max and prostate volume. Postoperative irritative symptoms (frequency, urgency, and nocturia) were more in vaporization group and improved gradually with time (80%, 47%, 29%) at 1, 3, and 9 months, respectively (Clavien1). After 6 months postoperatively, five patients (11%) developed urethral stricture and all were in the vaporization group (three were at bulbomembranous urethra and two at glandular urethra-Clavien3a) (Table 2).

There was no significant difference regarding hospital stay (1.3 days versus 1.8 days, $p = 0.25$) or catheterization period (1.5 days versus 1.9 days, $p = 0.22$).

Discussion

The treatment of LUTS due to infravesical obstruction secondary to BPE is constantly evolving. Therapeutic modalities for moderate and severe conditions begin with pharmacological treatment and may progress to minimally invasive, laparoscopic, robot-assisted or open surgical alternative.

Until recently, monopolar transurethral resection of the prostate (TURP) was considered a gold standard for the treatment of prostates with a volume lower than 80 cm^3 due to its effectiveness and low cost. However, this established technique is associated with some relevant complications, such as urethral stenosis, bleeding, bladder neck sclerosis and especially post-TURP syndrome, due to the need for hypotonic infusion fluid to avoid electrical conduction. Post-TURP syndrome consists of water intoxication alongside hyponatremia, and can lead to the occurrence of cerebral edema.

Table 2 Intra and postoperative variables

Variables (mean ± standard deviation)	Loop resection (Group I)	Vaporization (Group II)	*p* value
Operative time (min)	55.5 ± 9.8	81.4 ± 15.3	**< 0.001**
Postoperative Hg (% drop)	1.96 ± 0.2	0.8 ± 0.4	**< 0.001**
Q-max post-op (ml/s)			
1 month post-op	18.1 ± 7.2	17.2 ± 6.1	0.22
3 month post-op	18.7 ± 9.3	17.9 ± 1.1	0.52
9 month post-op	19.1 ± 1.3	18.3 ± 2.1	0.39
Prostate volume (g)	30.6 ± 6.3	31.8 ± 5.1	0.23
IPSS			
1 month post-op	7.8 ± 1.1	7.9 ± 1.3	0.22
3 month post-op	6.8 ± 1.7	6.9 ± 1.4	0.24
9 month post-op	5.2 ± 1.3	6.9 ± 1.1	0.25
Post-operative morbidity (frequency, urgency, nocturia)			
1 month	22 (50%)	36 (80%)	**< 0.001**
3 month	10 (23%)	21 (47%)	
9 month	1 (2%)	13 (29%)	
Hematuria with clots			
2 weeks	1 (2%)	2 (4%)	**< 0.001**
3 weeks	0	3 (7%)	
4 weeks	0	4 (9%)	
Stricture urethra			
6 month	0	5 (11%)	**< 0.001**

Bold values indicate statistical significance

The incorporation of bipolar technology represents a significant evolution in the TURP technique in recent years. Bipolar TURP presents a considerable advantage given the fact that it can be performed with normal saline solution, with excellent results in relation to a greater volume of resection within the same surgical time.

The search for new therapeutic modalities for any disorder is necessary and natural, even more so in times of rapid technological evolution. This is no different in the treatment of BPH, and new options are already beginning to be established in clinical practice in accordance with the consolidation and scientific support for such. Recently laser and electro-vaporization techniques are widely adopted [3]. In particular, bipolar Transurethral vaporization of the prostate (TUVP) provides better hemostasis [24], and the use of isotonic irrigation fluid permits better intraoperative visualization and treatment of patient with increased risk of bleeding [24]. This technique is gaining popularity as it is easy to do, easy to learn, and associated virtually with no or very minimal bleeding risk [25]. Additionally, bipolar TURP is proven a safe and highly effective treatment modality for BPE even in the elderly patients with prostate glands over 100 g. Its clinical efficacy and postoperative 12th month's results were similar to open suprapubic simple prostatectomy [26].

In our current study, we randomly compared bipolar loop TURP and bipolar vaporization in two comparable groups of patients with BPE.

Our data showed that while bipolar vaporization of the prostate was associated with equivalent efficacy and less bleeding, this benefit came at a significant cost. In our study, operative times were significantly (67%) longer for bipolar vaporization compared to bipolar loop resection. This fact has been reported by others, and is consistent with the assertion that vaporization achieves vaporization rates of no more than 1 min/1 cc of prostatic tissue [19]. Ho et al. also reported longer mean operative time for plasma kinetic vaporization compared with standard TURP (32.6 min versus 28.5 min) [12]. However, others have reported a similar operating time compared to TURP techniques. Dunsmuir et al. showed that bipolar electro-vaporization and TURP had similar operation time (33 versus. 26 min, $p=0.78$) [27]. Geavlete et al. actually had shorter operating time (39.7 min) with bipolar vaporization over bipolar TURP (52.1 min) and monopolar TURP (55.6 min) ($p=0.0001$) [19].This was also confirmed by Falahatkar et al. [28].

In our study there was no significant difference in both groups between hospital stay or catheterization period (1.3, 1.8 and 1.5, 1.9) for group 1 and 2, respectively. These results are in accordance with previous publications [4, 29, 30].

We and other published studies have found significant improvement in IPSS and Q-max along various follow-up durations for vaporization and vaporization-resection (including bipolar technology) [4, 6, 19, 30–32]. In Geavlete et al. [19] trial, bipolar vaporization actually had significantly better voiding results compared to bipolar or monopolar TURP.

There was significantly less bleeding in our vaporization group compared to bipolar loop TURP (hematocrit drops of 0.8% versus 1.9%, respectively, $p=0.0001$) but this was not clinically significant as all but one patient in vaporization group manifested hemodynamic instability or required blood transfusion.

The mean hemoglobin drop after bipolar vaporization (0.5 g/dL) was significantly lower than bipolar TURP (1.2 g/dL) and monopolar TURP (1.6 g/dL) in Geavlete et al. [19]. Ho et al. [12] also reported bipolar plasma kinetic vaporization had significantly lower hemoglobin drop (0.8 g/dL) compared with standard monopolar TURP (1.4 g/dL).

The presence of significant number of delayed postoperative hematuria after bipolar vaporization was a surprising and concerning finding in our series. Significant postoperative bleeding occurred in only one patient (2%) 2 weeks after bipolar loop TURP, and was managed conservatively (Clavien 1). In the bipolar vaporization group, bleeding occurred in 9 patients (20%): 2 after 2 weeks, 3 after 3 weeks and in 4 patients after 4 weeks, all managed conservatively (Clavien 1) except one patient who developed clot retention and significant hematuria requiring cystoscopic management and blood transfusion due to significant hemoglobin drop (Clavien3b). Other studies also reported bleeding after bipolar vaporization, but at levels similar to bipolar loop TURP. Ahyai et al. found no significant difference in perioperative complication rates in TUVP (14%) and bipolar loop TURP (12%) as well as in the intraoperative or late complications [33]. Similarly, no significant difference between bipolar TUVP and bipolar loop TURP in the complications rate was observed according to modified Clavien classification of complications (10% versus 12%), respectively. These reported complications included gross hematuria requiring re-catheterization, blood transfusion, transient incontinence, frequency and nocturia. [28, 32].

In addition to a higher incidence of delayed bleeding, there were more storage symptoms in the early postoperative period surfaced with bipolar vaporization, which had previously been a common general impression of practitioners worldwide.

Urethral stricture occurred in 5 cases (11%) of group 2 and discovered after 6 months of postoperative follow-up period. All patients had annular strictures and managed by urethral dilation. The bipolar TURP system with its passive electrode located on the sheath of the resectoscope has consistently raised speculation about the electrical current leakage, which potentially can cause urethral stricture. In addition, urethral stricture

formation appears to be associated with longer operative time, which is the case in our vaporization group. This could be due to prolonged ischemia of urethra from contact with resectoscope sheath. The returning current flow, which can induce heat in the resectoscope sheath, could be another factor. These possibilities should be confirmed with further studies. In the study by Komura et al., the incidence of postoperative urethral stricture after the "quasi-bipolar" TURIS system appeared to be significantly higher in the TURIS group and was more commonly located in the membranous urethra [34]. The authors believed that the mechanism of urethral stricture after TURIS was different from what is described for bladder neck contracture after monopolar TURP. They suggested that different mechanism of current flow in the TURIS system might cause some electrophysiological stress to the membranous urethra, a point where the returning current interacts with the urethral tissue and the passive electrode sheath. No patient developed bladder neck contracture in our study in either of the treatment arms. In the same study by Komura et al., it was observed that the higher urethral stricture rate in the TURIS group was significantly associated with longer operation time and larger preoperative prostate volume of > 70 ml. Tan et al., reported urethral stricture rate of about 3.5% after bipolar Gyrus Plasma Kinetic Tissue Management System (PK-TURP) and postulated that this risk factor is intimately associated with the returning current flow of the PK-TURP system to cause Urethral Stricture [35]. Similarly, Kumar et al. reported urethral stricture rate of about 7.5% after TURIS method [36]. On the other hand, TURP by whatever modality invariably leads to mechanical and thermal stress. Besides longer operative time and longer catheter time, the other factors that cause mechanical stress are an oversized resectoscope and its inappropriate axial and rotating movements [37]. In our study, the fact that a larger resectoscope size might be responsible for urethral stricture was nullified using a 24 Fr resectoscope for both the treatment arms.

Although this study presents new data comparing bipolar vaporization to loop resection TURP in prospective cohort, our study is not without limitations. The limited sample size and the relatively short follow-up period make it difficult to ascertain long-term efficacy, and late failures. In addition, our patients as part of informed consent were informed as to the type of surgery they had, and this factor may have influenced their subjective reporting afterwards post operatively. Further studies of longer duration and larger sample size are required to compare the efficacy and cost-effectiveness of vaporization technique with the standard loop resection of prostate.

Conclusions

Bipolar vaporization of the prostate, despite being a technically robust, speedy procedure with less intraoperative bleeding, it appears to be associated with increased postoperative irritative symptoms, greatly increased delayed postoperative bleeding, and noticeable high urethral stricture rates.

Compliance with ethical standards

Conflict of interest All authors declare that there are no competing financial interests.

Ethical approval All procedures performed in this study involving human participants were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in this study.

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