ORIGINAL PAPER

Holmium versus bipolar en bloc transurethral resection of urinary bladder tumors: a randomized controlled trial

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Citation: Higazy A, Lotfy A, Tawfeek AM, et al. Holmium versus bipolar en bloc transurethral resection of urinary bladder tumors: a randomized controlled trial. Cent European J Urol 2026; doi: 10.5173/ceju.2025.0268

Article history
Submitted: Nov. 3, 2025
Accepted: Feb. 1, 2026
Published online: Mar. 5, 2026

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Introduction The study evaluated the safety, efficacy, and pathological outcomes of holmium laser en bloc resection of bladder tumor (HoL-ERBT) vs bipolar en bloc resection of bladder tumor (Bp-ERBT).

Material and methods Adult patients with bladder masses less than 5 cm with no signs of extravesical extension on preoperative imaging were included in our study and were randomly allocated to two equal groups representing HoL-ERBT and Bp-ERBT. The primary outcome was the conversion rate of the surgical technique in each group to either conventional resection or using another energy source. Secondary outcomes were perioperative complications and pathological evaluation outcomes in each group.

Results Ninety-four patients were finally evaluated in our study. Demographic data and tumor characteristics were comparable between the two groups. The surgical conversion rate was higher in the Bp-ERBT group (9 cases) compared to the HoL-ERBT group (4 cases) (p = 0.038). No obturator nerve reflex was observed in the HoL-ERBT group compared to 8 cases in the Bp-ERBT group. Perioperative complications were comparable between the two groups. Pathological assessment revealed better T1 substaging and fewer thermal artifacts in the HoL-ERBT group (p-value 0.011 and 0.027, respectively).

Conclusions Both holmium laser and bipolar energy sources are safe and effective in en bloc bladder tumor resection. HoL-ERBT showed a superior safety profile with no occurrence of ONR and a lower conversion rate, and offers an enhanced tumor pathological assessment regarding T1 substaging and the artifact score.

Key Words: holmium laser ‹› bipolar ‹› en bloc resection ‹› bladder tumors ‹› transurethral resection of bladder tumor

INTRODUCTION

Transurethral resection of a bladder tumor (TURBT) is the standard of care for bladder masses that serve both diagnostic and therapeutic purposes. It is an initial step for proper staging and management, where it provides valuable information regarding the histological nature and degree of invasion and, consequently, proper decision-making [1, 2].

Proper staging with an adequate muscle layer and complete resection is the cornerstone of the procedure. However, TURBT has some drawbacks, including charring, inadequate tumor removal, absence of the muscle layer, and the occurrence of obturator nerve reflex (ONR) even with a bipolar current [3]. En bloc bladder tumor resection (ERBT) was introduced by Kawada et al. [6] to overcome the drawbacks of TURBT and to provide proper histological grading and staging with adequate resection, less specimen charring, and less post-resection tumor cellular dispersion. En bloc compared to the traditional resection has shown superiority in pathological staging and adequate muscle layer, fewer artifacts, and better T1 substaging [4–6].

Different energy sources can be used to perform en bloc resection; however, a head-to-head comparison in a randomized clinical trial is still lacking [7]. Our study aimed to evaluate holmium laser (HoL-ERBT) vs bipolar en bloc resection of bladder tumor (Bp-ERBT) in the management of a urinary bladder mass in terms of safety and efficacy of resection.

MATERIAL AND METHODS

A randomized controlled trial was conducted at our tertiary center to evaluate the use of bipolar and holmium energy sources in en bloc resection. Adult patients (over 18 years) diagnosed with a urinary bladder mass were included in our study after obtaining informed consent. Patients with an invasive bladder mass, hydronephrosis, or extravesical extension, as shown by contrast CT or MRI, were excluded from our study. Patients with bladder masses exceeding 5 cm or with more than three bladder masses were excluded. Although en bloc resection of tumors up to 7 cm has been reported in the literature [12], such cases were considered technically challenging and were not routinely performed at our institution. Therefore, the size and number cutoffs were predefined in the study protocol based on the surgeons' experience and institutional practice. After fulfilling the inclusion criteria, patients were randomly allocated to two equal groups with a 1:1 ratio, representing HoL-ERBT and Bp-ERBT groups, using computer-generated randomization preoperatively after outpatient evaluation and before cystoscopic resection. Surgeons and data collectors were not involved in patient selection. Patients, the pathologist, data collectors, and analysts were blinded to the type of intervention.

Preoperative patient evaluation included documentation of tumor site and size by ultrasound and contrast CT for the study population. All procedures were performed by two expert surgeons, and they contributed equally to both techniques.

Study procedure

Patients were positioned in the lithotomy position under spinal or general anesthesia, while in the case of lateral bladder wall tumors, all patients received general anesthesia. Routine diagnostic cystoscopy was initially conducted before tumor resection.

Bipolar en bloc resection was performed using a 26 Fr. Resectoscope (Karl Storz, Tuttlingen, Germany) and Karl Storz AUTOCON IV 400 with saline irrigation. A standard loop was used with energy settings of 120 W for cutting and 80 W for coagulation. Holmium en bloc resection was performed using a 550 μm laser fiber (Maxi Fibre, NEUWEG, Germany) and device setting (SPHINX JR Holmium laser device, Germany; power: 10–15 W, 1–1.5 J-10 Hz frequency).

After proper cystoscopic evaluation and identification of the correct size, number, and locations of the bladder masses, the surgical technique was similar in both groups: a circumferential incision around the tumor with a safety margin of approximately 5 mm and then a blunt dissection aided by thermal dissection to perform the en bloc resection. Finally, tumor retrieval was performed using an Ellik evacuator or Toomey syringe. A grasper was used for the retrieval of tumors that failed to be aspirated passively. Two expert surgeons from our tertiary center participated in the study, each contributing equally. Prior to the initiation of the study, each surgeon had extensive experience in ERBT using monopolar and bipolar energy sources and had already incorporated laser-based ERBT with the holmium laser, demonstrating deep familiarity with the technique using various energy sources.

Intraoperative complications such as ONR, perforation, significant bleeding, need for blood transfusion, and conversion to conventional resection were recorded. Operative time was recorded from the timing of cystoscopy to urethral catheter insertion. Intraoperative perforation was diagnosed based on the visualization of peri-vesical fat, and the method of management was documented.

Postoperative patient monitoring was done, and any postoperative complications were recorded according to the Clavien-Dindo classification [8]. Patients received adjuvant therapy in the form of mitomycin C 40 mg as per European Association of Urology (EAU) guidelines. Adjuvant treatment was withheld in cases of bladder perforation or persistent hematuria [9].

Pathological evaluation of all specimens was carried out by the same expert pathologist, who was blinded to the energy source used for the resection to minimize inter-observer variability. Pathological staging and grading were performed according to the EAU recommendations. The identification of the detrusor muscle layer, the presence of artifacts, and the ability to perform T1 group substaging were recorded in our study. For cases requiring T1 substaging, it was assessed, and the feasibility of T1 substaging to stages 1a, 1b, and 1c was documented [9, 10]. Thermal artifacts in the resected specimen were graded by the WHO grading system based on cellular architecture. Artifact grades 0–1 are considered to have minimal or no impact on pathological interpretation, grade 2 may be equivocal, while grade 3 represents artifacts that may interfere with accurate staging [11].

Our primary objective was to evaluate the conversion rate of en bloc resection to standard resection in each group or from one energy source to another. Conversion was defined by technical difficulties that prevented safe completion of en bloc resection or the need for bipolar coagulation to achieve adequate hemostasis during HoL-ERBT. Intraoperative bladder perforation, irrespective of the energy source used, required conversion to conventional resection to allow faster completion, a safer procedure, and to avoid extension of the perforation unless procedure termination was required. In addition, conversions due to obturator nerve reflex (ONR) required a switch from bipolar to holmium to avoid electric current-induced ONR.
Our secondary outcomes included the intraoperative complication rate with special consideration for the ONR, intraoperative perforation, and hemoglobin drop. In addition, we evaluated the impact of energy sources on pathological outcomes.

Statistical analysis

IBM SPSS Statistics for Windows, version 27.0 (IBM Corp., Armonk, NY) was used for data analysis. Before analysis, data were collected, revised, coded, and entered into the software. Descriptive statistics for quantitative variables included means, standard deviations, and ranges for normally distributed data, and medians with interquartile ranges (IQR) for non-normally distributed data. Qualitative variables were described using frequencies and percentages. The normality of quantitative variables was assessed using the one-sample Kolmogorov-Smirnov test. Differences in qualitative variables between groups were examined using the chi-square test, with Fisher's exact test employed when any expected cell count was less than 5. For quantitative variables, comparisons between two independent groups were conducted using the independent t-test for parametric data and the Mann-Whitney U test for non-parametric data. Statistical significance was defined as a p-value less than 0.05 ($\alpha = 0.05$), corresponding to a 95% confidence level.

Sample size calculation

The sample size was calculated using the STATA program, with a type 1 error (α) of 0.05 and a power ($1-\beta$) of 0.8. Results from a previous study by Kramer et al. (2015) [12] showed a 26.3% conversion rate in the E-ERBT group compared to 1.5% in the L-ERBT group. Calculations according to these values produce a sample size of at least 45 cases per group, considering a 10% dropout rate.

Bioethical standards

The study was approved by the Research Ethics Committee of the Faculty of Medicine, Ain Shams University, Cairo, Egypt (FWA000017585) with ethical approval number R32/2020. The study was registered at clinicaltrials.gov with registration number NCT04576286.
Written informed consent was obtained from all patients' parents or legal guardians before participation.

RESULTS

At the end of our study, 94 patients were evaluated (Figure 1). Six patients were excluded because their pathological specimens were assessed by a different pathologist, which was considered a deviation from the study protocol designed to minimize interobserver variability in assessment. Table 1 presents patients' demographic data and tumor characteristics.
Perioperative data are presented in Table 2. ONR was observed in the Bp-ERBT group, and all instances were associated with lateral bladder wall masses, while no ONR was noted in the HoL-ERBT. Bladder perforation was noted during cystoscopy in 2 (4.2%) and 4 (8.7%) cases in the HoL-ERBT and Bp-ERBT groups, respectively, with no statistically significant difference (p-value 0.369). No patient in our study required surgical exploration.
When perforation was observed or suspected, often following ONR, the procedure was converted to either standard resection or HoL-ERBT. The surgical conversion rate was statistically significant

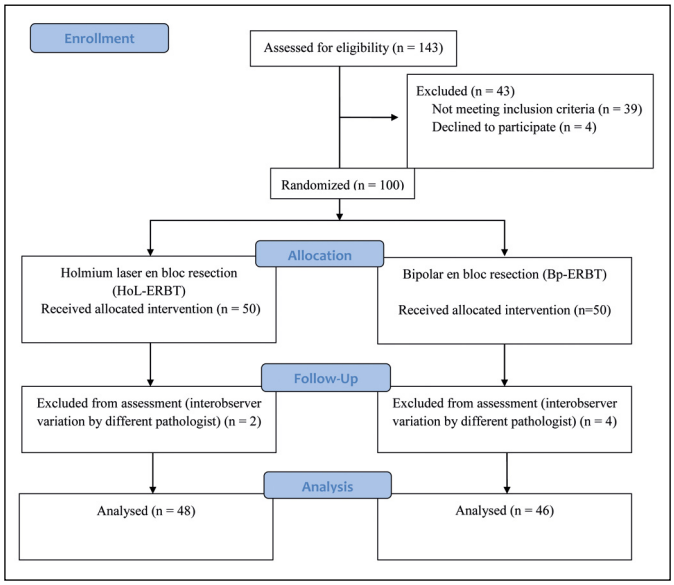

Figure 1. *CONSORT flow diagram.*

in the Bp-ERBT group (9 cases, p = 0.038). Two cases were converted to the standard resection technique, while 7 cases were switched to HoL-ERBT to manage ONR. On the other hand, 4 cases in the HoL-ERBT group were converted to the standard resection technique due to intraoperative bleeding that required adequate hemostasis using bipolar coagulation to allow for safe resection.

Table 1. *Demographic data and tumor characteristics*

Variable		Laser en bloc resection (HoL-ERBT) n = 48	Bipolar en bloc resection (Bp-ERBT) n = 46	p
Sex	Female	8 (16.7%)	5 (10.9%)	0.416
	Male	40 (83.3%)	41 (89.1%)	
Age	Mean ±SD	66.9 ±5.35	66.83 ±4.7	0.947
	Range	58–77	59–75	
Size (cm)	Mean ±SD	3.44 ±0.75	3.04 ±1	0.032
	Range	2.1–4.8	1.5–5	
Number	Mean ±SD	1.90 ±0.81	1.89 ±0.82	0.968
	Range	1–3	1–3	
Site	Right lateral	11 (22.9%)	14 (30.4%)	0.944
	Left lateral	12 (25.0%)	11 (23.9%)	
	Posterior wall	15 (31.3%)	12 (26.1%)	
	Trigone	5 (10.4%)	4 (8.7%)	
	Anterior wall	2 (4.2%)	3 (6.5%)	
	Bladder neck	3 (6.3%)	2 (4.3%)	

Table 2. *Perioperative data*

Variable			Laser en bloc resection (HoL-ERBT) n = 48	Bipolar en bloc resection (Bp-ERBT) n = 46	p
Operative time (in minutes)			32.848 ±6.834 Range: 23–40	38 ±10.325 Range: 20–49	0.006
Surgical technique conversion			4 (8.3%)	9 (19.5%)	0.038
Obturator reflex (ONR)			0 (0.0%)	8 (17.4%)	0.003
Perforation			2 (4.2%)	4 (8.7%)	0.369
Hb drop			0.47 ±0.23	0.35 ±0.11	0.421
Catheter time in days			2.11 ±0.47	2.52 ±0.86	0.013
Clavien-Dindo Classification	Grade 1	Transient hematuria	6 (12.5%)	3 (6.5%)	0.411
		Prolonged catheterization	2 (4.2%)	4 (8.7%)	
		Total	8 (16.7%)	7 (15.2%)	
	Grade 2	Urinary tract infection	3 (6.25%)	4 (8.7%)	0.21

No statistically significant difference between groups was observed regarding catheter removal time or perioperative complications. No patient required a postoperative cystogram to evaluate the minor perforation. Catheter time was prolonged for 5 days in patients with perforation. No Clavien-Dindo complications of grade 3, 4, or 5 were noted in our study.

Pathological evaluation in our study is shown in Table 3. No specimens in either group were deemed inadequate for histopathological diagnosis due to thermal artifacts. The detrusor muscle layer was present in the resected specimen in 98% of cases, with no statistically significant difference between the groups. T1 substaging was more accurately evaluated in the HoL-ERBT group, with a statistically significant difference (p = 0.011). The thermal artifact score from energy dispersion was higher in the Bp-ERBT group, with a statistically significant difference (p = 0.027).

DISCUSSION

ERBT is a technique that evolved from conventional TURBT by removing the bladder tumor in one piece rather than cutting it into small pieces.

Table 3. *Pathological evaluation*

Variable		Laser en bloc resection (HoL-ERBT) n = 48	Bipolar en bloc resection (Bp-ERBT) n = 46	p
Histology	Urothelial carcinoma	47 (97.9%)	44 (95.7%)	0.590
	Squamous cell carcinoma	1 (2.1%)	1 (2.2%)	
	Adenocarcinoma	0 (0.0%)	1 (2.2%)	
Muscle layer	Present	47 (98%)	45 (97.8%)	0.304
	Absent	1 (2%)	1 (2.2%)	
T1 substaging	Not applicable	2 (4.2%)	6 (13.0%)	0.011
	Applicable	46 (95.8%)	36 (78.3%)	
Artifact score (0-3)	Mean ± SD	0.08 ± 0.28	0.39 ± 0.74	0.027
	Range	0 – 1	0 – 2	
Stage	Ta	20 (41.7%)	22 (47.8%)	0.321
	T1	23 (47.9%)	21 (45.7%)	0.548
	T2	5 (10.4%)	3 (6.5%)	0.122
Grade	Low	18 (37.5%)	17 (37.0%)	0.957
	High	30 (62.5%)	29 (63.0%)	0.782
	G1	10	12	0.212
	G2	8	5	0.09
	G3	30	29	0.66

Its efficacy has been documented in previous trials with tumors up to 7 cm [12, 13]. ERBT provides complete resection with better histological evaluation and staging than the standard resection [7, 12]. Different energy sources can be used for ERBT, such as electric current (monopolar, bipolar) or laser energy (holmium, thulium). Laser energy offers the advantage of reduced thermal damage in the resected specimen. This is crucial, because excessive heat charring can hinder accurate tumor staging, potentially leading to undertreatment [11, 14, 15].

We conducted our study to evaluate two different energy sources in ERBT and their impact on perioperative outcomes. Preoperative parameters were similar in both groups, with a mean tumor size of 3.4 ±0.75 and 3.04 ±1 cm in the HoL-ERBT and the Bp-ERBT groups, respectively.

The technique was feasible in both groups. There were 9 cases of surgical conversion in the Bp-ERBT group compared to 4 cases in the HoL-ERBT group, with a statistically significant difference ($p = 0.038$). The higher conversion rate in the Bp-ERBT group was mainly due to the occurrence of ONR in 7 cases and minor perforation in the other 2 cases, while conversion in the HoL-ERBT group was due to the need for adequate hemostasis. In some cases, conventional resection with bipolar current for random bladder biopsies was used after HoL-ERBT or to enhance hemostasis; this adjunctive use of bipolar current was not systematically recorded or quantified and was therefore not included in the outcome analysis; however, these additional maneuvers were performed after completion of the primary en bloc resection and did not affect the integrity of the en bloc specimen or the primary outcome of conversion.

Kramer et al. [12] reported a conversion rate in favor of laser en bloc resection, with 1 (1.5%) case of conversion to conventional resection compared to 41 (26.3%) cases in the electric en bloc resection (including mono- and bipolar current) [12]. On the other hand, Mancon et al. [1] and Diana et al. [16] reported no statistically significant differences between monopolar, bipolar, and laser en bloc resection.

No cases of ONR were reported in the holmium group compared to 8 (17.4%) cases in the Bp-ERBT group. Kramer et al. [12], Nayak et al. [16], and Mancon et al. [17] reported similar results, with no incidence of ONR in laser resection and an occurrence of ONR in electric resection.

ONR was mainly reflected in a higher conversion rate in the Bp-ERBT group, while the incidence of bladder perforation, as noted intraoperatively, showed no significant difference between the two groups. Similar results regarding the incidence of perforation were reported by Mancon et al. [16] and Diana et al. [1].

Although operative time showed a statistically significant difference in favor of HoL-ERBT, this difference is unlikely to be clinically meaningful. These few minutes do not indicate clinical superiority and could be attributed to many factors, such as ONR occurrence, energy-specific ergonomics, intraoperative bleeding requiring hemostasis, tumor characteristics (size, location, and number), and case-to-case variability, rather than true superiority of one technique over another.

The energy source used during the en bloc resection did not impact the Clavien-Dindo classification between the groups, as shown in Table 2. Previous studies reported similar results [1, 12, 16]. In our study, catheter removal time was higher in the Bp-ERBT group, with a statistically significant difference ($p = 0.013$). Although it was statistically significant, we believe it is clinically negligible. Kramer et al. [12] reported no difference in the catheter removal time in their study groups. Diana et al. [1] reported a shorter catheter time in favor of monopolar current, while bipolar current and laser energy showed no statistically significant difference.

Pathological assessment of the resected specimen for tumor histology, grade, stage, presence of muscle layer, feasibility of T1 substaging, and artifact score was conducted in both groups. The presence of the detrusor muscle layer in the resected specimen showed no statistically significant difference between the two groups. However, T1 substaging was more feasible in the HoL-ERBT group, with success observed in 26 specimens (92.9%) out of 28 requiring substaging, compared to 18 (75%) out of 24 cases in the Bp-ERBT group, and this difference was statistically significant ($p = 0.011$).

Thermal artifacts in the resected specimen were graded according to the WHO grading system based on cellular architecture. This scoring system is classified into 4 grades from 0 to 3, where a higher grade represents a higher degree of artifacts. In our evaluation, the artifact score was significantly higher in the Bp-ERBT group compared to the HoL-ERBT group ($p = 0.027$). Holmium laser produces fewer thermal artifacts due to shallow tissue penetration, pulsed emission, and high water absorption. These characteristics limit thermal spread and tissue charring compared to bipolar current. Diana et al. [1] reported the feasibility of T1 substaging in all en bloc cases regardless of the energy source, finding no statistically significant difference. However, the artifact score in their study was impacted by tumor location rather than the energy source.

We concluded from our study that ERBT is feasible and safe regardless of the energy source, either holmium laser or bipolar current. Holmium is beneficial in lateral wall tumors, allowing safe and effective resection with no ONR and a lower conversion rate compared to Bp-ERBT, which was associated with ONR. It is worth noting that transitioning from en bloc resection to conventional resection is more straightforward with bipolar current, as it avoids the need to change instruments while using the same energy source. Adequate hemostasis may necessitate bipolar current in certain situations. Consequently, for cases where significant hemostasis is anticipated, such as large tumors or in the presence of hematuria, Bp-ERBT might be the preferred choice. Conversely, for lateral wall tumors, HoL-ERBT appears more beneficial. Tailoring the choice of energy source can lead to better ergonomics and prevent the need to switch between energy sources during the operation.

In our study, pathological evaluation showed superiority of HoL-ERBT in terms of fewer specimen artifacts and better T1 substaging analysis. However, we did not evaluate the impact of this evaluation on the treatment plan, tumor recurrence, or progression, as the study focused on technical and pathological feasibility rather than oncological outcomes.

Our study has some limitations. Firstly, it was a single-center study. Secondly, we did not evaluate the impact of the energy source on tumor recurrence and progression in the ERBT, as it was not part of our initial study plan. Thirdly, we did not evaluate the impact of tumor location on the efficacy and safety of ERBT, as our primary focus was to evaluate the impact of energy source rather than tumor site, and there was a limited number of cases. Six patients were excluded before our final analysis, as reported in the CONSORT flow diagram, because their pathological specimen was assessed by a different pathologist, which was considered a deviation from the study protocol designed to minimize interobserver variability in assessment. Finally, the occasional use of bipolar resection for random biopsies following HoL-ERBT was not recorded after completion of the primary en bloc resection, although it did not impact the primary outcome or safety of the procedure. In future studies, surgical margin status should be systematically evaluated for each technique and correlated with oncological outcomes. The availability of the holmium laser may have influenced the observed conversion pattern in our study. This conversion reflects a real-world practice prioritizing patient safety rather than technical failure.

CONCLUSIONS

Both holmium and bipolar energy sources are safe and effective in ERBT. However, HoL-ERBT demonstrated a better safety profile, characterized by the absence of ONR, a lower conversion rate, and improved tumor pathological assessment in terms of T1 substaging and the artifact score.

CONFLICT OF INTERESTS

The authors declare no conflict of interest.

FUNDING

This research received no external funding.

ETHICS APPROVAL STATEMENT

The study was approved by the Research Ethics Committee of the Faculty of Medicine, Ain Shams University, Cairo, Egypt (FWA000017585) with ethical approval number R32/2020.

The study was registered at clinicaltrials.gov with registration number NCT04576286.

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