



When to Avoid a Restaging Procedure for Non-muscle Invasive Bladder Cancer? Inferences from a Tertiary Care Center

Deepak Prakash Bhirud¹ · Ankur Mittal¹ · Sunil Kumar¹ · Tushar Aditya Narain¹ · Sanjeev Kishore² · Shiv Charan Navriya¹ · Satish Kumar Ranjan¹ · Vikas Kumar Panwar¹

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Abstract

The increasing incidence of urinary bladder carcinoma is alarming. Approximately seventy percent of these patients are non-muscle invasive bladder cancer (NMIBC). Restage transurethral resection of bladder tumor (TURBT) is the current recommendation for any T1 and or high-grade non muscle invasive bladder cancers (NMIBC) to accurately stage the malignancy. The question whether a second surgery is always required as a restage procedure is still unanswered. The patient's concern about completeness, morbidity, and financial considerations of a major surgery cannot be overlooked. Moreover, it also puts a strain on the already overburdened healthcare system. To answer this question, whether it is oncologically sound to omit a second resection, the current study evaluated the outcomes of patients undergoing restage TURBT, and analyzed the preoperative factors predicting a change in the staging of this malignancy. The study design was a prospective observational including NMIBC patients from September 2018 to February 2020. A total of 72 patients underwent restage TURBT. Their demographic data, imaging and cystoscopic findings, and histopathological data were recorded. The objective was to study the clinico-pathological correlations and factors predicting recurrence and upstaging of tumor in NMIBC patients undergoing restage TURBT. A total of 101 patients were found eligible for restage TURBT. Eventually, 72 underwent restage TURBT. Twelve (16.7%) patient had recurrence at restage while 3(4.16%) were upstaged to T2. Presence of lower urinary tract symptoms (LUTS) was independently associated with the risk of recurrence of same stage compared to no recurrence ($p=0.025$, OR-8.793, 95% CI-1.316–98.773). Chemical exposure ($p=0.042$) was also significantly associated with the same. Presence of lymphadenopathy on CT was independently associated with the risk of upstaging compared to no recurrence ($p=0.032$, OR-18.25, 95% CI-1.292–257.85). The study concluded that in the presence of a well-performed and adequate initial TURBT, restage TURBT could be skipped for further management. However, in small subgroup of patients with lymphadenopathy on preoperative imaging having a higher risk of tumor recurrence and upstaging, and patients with a history of chemical exposure and previous lower urinary tract symptoms having a high risk of recurrence alone, restage TURBT should still be performed to accurately stage the disease. Further studies with large patient cohort are needed to confirm and reinforce the facts proposed.

Keywords Urothelial bladder cancer · Non-muscle invasive bladder cancer (NMIBC) · Restage TURBT · Lower urinary tract symptoms (LUTS)

Introduction

The incidence of urinary bladder cancer is increasing and it is alarming. Urinary bladder cancer is the ninth most common cancer in the world. According to GLOBOCAN 2018, around 550,000 new urinary bladder cancer cases were diagnosed globally with a male to female ratio of approximately 3.5:1 [1]. Seventy percent of these cases are non-muscle invasive [2]. As per Indian cancer registry data, urinary bladder cancer accounts for 3.9% of all cancer cases. The

✉ Ankur Mittal
departmenturologyaiimsrksh@gmail.com

¹ Department of Urology, AiiimsRishikesh, Uttarakhand, India 249203

² Department of Pathology, AiiimsRishikesh, Uttarakhand, India

rising trend of bladder cancer cases in India is attributed to increased use of different forms of tobacco, besides the ever increasing menace of air pollution and industrial chemical and fertilizer exposure in our country [3]. This cancer is considered a heterogeneous entity and broadly divided into NMIBC and muscle invasive bladder cancer (MIBC). Transurethral resection of bladder tumor (TURBT) is the preferred treatment for NMIBC. NMIBC represents a wide spectrum of disease with different clinical course, owing to noteworthy risk of progression and possible recurrence. According to existing guideline and evidence, high-grade urothelial cancers or tumors restricted to lamina propria undergo restage to accurately stage the malignancy, whereas MIBC needs a radical cystectomy and chemotherapy due to its high risk of progression and metastasis [4].

Incidence of recurrence and upstaging in NMIBC particularly in T1 and high-grade tumors is 50–70% and 20–30%, respectively [4]. This constitutes the basis of guideline advocating the restage TURBT in all T1 and high-grade carcinoma of urinary bladder. However, few experts have different opinion on this subject and they suggest that restaging TURBT may not be necessary when initial TURBT is properly preformed [5]. The present study attempts to find the utility of restage TURBT and finding the clinical and other factors which predict the probability of upstaging and recurrence of tumor.

Materials and Methods

A prospective observational study with period prevalence was conducted in Department of Urology of our institute in association with Pathology Department from September 2018 to February 2020. Aim of the study was to evaluate the role of restage TURBT in non-muscle invasive bladder cancer (NMIBC) and its clinical implications. Primary objectives were to study the clinico-pathological correlation and factors predicting recurrence and up-staging of tumor in non-muscle invasive bladder cancer (NMIBC) undergoing restage transurethral resection of bladder tumor (TURBT). Secondary objectives were to estimate the incidence of recurrence and up-staging of tumor in non-muscle invasive bladder cancer (NMIBC) undergoing restage TURBT and to find the patients with non-muscle invasive bladder cancer (NMIBC) in whom restage TURBT can be omitted. Patients with tumor size more than 3 cm, multiple tumors on cystoscopy, any T1, any high grade, absence of deep muscle on histopathological examination, and those who were willing to participate in study with informed consent were included. However, those with endoscopically non-manageable disease, TaLG (low grade), muscle invasive bladder cancer (MIBC), and metastatic disease were excluded.

This study was carried out in accordance with the ethical standards laid down by Declaration of Helsinki and ICMR guidelines for biomedical research on human subjects with institutional ethical board approval. All consecutive subjects presenting during the study period fulfilling the criterion were included in the study. A total of 72 patients fulfilled the criterion and underwent restage TURBT during the study period.

Detailed clinical history of patients was taken including history of haematuria, presence of lower urinary tract symptoms, history of smoking, chemical exposure, and previous TURBT if any. Patients were subjected to further evaluation using ultrasound, CT urography prior to surgery, and presence of hydronephrosis and lymphadenopathy on CT was noted. Bladder mapping of initial TURBT was done. Morphological characteristics of tumor-like single/multiple, pedunculated/sessile, and solid/papillary were noted. At our center TURBT was performed using 26 Fr Iglisias continuous flow resectoscope using monopolar or bipolar cautery and irrigation with 3% glycine or normal saline respectively. TURBT was performed either by consultant himself or residents supervised by him. Complete resection was ensured. Patient undergoing complete TURBT and meeting the inclusion criteria were advised to undergo restage TURBT at 2 to 6 weeks of initial TURBT. Findings on restage TURBT like healthy or unhealthy scar, presence of recurrent tumor, site of recurrent tumor (same/distant), and morphology of recurrent tumor were documented. Resection of scar, recurrent tumor, and deep muscle from both previous scar and new growth was ensured. All samples were sent in separate vials for histopathology examination. Examination and reporting were done by a senior pathologist according to WHO/ISUP 2004 classification. Presence of any tumor on histopathology was considered as recurrence whereas upstaging was defined as presence of MIBC at restage TURBT. Major complications like perforation and reintervention to control bleeding in post-operative period were noted.

Statistical Analysis

All statistical analysis was performed using SPSS software (version 26, SPSS Inc., Chicago, IL, USA). Categorical variables were described as frequency and proportion. Continuous variables were described as mean and standard deviation or median with interquartile range as applicable.

Proportions were compared using Chi square test and Fishers exact test. The means in two groups were compared using Student's *t* test and Mann–Whitney *U* test. Paired *t* test was used for readings of continuous variables at end point of time. Univariate analysis was done to find factors responsible for recurrence at restage TURBT. Multiple logistic

regression analysis was used to document independent predictors of desired outcomes.

Results

A total 299 patients underwent TURBT during the study period. Forty-four amongst 299 were metastatic on presentation and fifty-four patients underwent incomplete resection. Out of 201 patients undergoing a complete resection, thirty-six turned out to be MIBC whereas fifty-two patients had Ta, LG. One hundred and one patients met the criteria

for restage TURBT. Twenty-nine patients did not comply the advice, and finally, seventy two underwent restage TURBT. Amongst these patients, forty-seven had T1HG, 14 had T1LG, 9 had TaHG, 2 had TaLG tumors, and nine did not had deep muscle at initial TURBT. Two TaLG patients were included as they were large (> 3 cm), multiple, sessile, and needed 2 resection for completion and classified as intermediate risk tumors. No patient had CIS on pathology of tumor (Fig. 1).

Demographic profile and patient characteristics of the NMIBC patients who underwent restage are given in Table 1. Mean age of presentation was 55 ± 14.7 years.

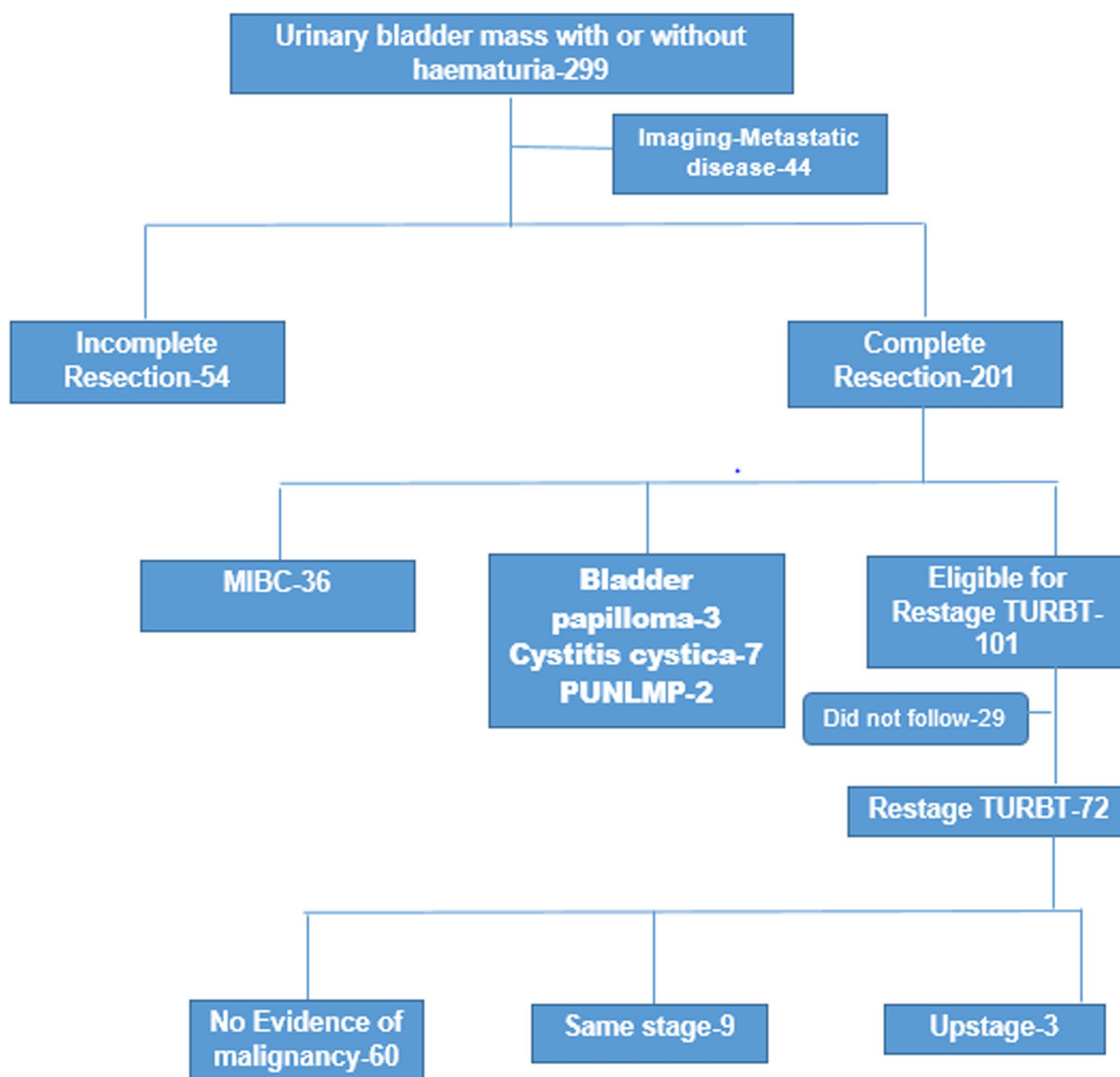


Fig. 1 Flow chart of patient enrollment

Table 1 Demographic profile and patient details

Characteristics	Value
Number of patients(n)	72
Age(year), mean(\pm SD)	55 \pm 14.71
Gender <i>n</i> (%)	64 (88.9)
Male	8 (11.1)
Female	
Smokers	57 (79.2)
Non-smokers	15 (20.8)
Duration of smoking (years, mean \pm SD)	26.56 \pm 10.29
Chemical exposure <i>n</i> (%)	8 (11.1)
Duration of chemical exposure (years, mean \pm SD)	18.63 \pm 6.14
Presenting complaints <i>n</i> (%)	67 (93.1)
Hematuria	16 (22.2)
LUTS	
Duration of hematuria (months, median interquartile range)	3 (3–6)
Comorbidities <i>n</i> (%)	12 (16.7)
Diabetes	4 (5.56)
Hypertension	4 (5.56)
Asthma	1 (1.4)
Both (HTN + DM)	3 (4.16)
Previous surgery <i>n</i> (%)	9 (12.5)
CT urography <i>n</i> (%)	9 (12.5)
Hydroureteronephrosis	8 (11.1)
Lymphadenopathy	
Blood transfusion <i>n</i> (%)	11 (15.3)

Approximately 89% of patients were males. Amongst them, 79.2% of patients were smokers while 8(11%) had chemical exposure at their place of work at their place of work like paint, rubber, and petroleum industries. They were involved in various processes of making paint, processing crude rubber to convert into various rubber products like tire, tubes, and processing and segregation of petroleum products. These processes involve handling many different chemicals for industrial work. Detailed description of individual chemical could not be ascertained. They were provided with protective equipment's like gloves, dresses, and mask. Their utilization and availability were not universal. Painless gross hematuria was the presenting complaint in 67 (93%) of patients. Lower urinary tract symptoms were present in 16 (22.2%) of patients.

Twelve (16.7%) patients had various comorbidities including diabetes, hypertension, and asthma. Nine (12.5%) patients had history of previous surgery for bladder mass. Preoperative CT urography showed hydroureteronephrosis in 9 (12.5%) while significant lymphadenopathy in 8 (11.1%). Mean hemoglobin was 12.29 \pm 2.13 (mean \pm SD in gm/dl) and blood transfusion was needed in 11 (15.3%) patients due to ongoing hematuria and anemia.

On cystoscopy, 41 (56.9%) had tumors of size < 3 cm, 44 (61.1%) had single tumor, 49 (68.1%) had sessile tumor,

Table 2 Clinico-pathological factors at primary TURBT

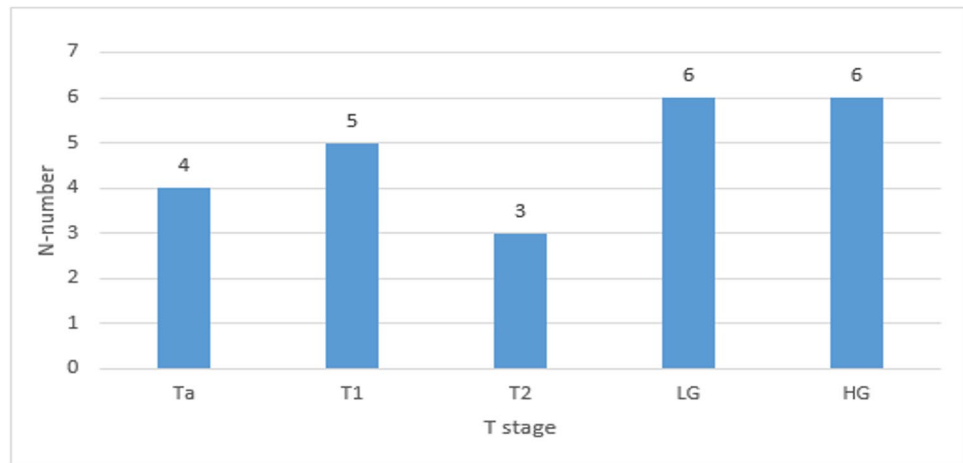
Characteristics	Value, <i>n</i> (%)
Size of tumor	41 (56.9)
< 3 cm	31 (43.1)
> 3 cm	
Number of tumor	44 (61.1)
Single	28 (38.9)
Multiple	
Morphology	49 (68.1)
Sessile	23 (31.9)
Pedunculated	
Morphology	21 (29.2)
Solid	51 (70.8)
Papillary	
T stage	11 (15.3)
Ta	61 (84.7)
T1	
Grade	16 (22.2)
Low grade	56 (77.8)
High grade	
CIS	0
Deep muscle of initial TURBT	63 (87.5)
Present	9 (12.5)
Absent	

while 21 (29.2%) had solid tumor. Complete resection of tumor was ensured during TURBT. Sixty-one (84.7%) had T1 stage while 56 (77.8%) had high-grade histology. Deep muscle was present in 63 (87.5%) of patients at initial resection (Table 2). Six patients received intravesical mitomycin C postoperatively.

The mean interval between initial and restage TURBT was 6.58 weeks with a range of 3 to 14 weeks, although 2 to 6 weeks is ideal time for restage TURBT, due to unavoidable circumstances and multifactorial reasons cannot be done. There was no statistically significant difference in the two at restage TURBT ($p=0.545$). Healthy scar at restage TURBT was noted in 57 (79.1%) patients while unhealthy scar was noted in 15 (20.9%). Sixty (83.34%) patients did not have any recurrence at restage; however, twelve patients (16.7%) had histologically proven recurrence of tumor either at the same site or a different one. Three patients had recurrence at same site while 9 patients had recurrence at different site. Two had T1HG, 3 had T1LG, 4 had TaLG, while three (4.16%) patients had upmigration of stage to T2 (Fig. 2). Two of these patients did not have deep muscle on initial TURBT, one was upgraded to muscle invasive disease, while other had same stage recurrence. No patient had significant intra- and postoperative complications at restage TURBT needing reintervention.

For analysis of clinico-pathological factor correlation between recurrence at restage, patients were grouped in 2 different groups. Group 1 included patients with no recurrence at restage while group 2 included patients with recurrence at

Fig. 2 Histopathology stage and grade at restage TURBT



restage. Group 2 was further subcategorised into 2a and 2b with former consisting of patients with same stage (T1 or less) while the later include those who were upstaged to T2.

On univariate analysis, presence of lower urinary tract symptoms and history of occupational chemical exposure ($p=0.057$) was significantly associated with risk of tumor positivity when compared between recurrence of same stage vs no recurrence at restage (Table 3). The rest of the variables like age, duration of smoking, size of tumor, focality of tumor, histological grading, initial stage, presence, or absence of deep muscle were not significantly associated with any recurrence at restage (group 1 vs group 2a).

Presence of lymphadenopathy on preoperative CT scan was significantly associated with risk of tumor positivity and upstaging when compared between upstage and no recurrence at restage ($p=0.03$) (group 1 vs group 2b). No other factors were found statistically significant.

On multivariate analysis, presence of LUTS after adjusting for age, sex, and smoking was found to have a 8.79 times higher chance of same stage recurrence compared to no LUTS ($p=0.025$, OR-8.793, 95% CI-1.316–98.773). Presence of enlarged lymph nodes on CT scan was associated with 18.25 times higher chance of upstaging as compared with no lymphadenopathy on imaging, when adjusted for age, sex, and smoking status. ($p=0.032$, OR-18.25, 95% CI-1.292–257.85).

The incidence of recurrence and stage progression at restage was 16.7% and 4.16%, respectively. The factors that emerged to be associated with recurrence or stage migration were history of chemical exposure, history of LUTS, and lymphadenopathy on preoperative CT scan.

Discussion

Risk stratification of superficial bladder cancer is important to facilitate the treatment recommendations. NMIBC is stratified into low-, intermediate-, and high-risk groups

and is advocated by all major guidelines. Restage TURBT is indicated for all high risk, T1, high grade, and absence of deep muscle in initial biopsy according to the guidelines of major urological societies [4].

Application of these guidelines involves thorough evaluation and individual practice for managing the patient of carcinoma urinary bladder may vary widely. Tobert et al. in his study found that factor independently associated with compliance for these guidelines was receiving treatment at tertiary academic institute [6]. Gotto et al. highlighted the rate of restage in indicated patients between 26 and 28% in non-Canadian area while in Canada it is mostly unreported [7]. In our study, about a third of the patients did not comply the advice of a restaging procedure. The reason for this could be the patients becoming completely asymptomatic after TURBT and might consider themselves cured of the disease or possibly because of financial limitations. The reasons for this poor compliance are multifactorial, interwoven, and interdependent.

Even if the patient becomes compliant and undergoes restage TURBT, it is not always feasible at desired time. Tseng et al. noted that interval for restage was average of 7.4 week in his study [8]. Manoharan et al. from India also noted delay in restage in their study [9]. In our study, restage was done at an average time interval of 6.58 weeks with a range of 3 to 14 weeks after initial TURBT.

The very need of restage TURBT is probably incompleteness of initial TURBT. It is dependent either on tumor-related factors or surgeon-related factors. Tumor-related factors include large size, difficult location, multiple, obturator jerk, CIS, overt bleeding, quality of specimens provided, and sometimes hardware issues like problem with vision. Pathological analysis also had impact on same. Surgeon-related factors include low experience and expertise in resection. Many studies have shown that limited experience of TURBT, which is generally with resident urologist, is associated with an increased risk of disease recurrence as

Table 3 Univariate analysis of clinico-pathological factors

Characteristics	Group 1 (n-60)	Group 2a (n-9)	Group 2b (n-3)	P value (Group 2a vs 1)	P value (Group 2b vs 1)
Smoker	47	8	2	0.674	0.536
Non-smoker	13	1	1		
Haematuria	57	8	2	0.436	0.181
(Y)	3	1	1		
(N)					
LUTS	11	5	0	0.026	1
Present	49	4	3		
Absent					
Chemical exposure	4	3	1	0.042	0.223
(Y)	56	6	2		
(N)					
Past TURBT	8	1	0	1	1
Yes	52	8	3		
No					
CT	7	2	0	0.333	1
HDUN	53	7	3		
No HDUN					
CT	5	1	2	0.582	0.030
Lymphadenopathy (Y)	55	8	1		
Lymphadenopathy (N)					
Size of mass	35	5	1	1	0.572
< 3 cm	25	4	2		
> 3 cm					
Tumor	38	5	1	0.720	0.552
Unifocal	22	4	2		
Multifocal					
Morphology	38	8	3	0.254	0.546
Sessile	22	1	0		
Pedunculated					
Morphology	16	3	2	0.699	0.194
Solid	44	6	1		
Papillary					
Histopathology	8	2	1	0.609	0.375
Ta	52	7	2		
T1					
Histopathology	13	3	0	0.423	1
Low grade	47	6	3		
High grade					
Deep muscle	53	8	2	1	0.339
Present	7	1	1		
Absent					
Interval at restage	39	7	3	0.707	0.545
< 6 weeks	21	2	0		
> 6 weeks					

compared to the consultants [10–12]. Mariappan et al. studied 473 NMIBC patient's specimens and its correlation to the second TUR findings. They showed that lower rate of recurrence of bladder tumor was associated with surgeon experience and the presence of muscle in initial TURBT specimen [13].

To get accurate staging and complete resection on initial TURBT, concept of quality control of initial TURBT has been brought up and many researchers had done work on

this. Herr and Donat defined quality of TURBT by asking three questions: (1) Is complete resection done?; (2) deep muscle present or not in pathology; (3) how often tumor recur at site of first TURBT [11].

Over the period in past, second intervention in patient of bladder mass was redefined, refined, and renamed according to its indications. Divrik et al. have proposed many strict criteria for the next level concepts in TURBT. In his terms, repeat TURBT is defined a TUR after incomplete

initial resection due to various factors. The term “restaging TUR” (re-TUR) is used whenever a second TUR was done to gather additional histopathologic information from the muscularis propria. And “second TUR” is defined as intervention done after a correct and complete TURBT [14].

There are only few studies from India related to the role of restage. Studies done in the Indian subcontinent on restage TURBT showed rate of recurrence of 28 to 60% and upstaging from 4 to 23% [15–17]. Various studies from the foreign countries noted recurrence rate from 16 to 78% and upstaging of 1 to 28% [5, 8, 18]. Current study depicts rate of recurrence as 16.7% which is lower compared to other Indian studies.

A largest retrospective study on restage TURBT by Gontero et al. did not find any survival benefit after second surgery. This study strongly questions the real need for the need of second procedure considering its cost implication to patient and burden on healthcare system⁵. Similarly, a recent prospective study questioned the utility of restage in completely resected T1 tumors with muscle included as it did not incur any survival benefit [19].

A systematic review too found a very low risk of upstaging (1–4%), which was attributed to surgeon experience and centralization of procedure [20]. Resident urologist is considered to be having less experience and was associated with recurrence [10]. In our study, all resection was done by faculty or resident always supervised by consultant.

A study from Asian country noted the recurrence rate of 18% and upstaging of 1% [8]. Our study had a recurrence rate of 16.7% and upstaging rate of 4.16% which is comparable to the above study. It could be attributed to the good quality initial TURBT and consultant supervision. There is substantial variability in reported risk factors in different studies. Also, the population characteristics and methodologies used for it were diverse. It might also be affected by complex nature of bladder cancer and heterogeneous surgical technique used [21].

Chemical exposure was found to be significantly associated with the recurrence at restage. Chemicals excreted through the urinary tract lead to the exposure of the bladder urothelium. Prolonged excretion of accumulated carcinogenic chemicals through urinary tract may be the cause of recurrence. Tumorigenic properties of these chemicals are the cause of bladder cancer [22].

Presence of LUTS is significantly associated with risk of same stage recurrence compared to no recurrence ($p=0.026$) in our study. It has been hypothesized that presence of LUTS might lead to prolonged exposure of bladder mucosa to tobacco products excreted in urine which had tumorigenic properties and increased recurrence [23]. A meta-analysis suggested the decreased risk of recurrence in superficial bladder cancer in patients with BPH and LUTS who underwent simultaneous TURBT and TURP.

This highlights the significant association of LUTS with recurrence [24].

Preoperative imaging has important role in clinical staging. Ark et al. found that CT hydronephrosis ($p=0.008$) and lymphadenopathy ($p=0.05$) at radical cystectomy are associated with understaging of NMIBC and indicate presence of extravesical disease or higher clinical stage [25]. Dijk et al. emphasized that hydronephrosis and lymph node involvement is not associated with downstaging of bladder cancer [26]. In our study too, lymphadenopathy on CT urogram is significantly and independently associated with stage progression and increased chance of recurrence at restage.

Atta et al. underlined that restage TURBT can be safely omitted in select patients in whom surgeries were done by experienced urologist and teamwork by doubly ensuring the completeness of initial resection [12].

We also propose that in a patient with complete resection by experienced surgeon and teamwork with no risk factors like chemical exposure, LUTS, and lymphadenopathy, restage TURBT can be avoided and patients can be started on intravesical BCG without delay. However, a normal check cystoscopy under local anesthesia at six weeks of initial TURBT would suffice to rule out any recurrence or residual disease before venturing into intravesical BCG. Limitation of the study was the performance of TURBT and restage TURBT by different surgeons and its small sample size.

Conclusion

T1, high-grade disease, tumor > 3 cm, multiple tumors, and CIS are not associated with increased risk of upstaging or recurrence in the setting of well-performed TURBT. However, patients with lymphadenopathy on preoperative imaging are at a higher risk of tumor recurrence and upstaging; and patients with a history of chemical exposure and previous lower urinary tract symptoms were at high risk of recurrence alone. The absence of these factors in the presence of a well-performed and adequate TURBT may obviate the need for another restaging procedure. Further randomized controlled, multicentre trials with large patient cohort are needed to confirm and reinforce the facts.

Supplementary Information The online version contains supplementary material available at <https://doi.org/10.1007/s13193-022-01516-8>.

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Bhirud; review and editing: Sunil Kumar, Tushar Aditya Narain, Vikas Kumar Panwar; all authors read and approved the final manuscript.

Declarations

Ethics Approval This study was performed in line with the principles of the Declaration of Helsinki. Approval was granted by the Ethics Committee of AIIMS, Rishikesh, on 29.12.2018 with letter number AIIMS/IEC/18/573.

Consent to Participate Informed consent was obtained from all individual participants included in the study.

Consent for Publication Patients' informed consent regarding publishing their data was obtained.

Conflict of Interest The authors declare no competing interests.

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