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Comparison of Bipolar and Monopolar Transurethral Resection of Bladder Tumours: A Randomised Clinical Study

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ABSTRACT

Surgery Section

Introduction: The standard treatment of Urinary Bladder Cancer (UBC) is Transurethral Resection of Bladder Tumours (TURBT) commonly using a monopolar resection system. Bipolar-TURBT (B-TURBT) is associated with better haemostasis than Monopolar-TURBT (M-TURBT). Despite this, there exists controversy whether B-TURBT can completely replace M-TURBT.

Aim: To assess the perioperative outcomes of B-TURBT and compare it with the conventional monopolar system (M-TURBT).

Materials and Methods: The present randomised clinical study was conducted in the Department of Urology at SCB Medical College, Cuttack, Odisha, India between January 2018 and January 2020. Fifty patients of either sex, aged >18 years with urinary bladder tumour size of \leq 4 cm were included in the study. Patients were randomly assigned into B-TURBT and M-TURBT treatment groups. Demographic data (age and sex), morphology, location, shape, grade, stages of transitional cell carcinoma, degree of artifact were analysed and compared. Data were analysed using Statistical Package for the Social Sciences (SPSS) version 23.0. The qualitative and quantitative variables between

the groups were compared using independent sample t-test and chi-square test, respectively. A p-value <0.05 was considered statistically significant.

Results: A total of 50 patients with UBC were evaluated in the present study where the majority of patients were male 45 (90.0%) with mean age 60.9 years. The most common morphologies were papillary tumour (28.0%), broad solid mass (22.0%), and papillary solitary (22.0%). Total 25 patients underwent M-TURBT and 25 patients underwent B-TURBT. Older patients (>55 years) had a higher rate of severe artifact compared to younger patients (<55 years). The B-TURBT had a significantly lower rate of artifact compared to M-TURBT (p-value <0.001). The need for secondary procedure was comparatively higher in M-TURBT than in bipolar resection (p-value=0.253). The obturator jerk and bladder perforation were not observed in this study.

Conclusion: The B-TURBT had a lower incidence of severe artifact and restaged TURBT as compared to M-TURBT. Thus, B-TURBT is a safer and more effective treatment for patients with UBC.

Keywords: Artifact, Bladder perforation, Haemostasis, Papillary tumour

INTRODUCTION

Urothelial carcinoma of urinary bladder is one of the most common urological malignancies which is enormously rising in India and worldwide with a prevalence rate of 1.8% in Indians [1]. As per the GLOBOCAN 2020, bladder cancer is the most frequently encountered cancer among men. It was estimated to have nearly 440,864 new cases of bladder cancer per year accounting for 4.4% of total new detected cases globally [2].

TURBT is the cornerstone of diagnosis of bladder cancer and remains as an initial therapy of the urothelial carcinoma of urinary bladder [3]. Monopolar systems used for resection of urinary bladder utilise patients' bodies as electrical conduits. The heat generated from M-TURBT mainly facilitates the cutting of tissues [4]. Unfortunately, it is associated with obturator jerk, intraoperative bleeding, bladder perforation, and desiccation of small cells [5]. The introduction of bipolar technology is acquiring recognition among urologists for its efficacy in TUR of urothelial carcinoma of urinary bladder with fewer complications [5]. In this technique, the electric current flowing between the active and passive pole situated on a specifically developed sheath completes the circuit, without passing through the patient [6]. Moreover, B-TURBT is associated with better haemostasis with a lesser risk for developing obturator jerk and further damage [7,8].

Despite this, whether B-TURBT can completely replace M-TURBT as a safer alternative for TUR, it remains controversial as the previous studies comparing bipolar to monopolar energies for TUR provided conflicting results [9-12].

Previous studies did not find any significant difference related to blood loss, obturator nerve reflex, operative time, catheterisation time, need for secondary procedure, and recurrence-free survival rate [13,14].

Therefore, the present study efforts are made to compare the impact of bipolar and monopolar resection on obturator nerve reflex, degree of artifacts, muscularis propria invasion, need for secondary procedure, obturator jerk, and bladder perforation.

MATERIALS AND METHODS

This was a single center randomised, clinical trial conducted in the Department of Urology at SCB Medical College, Cuttack, Odisha, India between January 2018 and January 2020. The study was conducted in accordance with ethical principles that are consistent with the Declaration of Helsinki. The study protocol was approved by Institutional Review Board/Ethics Committee (SCB Medical College and Hospital, Cuttack, Odisha; Approval No.: 55). Written informed consent was obtained from all the patients.

Inclusion criteria: The patients with UBC undergoing TURBT were evaluated in this study. Patients of either sex, aged >18 years, with patients with urinary bladder tumour size of \leq 4 cm on Contrast Enhanced Computed Tomography (CECT) scan were included in the study.

Exclusion criteria: Patients with recurrent bladder tumours, metastatic disease, tumour size of >4 cm, young patients aged \leq 18 years, or who were not giving consent or unfit for general anaesthesia were excluded from the present study.

Sample size calculation: Sample size (N) was calculated using 80% power and a 95% significance level for obturator jerk. Assuming

a 30% incidence for the M-TURBT and a 5% incidence for the B-TURBT [12]. The sample size was determined with the formula:

$$N=K \times \frac{P_{1}(1-P_{1})+P_{2}(1-P_{2})}{(P_{1}-P_{2})^{2}}$$

Where: N=sample size;

P₁=prevalence of obturator jerk in M-TURBT;

P₂=prevalence of obturator jerk in B-TURBT;

K=constant (The significance level was set as α =0.05).

A sample size of 25 in each arm was calculated using above formula, estimating a drop out of 10%.

Study Procedure

Spinal or General Anaesthesia (GA) was used for performing all the surgeries. Urology specialists having experience in performing both monopolar and B-TURBT conducted the surgery. GA and endotracheal intubation were carried out by placing the patient in supine position. Further, the patient was placed in the lithotomy position followed by cleaning of perineal skin with the antiseptic povidone-iodine solution (10%). The obturator nerve block was not performed before the procedure; TURBT was performed after a routine cystourethroscopy.

M-TURBT and B-TURBT [8]: Monopolar resection was performed with a Storz Vaporcut (Karl Storz Endoscopy, Culver City, CA) (4 mm) resection loop 1.5% in case of M-TURBT, glycine was used as the irrigant. It was performed with a U-shaped cutting loop, 26 Fr continuous flow resectoscope with a 30° telescope, and an electrosurgical generator with power settings of 120 W for cutting and 80 W for coagulating using glycine irrigation. Bipolar resections resectoscope (Gyrus-AMCI TM, Superpulse generator, USA) was carried out using a plasma-kinetic superpulse generator with power settings of 100 W for cutting and 80 W for coagulating using normal saline irrigation. A thin plasmakinetic superloop was used to conduct resection, with normal saline as an irrigant. At the end of the operation, 26 Fr outer sheath with 24 Fr inner sheath 3-way Foley catheter was placed in all patients with continuous saline irrigation until the urine efflux was completely clean [8]. In uncomplicated cases, a Foley catheter was removed after 24 to 48 hour and the patient was discharged. All patients underwent complete TURBT and deep muscle biopsies (resection loop) were taken in each patient. The specimen was observed for histopathological examination.

All patients with bladder tumour were evaluated with demographic characteristics (age and sex), morphology, size, stages of invasion [15], grade [16], and location of tumour, degree of artifact [17], and perioperative outcomes including age wise analysis with patients >55 years and \leq 55 years were compared between B-TURBT and M-TURBT.

The American Joint Committee on Cancer (AJCC) Tumour-Node-Metastasis (TNM) system is widely used staging system to predict bladder cancer patient prognosis. T describes the growth of main (primary) tumour through the bladder wall, N indicates any lymph node involvement ranges from, and M indicates the metastasis of cancer at locations distant from the bladder such as lymph nodes or organs like the liver or lungs [15].

- Stage pT1 bladder carcinoma: Invasion into lamina propria, but not into muscularis propria.
- Stage pT2 bladder carcinoma: Tumour invasion into muscularis propria. It is subclassified into two categories:

pT2a- invasion of cancer less than one-half of the depth of muscular propria and

pT2b- invasion of cancer greater than one-half of the muscle wall.

 Stage pT3 bladder carcinoma: Invasion of tumour into perivesical soft tissue or spread to the prostate, uterus, or vagina [15]. **Outcomes:** The primary outcome of the present study was to evaluate the presence of muscularis propria and invasion of muscularis propria and degree of cautery artifact in each specimen. The secondary outcome was to evaluate the efficacy of monopolar and B-TURBT along with complete tumour resection, need for secondary procedure, obturator jerk, and bladder perforation.

Definition: Cautery artifact is enlarged inflamed connective tissue fibers, blurring of nuclei, and vacuolisation as a consequence of the heating loop contact. It can be observed virtually in pathological specimens when M-TURBT and B-TURBT is used for TURBT, but can vary in severity [18]. Based upon percentage of resected specimen involved the severity of cautery artifacts was categorised into absent (none), mild (<25%), moderate (25-50%), severe (>50%) [17].

Allocation concealment and blinding: Randomisation was done by the operating room technician and allocation concealment was done by a sealed envelopes. The surgery was then performed according of the randomisation results. Until the patient was on the operating table, the surgeon performing the procedure had no knowledge to which arm the patient had been assigned. A single central pathologist analysing all the samples was blinded to the procedure performed.

[Table/Fig-1] shows the CONSORT flow diagram.



STATISTICAL ANALYSIS

Data were analysed using SPSS version 23.0 (IBM Corporation, USA). Descriptive statistics were used to describe categorical variables (frequency and percentages) and continuous variables {mean and Standard Deviation (SD) or median and range (depending on the normality of data)}. Shapiro-Wilk test assessed the normal distribution of quantitative data. The Independent Sample t-test was used for the continuous variables and the Chi-square test for the categorical variables. A p-value <0.05 was considered statistically significant.

RESULTS

A total of 50 patients with UBC undergoing TURBT were included in the analysis. The mean age was 60.9 years. The majority of patients were male 45 (90.0%) with male-female ratio of 9:1. The most common morphologies were papillary tumour (28%), broad solid mass (22%), and papillary solitary (22%). While, other less common morphologies reported were papillary broad-base tumour, solid, solitary broad-base solid, solitary solid, papillary solid, solitary broadbase papillary. Total 27 (54.0%) patients had low grade transitional cell carcinoma. Pathological results revealed 22 (44.0%) pTa low grade, 18 (36.7%) pT1 high grade, 8 (16.3%) and 2 (4.1%) pT2 high grade urothelial carcinomas. During the study period, 25 patients underwent M-TURBT and 25 patients underwent B-TURBT [Table/Fig-2].

Age groupwise analysis: The most common morphologies in the younger age group were papillary tumour (29.4%) and broad

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Age (in years) (mean±SD) Gender Male Female Morphology Papillary tumour Broad solid mass	60.9±14.9 45 (90) 5 (10)
Male Female Morphology Papillary tumour Broad solid mass	. ,
Female Morphology Papillary tumour Broad solid mass	. ,
Morphology Papillary tumour Broad solid mass	5 (10)
Papillary tumour Broad solid mass	
Broad solid mass	
	14 (28)
	11 (22)
Papillary solitary	11 (22)
Papillary broad-base tumour	4 (8)
Solid	4 (8)
Solitary broad-base solid	2 (4)
Solitary solid	2 (4)
Papillary solid	1 (2)
Solitary broad-base papillary	1 (2)
Location	
Anterior	21 (42)
Posterolateral	12 (24)
Posterior	6 (12)
Anterolateral	5 (10)
Base of wall	5 (10)
Bladder neck	1 (2)
Size (cm)	
<2×2	38 (76)
≤3×3	10 (20)
<4×4	2 (4)
Grade	
Low grade transitional cell carcinoma	27 (54)
High grade transitional cell carcinoma	22 (44)
PUNLMP	1 (2)
Stages	Γ (<i>Δ</i>)
No lamina propria/muscularis propria invasion (pTa)	22 (44)
Lamina propria invasion (pT1) Muscularis propria invasion (pT2)	18 (36.7) 8 (16.3)
Muscularis propria and LVI invasion present (pT2)	. ,
Procedure	2 (4.1)
B-TURBT	25 (50)
	25 (50)
M-TURBT	25 (50)
Degree of artifact (n=36)	10 (44 4)
Mild	16 (44.4)
Moderate	8 (22.2)
Severe [Table/Fig-2]: Patients' demographics.	12 (33.3)

solid mass (23.5%). While in the case of older age group the most common morphologies were papillary solitary tumour (30.3%) and papillary tumour (27.3%) (p-value=0.065). Older patients (>55 years) had a higher rate of severe artifact compared to younger patients (≤55 years). The need for the secondary procedure was comparatively higher for older patients than for younger patients (48.5% vs. 23.5%) [Table/Fig-3].

Procedure wise analysis: There were 50 patients in the study, 25 in each of the two groups. In both the groups, the numbers of male patients were higher (B-TURBT: 92.0% vs. 8.0% and M-TURBT: 88.0% vs. 12.0%) than female patients. The mean age in M-TURBT and B-TURBT groups were 60.3 and 61.4 years, respectively (p-value=0.800). The most common morphologies

Parameters	≤55 years (n=17)	>55 years (n=33)	p-value				
Gender							
Male	13 (76.5)	32 (97.0)	0.022				
Female	4 (23.5)	1 (3.0)	0.022				
Morphology							
Papillary tumour	5 (29.4)	9 (27.3)					
Broad solid mass	4 (23.5)	7 (21.2)					
Papillary solitary	1 (5.9)	10 (30.3)					
Papillary broad-base tumour	1 (5.9)	3 (9.1)					
Solid	4 (23.5)	-	0.065				
Solitary broad-base solid	1 (5.9)	1 (3.0)					
Solitary solid	-	2 (6.1)					
Papillary solid	1 (5.9)	-					
Solitary broad-base papillary	-	1 (3.0)					
Location							
Anterior	6 (35.3)	15 (45.5)					
Posterolateral	4 (23.5)	8 (24.2)					
Posterior	3 (17.6)	3 (9.1)	0.635				
Anterolateral	1 (5.9)	4 (12.1)	0.000				
Base of wall	2 (11.8)	3 (9.1)					
Bladder neck	1 (5.9)	-					
Size (cm)							
<2×2	13 (76.5)	25 (75.8)					
≤3×3	3 (17.6)	7 (21.2)	0.861				
≤4×4	1 (5.9)	1 (3.0)					
Grade							
Low grade TCC	8 (47.1)	19 (57.6)					
High grade TCC	9 (52.9)	13 (39.4)	0.545				
PUNLMP	-	1 (3.0)	1				
Stages							
No lamina propria/muscularis propria invasion (pTa)	8 (47.1)	14 (40.6)					
Lamina propria invasion (pT1)	5 (29.4)	13 (40.6)	0.511				
Muscularis propria invasion (pT2)	4 (23.5)	4 (12.5)	0.011				
Muscularis propria and LVI invasion present (pT2)	-	2 (6.3)					
Procedure			,				
M-TURBT	11 (64.7)	14 (42.4)	0.232				
B-TURBT	6 (35.3)	19 (57.6)	0.202				
Degree of artifact	[n=11]	[n=25]					
Mild	6 (54.5)	10 (40.0)	0.527				
Moderate	3 (27.3)	5 (20.0)					
Severe	2 (18.2)	10 (40.0)					
Need for the secondary procedure	4 (23.5)	16 (48. 5)	0.091				
[Table/Fig-3]: Summary of results based on age of patients (≤55 years versus >55 years). Data shown as n (%). B-TURBT: Bipolar trans urethral resection of bladder tumour; LVI: Lymphovascular invasion; M-TURBT: Monopolar trans urethral resection of bladder tumour; PUNLMP: Papillary urothelial neoplasm of low malignant potential; TCC: Transitional cell carcinoma							

neoplasm of low malignant potential; TCC: Transitional cell carcinoma *Chi-square test; A p-value <0.05 was considered statistically significant

in the B-TURBT group were papillary tumour (24%) and broad solid mass (28%). The proportion of muscularis propria invasion (pTa) (52.0% vs. 36.0%), lamina propria invasion (pT1) (40.0% vs. 32.0%) was higher in patients who underwent M-TURBT than B-TURBT. While the proportion of muscularis propria invasion (pT2) was higher in patients who underwent B-TURBT than M-TURBT (p-value=0.142). While in the case of M-TURBT the most common morphologies were papillary tumour (32.0%) and papillary solitary tumour (24.0%). The proportion of low and high grade urothelial carcinomas between B-TURBT and M-TURBT groups (p=0.142).

Bipolar resection had a significantly lower rate of artifact compared to monopolar resection (p-value<0.001). The need for secondary procedure was comparatively higher in M-TURBT than in bipolar resection (p-value=0.253). The findings of obturator jerk and bladder perforation were not reported in this study [Table/Fig-4].

Parameters	B-TURBT (n=25)	M-TURBT (n=25)	p-value	
Gender				
Male	23 (92.0)	22 (88.0)	0.007	
Female	2 (8.0)	3 (12.0)	0.637	
Age group (in years)				
≤55	11 (44.0)	6 (24.0)		
>55	14 (56.0)	19 (76.0)	0.136	
Mean±SD	60.3±15.4	61.4±15.1	0.800	
Morphology			,	
Papillary	6 (24.0)	8 (32.0)		
Broad solid mass	7 (28.0)	4 (16.0)	1	
Papillary solitary	5 (20.0)	6 (24.0)	1	
Papillary broad-base	2 (8.0)	2 (8.0)		
Solid	1 (4.0)	3 (12.0)	0.839	
Solitary broad-base solid	1 (4.0)	1 (4.0)		
Solitary solid	1 (4.0)	1 (4.0)		
Papillary solid	1 (4.0)	-		
Solitary broad-base papillary	1 (4.0)	-		
Location			1	
Anterior	10 (40.0)	11 (44.0)		
Posterolateral	5 (20.0)	7 (28.0)		
Posterior	5 (20.0)	1 (4.0)		
Anterolateral	3 (12.0)	2 (8.0)	0.487	
Base of wall	2 (8.0)	3 (12.0)		
Bladder neck	-	1 (4.0)		
Size (cm)		. ,	1	
<2×2	18 (72.0)	20 (80.0)		
≤3×3	6 (24.0)	4 (16.0)	0.777	
≤4×4	1 (4.0)	1 (4.0)		
Grade		, , , , , , , , , , , , , , , , , , ,		
Low grade TCC	12 (48.0)	15 (60.0)		
High grade TCC	13 (52.0)	9 (36.0)	0.357	
PUNLMP	-	1 (4.0)		
Stages		1 (1.0)		
No lamina propria/muscularis propria invasion (pTa)	9 (36.0)	13 (52.0)		
Lamina propria invasion (pT1)	8 (32.0)	10 (40.0)		
Muscularis propria invasion (pT2)	7 (28.0)	1 (4.0)	0.142	
Muscularis propria and LVI invasion present (pT2)	1 (4.0)	1 (4.0)		
Degree of artifact	[n=12]	[n=24]		
Mild	12 (100.0)	4 (16.7)		
Moderate	-	8 (33.3)	<0.001	
Severe	-	12 (50.0)		
Need for secondary procedure	8 (32.0)	12 (48.0)	0.253	
[Table/Fig-4]: Procedure wise comparise	,	. ,	0.200	

Data shown as n (%) B-TURBT: Bipolar trans urethral resection of bladder tumour; LVI: Lymphovascular invasion;

M-TURBT: Monopolar trans urethral resection of bladder tumour: PUNLMP: Papillary urothelial neoplasm of low malignant potential; TCC; Transitional cell carcinoma chi-square test; A p-value <0.05 was considered statistically significant

DISCUSSION

A TURBT is the gold standard for the initial management of bladder cancer [19]. The present study compared the feasibility and safety

of M-TURBT versus B-TURBT technique in the management of bladder cancer. The salient observations from the present study were: i) male preponderance; ii) the most common morphologies were papillary tumour, broad solid mass, and papillary solitary; iii) the results showed that older patients (>55-year-old) had a higher rate of severe artifact than younger patients (\leq 55 years); iv) bipolar resection had a significantly lower incidence of severe artifact compared to monopolar resection; v) need for the secondary procedure was comparatively higher in M-TURBT than in bipolar resection; vi) obturator jerk and bladder perforation was not found in this study.

The sex differences in bladder cancer appear to have a higher incidence in men than in women. Bolat D et al., found a similar incidence of higher prevalence of male patients over female patients (Men: n=72; women: n=8) [8]. In another study, Teoh JY et al., reported men predominance over women in UBC [20]. Similarly, the present study also revealed the same trend related to the sex ratio (M:F=9:1). In the present study, higher number of patients had low grade disease (n=27, 54%) which is consistent with Hashad MM et al., (n=115, 57.5%) and Bolat D et al., (n=58, 73.4%) [7.8]; however, 36.7% patients had pT1 (lamina propria invasion) similar to Bolat D et al., [8].

Histologically, common morphological characteristics of UBC are papillary carcinoma, solid, and tubular and depending on the cell aspect, eosinophilic, and basophilic carcinomas [21]. T1 lesions may have either a papillary or a broad-based appearance and T2 consists of higher lesions generally have heterogeneous hypointense or mixed signal solid based appearance [22,23]. In the present study, most common morphologies of UBC were papillary tumour, broad solid mass, and papillary solitary.

The incidence of cautery artifact mainly relies on the amount of heat generated during resection, duration of loop contact with tissue, loop size, and tissue composition [22]. Venkatramani V et al., demonstrated a significantly lower incidence of severe cautery artifact in the B-TURB than in the M-TURBT (25 vs. 46.7%, p-value=0.0096) [11]. Recently published meta-analysis study also noted lower risk of thermal damage for B-TURBT relative to those treated via M-TURBT {Relative Risk (RR)=0.66; 95% CI=0.55-0.78; p-value <0.0001} [24]. In concordance with previous studies, the present study demonstrates that B-TURBT is more effective and safer that exhibits a lower incidence of severe cautery artifact than M-TURBT. Further, in contrast to the above aforementioned literature, the other three randomised clinical trials revealed that there were no statistically significant differences between B-TURBT and M-TURBT with regards to cautery artifact incidence [8,13,25].

A previous prospective study by Bolat D et al., revealed that complete resection was comparatively higher for B-TURBT than M-TURBT (89.2% vs. 78.5%) [8]. Murugavaithianathan P et al., conducted a randomised clinical trial assessing the efficacy of M-TURBT and B-TURBT. The results alluded that complete resection of the tumours was noted in all cases, in both groups. Moreover, the restaged TURBT was associated with the M-TURBT technique [26]. This outcome is consistent with the results of the present study wherein need for secondary TURBT was highly associated with M-TURBT than B-TURBT.

Most urologists face a major concern of achieving complete resection of the bladder tumour without any contraindications. An incidence of obturator jerk during TURBT mainly depends upon the site of the tumour and type anaesthesia used [27]. In the previous prospective study, evaluating short-term outcomes of M-TURBT and B-TURBT, the incidence of obturator reflex was significantly higher in patients who underwent M-TURBT than B-TURBT (16.7% vs. 2.1%, p-value=0.007) [14]. In another study, obturator reflex was significantly higher in the M-TURBT group, than in the B-TURBT group (p-value=0.025) [28]. Additionally, Del Rosso A et al., Mashni J et al., and Liem EIML et al., reported equal incidence of obturator jerks between both techniques [13,27,29]. In contrast to these studies, the present study did not reported the incidence of obturator jerk in both groups. Conversely, Gupta NP et al., and Ozer K et al., reported a significantly the higher incidence of obturator jerks in three patients for B-TURBT due to higher power setting of the bipolar machine [30,31].

Limitation(s)

There were certain limitations in the present study. The present study did not analyse the serum electrolyte levels. Lastly, this was a single centre, single arm study with a smaller sample size which restricts the overall inference in terms of safety and efficacy of TURBT technique to generalised population.

CONCLUSION(S)

The M-TURBT and B-TURBT are feasible techniques for the management of UBC. The B-TURBT has a lower incidence of severe artifact and a lower rate of restaged TURBT as compared to M-TURBT. Thus, the present study recommends B-TURBT as a safer and more effective treatment for patients with UBC.

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AUTHOR DECLARATION:

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