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Screening Logs From A Pilot Randomized Controlled Trial Of Radical Cystectomy Versus Chemoradiation Therapy For Muscle-Invasive Bladder Cancer

Dharam Kaushik, MD¹, Zheng Shi, MD², Michael A. Liss, MD¹, Hanzhang Wang, MS¹, Richa Priya Jha, MS¹, Byeong Yeob Choi, PhD³, Deepak K. Pruthi, MD¹, Chul Ha, MD², Ahmed M. Mansour, MD¹, Robert S. Svatek, MD¹

¹Department of Urology, University of Texas Health, San Antonio, TX

²Department of Radiation Oncology, University of Texas Health, San Antonio, TX

³Department of Epidemiology and Biostatistics, University of Texas Health, San Antonio, TX

Abstract

Introduction and Objectives: There is growing interest in a bladder preservation approach using chemoradiation therapy with transurethral resection of bladder tumor (TURBT), i.e., combined modality treatment (CMT), for muscle-invasive bladder cancer (MIBC). We have initiated a pilot study to determine feasibility of conducting a larger-scale clinical trial comparing CMT to radical cystectomy (RC) in patients with MIBC. Here we present the screening logs from the recruitment phase of this trial.

Methods: Patients who were diagnosed to have MIBC after TURBT between April 2016 and August 2017 and considered to be candidates for surgery were enrolled in this prospective, single center, randomized controlled pilot feasibility trial and scheduled to undergo RC (with neoadjuvant chemotherapy if appropriate) or CMT.

Results: Of 62 patients screened during the recruitment phase, only 5 were found to be suitable candidates for either treatment modality hence eligible for randomization. The reasons for exclusion were as follows: multifocal disease (n=24, 40%), variant histology (n=15, 25%), previous pelvic radiation (n=6, 10%), severe lower urinary tract symptoms (n=5, 8.3%), unwillingness to be enrolled (n=8, 13.3%) and receipt of neoadjuvant chemotherapy (n=2, 3.3%). One of the 5 eligible patients was randomized to CMT but was subsequently switched to RC because of a high tumor burden, one was randomized to RC, two were randomized to CMT but subsequently underwent TURBT and were considered ineligible because of extensive bladder disease, and one elected to undergo RC.

Corresponding author: Dharam Kaushik, MD, UT Health Science Center, Department of Urology, Division of Urologic Oncology, 7703 Floyd, Curl Drive, San Antonio, TX 78229-3900, USA, Tel: +1 210 567 5676, Fax: +1 210 567 6868, kaushik@uthscsa.edu.

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Conclusions: We identified many patients with MIBC over a period of 16 months. However, the number of patients eligible to receive chemotherapy and in whom cystectomy and radiation therapy were both valid options was not as high as previously reported in retrospective CMT series. Many patients were excluded after TURBT. Our preliminary data indicate that only a very small subset of patients with MIBC are ideal candidates for CMT. Further research is required to identify patients who are suitable for CMT.

Keywords

Screening log; pilot study; radical cystectomy; chemoradiation therapy; overall survival

Introduction

In 2018, there were approximately 81,190 new bladder cancer cases and 17,240 bladder cancer-related deaths in the US alone. [1] Radical cystectomy (RC) is the gold standard treatment for muscle-invasive bladder cancer (MIBC). However, RC is associated with a 90-day adverse event rate of 25%–65% and a perioperative mortality rate of 5%–10%. [2, 3] Furthermore, patients who are treated surgically report poor overall satisfaction and health-related quality of life. [4] Given the high morbidity, mortality, and quality of life concerns with RC, there is considerable interest in a bladder preservation approach. A combination of chemotherapy and radiotherapy with aggressive debulking transurethral resection of bladder tumor (TURBT), i.e., combined modality treatment (CMT), is now a widely used bladder preservation strategy. [5] CMT is a curative treatment option usually offered to patients who are not surgical candidates, i.e., those with extensive comorbidities and/or poor performance status. CMT as an acceptable modality for MIBC is now endorsed by multiple international cancer organizations that have developed evidence-based consensus guidelines, including the American Urologic Association, American Society of Clinical Oncology, Society of Urologic Oncology, National Comprehensive Cancer Network and European Association of Urology. [5, 6]

Retrospective studies have shown that CMT achieves a clinical response in the majority of patients and preserves the native bladder in more than 70% of cases while affording long-term survival rates comparable with those in contemporary cystectomy series. [7] Efstathiou et al reported respective 5-year disease-specific survival (DSS) and overall survival (OS) rates of 64% and 52% at Massachusetts General Hospital. [7] Similarly, Mak et al found a 5-year DSS rate of 71% and an OS rate of 57% in their pooled analysis of the Radiation Therapy Oncology Group protocol data. [8] These rates are compatible with the 5-year DSS rate of 71.2% and OS rate of 58% reported to be achieved by contemporary RC. [9]

Our understanding of the role of CMT as an alternative to RC for MIBC is still evolving. Several comparative studies of RC versus CMT identified a reduction in the overall mortality risk after RC [10–13] while others found no difference in OS. [14–16] Most of the comparisons of RC with CMT have been either retrospective reviews of data in institutional cohort/national databases [10–16] or systematic reviews based on retrospective analyses and have had discordant findings. [17–19] Any direct comparison of CMT with RC must account for selection bias and confounding variables resulting from discordance between

clinical and pathologic staging, functional status, and comorbidities. Given the paucity of data regarding the effects of these two treatment modalities on OS and lack of relevant RCTs, we performed this preliminary feasibility study with the aim of paving the way for a larger randomized clinical trial comparing the efficacy and safety of CMT and RC.

Materials and Methods

The protocol for this prospective, single-center, randomized non-inferiority pilot trial was approved by our institutional review board (IRB #15–620H) and registered at [ClinicalTrials.gov](https://clinicaltrials.gov) (). The primary outcome was the feasibility of randomizing patients to either radical cystectomy or combined modality therapy. Our main goal of this trial was to perform feasibility assessment and answering methodological questions, such as assessing recruitment difficulty in a surgical trial, coordination of the complex interactions between the various health care providers involved in treatment of bladder cancer patient.

A complete study schema is shown in Figure 1.

Screening, consent and enrollment

Potential study candidates were identified by research staff by review of our clinic schedules and by attending physicians, physician's assistants, and nurse practitioners in our urology clinics. The treating physician, physician's assistant, or nurse practitioner made the initial contact when a patient's pre-screening/chart review indicated that they may be eligible. Patients interested in participating in the trial could also contact the research staff for assessment of their eligibility to participate.

The technical aspects of the study were discussed with each potential participant by the principal investigator or another member of the research team. The following consent elements were discussed: the voluntary nature of participation, the purpose of the study, study procedures, risks and benefits, the collection of protected health information, confidentiality, and participant rights. Each patient was given a copy of the informed consent to read and consider and the opportunity to answer any questions. A copy of the signed consent form was provided to each study participant. A screening log of these patients was maintained.

The study inclusion criteria were as follows: a pathologic (histologic) diagnosis of primary carcinoma of the bladder (transitional cell cancer) within 8 weeks of registration; operable primary carcinoma of the bladder with histologic evidence of invasion of the muscularis propria and AJCC clinical stage T2-T4a, Nx or N0, M0; an adequately functioning bladder after careful evaluation by a urologist and as thorough a TURBT as was safely possible; and ability to tolerate systemic chemotherapy combined with pelvic radiation therapy or RC in the opinion of the treating physician. Patients were excluded if they were unable or unwilling to provide informed consent, had evidence of distant metastases or proven lymph node metastases, had previously received systemic chemotherapy (for any cancer) or pelvic radiation therapy, had clinical T4 bladder cancer, or had lymph node-positive bladder cancer with grossly enlarged pelvic or retroperitoneal lymph nodes. Radiation therapy protocol is

uploaded as supplementary file #2. Full list of inclusion and exclusion criteria are provided in the supplementary file #2.

Randomization and statistical analysis

Sample size calculation for pilot study: Assuming the 50% (p_2) of patients randomized to radical cystectomy and 60% (p_1) of patients randomized to chemoradiation will experience improvement in quality of life at 3 years relative to baseline and a 10% margin () of non-inferiority, this study would require $n=171$ subjects per group to attain 80% power for testing $H_0: p_1-p_2$ versus $H_1: p_1-p_2>$ with $\alpha=5\%$. We rounded 10% of that into $n=30$ for a pilot study. [20]

Therefore, we planned to randomize 30 patients to receive either CMT ($n=15$) or RC ($\pm$ neoadjuvant chemotherapy; $n=15$). The study participants were assigned to the study groups by permuted block randomization with sequentially numbered, opaque sealed envelopes. We planned that all subjects would be randomized in a block size of 2. A randomization list containing the sequence numbers and treatment assignments was prepared by a statistician and used as the sole basis for treatment assignment during the study. The association between categorical variables was evaluated using Fisher's exact test and the chi-square test. Differences in variables with a continuous distribution across dichotomous categories were assessed using the Mann-Whitney U test. All statistical analyses were performed using Stata software (version 10.1; StataCorp LP, College Station, TX). All reported p -values were 2-sided and statistical significance was set at $p<0.05$.

Results

Sixty-two patients were screened for eligibility to participate in this trial between April 2016 and August 2017. The patient demographics and clinical staging information are shown in Table 1. Only 5 of the 62 patients were found to be ideal candidates for either treatment modality, hence, candidates for randomization. The reasons for exclusion were multifocal disease ($n=24$, 40%), variant histology ($n=15$, 25%), previous pelvic radiation ($n=6$, 10%), severe lower urinary tract symptoms ($n=5$, 8.3%), and unwillingness to be enrolled in the study ($n=8$, 13.3%; Table 2).

Of the 5 patients who consented to enrollment, one was randomized to CMT but was subsequently found to have a high tumor burden and switched to RC, one was randomized to RC, two patients were reassessed before randomization for TURBT and found to have extensive disease in the bladder that precluded CMT, and one opted for RC after enrollment (Figure 2).

Discussion

Our main objective of this study was assessing the feasibility of randomizing patients to either radical cystectomy or combined modality therapy. In addition, we evaluated the institutional capability to conduct the clinical trial by understanding specific ethical regulatory requirements, tools for randomization, obtaining informed consent from the study subjects and accruing patients for this study. In this single-institution pilot feasibility trial,

we noticed that the proportion of patients with a diagnosis of MIBC in whom cystectomy and radiation therapy were both valid options was not as high as reported in the previous retrospective CMT series. [7, 16, 17, 21–23] This may reflect certain degree of selection bias. For example, Kulkarni et al [16] observed no difference between RC and CMT in regard to OS (35.7% vs 39.3%; $p=0.63$) in a single institutional series. They performed a robust statistical analysis to compare the two treatment modalities, however, their study was limited by selection bias in that patients with multifocal disease, a large tumor (>5 cm), hydronephrosis, or carcinoma in situ were not candidates for CMT. This pre-screening of patients in a retrospective study may have introduced a degree of selection bias that may have undermined the external validity of their results.

In our study, a considerable proportion of patients (40%) were excluded after TURBT because of a high degree of multifocality and incomplete resection. Data from several studies have shown that patients treated by CMT without complete TURBT have a poor complete response rate and a higher likelihood of needing salvage RC. [24] Efstathiou et al reported salvage cystectomy rates of 22% in patients who had undergone complete TURBT and 42% in those with incomplete TURBT in their review of CMT data for 348 patients with clinical T2-T4a disease at Massachusetts General Hospital. [7] Furthermore, the patients who underwent complete TURBT had a higher complete remission rate than those who underwent incomplete TURBT (79% vs 57%; $p<0.001$). Their updated analysis of 475 patients shows consistent results, i.e., patients requiring salvage cystectomy after failure of CMT had a significantly higher rate of initial incomplete TURBT (43% vs 24%; $p<0.001$). Given that salvage cystectomy is associated with higher morbidity rates and poor cancer-specific survival, patient selection at the time of TURBT plays an essential role in the decision for CMT. [25] Approximately 13% of our screening population had concomitant carcinoma in situ. CMT is not effective for carcinoma in situ because it is often diffuse and complete surgical removal is difficult, rendering this tumor non-responsive to a bladder-preserving strategy. [26]

Approximately 25% of our screened cohort had variant histology. This is an interesting observation given that squamous cell carcinoma, micropapillary carcinoma, and the nested and lympho-epithelioid variants are typically refractory to radiotherapy, usually present as locally advanced disease (cT3, cT4) with lymph node metastasis, and have a poor prognosis. [27–29]

Eight (13.3%) of the 62 patients screened in this study expressed a strong preference for a particular treatment, thereby refusing enrollment. This reflects an inherent recruitment difficulty in a surgical trial, especially when the comparison arm is another treatment modality, such as radiotherapy. We attempted to mitigate some of the recruitment issues by simplifying the patient information sheet and consent process and by hiring a dedicated research coordinator (RJ), as well as ensuring that all study information was explained to the patients by either one of two urologic oncologists (DK, RSS) or a radiation oncologist (ZS). One of the main challenges faced by our group when recruiting patients for this trial was coordination of the complex interactions between the various health care providers involved in their treatment; for example, the referring physician (typically a community urologist who had counseled the patient to undergo RC), academic urologic oncology faculty, radiation and

medical oncologists, residents and fellows in the urology and radiation oncology departments, and research nurses. After opening this clinical trial to recruitment, it took our group almost 6–8 months to streamline the logistics and flow of the trial. In an effort to improve patients' perception of this clinical trial and address issues of equipoise on the part of the urologists and radiation oncologists, all the clinicians involved in the trial regularly discussed potential patients and the possibility of enrollment at a biweekly genitourinary tumor board meeting. However, our screening log for this study reflects the challenges faced when undertaking complex surgical trials. Previous RCTs that have attempted to compare RC with CMT have suffered a similar fate. Notable among these was SPARE (Selective Bladder Preservation Against Radical Excision), which was a multicenter RCT comparing RC and CMT in patients with stage T2–3 N0 M0 MIBC who were suitable for either treatment strategy and had received three cycles of neoadjuvant chemotherapy.[30] Trial recruitment was challenging and below the predefined target, with only 45 patients recruited in 30 months (25 RC; 20 CMT). In that trial, fewer than 250 of more than 800 patients screened were potentially eligible for either treatment modality, which demonstrates the inherent difficulty in conducting such a trial. For a similar future clinical trial, we recommend maximizing use of social media and internet for spreading information regarding availability of clinical trial. This will be a cost-effective strategy and improve recruitment efficiency. In addition, utilization of print material such as posters, study brochure, paper flyers would enhance recruitment.

Conclusions

The screening log from the study reflects challenges faced in recruitment as well as accrual of patients for a randomized surgical trial. Only a very small subset of patients with MIBC are ideal candidates for CMT. Further research is required to identify patients who are suitable for this treatment strategy.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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- In patients with muscle-invasive bladder cancer, number of patients in whom radical cystectomy and chemoradiation therapy (CMT) are both valid options is not as high as previously reported in retrospective series
- Many patients were excluded from CMT treatment after transurethral resection of bladder tumor
- Only a very small subset of patients with muscle-invasive bladder cancer are ideal candidates for CMT

Figure 1.

Study synopsis: Radical cystectomy vs chemoradiation study

Abbreviations: SOC, standard of care; TURBT, transurethral resection of bladder tumor

Figure 2.
CONSORT flow diagram demonstrating the study cohort.
Abbreviations: CMT, combined modality treatment; RC, radical cystectomy; TURBT, transurethral resection of bladder tumor

Table 1

Demographics and clinical staging of study participants

Age, median (IQR)	71 (62–78)
Sex, n (%)	
Male	52 (83.87)
Female	10 (16.13)
BMI, median (IQR)	26.65 (23.6–30.42)
Clinical stage, n (%)	
cT2	45 (72.58)
cT3	9 (14.52)
cT4	8 (12.90)
Ethnicity, n (%)	
Hispanic	20 (32.26)
Non-Hispanic	41 (66.13)
Other	1 (1.61)

Abbreviations: BMI, body mass index; IQR, interquartile range

Table 2:

Reasons for exclusion from participation in the study

Reason for exclusion	% (n=60)
1. Multifocal disease	40% (n=24)
A. Multifocal tumor with concurrent severe CIS	13.3% (8)
B. Upper tract involvement	8.3% (5)
C. Prostatic stromal involvement	8.3% (5)
D. Vaginal involvement	5% (3)
E. Pelvic lymphadenopathy	5% (3)
2. Variant histology	25% (n=15)
A. Squamous cell carcinoma	11.6% (7)
B. Micropapillary carcinoma	3.3% (2)
C. Small cell carcinoma	3.3% (2)
D. Other (nested variant, lymphoepitheloid)	6.6% (4)
3. Previous pelvic radiation	10% (n=6)
4. Severe lower urinary tract symptoms (urethral stricture, multiple sclerosis)	8.3% (n=5)
5. Patient refused enrollment	13.3% (n=8)
6. Already received neoadjuvant chemotherapy	3.3% (n=2)