Low compliance with guidelines for re-staging in high-grade T1 bladder cancer and the potential impact on patient outcomes in the province of Alberta

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Abstract

Introduction: Despite high-level evidence of benefit, early repeat resection (ERR) among high-grade T1 bladder cancer (HGT1-BC) patients remains low in several non-Canadian jurisdictions and rates in Canada are largely unreported. We evaluated rates of ERR and trends over time in Alberta. We also examined factors associated with uptake of ERR.

Methods: We conducted a retrospective review of data from all patients diagnosed with HGT1-BC from 2007 through 2011. Patients were identified from the Alberta Cancer Registry. Patients with a non-urothelial carcinoma of the bladder and those with invasion into the prostate or metastatic disease were excluded. We collected demographic and clinicopathologic information from patients' electronic medical records.

Results: A total of 600 patients diagnosed with HGT1-BC were included. Overall, 167 patients (27.8%) received an ERR; however, the rate increased in a non-linear fashion from 27.4% in 2007 to 37.8% in 2011. Factors associated with ERR included age <80 years (p=0.021) and centre at which the initial transurethral resection of bladder tumour (TURBT) was performed (p=0.013). Median overall survival (OS) was not reached, but five-year OS was 72.7% (95% CI 68.9, 76.5) for those who received an ERR and 55.3% (95% CI 52.5, 58.1) for those who did not.

Conclusions: Use of ERR in patients with HGT1-BC is improving over time. Regional variation in practice suggests the need for implementation strategies (i.e., provincial clinical care pathways) to standardize practice and set indicators for future measurement and reporting. Targeted interventions would require further investigation around the reasons for variation in practice.

Introduction

Bladder cancer (BC) is among the top five most frequently diagnosed malignancies, occurring at an age standardized rate of 16 cases per 100 000[1] and translating to approximately 8000 new cases annually in Canada.[2] Non-muscle invasive bladder cancer (NMIBC) accounts for 80% of cases[3] and typically responds well to TURBT with or without adjuvant intravesical therapy, followed by surveillance.[4] Radical cystectomy in patients with high-risk features or those who fail intravesical therapy is associated with a five-year recurrence-free survival (RFS) rate of over 80%.[5]

Patients with pathologically-confirmed high-grade urothelial carcinomas of the bladder that demonstrate lamina propria invasion (high-grade T1 or HGT1-BC) may harbour MIBC that is missed at the time of initial TURBT. This is especially true when no muscle is present in the initial specimen.[6-9] For this reason, guidelines recommend that patients with HGT1-BC undergo ERR at two to three months following initial TURBT.[10,11] Randomized, controlled trial data have demonstrated superior RFS in HGT1-BC patients undergoing ERR, compared to no repeat resection (68.7% vs. 37.0% at three years), but no difference in OS.[12] Similar data showing gains in RFS, but not OS have been reported elsewhere.[13,14]

Despite high-level evidence of benefit, the rates of repeat TURBT among patients with HGT1-BC remain low (26–28%) in several non-Canadian jurisdictions[15,16] and rates in Canada are largely unreported. We were, therefore, interested in measuring uptake of the Alberta Genitourinary Tumour Team's evidence-based provincial guideline on the management of HGT1-BC, specifically regarding recommendations for ERR.[10] The guideline was developed in 2005 and then updated regularly through to the end of the study period (2011). We also wanted to examine trends over time and factors associated with uptake of ERR.

Methods

Patients diagnosed with BC between January 1, 2007 and December 31, 2011 were identified from the Alberta Cancer Registry. A TURBT indicating lamina propria invasion, but

not muscularis propria invasion (when present in the specimen), resulted in inclusion in the cohort. Patients with a BC primary other than urothelial carcinoma and those with evidence of invasion into the prostate or metastatic disease were excluded. Electronic medical records were reviewed for 600 patients. This quality improvement study was deemed minimal risk by the ethics tool: A pRoject Ethics Community Consensus Initiative (ARECCI).[17]

We defined ERR as resection within three months of initial TURBT and delayed repeat resection (DRR) as resection in the three- to six-month period following initial TURBT. Repeat resections occurring after six months of initial TURBT were classified as late repeat resections (LRR). In many cases, DRR and LRR would have been performed for persistent or recurrent tumour identified either at the initial TURBT site or elsewhere within the bladder at the time of scheduled surveillance cystoscopies. Early recurrence is a predictor of poor prognosis.[18]

Demographic and clinicopathologic information (i.e., date of diagnosis, date of TURBT, surgeon, date of repeat resection, date of cystectomy, and pathologic stage) were collected from electronic medical records. The cohort was described using median and range for continuous variables and percentages for categorical variables. Demographic and clinicopathologic features were compared using logistic regression. Similarly, logistic regression analysis was used to determine factors associated with receiving an ERR. OS was described using a Kaplan-Meier estimate. Patients still alive were censored at their last observation. Potential differences in OS due to demographic and clinicopathologic variables were examined using a Cox proportional hazards model. A multivariable model predicting OS was developed using the same procedure as for the logistic regression. All tests were two-sided, with $p<0.05$ defined as statistically significant. SPSS 19.0 (IBM, Inc.) was used to perform all analyses.

Results

A total of 1737 patients diagnosed with BC between 2007 and 2011 were identified from the Alberta Cancer Registry. Among them, 600 patients with HGT1-BC met the inclusion criteria for this study. The median age of the cohort was 74.0 (33–98) years and most (54.5%) were between 60 and 79 years of age. Male patients dominated (80.3%) and almost half (46.2%) were treated in Edmonton, with about one-third (30.7%) in Calgary, and the remaining (22.1%) in community/rural areas in the province (Table 1). Muscle was present in the initial TURBT specimen for 447 patients (74.5%). Over the five-year period of study, a total of 167 patients (27.8%) received an ERR. The remainder received either a DRR (n=113, 18.8%), a LRR (n=61, 10.2%), or no repeat resection (n=259, 43.2%) (Table 1).

Among patients with no muscle sampled at the time of the initial TURBT (153 or 25.5%), the rate of ERR remained low at 29.4% (45 of 153 patients). Of the 153 patients whose original TURBT did not sample muscle, 30 (19.6%) were subsequently diagnosed with MIBC at a median 8.6 (0–51.7) months after initial TURBT. Another 77 of the 447 patients whose initial TURBT specimen included uninvolved muscle (17.2%) were subsequently diagnosed with MIBC at a median 9.0 (0.5–55.5) months after initial TURBT. Among the 167 patients who underwent ERR, the rate of upstaging to MIBC at the first repeat resection (≤3 months) was 9.8% (12 of 122 patients) for patients whose initial TURBT specimen included uninvolved muscle vs. 11.1% (5 of 45 patients) for patients with no muscle sampled at initial TURBT.

Among the entire cohort, upstaging to MIBC on any subsequent TURBT occurred in 107 patients, including 35 of 167 (21.0%) ERR patients, 34 of 113 (30.1%) DRR patients, and 38 of 61 (62.3%) of LRR patients. Among these 107 patients, 42 (39.3%) went on to receive a cystectomy, including 17 of 35 ERR patients (48.6%), 13 of 34 (38.2%) DRR patients, and 12 of 38 (31.6%) LRR patients. Interestingly, the median age among those who received a cystectomy was 69.5 (49–87) years, as compared to 82.5 (42–98) years for those who didn't. The median time from initial TURBT to cystectomy among patients upstaged to MIBC was 8.3 (3.1–26.8), 8.2 (4.2–34.1), and 23.5 (0.9–52.8) months, respectively. Cystectomy specimen pathologic assessment among these 42 patients revealed MIBC (pT2 and higher) in

Table 1. Characteristics of patients with HGT1 bladder cancer

Characteristic	N=600
Age (years)	
Years: median (range)	74.0 (33–98)
<60 years: n (%)	90 (15.0)
>60 to <80 years: n (%)	321 (53.5)
>80 years: n (%)	189 (31.5)
Male sex: n (%)	482 (80.3)
TURBT location: n (%)	
Southern Alberta Institute of Urology, Calgary	184 (30.7)
Alberta Urology Institute, Edmonton	277 (46.2)
Community practice, North Zone	42 (7.0)
Community practice, Central Zone	40 (6.7)
Community practice, South Zone	51 (8.5)
Not reported	6 (1.0)
Year of diagnosis: n (%)	
2007	95 (15.8)
2008	113 (18.8)
2009	128 (21.3)
2010	129 (21.5)
2011	135 (22.5)
Repeat resection performed: n (%)	
Early*	167 (27.8)
Delayed**	113 (18.8)
Late†	61 (10.2)
Not at all	259 (43.2)

TURBT: transurethral resection of bladder tumour; *Within 3 months of initial TURBT; **At >3 to <6 months of initial TURBT; †After 6 months of initial TURBT.

33 patients (78.6%), including 15 of 17 (88.2%) ERR patients (Table 2). Median followup for the entire cohort was 36.7 (22.8–54.5) months. Of the 65 patients with MIBC that did not receive a cystectomy, 44 (67.7%) were deceased at the time of last followup, with a median time to death of 6.1 (0.2–33.8) months.

Between 2007 and 2011, the rate of ERR increased from 27.4% to 37.8%, but in a non-linear fashion (Fig. 1). ERR was not influenced by patient sex (p=0.971); however, initial TURBT location (p=0.013), year of diagnosis (p=0.024), and patient age (p=0.028) were significant predictive factors of ERR on multivariate analysis (Table 3).

Median followup for the entire cohort was 36.7 months (quartile range 22.8–54.5). Median OS was not reached. The five-year cumulative OS rates were 72.7% (95% CI 68.9, 76.5) and 55.3% (95% CI 52.5, 58.1), respectively, for those who received an ERR and those who did not. The difference between ERR vs. DRR/LRR/no repeat resection was highly significant, with a p-value of 0.003 (Fig. 2). The only variables that were significant predictors of OS at p<0.05 were patient age (HR=1.82, 95% CI 1.59, 2.08, p<0.001) in favour of age <80 years and ERR (HR=0.60, 95% CI 0.43, 0.85, p=0.002). TURBT location and year of diagnosis were not significant factors. On multivariate analysis, both age (HR=1.79, 95% CI 1.59, 2.05, p<0.001) and ERR (HR=0.70, 95% CI 0.50, 0.99, p=0.045) remained significant predictors (Table 4).

Table 2. Outcomes related to timing of repeat resection in patients with HGT1 bladder cancer

Outcomes	Early* (n=167)	Delayed** (n=113)	Late† (n=61)
Upstaged to ≥pT2 on any subsequent TURBT: n (%)	35 (21.0)	34 (30.1)	38 (62.3)
Received cystectomy after upstaging to ≥ pT2: n (%)	17 (48.6)	13 (38.2)	12 (31.6)
Months from initial TURBT to cystectomy: Median (range)	8.3 (3.1–26.8)	8.2 (4.2–34.1)	23.5 (0.9–52.8)
Final pathology at cystectomy: n (%)			
Tumour invasion			
pT3/pT4	10 (58.8)	7 (53.8)	5 (41.7)
pT2	4 (23.5)	2 (15.4)	5 (41.7)
pT0/pTa/pT1	3 (17.6)	3 (23.1)	2 (16.6)
Positive margins	2 (11.8)	2 (15.4)	1 (8.3)
Lymph node status			
pN1-3	5 (29.4)	3 (23.1)	0
pN0	8 (47.1)	8 (61.5)	8 (66.7)
pNx	4 (23.5)	2 (15.4)	4 (33.3)
Lymphvascular invasion present	8 (47.1)	5 (38.5)	6 (50.0)
Overall survival at 5 years: % (± SE)	58.8 (11.9)	61.5 (13.5)	52.5 (16.2)

MIBC: muscle-invasive bladder cancer; TURBT: transurethral resection of bladder tumour; *Within 3 months of initial TURBT; **>3 to<6 months after initial TURBT; †6 months after initial TURBT.

Discussion

We evaluated compliance with provincial recommendations for ERR. This recommendation is based on randomized, controlled trial data showing that ERR among patients with HGT1-BC results in improved RFS.[12-14] We identified 600 patients with newly diagnosed HGT1-BC between 2007 and 2011. The overall rate of ERR among our cohort was 28%. In comparison, single-institution data from non-Canadian jurisdictions reveals a highly variable rate of ERR, from 26% in Sweden and 27% in China to 62% in the U.S. and 67% in Germany.[15,16,19,20] Astonishingly, in our cohort only 29% of patients with no muscle sampled at the time of the initial TURBT underwent an ERR. The rate of residual tumour is typically about 30%,[7,8] so not surprisingly approximately 20% of our cohort experienced progression to MIBC. Interestingly, upstaging to MIBC on any subsequent TURBT occurred in 35 of 167 (21.0%) ERR patients, 34 of 113 (30.1%) DRR patients, and 38 of 61 (62.3%) of LRR patients, suggesting that late recurrence (or late diagnosis of recurrence) may be associated with a higher rate of upstaging to MIBC.

In our cohort, receipt of cystectomy among patients with subsequent MIBC varied by timing of repeat resection (i.e., 48.6%, 38.2%, and 31.6%, respectively for ERR, DRR, and LRR), which could be due to several factors, including patient age, performance status, and the presence of metastatic disease that would preclude cystectomy with curative intent. Among those with subsequent pathologically confirmed MIBC who received cystectomy, final pathology confirmed MIBC in all but nine patients, seven of whom were provided consultation for neoadjuvant chemotherapy and may have been downstaged prior to cystectomy.

Evidence suggests age is an independent predictor of disease recurrence, progression, cancer-specific mortality, and all-cause mortality in HGT1-BC.[21] In our cohort, patients aged ≥80 years were significantly less likely to receive an ERR. We did not have access to data on performance status or comorbidities, but postulate that perceived benefit from ERR weighed against these factors may have influenced decision-making. To our knowledge, there are no studies on the influence of these factors on receipt of ERR; such data would not only be interesting as a future area of study, but would help inform future guidelines.

In our cohort, location of TURBT was another predictive factor. As compared to patients treated in Calgary, those treated in Edmonton were 85% more likely to receive an ERR, while patients treated in the community setting were 31% less likely. We have previously observed regional variation in practice patterns for BC, specifically on the use of neoadjuvant chemotherapy in MIBC.[22] One possible reason for decreased uptake in Calgary and in the rural setting may be urologist skepticism regarding the benefits of

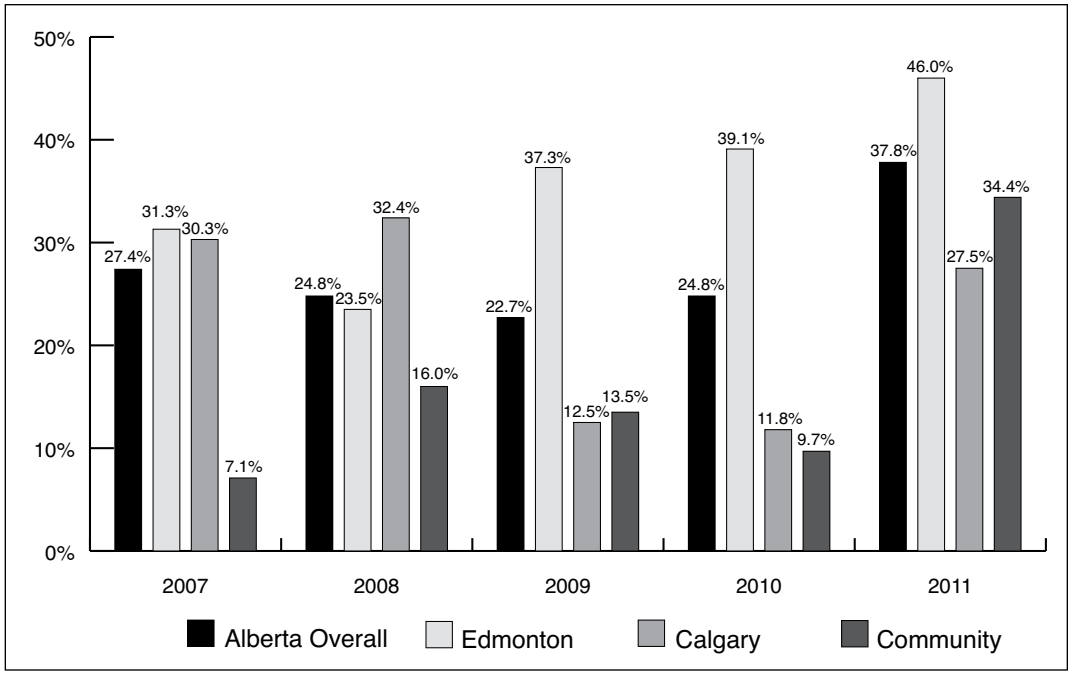

Fig 1. Trends over time in the rates of early repeat resection in patients with HGT1-BC in Alberta overall, in Edmonton, in Calgary, and in the community setting.

ERR. There is a formal urology residency training program in Edmonton, which may help to promote guideline adherence and evidence-based practice; no such program exists in Calgary. Other factors may include higher patient volumes in Edmonton and differences in access to operating room time. The Alberta Genitourinary Tumour Team hosts an annual provincial meeting in which best practice is discussed and recommendations are revised as appropriate; however, community urologist attendance at these events is low. Engagement of community urologists at these meetings and through regular communication from the Provincial Tumour Team may be one way to address this gap.

ERR increased overall from 27.4% in 2007 to 37.8% in 2011. Interestingly, the dramatic increase in ERR in 2011

Table 3. Logistic regression for factors associated with early repeat resection in patients with HGT1 bladder cancer

Variable	Bivariable				Multivariable			
	OR	95% CI		*p* value	OR	95% CI		*p* value
Year of diagnosis								
2007	1.00			0.024	1.00			0.044
2008	0.87	0.47	1.63		0.98	0.51	1.87	
2009	0.78	0.42	1.44		0.90	0.48	1.70	
2010	0.88	0.48	1.60		0.93	0.50	1.72	
2011	1.66	0.94	2.94		1.86	1.03	3.36	
Sex								
Male	1.00			0.971				
Female	1.01	0.64	1.58					
TURBT location								
Calgary	1.00			0.013	1.00			0.013
Edmonton	1.85	1.22	2.82		1.87	1.22	2.87	
Community practice	0.69	0.39	1.21		0.66	0.38	1.15	
Age								
≥80	1.00			0.028	1.00			0.021
60–79	1.67	1.09	2.55		1.78	1.15	2.76	
<60	2.02	1.15	3.54		2.11	1.19	3.76	

CI: confidence interval; OR: odds ratio; TURBT: transurethral resection of bladder tumour.

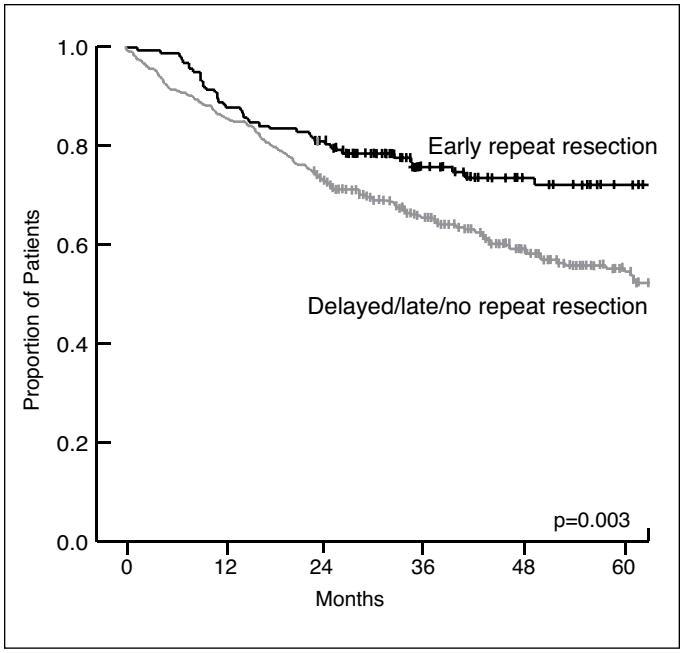

Fig. 2. Kaplan-Meier analysis of overall survival for patients who received an early or a delayed/late/no repeat resection.

coincides with the recruitment to Alberta of two fellowship-trained urologic oncologists with special interests in BC. Unfortunately, analysis on this potential factor would be underpowered. In other jurisdictions reported rates of ERR range from 26 to 67%.[15,16,19,20] While encouraging to see the rates of ERR on the rise in Alberta, there remains room for improvement and, given the non-linearity of the increasing trend, further followup is necessary to monitor the rate in future years. Ongoing measurement and reporting of surgical outcomes has been shown to positively influence surgical practice and may be one way of ensuring guideline adherence.[23,24]

Published trials have yet to demonstrate that ERR results in improved OS.[11-13] The five-year OS rates in our cohort were 72.7%, 60.0%, and 53.8%, respectively, for those who received an ERR, a DRR, and a LRR/no repeat resection. Median OS for the cohort was not reached. Factors associated with OS included age <80 years at diagnosis and ERR. The literature on RFS demonstrates an advantage with ERR.[12,13] Due to limitations of the data, we did not examine RFS or PFS in this cohort. Published data from 52 consecutive patients with NMIBC at the time of initial TURBT who underwent a planned repeat TURBT, showed that the incidence of residual tumour (44.2%) and tumour upstaging (23.1%) was correlated with stage, grade, presence of concomitant carcinoma in situ, presence of muscle in the initial specimen, tumour size, and focality.[25] These factors may have influenced decision-making among urologists treating our cohort. Further study on factors associated with urologists' decision to perform ERR or not may help to inform initiatives aimed at increasing guideline uptake.

Our study has several limitations, including the retrospective nature of the data. Not all data elements could be collected from the electronic medical record. For example, surgeon of record could not be obtained in every case. We were unable to collect information regarding the reasons for delayed or non-receipt of ERR, including comorbidities, tumour characteristics, and patient preference; other relevant components of care, such as intravesical Bacillus Calmette-Guérin therapy; and new resection or diagnostic techniques. A strength of this study is the inclusion of population-based data; all new HGT1-BC cases diagnosed between 2007 and 2011 were captured, eliminating selection bias and allowing for comparison between community and academic centres. To our knowledge, this is the first Canadian study to report compliance with guidelines for ERR in HGT1-BC and the potential impact of compliance on patient outcomes.

Table 4. Cox proportional-hazards regression for factors associated with overall survival

Variable	Bivariable				Multivariable			
	HR	95% CI		*p* value	HR	95% CI		*p* value
Repeat resection								
Delayed/Late/None	1.00			**0.002**	1.00			**0.045**
Early	0.60	0.43	0.85		0.70	0.50	0.99	
TURBT Location								
Edmonton	1.00			0.252				
Calgary	1.10	0.89	1.37					
Community practice	1.07	0.90	1.29					
Year of diagnosis								
Per year increase	0.98	0.89	1.09	0.752				
Age								
<80	1.00			**<0.001**	1.00			**<0.001**
≥80	1.82	1.59	2.08		1.79	1.59	2.05	

CI: confidence interval; HR: hazard ratio; TURBT: transurethral resection of bladder tumour.

Conclusions

Use of ERR in patients with HGT1-BC undergoing TURBT is improving over time in Alberta, but remains lower than expected, at just under 40% in 2011. Because early repeat TURBT appears to be associated with lower rates of progression to MIBC on repeat TURBT and improved OS, we recommend that Alberta and other jurisdictions with low rates of ERR investigate mechanisms for increasing use. Regional variation and patient age appear to play a role and suggest the need for standardizing practice, perhaps through the development of a provincial clinical care pathway. Targeted interventions would require further investigation around the reasons for variation in practice.

Competing interests: Ms. Shea-Budgell declares no competing financial or personal interests. Dr. Gotto is or has been an Advisory Board member for Amgen, Astellas, and Janssen. He has also received honoraria from Amgen, Astellas, Janssen, and Novartis, and is or has participated in clinical trials SPARTAN, ENZAMET, and COSMiC. Dr. Ruether is or has been an Advisory Board member for and has received honoraria from Amgen, Astella, Johnson & Johnson, Novartis, and Pfizer. He is a member of Speaker Bureaus with Amgen and Astellas and has or is participating in clinical trials supported by Astellas, Johnson & Johnson, Novartis, and Pfizer.

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