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TOPIC PAPER

Energy source comparison in en-bloc resection of bladder tumors: subanalysis of a single-center prospective randomized study

Pietro Diana[1,2] · Andrea Gallioli[1] · Matteo Fontana[1] · Angelo Territo[1] · Alejandra Bravo[1] · Alberto Piana[1] · Michael Baboudjian[1,3,4] · Pavel Gavrilov[1] · Óscar Rodriguez-Faba[1] · Josep Maria Gaya[1] · Ferran Algaba[5] · Joan Palou[1] · Alberto Breda[1]

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Abstract

Purpose Different energy sources are employed to perform en-bloc transurethral resection of bladder tumor (ERBT). No study compared different energy sources in ERBT. The aim is to compare the different ERBT sources in terms of pathological, surgical and postoperative outcomes.

Methods This is a sub-analysis of a prospective randomized trial enrolling patients submitted to ERBT vs conventional TURBT from 03/2018 to 06/2021 (NCT04712201). 180 patients enrolled in ERBT group were randomized 1:1:1 to receive monopolar (m-ERBT), bipolar (b-ERBT) or thulium laser (l-ERBT). Endpoints were the comparison between energies in term of pathological analysis, intra, and post-operative outcomes.

Results 49 (35%) m-ERBT, 45 (32.1%) b-ERBT, and 46 (32.9%) l-ERBT were included in final analysis. The rate of detrusor muscle (DM) presence was comparable between the energies used ($p=0.796$) or the location of the lesion ($p=0.662$). Five (10.2%), 10 (22.2%) and 0 cases of obturator nerve reflex (ONR) were recorded in m-ERBT, b-ERBT and I-ERBT groups, respectively ($p=0.001$). Conversion to conventional TURBT was higher for lesions located in the anterior wall/dome/neck ($p<0.001$), irrespective from the energy used. The presence of artifact in the pathological specimen was higher for lesions at the posterior wall ($p=0.03$) and trigone ($p=0.03$).

Conclusions In our study, no difference in staging feasibility among energies was found. Laser energy might be beneficial in lateral wall lesions to avoid ONR. Since there is an increased risk of ERBT conversion to conventional TURBT for lesions of the anterior wall, electrocautery might be preferred over laser to avoid waste of material.

Keywords Urothelial cancer · Endoscopy · Resection · Diagnosis · Treatment · Energy · Energies

Abbreviations

BC	Bladder cancer
EAU	European association of urology
ERBT	En-bloc resection of bladder tumor
b-ERBT	ERBT-bipolar energy
m-ERBT	ERBT-monopolar energy
l-ERBT	ERBT-thulium laser energy
cTURBT	Conventional transurethral resection of bladder tumor
MIBC	Muscle-invasive bladder cancer
NMIBC	Non-muscle invasive bladder cancer
TURBT	Transurethral resection of bladder tumor
UUT	Upper urinary tract

Pietro Diana and Andrea Gallioli equally contributed to the manuscript.

✉ Pietro Diana
pietros.diana@gmail.com

1 Fundació Puigvert, Department of Urology, Autonomous University of Barcelona, Cartagena 340-350, 08025 Barcelona, Spain

2 Department of Urology, Humanitas Research Hospital-IRCCS, Rozzano, Italy

3 Department of Urology, APHM, North Academic Hospital, Marseille, France

4 Department of Urology, La Croix du Sud Hôpital, Quint Fonsegrives, France

5 Fundació Puigvert, Department of Pathology, Autonomous University of Barcelona, Barcelona, Spain

Introduction

Conventional transurethral resection of bladder tumor (cTURBT) is the standard treatment for non-muscle-invasive bladder cancer (NMIBC) [1]. Optimal staging at tumor resection is a crucial step in the management of BC, as it provides valuable information and prognostic elements that help guide further treatment decisions. Detrusor muscle presence/absence appears to be a surrogate marker of resection quality by independently predicting early bladder recurrence [2]. However, absence of detrusor muscle has been reported up to 40% using the cTURBT technique [3]. To overcome this and other drawbacks, en-bloc resection of bladder tumor (ERBT) has been introduced by Kawada et al. two decades ago [4]. Thus, ERBT is employed to improve the quality of pathological analysis, obtaining a more informative specimen, to preserve tumor integrity avoiding tumor cell dispersion and improve oncological outcomes [5, 6].

To date, different energy sources (monopolar, bipolar, laser, and hybridknife) have been introduced in performing ERBT [6]. In this scenario, multiple studies have compared the different energy sources used without providing clear conclusions due to heterogeneity in study design and ERBT energy sources [7]. In addition, high-quality data from head-to-head randomized controlled trials (RCTs) are still lacking. To address this question, we designed the a RCT comparing cTURBT versus ERBT employing all available energies to perform a sub-analysis comparing the different ERBT sources (monopolar, bipolar and laser) in terms of operative and postoperative outcomes and to provide guidance based on lesion location and energy source.

Materials and methods

Study design and population

This is a subanalysis of a single-center prospective, randomized, controlled, non-inferiority trial analyzing patients subjected to ERBT versus cTURBT for bladder cancer (BC). Only patients treated with ERBT were included for the purpose of this study. Eligible patients were aged ≥ 18 years, had primary or recurrent BC with a maximum of 3 concomitant lesions and a maximum of 3 cm of diameter. Patients with suspicion of MIBC or ureteral involvement were excluded from the randomization. Patients randomly allocated to ERBT were further randomized depending on energy source: monopolar (m-ERBT), bipolar (b-ERBT-b) or thulium laser (l-ERBT) energy in a 1:1:1 manner using computer-generated randomization tables. In particular, 180 patients were randomized to the ERBT test group (60 patients each for the m-ERBT, b-ERBT, and l-ERBT subgroups). Re-evaluation was ultimately performed before the endoscopic procedure and in case inclusion criteria were not met (e.g. increase in tumor size and/or number or absence of tumor) the patient was excluded and recorded as drop-out. The study was suspended between March 2020 and September 2020 due to Sars-COV2 pandemic and in this period of time, no patient was considered for eligibility. This study was carried out according to the principles of the Declaration of Helsinki and was approved by the Institutional Review Board (2017/09c). The study was registered on ClinicalTrials.gov (NCT04712201). All participants were adequately informed and provided a written consent.

Pre-operative evaluation, surgical procedure, and histopathological analysis

Pre-operative evaluation included patients' anthropometric variables, comorbidities, history of NMIBC, bladder ultrasound and/or flexible cystoscopy, and urine cytology. An abdominal computed tomography (CT) scan was performed in case of suspicion of muscle-invasive bladder cancer (MIBC) or upper urinary tract (UUT) involvement. The resections were performed by 7 senior urologists (> 5 year of experience), 4 junior urologists (< 5 year of experience), and by 3rd–5th residents supervised by at least one urologist of the team. Surgical procedures were performed with the patient in the standard lithotomy position under spinal or general anesthesia. Resectoscope of 26Ch. (*Karl Storz*, Tuttlingen, Germany) were employed and saline (b-ERBT and l-ERBT) or glycine (m-ERBT) solutions as bladder distension mediums depending on energy source. After initial intra-operative cystoscopy, the lesion was identified and described according to number of lesions, dimension, and position (trigon, posterior wall, lateral walls, anterior wall, dome, and bladder neck). Collins loop and rectangular (*Karl Storz*, Tuttlingen, Germany) loop were employed when m-ERBT and b-ERBT were performed, respectively (Fig. 1) using Karl Storz UH 400 surgical generator. l-ERBT was carried out with the employment of a 550 µm fiber connected to a thulium laser generator (Revolix Duo, *LisaLaser*, Katlenburg-Lindau, Germany) set to 10–20 W power. ERBT, regardless of the energy employed, was performed as a circular incision around the tumor base, cutting through macroscopically healthy mucosa with a safety margin of 5–10 mm and bluntly dissecting the tumor from the bladder wall at the desired depth. The specimen was extracted by grabbing it with the electrode or using a glass Toomey evacuator, and it was subsequently processed for pathological evaluation according to a standard internal protocol. In cases in which the specimen was too large to pass through the

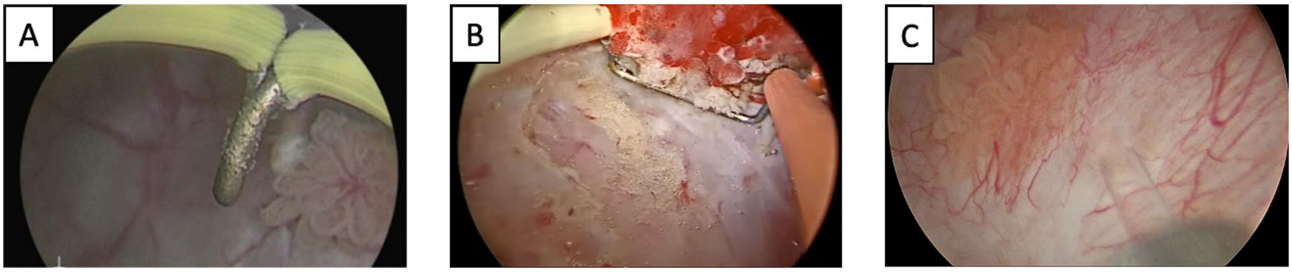

Fig. 1 Collins monopolar knife (**A**), rectangular bipolar loop-*Karl Storz*, Tuttlingen, Germany (**B**) and 550 µm Thulium: YAG laser fiber (**C**)

resectoscope, the lesion was subsequently cut in two or three pieces for extraction. Perforation was defined as a resection depth reaching the perivesical fat and beyond. A 20–22 Ch three-way bladder catheter was inserted at the end of the procedure, and continuous bladder irrigation was started. Early one-shot instillation of 40 mg mitomycin C or 50 mg epirubicin was administered according to current guidelines, recording if the instillation was indicated but not given due to bladder wall perforation or excessive bleeding. Patients followed the postoperative care and follow-up protocols of our institution in line with current EAU NMIBC guidelines [1]. Finally, a dedicated uropathologist (F.A.) blinded to the type of energy used analyzed all specimens for staging. BC staging of the lesion was classified according to the American Joint Committee on Cancer/Union for International Cancer Control TNM system and the World Health Organization classification [8]. In case of a T1 tumor, T1 substaging was performed if feasible according to the T1a, T1b, and T1c substaging system depending on the depth of invasion of the muscularis mucosae–vascular plexus [9].

Endpoints

Primary endpoint of the subanalysis was the comparison between energies in term of pathological analysis (detrusor muscle (DM) presence, staging feasibility, and presence of artifacts). Secondary endpoints were intra-operative (obturator nerve reflex (ONR), hemoglobin (Hb) drop, and bladder wall perforation) and post-operative (the rate of post-operative intravesical instillation feasibility after BC resection in patients meant to receive it according to the European Association of Urology (EAU) guidelines [1], irrigation and catheterization time, hospital stay, and post-operative complications scored according to the Clavien-Dindo classification [10]) outcomes.

Statistical analysis

Data were complemented by descriptive statistical analysis. Categorical variables were reported as frequencies and percentages (%), and continuous variables as means and standard deviations (SD). Differences between study groups in baseline variables were analyzed with ANOVA for continuous variables or chi-squared test for categorical ones. All the tests were conducted at a significance level $p = 0.05$. Statistical analyses were performed using SPSS v.26 (IBM Corp., Armonk, NY).

Results

A total of 180 participants were enrolled between April 2018 and June 2021. Fourty (22.2%) patients were subsequently excluded because they did not meet inclusion criteria. One hundred and forty patients were included in the final analysis: 49 (35%) m-ERBT, 45 (32.1%) b-ERBT, and 46 (32.9%) l-ERBT. One-hundred nine (77.9%) patients were male and mean age was 71 years (± 11.8). Each energy group were similar in terms of patient (Supplementary Table 1) and tumor (Supplementary Table 2) characteristics, except for the baseline number of tumor which was higher in the l-ERBT patients (1.62 ± 0.59) than patients who underwent m-ERBT (1.24 ± 0.48) and b-ERBT (1.3 ± 0.78; $p = 0.009$). Pathological tumor staging was as follow: 11 T0 (7.8%), 6 Tx (4.3%), 2 CIS (1.4%), 90 Ta (64.3%), 20 T1a (14.3%), 5 T1b (3.6%), 6 T2 (4.3%) tumors.

Tables 1, 2 show the intra- and post-operative outcomes by either energy source employed (m-ERBT, b-ERBT, and l-ERBT) or by bladder walls (group 1: trigone and the posterior wall; group 2: right and left lateral walls; and group 3: anterior wall, dome, and bladder neck), respectively. In total, DM was present in 133 pathological specimens (95%). The rate of DM presence was comparable between the energies used ($p = 0.796$) or the location of the lesion ($p = 0.662$). The rate of DM presence was similar between residents and attendings (96.4 vs. 94% $p = 0.702$). While no case of ONR occurred in the I-ERBT group, five (10.2%) and ten (22.2%) cases were recorded in the m-ERBT and b-ERBT patients, respectively ($p = 0.001$). The overall length of postoperative catheterization was 2.4 days (± 1.8) and was significantly shorter in the m-ERBT group ($p = 0.034$). As shown in Table 2, conversion from EBRT

Table 1 Intra-operative and post-operative outcome divided by energy source (monopolar, bipolar, and laser) and ANOVA or Fisher exact test analysis of the overall distribution between the three groups and pair comparisons

Energy employed	Overall	Monopolar	Bipolar	Thulium laser	ANOVA or fisher exact test (*p* value)	Monopolar vs bipolar	Monopolar vs thulium laser	Bipolar vs thulium laser
Number of patients, *n* (%)	140	49 (35)	45 (32.1)	46 (32.9)	–	–	–	–
Lesion location, *n* (%)					0.505	–	–	–
Posterior/trigone	39 (27.9)	15 (30.6)	15 (33.3)	9 (19.6)				
Lateral walls	79 (56.4)	25 (51)	25 (55.6)	29 (63)				
Anterior/dome/neck	22 (15.7)	9 (18.4)	5 (11.1)	8 (17.4)				
Surgery duration, mean (SD)	33.4 (17.5)	31.8 (16.9)	34.7 (17.6)	33.8 (18.3)	0.72	–	–	–
Conversion to cTURBT, *n* (%)	6 (4.3)	2 (4.1)	2 (4.4)	2 (4.3)	1	–	–	–
Obturator nerve reflex, *n* (%)	**15 (10.7)**	**5 (10.2)**	**10 (22.2)**	**0 (0)**	**0.001**	0.159	**0.056**	**< 0.001**
Perforation, *n* (%)	28 (20)	7 (14.3)	13 (28.9)	8 (17.4)	0.193	0.129	0.781	0.221
Planned early CT instillation, *n* (%)	69 (49.3)	26 (53.1)	22 (48.9)	21 (45.7)	0.633	–	–	–
Performed early CT instillation of planned, n (%)	65 (94.2)	26 (100)	20 (90.9)	19 (86.4)	0.494	–	–	–
Complications, *n* (%)					–	–	–	–
No complications	111 (79.3)	43 (87.8)	23 (73.3)	35 (76.1)				
Clavien-dindo 1–2	23 (16.4)	5 (10.2)	8 (17.8)	10 (21.7)				
Clavien-dindo 3	6 (4.3)	1 (2)	4 (8.9)	1 (2.2)				
Overall complications, *n* (%)	29 (20.7)	6 (12.2)	12 (26.7)	11 (23.9)	0.172	0.114	0.182	0.812
Major complications, *n* (%)	6 (4.3)	1 (2)	4 (8.9)	1 (2.2)	0.282	–	–	–
Artifacts	11 (7.9)	2 (4.1)	6 (13.3)	3 (6.5)	0.253	–	–	–
Detrusor muscle					0.796	–	–	–
Yes	133 (95)	47 (95.9)	42 (93.3)	44 (95.7)				
No	7 (5)	2 (4.1)	3 (6.7)	2 (4.3)				
T1 substage feasibility					1	–	–	–
Yes	25 (100)	9 (100)	8 (100)	8 (100)				
No	0 (0)	0 (0)	0 (0)	0 (0)				
Length of irrigation, mean (SD)	0.9 (0.9)	0.9 (0.9)	1 (0.9)	0.9 (0.8)	0.692	–	–	–
Length of catheterization days, mean (SD)	**2.4 (1.8)**	**1.9 (1.3)**	**2.5 (1.8)**	**2.8 (2.1)**	**0.034**	0.162	**0.033**	0.779
Length of stay, mean (SD)	2.1 (1.2)	2.1 (1.4)	2.4 (1.3)	2.1 (0.9)	0.525	–	–	–
Post-op hemoglobin, mean (SD)	9 (9.4)	6.8 (8.8)	9.7 (9.8)	10.7 (9.3)	0.167	0.374	0.166	0.891

cTURBT conventional transurethral resection of bladder tumor, *SD* standard deviation, *CT* chemotherapy, *ANOVA* analysis of variance

to cTURBT was found to be higher for lesions located in the anterior wall, dome or bladder neck, reaching 22.7% (5/22; $p < 0.001$). The presence of artifact in the pathological specimen ($p = 0.030$) was higher for lesions located to the posterior wall and trigone (17.9%; 7/39, $p = 0.03$). Overall complication rate and major complication rate was 12.2/2%, 26.7/8.9%, and 23.9/2.2% for m-ERBT, b-ERBT, and l-ERBT, respectively. Subgroup analysis comparing the energy used per bladder wall is provided in supplementary Tables 3, 4. In case of anterior wall lesions, the rate of conversion from ERBT to cTURBT was significantly higher for both monopolar ($p = 0.031$) and laser energy ($p = 0.027$); the occurrence of ONR, recorded only in the lateral walls, was significantly higher when we used monopolar and bipolar electrocautery energies ($p = 0.016$ and $p < 0.001$, respectively).

Table 2 Intra-operative and post-operative outcome divided by bladder walls (posterior/trigone, lateral walls, and anterior/dome/neck) and ANOVA or Fisher exact test analysis of the overall distribution between the three groups and pair comparisons

Energy employed	Overall	Posterior/trigone (1)	Lateral walls (2)	Anterior/dome/neck (3)	ANOVA or fisher exact test (*p* value)	1 vs. 2	1 vs. 3	2 vs. 3
Number of patients, *n* (%)	140	39 (27.9)	79 (56.4)	22 (15.7)	–	–	–	–
Energy, *n* (%)					0.285	–	–	–
Monopolar	39 (27.9)	15 (38.5)	25 (31.6)	9 (40.9)				
Bipolar	79 (56.4)	15 (38.5)	25 (31.6)	5 (22.7)				
Thulium laser	22 (15.7)	9 (23)	29 (36.8)	8 (36.4)				
Surgery duration, mean (SD)	33.4 (17.5)	29.6 (16.8)	35.2 (16.4)	33.6 (21.9)	0.261	–	–	–
Conversion to cTURBT, *n* (%)	**6 (4.3)**	**1 (2.6)**	**0 (0)**	**5 (22.7)**	**< 0.001**	0.33	**0.019**	**< 0.001**
Obturator nerve reflex, *n* (%)	15 (10.7)	3 (7.7)	13 (16.5)	0 (0)	0.071	0.257	0.547	0.065
Perforation, *n* (%)	28 (20)	8 (20.5)	16 (20.3)	4 (18.2)	1	–	–	–
Planned early CT instillation, *n* (%)	69 (49.3)	16 (41)	42 (53.2)	11 (50)	0.461	–	–	–
Performed early CT instillation of planned, *n* (%)	65 (94.2)	15 (38.5)	40 (50.6)	10 (45.5)	0.787	–	–	–
Complications, *n* (%)					–	–	–	–
No complications	111 (79.3)	31 (79.5)	65 (82.3)	15 (68.2)				
Clavien-dindo 1–2	23 (16.4)	6 (15.4)	11 (13.9)	6 (27.3)				
Clavien-dindo 3	6 (4.3)	2 (5.1)	3 (3.8)	1 (4.5)				
Overall complications, *n* (%)	29 (20.7)	8 (20.5)	14 (17.7)	7 (31.8)	0.357	–	–	–
Major complications, *n* (%)	6 (4.3)	2 (5.1)	3 (3.8)	1 (4.5)	1	–	–	–
Artifacts	**11 (7.9)**	**7 (17.9)**	**3 (3.8)**	**1 (4.5)**	**0.03**	**0.014**	0.238	1
Detrusor muscle					0.662	–	–	–
Yes	133 (95)	36 (92.3)	76 (96.2)	21 (95.5)				
No	7 (5)	3 (7.7)	3 (3.8)	1 (4.5)				
T1 substage feasibility					1	–	–	–
Yes	25 (100)	6 (100)	18 (100)	2 (100)				
No	0 (0)	0 (0)	0 (0)	0 (0)				
Length of irrigation, mean (SD)	0.9 (0.9)	0.8 (0.6)	0.9 (0.9)	1.3 (1.2)	0.069	0.671	0.057	0.152
Length of catheterization days, mean (SD)	2.4 (1.8)	2.1 (1.4)	2.5 (1.8)	2.6 (2.3)	0.382	–	–	–
Length of stay, mean (SD)	2.1 (1.2)	1.9 (0.9)	2.3 (1.3)	2.4 (1.5)	0.275	–	–	–
Hemoglobin drop, mean (SD)	9 (9.4)	7.2 (6.7)	8.8 (9.2)	12.1 (12.4)	0.203	0.746	0.182	0.349

cTURBT conventional transurethral resection of bladder tumor, *SD* standard deviation, *CT* chemotherapy, *ANOVA* analysis of variance

Discussion

Presence of DM in the histopathological specimens after resection of BC is the most reliable indicator for an adequate and high-quality resection [11]. This concept is fundamental to decide the surgical strategy in the setting of BC as the lack of DM could bring to a suboptimal staging of BC and subsequent management and prognosis. ERBT has proven to be the a highly reliable method for obtaining DM in resected specimens [12, 13], but whether the different energy sources available are capable of providing the same results was an unresolved question until then. Here we report the first evidence analyzing and comparing the different energies available to achieve ERBT in a RCT. We found that both electrocautery and laser energies are suitable for an apparently satisfactory staging rate resulting in low rates of DM absence regardless of the energy employed and a comparable rate of artifacts in the specimens. Our results are in line with the previously reported rate of detrusor muscle presence in ERBT specimens, ranging from 87–98, 40–100, and 51–100% for laser [14–16], monopolar [17, 18], and bipolar [19–21] electrocautery energies, respectively. Given the number of patients included, the prospective, randomized design, and the head-to-head comparison of each energy used for ERBT, our study provides the best available evidence of what can be expected from each energy source to achieve detrusor muscle presence during ERBT.

The energy source to be used to perform ERBT may vary depending on the location of the lesion. For the lateral wall, we found a higher rate of ONR using monopolar or bipolar energies compared to a laser source. Therefore, l-ERBT seems to potentially be the best option to ensure a safer procedure.

Bipolar resection has been suggested to reduce the risk of perforation compared monopolar energy with rates of 21.5 vs 6.1%, respectively ($p=0.039$) [22]. The hypothesis is founded on the decreased elicitation of ONR using bipolar energy. However, this advantage is debated with RCT reporting the lack of this superiority ($p=1$) [23]. Our study is the first comparing bipolar and monopolar energies in the ERBT setting. The results show no significant difference in terms of either bladder perforation and post-operative.

Major importance should also be given to the rate of conversion to cTURBT. Out of 6 conversion, in 5 cases BC was found on the anterior wall and dome and in one case it was in the proximity of the meatus. In 22.7% of lesions of the anterior wall, conversion was necessary as no adequate visibility could be reached to perform ERBT. This limitation of laser should be kept in mind when planning the surgical approach as, in these cases, electrical energies (either monopolar or bipolar) should be preferred to avoid the increased potential risk of changing instruments and the subsequent waste of surgical material. The study by Kramer et al. compared the rate of conversion between different energies and found a higher rate of conversion to cTURBT compared to our study (19.9 vs. 4.3%) and almost all cases of conversion occurred in case of electrical energy employment [24]. As stated by the authors the change to cTURBT was influenced by an easier switch in case of employment of electrical energy as it does not require a change of the instrumentation. Most importantly, we believe that the location of the lesion is the main factor influencing the feasibility of ERBT rather than the kind of energy employed.

Finally, despite the shorter mean time of catheterization when monopolar is employed in case of posterior wall or trigone lesions was a statistically significant, the comparable length of irrigation and hospital stay make this difference less clinically relevant.

Our study is not devoid of limitations. First of all, this is a single-center study conducted in a high-volume center with expertise in performing EBRT which does not reflect low and medium volume centers performance. The numerosity of the population was calculated for the comparison between cTURBT versus ERBT and it was not focused on this sub-analysis that may result in underpowered analysis, thus these results should be confirmed by a tailored study design. Moreover, despite these were not the objective of this study, is the lack of comparison with cTURBT and of the oncological outcome that could give further information on energy employment indications. This study is first prospective randomized trial analyzing the energy sources available to perform ERBT. The results underline that there is no difference in the employment of monopolar, bipolar or laser energies in terms of diagnosis and staging when performing ERBT. The coexistence of different energy sources allows to provide indication to decide the surgical strategy and define what and where to employ different techniques ensuring safer, high quality, and cost-effective procedures.

Conclusion

This is the first prospective randomized trial comparing the different energy sources available to perform ERBT. In our study, no difference was found in staging and diagnosis of BC as all energies ensure a high-quality specimen. Laser energy might be beneficial in lateral wall lesions to avoid ONR. Since there is an increased risk of ERBT conversion to cTURBT for lesions of the anterior wall, electrocautery might be preferred over laser to avoid waste of material. The energy source to be used during ERBT should be tailored to the lesion location to provide safest and highest quality procedure.

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Author contributions PD: data collection, data analysis, manuscript writing. AG: protocol/project development, data analysis, manuscript writing. MF: data collection. AT: data collection, data analysis, manuscript editing. AB: data collection, manuscript writing. AP: data collection. MB: manuscript editing. PG: data collection. ÓR: data collection, data analysis. JG: data collection, data analysis. FA: data collection, data analysis. JP: project development. AB: protocol/project development, manuscript editing.

Declarations

Conflict of interest The authors report no conflict of interest.

Research involving human participants and/or animals This study respected the principles of the Declaration of Helsinki and was approved by the Institutional Review Board (2017/09c).

Informed consent All participants were adequately informed and provided a written consent.

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