A randomized, controlled trial for transurethral treatment of bladder tumors using PlasmaButton vaporization electrode or monopolar loop electrocautery

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Introduction: *The use of an electrocautery device (monopolar loop) for patients undergoing transurethral resection of bladder tumors (TURBT) is standard of care. The aim of this study is to establish non-inferiority of complication rates for a bipolar energy device, the PK PlasmaButton (PK Button), when compared to the monopolar loop.*

Materials and methods: *Seventy-eight subjects (41 monopolar loop and 37 PK Button), were enrolled in a single-center, prospective, randomized study with cystoscopically detected bladder tumors that were judged endoscopically resectable with only one trip into the operating room. Intra and postoperative data on complication rates, operative time, catheterization time and disease recurrence rates at 3 month follow up were collected.*

Results: *Overall complication rates after TURBT with the monopolar loop or PK Button were similar, (56% versus 38% respectively, p = 0.107), however there were more bladder perforations in the monopolar loop arm compared to the PK Button arm (12.2% versus 0%, respectively, p = 0.028). There was no difference in overall operative time (p = 0.170), catheterization time (p = 0.709) and disease recurrence (p = 0.199).*

Conclusion: *The results of this study demonstrated no difference between the monopolar loop and PK Button in regard to overall complications; however, there was a higher rate of bladder perforation with monopolar TURBT. PK Button vaporization for bladder tumors represents a promising alternative to traditional monopolar TURBT without compromising short term (3 month) cancer recurrence rates.*

Key Words: TURBT, bladder tumors, PK Button, vaporization, bladder cancer

Introduction

The burden of bladder cancer in the United States is enormous and accounts for almost 5% of all new cancers. In 2019 alone, it is estimated that over 80,000 new cases will be diagnosed with approximately 17,760 deaths resulting from bladder cancer.[1] Approximately 75% of newly diagnosed bladder cancers have not invaded the bladder smooth muscle and are considered non-muscle invasive bladder cancers (NMIBC). NMIBC is generally associated with a 5 year survival rate greater than 88%.[2] However, up to 70% of NMIBC tumors recur after initial treatment, with a 10% to 20% risk of progression to muscle invasive bladder cancer.[3]

The current standard of care for patients who present de novo or with a recurrent NMIBC is transurethral resection of bladder tumor (TURBT), with the procedural goal being tissue acquisition for disease staging and removal of all visible lesions

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for treatment. Adequate pathological specimens are essential for tumor grading and staging information to guide the treatment paradigm.[4] TURBT, using monopolar electrocautery with a loop electrode (monopolar loop) has been used since its introduction in 1952. Although usually safe and sufficient, this technique can create technical challenges because of difficulty in positioning the loop electrode to access locations such as the bladder dome or anterior bladder wall. Additionally, resection of large bladder tumors can result in intraoperative bleeding that obscures visualization and result in incomplete tumor resection and inadequate sampling of the layers of bladder needed to establish tumor staging. Furthermore, a bladder tumor on the lateral bladder wall may result in stimulation of the obturator nerve, resulting in violent adduction of the leg with potential bladder perforation, necessitating prolonged catheterization and hospitalization.[5]

As alternative technologies have developed, bipolar plasma vaporization has been readily adopted for the treatment of benign prostatic hyperplasia (BPH) during transurethral resection of the prostate (TURP) and has proven to be a safe and effective treatment option.[6] Refinement of the bipolar energy has led to the introduction of Plasma Kinetics Technology and a spherical designed "button" electrode, the PlasmaButton Vaporization Electrode (PK Button) (Olympus, Tokyo, Japan). The design of this electrode creates a plasma arc that glides over the tissue, transmitting energy to the cell layers adjacent to the arc, which are then quickly vaporized.

Given the success in the treatment of BPH, it was a logical transition to test the safety and effectiveness of the technology in patients with NMIBC. Geavlete et al have reported improved safety endpoints and decreased tumor recurrence rates with bipolar PK Button in this patient population.[7] The goal of this randomized, prospective study was to prove non-inferiority of PK Button vaporization as compared to monopolar loop electrocautery in terms of complications between groups.

Materials and methods

A single center, prospective, randomized trial was performed at a tertiary care center to assess the complication rate of two techniques, monopolar loop and PK Button for treatment of bladder tumors. The study was approved by the Institutional Review Board and all subjects gave informed consent.

The primary endpoint of the study was measurement of procedural complications, which included intraoperative bleeding, postoperative bleeding, need for blood transfusion, obturator nerve stimulation, bladder perforation, and need for bladder irrigation and hospitalization. The secondary endpoints were the assessment of operative time, catheterization time, and tumor recurrence at 3 months.

Consecutive subjects with cystoscopically detected bladder tumors, that were judged endoscopically resectable with only one trip into the operating room, were enrolled. Exclusion criteria included evidence of locally advanced, nodal or metastatic bladder cancer, hydronephrosis secondary to bladder cancer, diffuse tumors deemed unresectable, patients on anticoagulation, and patients unfit for surgery. Prior to randomization, all subjects underwent routine clinical examination, blood tests, urine culture and the appropriate staging imaging and complete cystoscopy. The majority of cases were performed by four board certified urologists, each with over 10 years of experience in practice post residency or fellowship training. A minority of the cases were done by junior faculty. In addition, as an academic residency training program, residents were involved with all surgical procedures. Biopsy specimens were read by pathologists blinded to treatment group. All procedures were performed under general or spinal anesthesia and prophylactic broad-spectrum antibiotics were administrated intraoperatively prior to the procedure.

Subjects were randomized 1:1 into either the PK Button arm (treatment group) or monopolar loop arm (control group). Randomization was performed immediately prior to surgery. A study coordinator drew from a concealed envelope containing six pre-labeled pieces of paper (three monopolar loop and three PK Button) to assign the patient treatment. The drawn piece of paper was not placed back into the envelope to ensure true 1:1 randomization for six patients at a time, and once all six papers were picked from the envelope, the process was repeated.

Monopolar loop procedure

Participants randomized to the control arm had TURBT performed using the standard of care monopolar loop resection technique.

PK Button procedure

PK Button vaporization was performed using Olympus PK SuperPulse bipolar generator (Olympus, Tokyo, Japan) and the bipolar PlasmaButton vaporization electrode. A brief description of our technique is outlined below. A more detailed explanation has been reported previously.[7]

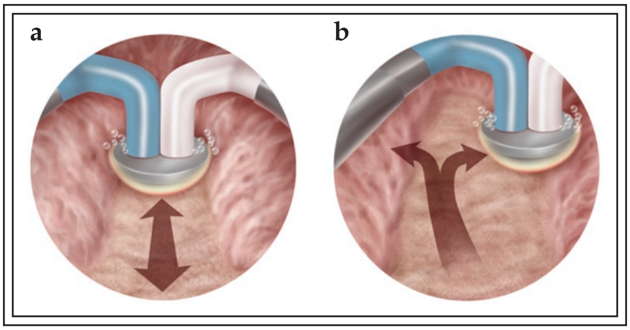

Figure 1a and 1b. Tumor is ablated down to muscle centrally **(a)**. Remainder of tumor is treated in side-to-side fashion until all visible tumor is ablated **(b)**.

Complete cystourethroscopy: Complete cystourethroscopy was performed in the standard fashion to identify the ureteral orifices, assess the bladder outlet and to ensure that all visible tumors had been identified.

Superficial biopsy: Once the cystourethroscopy was completed, the next step was to obtain biopsies to ensure that tissue was available for pathological analysis. To do so, the rigid biopsy forceps was placed through the resectoscope and multiple biopsies of the exophytic portions of the tumor were taken.

Vaporization of the tumor/ablation: The working element of the resectoscope with the PK Button was attached and tumor vaporization was initiated. Vaporization continued until the tumor base was reached. Surgeons need to be aware that normal bladder mucosa can easily be vaporized as well as the tumor, Figure 1a and Figure 1b.

Deep biopsy: Once the tumor base was reached, the surgeon either took deep biopsies (usually three to four) of the tumor bed using rigid biopsy forceps or switched to bipolar loop electrocautery to resect the tumor bed, attempting to obtain muscle in the specimen, Figure 2a and 2b.

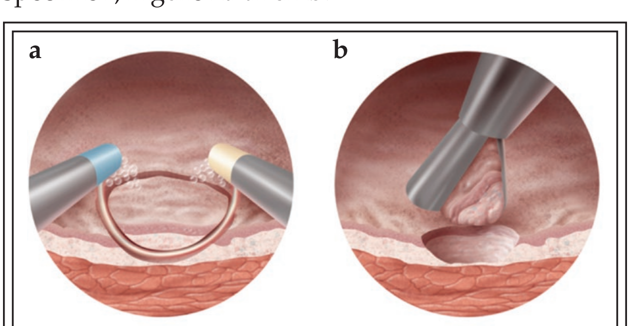

Figure 2a and 2b. Deep biopsy being performed with loop electrode **(a)** and cold cup biopsy forceps **(b)**.

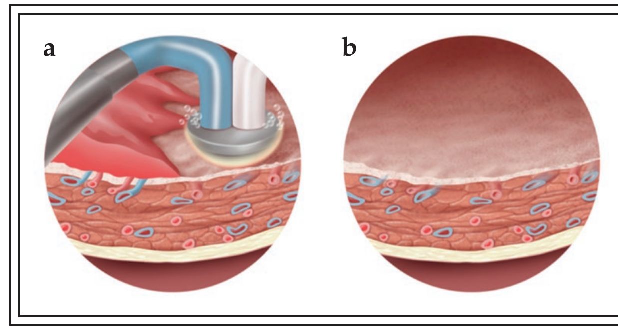

Figure 3a and 3b. Hemostasis is obtained using the cautery setting on the PK Button.

Hemostasis: Once all the deep biopsy specimens have been collected, hemostasis is achieved by using the coagulation mode with the PK Button and applying pressure to the tissue until a change in coloration is noted, Figure 3.

Post-procedure instructions (both arms)

Catheterization: It was at the discretion of the surgeon whether a foley catheter was necessary. For patients receiving immediate intravesical Mitomycin, a catheter was placed at the conclusion of the surgery and removed in the recovery room following the appropriate chemotherapy indwell time.

Discharge: Subject was observed according to the recovery room protocol. Once an acceptable post-void residual was documented, the subjects were allowed to go home. Need for hospital admission was determined by the treating surgeon.

Repeat TURBT: If the tumor was a high grade T1 tumor, a repeat TURBT was performed 4 to 6 weeks after the initial resection as per AUA guidelines.

Statistical analysis

Primary analysis was conducted by pooled z-test for comparison of complication rate in two arms. An unplanned interim analysis was conducted after the enrollment of the first 2/3rd subjects to establish a "go/no go" assessment and the results of the interim analysis showed non-inferiority in the two arms of the study for both primary and secondary endpoints. Based on the results of an interim analysis, sample size estimates were re-assessed. A sample size of approximately 40 participants per group was 75% powered to detect a difference of 9% by one-sided Z-test at significance level of 0.05.

Secondary endpoints of operative time, catheterization time, cautery artifact on pathological specimens and tumor recurrence at 3 months were analyzed by a

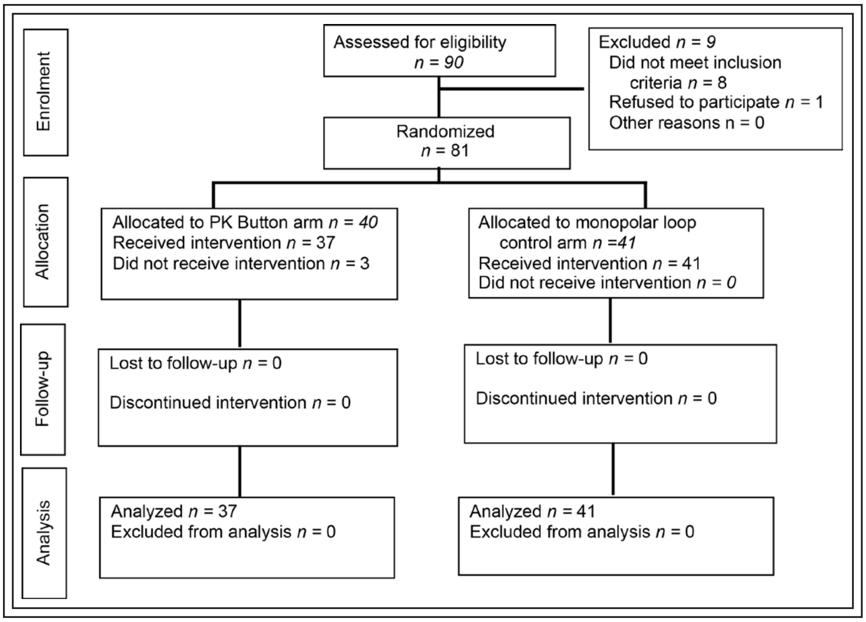

Figure 4. CONSORT flow diagram.

two-sample t-test/Wilcox sum rank test for continuous measurements, e.g., operative time and Chi-square test/ Fisher's exact test for categorical one, e.g., postoperative bleeding and Log-rank test have been performed for any time-to-event outcomes, e.g., time to recurrence.

Results

Between January 2013 and March 2017, 90 subjects were prospectively enrolled in the study. Eight subjects did not meet inclusion criteria and were excluded, and one subject elected not to participate. Eighty-one subjects were randomized to either PK Button arm or the monopolar loop control arm. Three subjects randomized to the PK Button arm did not receive this treatment due to technical challenges with the device or physician discretion and were excluded from analysis. In total, 78 subjects, with 37 randomized to the PK Button arm and 41 to the monopolar loop control arm were analyzed, see Consort Flow Diagram, Figure 4. Subjects randomized to each arm were well matched for age, gender, and race, with all differences being statistically non-significant, Table 1. Largest tumor size, location, and staging for each arm were also similar and statistically non-significant, Table 2. Overall complication rate was also not statistically significant, with complications for the PK Button in 14/37 (37.8%) and for the monopolar loop 23/41 (56.1%), p = 0.107, showing non-inferiority between the two groups, Table 3. Individual complication rates for the PK Button and monopolar loop arms, respectively, were as follows: postoperative bleeding that required transfusion rate (0% versus 2.4%), obturator nerve stimulation (18.9% versus 26.8%) and hospitalization rate (18.9% versus 22%) were statistically non-significant. The need for continuous bladder irrigation postoperatively trended towards being lower in the PK Button arm than the monopolar loop arm 10.8% versus 26.8% ($p < 0.073$). Additionally, there was no occurrence of bladder perforation in the PK Button arm

TABLE 1. **Demographics**

	Total	**Monopolar loop**	**PK Button electrode**	**p value**
Number treated	n = 78	n = 41	n = 37	
Median age (min-max)	70 (21-94)	69 (21-89)	71 (50-94)	NS^
Gender				NS*
Male	58 (74.4%)	29 (70.7%)	29 (78.4%)	
Female	20 (25.3%)	12 (29.3%)	8 (21.6%)	
Race				NS*
Caucasian	45 (76.3%)	24 (77.4%)	21 (75%)	
Non-Caucasian	14 (23.7%)	7 (22.6%)	7 (25%)	

NS = not significant, p > .05
*Chi-square test
^ANOVA

TABLE 2. **Tumor characteristics and short term recurrence**

	Total n = 78	Monopolar loop n = 41	PK Button electrode n = 37	p value
Largest tumor size# (cm)				NS*
Mean ± Std	2.5 ± 1.8	2.2 ± 1.4	2.7 ± 2.2	
Median (min-max)	2 (0.5-10)	2 (0.5-5)	2 (0.5-10)	
Largest tumor location#				NS*
Bladder base	2 (2.6%)	1 (2.4%)	1 (2.8%)	
Bladder dome	2 (2.6%)	1 (2.4%)	1 (2.8%)	
Bladder neck	20 (26.0%)	11 (26.8%)	9 (25%)	
Anterior wall	4 (5.2%)	2 (5.6%)	2 (5.6%)	
Lateral wall	34 (44.2%)	19 (46.3%)	15 (41.7%)	
Posterior wall	8 (10.4%)	3 (7.3%)	5 (13.9%)	
Trigone	4 (5.2%)	2 (4.9%)	2 (5.6%)	
Multiple locations of equal size	3 (3.9%)	2 (4.9%)	1 (2.8%)	
Muscle present for pathology	39 (52%)	22 (56.4%)	17 (47.2%)	NS*
Pathologic tumor stage				NS*
pT0	6 (7.7%)	4 (9.8%)	2 (5.4%)	
pTis	3 (3.9%)	2 (4.9%)	1 (2.7%)	
pTa	39 (50%)	22 (53.7%)	17 (45.9%)	
pT1	19 (24.3%)	9 (22%)	10 (27%)	
pT2	11 (14.1%)	4 (9.8%)	7 (18.9%)	
Received postoperative intravesical Mitomycin C	45 (58.4%)	27 (67.5%)	18 (48.6%)	NS*
3 month tumor recurrence rate				
Recurrence	24 (30.8%)	10 (24.4%)	14 (37.8%)	NS*

NS = not significant, p > .05
*Chi-square test
#numbers will not add to total due to missing data

versus 12.2% in the monopolar arm ($p < 0.028$). Bladder perforation was assessed endoscopically and defined by the identification of perivesical fat following tumor treatment (formal cystograms were at the discretion of the attending surgeon). Catheter placement rate trended towards being higher for the PK Button arm compared to 41.7% versus 27.5% ($p < 0.091$) in the monopolar loop arm. Median total operative time was similar for both arms with 50 minutes for PK Button and 38 minutes for monopolar loop electrode, ($p = 0.170$) and mean total catheterization time was also similar for both techniques, 37.2 hours for monopolar loop electrode and 31.4 hours for PK Button ($p = 0.709$), Table 4. Rate of postoperative administration of intravesical mitomycin was also not statistically different ($p = 0.094$) between the monopolar (67.5%) and PK Button group (48.6%). Post-procedure hospitalizations were nearly identical with 9 (22%) patients hospitalized in the monopolar loop arm and 7 (18.9%) hospitalized in the PK Button arm ($p = 0.741$).

All histological specimens were adequate for pathological analysis in both study arms. Muscularis propria was present for pathological analysis in 47.2% and 56.4% in the PK button and monopolar loop groups, respectively ($p = 0.283$). The two groups had similar pathologic tumor staging distribution, Table 2.

Three month follow up data was available on all subjects. Postoperative complications within 90 days were minimal for both treatment arms, with no significant difference between groups. Only one patient in the monopolar loop arm and two patients in the PK Button arm experienced complications rated as Clavien-Dindo Grade 3a or higher, Table 3.[8] Three month tumor recurrence rates between the two arms were not found to be statistically significantly at 37.8% (14/37) for PK Button and 24.4% (10/41) for monopolar loop, $p = 0.199$, Table 3. Of the 24 tumor recurrences, 18 were superficial and 6 were muscle invasive.

TABLE 3. **Complication rates**

	Total (%)	**Monopolar loop (%)**	**PK Button electrode (%)**	**p value**
Patients experiencing complications	37 (47.4)	23 (56.1)	14 (37.8)	NS*
Post-procedure bleeding requiring transfusion	1 (1.3)	1 (2.4)	0 (0)	NS*
Bladder perforation	5 (6.4)	5 (12.2)	0 (0)	0.028*
Obturator nerve stimulation	18 (23.1)	11 (26.8)	7 (18.9)	NS*
Need for continuous bladder irrigation	15 (19.2)	11 (26.8)	4 (10.8)	0.073*
Hospitalizations post-procedure	16 (20.5)	9 (22)	7 (18.9)	NS*
90-day postoperative complications by Clavien-Dindo classification				NS*
No complications	66 (84.6%)	35 (85.4%)	31 (83.8%)	
Grade 1 and 2	9 (11.5%)	5 (12.2%)	4 (10.8%)	
Grade 3a or greater	3 (3.8%)	1 (2.4%)	2 (5.4%)	

NS = not significant, p > .05
*Chi-square test

TABLE 4. **Intra/postoperative and catheterization characteristics**

	Total	**Monopolar loop**	**PK Button electrode**	**p value**
Operative time (minutes)				NS*
N	78	41	37	
Mean	50.9	46	56	
Median (min-max)	43 (5-174)	38 (5-122)	50 (6-174)	
Intraoperative bleeding				NS*
None	8 (10.3%)	4 (9.8%)	4 (10.8%)	
Minimal	47 (60.3%)	26 (63.4%)	21 (56.8%)	
Noticeable	23 (29.5%)	11 (26.8%)	12 (32.4%)	
Purpose of catheter placement#				0.091*
None placed	50 (65.8%)	29 (72.5%)	21 (58%)	
Surgeon preference	19 (25%)	6 (15%)	13 (36%)	
Concern for bleeding	3 (3.95%)	2 (5%)	1 (2.8%)	
Concern for perforation	3 (3.95%)	3 (7.5%)	0 (0%)	
Other	1 (1.3%)	0 (0%)	1 (2.8%)	
Catheterization time# (hours)				NS*
N	74	40	34	
Mean	34.6	37.2	31.4	

NS = not significant, p > .05
*Chi-square test/Fisher's Exact Test
ANOVA
#numbers will not add to total due to missing data

Additionally, quality of visualization and instrument ease of use data was subjectively assessed. The operator experience data collected for the PK Button and the monopolar loop were respectively as follows: The operator reported the quality of visualization with PK Button as excellent in 48.4% of cases and good/fair in 51.4% of cases vs. quality of visualization with monopolar loop as excellent 72.7% of cases and good/fair in 27.3% of cases (p = 0.046). Operators rated the instrument ease of use as excellent (51.6% verus 57.6%), good/fair (45.2% versus 39.4%) and poor/unacceptable (3.2% versus 3%) for PK Button and monopolar loop, respectively (p = 0.891).

Discussion

Recent advances in the technology and instrumentation used for the treatment of bladder outlet obstruction due to an enlarged prostate has resulted in the PK Button becoming a popular alternative to monopolar TURP. This new technology for the surgical management of BPH has proved to be safer, more efficient, more durable and to have a shorter learning curve.[6,9] Reich et al report on improved incidence of both short and long term bleeding, obturator nerve stimulation and lower rates of bladder perforation.[6]

Given the success of treatment with the PK Button, the use of this technology for the vaporization of bladder tumors may be a logical application. Geavlete et al reported on 120 subjects with bladder tumors > 3 cm that were randomized to TURBT with either the PK Button or monopolar loop with post-procedure follow up out to 4 weeks. This study demonstrated higher complication rates in the monopolar loop arm compared to the PK Button arm and also reported lower total operative, catheterization and hospitalization time with vaporization.[10] Additionally, a recent small study by Abotaleb et al demonstrated a novel technique in which patients underwent bipolar kinetic enucleation of non-muscle invasive bladder tumors (PKEBT) using the PK Button. In this initial experience they reported excellent preservation of surgical specimens for pathological analysis with minimal complications.[11]

Of particular note, the PK Button technology allows for successful acquisition of adequate pathological specimens.[7] As illustrated in our technique, an initial biopsy is taken at the beginning of the case prior to PK button vaporization. Subsequently, deep biopsies are then taken following superficial tumor ablation. In no cases was our blinded GU pathologist unable to stage or grade the tumor. Although the rate of acquisition of muscularis propria reported in this study is imperfect, it was found to be consistent with previously reported literature, including a series reviewed by Capogrosso et al, in which presence of muscle ranged from 48% to 82%.[12] Furthermore and of particular importance for our study, rates of muscle in pathological specimens between the PK Button arm and monopolar loop arm were similar and statistically nonsignificant (p = 0.283).

TURBT while considered a "minor" surgical procedure, is not without significant complications. In a large retrospective study of 984 patients, Bansal et al reported a 14% complication rate with the majority being Clavien-Dindo grade 1-2 (90%) versus grade 3-5 (10%). Increased risk of complications was associated with patient age, baseline serum creatinine, size of tumor, location of tumor, surgeon experience, resection time, and completion of tumor resection.[13] Although not a specific endpoint in the current study, it may be that tumors located in difficult locations such as the dome (risk of perforation) or lateral wall (obturator reflex) are best suited for the PK Button. Further studies are warranted to investigate whether the use of this technology may reduce the rate of bladder perforation and consequently reduce the need for prolonged catheterizations and hospitalizations for patients with these tumor types.

With an emphasis on patient safety and quality outcomes there have been two studies that have examined the impact of residency involvement during TURBT. Allard et al examined intra and postoperative outcomes related to intraoperative resident involvement in TURP and TURBT using the American College of Surgeons National Quality Improvement Program (NSQIP). Specifically, for TURBT they found resident involvement was associated with increased hospital length of stay (OR 1.4), operative time (OR 2.0), and 30 day readmission (OR 1.5).[14] Secondly, Bos et al, examined 463 TURBTs at a Canadian Healthcare Institution and found that residents were less likely to obtain muscle in specimens (OR 0.59). Among patients who underwent cystectomy, time to cystectomy was delayed by a median of 23 days compared with attending urologist only.[15] Both of these studies highlight the significant learning curve of TURBT. As such, the PK Button may provide resident trainees an easier to learn technique that results in less complications.

Another area of study pertains to patients with large, potentially unresectable tumors for which the PK Button may provide maximum debulking prior to neoadjuvant chemotherapy or treatment with chemotherapy and radiation.[16,17] Furthermore, our group has initial experience utilizing this technology for percutaneous treatment of upper urinary tract tumors in the kidney. Compared to bladder tumors, percutaneous treatment of upper urinary tract tumors may be even more technically difficult due to the complex anatomy of the collecting system.

While complications were our primary endpoint, a limitation of our study is the lack of longer term (> 3 month) cancer recurrence outcomes. Additionally, we are unable to determine if the PK Button may have actually decreased the risk of certain complications due to the relatively small cohort size. However, results of this study are promising, as they show non-inferiority of complications for this device compared to traditional monopolar loop during TURBT. Future studies examining this technology in resident training, difficult to manage bladder tumors based on size or location, and for debulking prior to radiation or systemic therapy are warranted.

Conclusion

In summary, this study measured the procedural (intraoperative) and short term (3 month) outcomes of TURBT using the PK Button or the traditional monopolar loop. We met the primary endpoint for non-inferiority of the PK Button complication rate and also showed no significant difference between secondary endpoints of tumor recurrence rate, operative time and catheterization time for the two technologies. The technique outlined in this paper ensures adequate tissue for pathological review, diagnosis and staging. This is the first randomized, prospective North American study showing non-inferiority of the PK Button for treatment of bladder tumors and validates this technique as a safe and effective alternative to the standard monopolar loop TURBT. □

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