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Incidence and Predictors of Understaging in Patients with Clinical T1 Urothelial Carcinoma Undergoing Radical Cystectomy

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Summary

Objective—To evaluate predictors of understaging in patients with presumed non-muscle invasive bladder cancer (NMIBC) identified on transurethral resection of bladder tumor (TURBT) who underwent radical cystectomy (RC) with attention to the role of a restaging TURBT.

Materials and Methods—We retrospectively evaluated 279 consecutive patients with clinically staged T1 (cT1) disease following TURBT who underwent RC at our institution from April 2000 to July 2011. 60 of these cT1 patients had undergone a restaging TURBT prior to RC. The primary outcome measure was pathological staging of T2 or greater disease at the time of RC.

Results—134 (48.0%) patients were understaged. Of the 60 patients who remained cT1 after a restaging TURBT, 28 (46.7%) were understaged. Solitary tumor (OR 0.43, 95% CI 0.25–0.76, $p = 0.004$) and fewer prior TURBTs (OR 0.84, 95% CI 0.71–1.00, $p = 0.05$) were independent risk factors for understaging.

Conclusions—Despite the overall improvement in staging accuracy linked to restaging TURBTs, the risk of clinical understaging remains high in restaged patients found to have persistent T1 urothelial carcinoma who undergo RC. Solitary tumor and fewer prior TURBTs are independent risk factors for being understaged. Incorporating these predictors into preoperative risk stratification may allow for augmented identification of those patients with clinical NMIBC who stand to benefit most from RC.

Keywords

Urinary Bladder Neoplasms; Outcome and Process Assessment (Health Care); Urinary Bladder; Cystectomy; Surgical Pathology

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Introduction

It is estimated that 73,510 new cases of bladder cancer were diagnosed in the United States and 14,880 deaths in 2012 were attributed to the disease (1). At initial presentation, non-muscle invasive bladder tumors—those that do not invade the muscularis propria—are identified in as many as 70% of patients (2,3). Progression to muscle-invasive disease, however, has been reported to occur in 15% of individuals with bladder cancer (3–7). The standard treatment for muscle-invasive bladder cancer (MIBC) remains radical cystectomy with bilateral lymph node dissection (RC) due to the high risk of progression to metastatic disease and cancer-specific death in these patients. On the other hand, recommended practice for patients with non-muscle invasive bladder cancer (NMIBC) is serial cystoscopy, urine cytology, transurethral resection of bladder tumor (TURBT), intravesical therapy, or any combination of these modalities (3,8–11). In NMIBC, RC is reserved for disease refractory to intravesical therapy or for select, high-risk cases, since progression to metastatic disease is rare in the absence of muscle invasion.

One of the pitfalls of TURBT for the diagnosis and staging of bladder cancer is the inability to accurately identify all cases of muscle-invasive disease. As a result, a patient may be clinically understaged and unwittingly suffer the increased risk of disease progression. A 2001 study at our institution reported that 40% of patients diagnosed with cT1 disease who underwent RC were found to actually harbor muscle invasion (4). Five-year cancer-specific mortality was 30% higher in patients who were understaged compared to those who were not, a finding that underscores the necessity of timely and accurate staging (4). As a result of these and other data, the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines recommend a restaging TURBT for those patients diagnosed with T1 disease that does not contain muscularis propria in the initial histological specimen. In addition, a restaging TURBT may also be appropriate for patients with high grade Ta or T1 disease even when muscle is present in the resection specimen due to the considerable risk of clinical understaging (8,10). Retrospective studies have supported the use of a restaging TURBT, citing residual tumor in as many as 70% of patients (3,11). Our study aims to identify the predictors of understaging in patients with NMIBC who undergo RC, with attention to the role of restaging TURBT.

Materials and Methods

The study cohort was culled from an existing prospective database of all patients who underwent RC at our institution between April 2000 and July 2011 (n=1283) (12). Patients with a history of non-muscle invasive urothelial carcinoma who were clinically staged T1 prior to RC were selected from this database (n=279). Seven urologic surgeons at our institution with fellowship training in oncology contributed cases to the RC cohort. Clinical and pathological information was supplemented by chart review. Clinical stage was assigned according to the 2010 American Joint Committee of Cancer (AJCC) guidelines (13).

The primary outcome measure of our study was clinical understaging, defined as the presence of muscle-invasive disease at RC (pT2 or greater) in patients with clinical T1

NMIBC. Patients pathologically staged T1 or less at the time of RC were considered appropriately staged. We explored the effect of a restaging TURBT on clinical understaging and designated this as our primary exposure variable. Restaging TURBT was defined as a TURBT or bladder biopsy performed within 90 days of the previous TURBT and less than 90 days prior to RC. These criteria were chosen to ensure with reasonable confidence that upstaging at RC was due to clinical understaging rather than disease progression between the diagnostic TURBT and RC. In order to control for confounding, we compared the following variables between patients who were understaged with those who were not: gender, race, age at RC, preoperative tumor stage, postoperative tumor stage, presence of preoperative hydronephrosis or lymphadenopathy on CT, history of intravesical therapy, number of prior TURBT, location of most recent TURBT, completeness of resection at last TURBT, presence of muscle in biopsy specimen, histological grade of tumor, multifocal tumor, presence of CIS, and tumor size at last TURBT or RC if unmeasured at TURBT. Those variables that were significant on univariable analysis were included in a multivariable model.

Univariable comparisons were made using Chi-squared tests and t-tests where appropriate. A multivariable logistic regression model was fit to identify predictors of clinical understaging. The model included restaging TURBT a priori, as well as any variables that were significantly associated with the outcome on univariable analysis. All tests with a p value of <0.05 were deemed as significant. STATA 11.0 software (Stata Corporation, College Station, TX, USA) was used for statistical analysis.

Results

A total of 279 patients who were clinically staged T1 underwent RC at our institution between April 2000 and July 2011. Of these, 266 (95.3%) had documented full bilateral pelvic lymph node dissections. The average age (SD) was 68.1 (10.0) years old and the male to female ratio was 4.2:1. Cohort demographics are listed in Table 1.

Final pathology specimens from RC revealed muscle invasion—clinical understaging—in 134 (48.0%) patients. Clinical understaging was associated with female gender, hydronephrosis, solitary tumor, and fewer prior TURBTs in unadjusted analysis. Presence of muscularis propria in the biopsy specimen was associated with being appropriately staged at subsequent RC (Table 1). Age, race, history of intravesical therapy, history of neoadjuvant chemotherapy, complete resection, CIS, high tumor grade, location of most recent TURBT, and tumor size were not associated with clinical understaging at final pathology. Absence of tumor at RC (pT0) was noted in 14 (5.0%) patients.

Restaging Cohort

We then sought to evaluate the rates of clinical understaging in patients with persistently identified T1 disease after restaging TURBT. Of the 279 patients in the cohort, 60 (21.5%) patients underwent a restaging TURBT. The patient demographics of this group were similar to the total cohort, with an average age (SD) of 66.7 (10.9) years and a male to female ratio of 3:1. On univariable analysis, restaged patients had a higher average number of prior TURBTs (2.6 vs. 1.9; $p = 0.016$) and a higher proportion had received a complete resection

(31.7% vs. 15.5%; $p = 0.005$). Complete resection was recorded only if specifically documented in the procedure note and, accordingly, may be underreported. Restaged patients were more likely to receive their last TURBT at our institution ($p < 0.001$) and had a shorter average interval to RC (48.1 days vs. 100.1 days; $p = 0.031$). Compared to restaged patients, those who were not restaged were more likely to have a history of intravesical therapy (42.0% vs. 21.7%; $p = 0.004$). Of patients who had undergone a restaging TURBT that continued to reveal NMIBC, final pathology from RC revealed muscle invasion—clinical understaging—in 28 (46.7%) patients. Lack of restaging TURBT was not associated with being understaged ($p = 0.812$).

On multivariable analysis, solitary tumor (OR 0.43, 95% CI 0.25–0.76, $p = 0.004$) and fewer prior TURBTs (OR 0.84, 95% CI 0.71–1.00, $p = 0.05$) were identified as independent risk factors for being understaged (Table 2). Preoperative hydronephrosis was associated with clinical understaging in unadjusted analyses but was not a statistically significant independent risk factor (OR 1.76, 95% CI 0.95–3.26, $p = 0.07$). Five-year survival analysis demonstrated a significantly higher rate of survival for those patients who were appropriately staged compared to those who were understaged at final pathology (Figure 1).

Discussion

Accurate clinical staging is a vitally important component in the appropriate management of patients with bladder cancer. However, given the fact that a clinical staging error occurs in 24 to 62% of T1 bladder cancer cases, this remains an elusive goal (14). Restaging TURBT has been cited as a method to improve the rate of accurate staging, particularly for those patients with high grade cT1 disease or absence of muscle in the transurethral resection specimen. Therefore, we sought to explore the predictors of understaging and the role of restaging TURBT in a cohort of patients with clinical NMIBC who underwent RC at our institution.

In this series, 48% of patients who underwent RC for NMIBC were understaged. The risk of being understaged was 47% higher in patients with solitary tumors and was lowered by 16% for each additional TURBT performed. Our findings corroborate those of Fritsche *et al.* who noted a 49.7% chance of understaging in 1136 patients with high grade clinical T1 urothelial carcinoma who underwent RC (15). Despite guidelines that recommend restaging TURBT for those with high grade cT1 disease or lack of muscle in the specimen, over 45% of patients in our series who received a restaging TURBT were still clinically understaged. The importance of accurate staging is exemplified in our data by the significantly lower five-year overall survival for those patients who were understaged. Our findings support the improved survival associated with accurate clinical staging reported by Dutta *et al.* who reported a 25% higher five-year cancer-specific mortality compared to patients who were appropriately staged (4).

Radiographic findings also contribute to the accuracy of clinical staging. In a cT1 patient, hydronephrosis is suggestive of extravesical disease and should raise suspicion for clinical understaging. In the current study, hydronephrosis was significantly associated with understaging on univariable analysis, however this relationship was not significant on

adjusted analysis. Stimson *et al.* identified hydronephrosis as an independent predictor of extravesical disease in an unselected cohort of RC patients. When viewed together, these data may suggest that the present study is underpowered to detect the independent effect of hydronephrosis as a predictor of understaging due to the smaller cohort of clinical NMIBC patients in this series (16). Newly discovered hydronephrosis in a cT1 patient suggests clinical understaging and warrants strong consideration for proceeding to RC.

Regardless of the perceived benefits of accurate staging, not all cT1 patients undergo repeat TURBT. Only 60 (21.5%) patients in this study met the definition of a restaged TURBT. A major obstacle to fulfilling this definition was of the performance of a second resection. In our cohort, 79 (28.3%) patients received their only TURBT at an outside facility within 90 days of RC at our institution. As a high-referral center, our hospital receives many patients for RC who elect to forego a repeat TURBT and proceed to RC. This is not unreasonable in cT1 patients who demonstrate a good understanding of the risks associated with RC, do not wish to delay definitive treatment, and express no interest in bladder preserving interventions. A 2009 study of pathologic T2 RC patients showed worse recurrence-free survival rates in upstaged cT1 patients compared to accurately staged cT2 patients (17). Three- and five-year recurrence-free survival rates of upstaged cT1 patients without a history of intravesical bacillus Calmette-Guerin (BCG) treatment were similar to accurately staged cT2 patients (65% and 65% vs. 77% and 69%, respectively; $P = 0.39$). This inferior outcome associated with BCG use in upstaged cT1 patients is hypothesized to be due to tumor progression secondary to delay in appropriate treatment of muscle invasive disease (17).

Though perceived as a routine outpatient procedure, complications associated with TURBT include bleeding and perforation. Significant TURBT-related bladder perforations are reported in 1.1 to 5.3% of cases (18). Overall, perforations are likely underreported as evidenced by their detection in 58% of patients who received a post-TURBT cystogram in a 2005 study (19). Reported risks for perforation include operator inexperience, tumors located laterally and on the bladder dome, and thin walled bladders of the elderly and those with a history of significant intravesical therapy (20,21). For those patients interested in bladder preservation, however, we believe the hopeful benefit of decreased understaging associated with a re-TURBT outweighs the risk of the procedure and is therefore recommended even in patients at higher risk of complication.

The decision to proceed with RC for cT1 disease comes from both the patient preference and physician concern for invasion but is difficult to determine in a retrospective fashion. Patients in this cohort sought RC without documented physician concern for muscle invasion in 23.7% of cases. Rationale for RC depended on previous history of genitourinary malignancy, symptomatology, comorbidities, and patient desires. Documented physician concern for muscle invasion was reported in 53.0% of the RC cohort and related to disease refractory to intravesical chemotherapy (28.3%), CT findings (16.1%), or unresectable tumor (8.6%).

Numerous studies support that restaging TURBT may improve staging accuracy and identification of residual disease (14,22,23). However, our data demonstrate that there

remains over a 40% chance of clinical understaging in patients believed to harbor persistent T1 disease on a restaging TURBT. Identifying these persistently understaged patients, though difficult, is necessary to deliver appropriate therapy and minimize cancer-specific mortality. As independent predictors of understaging, solitary tumor and fewer TURBTs prior to RC may guide the clinician towards improved patient selection for RC. The finding of solitary tumor as an independent predictor of understaging was surprising and counterintuitive. Rodriguez *et al.* reported multiple tumors increased the risk of recurrence and progression of primary superficial bladder cancer (24). Given those data, it is possible that multifocal tumors went to RC sooner in our series, lowering the chance for muscle invasion. On the other hand, patients with solitary tumors may have been treated less aggressively and allowed more time for potential tumor progression. Although this reasoning is speculative, these data emphasize that no superficial bladder cancer can be taken lightly.

While our study is robust and confirms prior research regarding the hazards of recurrent T1 urothelial carcinoma, it does have several limitations. In particular, these data represent a single-institution retrospective series and the processes of care may be specific to institution-specific practices and local referral patterns. Moreover, patients with T1 disease who go on to RC are, at baseline, a high-risk population for muscle invasion. Therefore, there may be considerable confounding by indication for RC. Lastly and importantly, patients with persistent cT1 disease who underwent bladder preserving interventions rather than RC may also be understaged but were not captured in this study. This “true denominator” is an important limitation we are addressing by prospectively following these patients currently.

Despite the limitations of this study, it is clear that understaging remains prevalent, and clinicians should remain vigilant. Even in the face of two successive TURBTs that demonstrate no muscle invasion, there may still be an approximately 40% chance of being upstaged at subsequent RC. Given the survival benefit of accurate staging, it is imperative that physicians maintain a high index of suspicion for undetected muscle invasion and take into account the entire clinical picture, including the independent risk factors, when selecting an appropriate therapy for patients with persistent T1 disease. In addition, the search for improved staging evaluation must continue.

Conclusions

The overall benefits of restaging TURBT are many and we support its recommendation. The risk of understaging remains high even after a restaging TURBT. A solitary tumor and fewer prior TURBTs are independent risk factors for being understaged. Due to the high risk of understaging even after a repeat TURBT, patients with persistent T1 disease and clinical risk factors of muscle invasion should undergo counseling for radical cystectomy.

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Figure 1.
Five-Year Survival Analysis of Understaged and Appropriately Staged Patients

Table 1

Comparison of Characteristics Between Understaged and Appropriately Staged Patients

Characteristic	Cohort N=279	Understage N=134	Appropriately Stage N=145	<i>p</i>
Age, yrs, mean (SD)	68.1 (10.0)	68.4 (10.1)	67.8 (9.9)	0.615
Race, n (%)				0.450
White	266 (95.7)	128 (96.2)	138 (95.2)	
African American	11 (4.0)	4 (3.0)	7 (4.8)	
Asian	1 (0.4)	1 (0.8)	0	
Sex, n (%)				0.032
Male	225 (80.6)	101 (75.4)	124 (85.5)	
Female	54 (19.4)	33 (24.6)	21 (14.5)	
History of previous therapy, n (%)				
Intravesical chemo, n (%)	105 (37.6)	45 (33.6)	60 (41.4)	0.179
Previous TURBT, mean (SD)	2.1 (1.8)	1.8 (1.4)	2.3 (2.1)	0.018
Neoadjuvant chemo	8 (2.9)	6 (4.5)	2 (1.4)	0.159
Pre-op Hydronephrosis on CT, n (%)	62 (22.5)	39 (29.3)	23 (16.1)	0.008
Pre-op Lymphadenopathy on CT, n (%)	12 (4.4)	9 (6.8)	3 (2.1)	0.056
Presence of muscularis propria, n (%)	167 (59.9)	71 (53.0)	96 (66.2)	0.024
Complete resection, n (%)	53 (19.0)	21 (15.7)	32 (22.1)	0.174
Multifocal, n (%)	83 (29.7)	26 (19.6)	57 (39.3)	<0.001
CIS, n (%)	64 (22.9)	27 (20.1)	37 (25.5)	0.287
High tumor grade, n (%)	247 (88.5)	121 (90.3)	126 (86.9)	0.373
TURBT done at which hospital				0.088
Vanderbilt	106 (38.0)	44 (32.8)	62 (42.8)	
OSH	173 (62.0)	90 (67.2)	83 (57.2)	
Size cm, mean (SD)	3.8 (2.4)	4.1 (2.6)	3.4 (2.1)	0.122
Restaged, n (%)	60 (21.5)	28 (20.9)	32 (22.1)	0.812

Table 2

Multivariable Analysis of Predictors of Clinical Understaging

Characteristic	OR	95% CI	<i>p</i>
Multifocal tumor	0.43	0.25–0.76	0.004
Prior TURBT	0.84	0.71–1.00	0.05
Hydronephrosis	1.76	0.95–3.26	0.07
Gender	0.55	0.28–1.07	0.08
Muscle in biopsy	0.65	0.39–1.09	0.10
Restaged	1.14	0.61–2.11	0.69