



Original article

Routine bladder cancer treatment dictates divergence from trial-derived regimens: Results of treatment at 44 radiotherapy centers

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Abstract

Purpose: To assess characteristics and outcome of patients treated with radiotherapy for muscle-invasive bladder cancer at 44 community-based radiotherapy centers and compare these to those on clinical trials.

Materials and methods: We reviewed 155 patients who had been treated from 2010 to 2014. Overall survival and progression-free survival were estimated using the Kaplan-Meier method. Results were compared to a pooled analysis of 6 Radiation Therapy Oncology Group (RTOG) protocols.

Results: What stood out was that our patients' characteristics were significantly inferior than those on RTOG studies: lower rate of complete transurethral resection of bladder tumor: 36.8% vs. 70% ($P < 0.0001$), higher median age: 79 years vs. 66 ($P < 0.0001$), more medically inoperable: (51.0%) vs. 0% in RTOG ($P < 0.001$), and 46.9% had refused surgery. Fewer patients underwent concurrent chemotherapy: 56.1% vs. 100% ($P < 0.0001$). It was also striking that at median follow-up 12.6 months (range: 3.1–49.2), the 36-month overall survival was 51.3% for those who refused surgery vs. 24.5% for medically inoperable ($P = 0.009$); 58.1% with complete transurethral resection of bladder tumor vs. 29.8% if incomplete ($P = 0.07$); 54.3% with chemoradiotherapy (CRT) vs. 17.2% without ($P = 0.03$); 66.3% for those who refused surgery and had CRT vs. 38.9% for medically inoperable who had CRT ($P = 0.04$).

Conclusions: The cohort at community-based centers was older, more medically inoperable, and less likely to receive CRT than clinical trial patients. This suggests that we may not be able to apply trial-derived regimens for many patients in this setting. There is a pressing need to find treatment options for such patients, especially given the aging population. Survival of medically operable CRT patients was comparable to results of RTOG protocols notwithstanding this study's smaller sample size, retrospective nature and suboptimal documentation of patient characteristics. © 2017 Elsevier Inc. All rights reserved.

Keywords: Bladder cancer; Chemoradiotherapy; Chemoradiation; Bladder preservation; Cisplatin; Radiotherapy

1. Introduction

Bladder-preserving trimodality chemoradiotherapy (CRT) is accepted as a first-line option in Europe [1,2] and elsewhere

since, compared to cystectomy it yields similar survival [3–5] and possibly improved outcome [6]. Only recently has it been included as a choice in the National Comprehensive Cancer Network Guidelines [7]. Instead, in the United States, it is common practice to offer definitive surgery to fit patients. Most of the data for CRT in the United States emerges from a few large academic centers [8] and Radiation Therapy Oncology Group (RTOG) trials. With the small volume of cases at most academic centers in the United States, the

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exposure of residents in training to this procedure may be limited, yet when practicing out in the community, radiation oncologists need to perform bladder CRT. We, therefore, examined the characteristics and outcome of patients who were treated for muscle-invasive bladder cancer (MIBC) at 44 community-based 21st Century Oncology radiotherapy (RT) centers in the United States and compared these to a pooled analysis of CRT from 6 RTOG protocols [9]. The incidence of treatment of this disease will continue to increase as life expectancy increases in developed countries [10] and as smoking becomes more prevalent in developing countries [11]. In 2012 an estimated 429,800 new cases of bladder cancer occurred worldwide [12].

2. Materials and methods

2.1. Study type

We, retrospectively, reviewed the characteristics and outcome of patients with MIBC who were treated with RT at 44 centers that shared a single registry after ethical Institutional Review Board approval. The registry is a cancer registry that is used to report cases to each state within the United States. It is a comprehensive database that collects up to 815 fields of data that may be required by individual states in accordance with standards of the North American Association of Central Cancer Registries. For example, data on patient demographics, stage, grade, tumor markers, and types of treatments received. It does not contain information on performance status (PS), or the details of radiation treatment. Patients were not treated according to any specific institutional protocol. To detect patient differences and outcome of treatment off-trial vs. on-trial, we compared the characteristics and results of our population to patients who were treated on 6 RTOG protocols [8].

2.2. Data collection

From the medical records of each patient we recorded the demographic, disease, and treatment characteristics that are listed in Table 1 as well as their smoking history, insurance status, reason for not having a cystectomy, history of superficial bladder cancer, tumor grade, largest tumor diameter, number of tumors, and RT technique. PS had been recorded in patient records as the Karnofsky scale [13] and was converted to the Zubrod [14] scale using a conversion table [15]. Acute and late complications were scored per RTOG grading [16]. Urology records were used to obtain cystectomy rate, local recurrence, nodal recurrence, distant metastases, and death.

2.3. Outcomes measured

Overall survival (OS), progression-free survival (PFS), and cystectomy-free survival (CFS) from the start of RT were estimated using the Kaplan-Meier method. PFS was

Table 1

Patient and tumor characteristics relative to that of patients on sequential Radiation Therapy Oncology Group (RTOG) trials

Treatment	Current study	RTOG	P value
	Nonselective	Selective ^a	
Cohort size	155	468	
Treatment dates	2010–2014	1988–2007	
Follow up			
Median	12.6 mo	4.3 y	
Range	3.1–49.2 mo		
Age, y			
Median	79	66	<0.0001
Range	45–95	34–93	
<70%	25.2	64.1	
70%–74%	12.9	18.8	
>74%	61.9	17.1	
Gender, %			
Male	77.4	82.5	0.1622
Female	22.6	17.5	
Race, %			
W	72.9	76.5	<0.0001
H	0.7	2.1	
B	5.2	2.4	
A	0.7	18.6	
ND	20.7	0.4	
PS, %			
0–1	32.9	100	<0.0001
>1	4.5	0	
ND	62.6	0	
Stage, %			
T2	83.9	60.6	<0.0001
T3	13.6	35.6	
T4	2.6	3.9	
Hydronephrosis, %			
Present	14.2	10.6	0.2418
Absent	85.8	89.4	
Histology, % ^b			
Urothelial	99.4	94.0	0.0270
Squamous	0.0	1.3	
Adenocarcinoma	0.7	1.3	
Other	0.0	3.4	
Baseline TURBT, %			
Complete	36.8	87.8	<0.0001
Incomplete	22.6	12.2	
ND	40.7	0	
CT, %			
Induction	11%	32.3	<0.0001
Concurrent	56.1	100	<0.0001
RT dose, %			
≤60 Gy	27.3		
>60 Gy	72.7		
% Unfit for surgery	51.0	0.0%	<0.001
Treated volume			
% Nodes and bladder	54.8%	100%	<0.0001
% Bladder only	45.2%	0%	

^aSelective: selection of patients after approximately 40 Gy. At that point, only patients without muscle-invasive were allowed to complete radiotherapy and all others were planned for cystectomy.

^bSmall cell carcinoma was excluded; W = White, H = Hispanic or Latino, B = Black or African American, A = Asian, ND = not documented.

calculated as any local, regional, or distant failure, or having had a cystectomy. CFS was defined as not having a cystectomy. To assess the variables associated with OS,

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