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Analysis of Urological Procedures in Men Who Died from Prostate Cancer Using a Population-Based Approach

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Abstract

- Repeated urologic procedures can impact quality of life in patients dying of cancer prostate cancer (PCa).
- Using a population-based approach, we sought to determine whether men with end-stage PCa who had definitive primary therapy might require fewer urological interventions.
- Utilizing the Marshfield Epidemiological Study Area (MESA) database and tumor registry, we compared end of life interventions in men who died from PCa between the years 1991–2009.
- Patient charts were queried for urologic procedures utilizing ICD9 codes for 3 years prior to death.
- Clinicopathologic information was examined including whether the patient had a history of primary therapy (radiation or radical prostatectomy).
- Among 280 patients dying of PCa, 52 (19%) required 153 urologic procedures during the last 3 years of life. The frequency of procedures increased closer to death. The most common procedures involved nephrostomy tube (56%), foley catheter (24%) and TURP (10%).
- Clinicopathologic features did not predict the need for an end-of-life urological procedure.
- There was no difference in the frequency of upper or lower tract procedures in surgery or radiation patients compared to patients without primary therapy ($p=0.556$ and $p=0.508$).
- Using a Kaplan-Meier analysis, there were no differences between groups in the proportion of patients not requiring a procedure ($n=280$; $p=0.179$).

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- This is the first population-based study to examine the frequency of urologic procedures in end-stage PCa patients.
- A minority of patients (19%) required urologic procedures during the final 3 years of life.
- A history of surgery or radiation did not influence the overall risk for urologic intervention.

Keywords

Prostate Cancer; Complications; Urological Surgical Procedures; Quality of Life; Watchful Waiting

Introduction

Prostate cancer (PCa) is the second leading cause of cancer death in men in the United States. The American Cancer Society projects that 28,170 men will die from this disease within the next year [1]. The short-term complications of PCa treatments, including radical prostatectomy, radiation, and watchful waiting have been well-characterized [2–5].

However, less emphasis has been placed on complications of end stage prostate cancer, subsequent surgical interventions, and other quality of life issues that arise in the last few years of life. Furthermore, it is unclear whether these primary therapies can subsequently influence the quality of life in men dying from prostate cancer. Population-based studies examining the health care costs related to PCa management conclude that the highest costs occur around the time of cancer diagnosis and at cancer death [6]. Urological procedures at the end of life can contribute to high costs and may be an important quality of life measure for men dying from PCa.

Patients who are treated with non-curative intent can undergo significant morbidity due to local and distant tumor progression in the final years of life [7, 8]. Metastatic disease can cause anemia, fractures, spinal cord compression, bone pain and other clinical sequelae. Local progression of end-stage PCa results in lower urinary tract symptoms (LUTS), obstructive uropathy, hematuria and pain that result in hospital admissions, invasive procedures, and surgical interventions [9]. Interventions required to treat local progression include transurethral resection of the prostate (TURP), urethral or suprapubic catheterization, nephrostomy tube placement, ureteral stent placement, and clot evacuation [10]. While radical prostatectomy and radiation are the standards for curative treatment, they may function primarily to decrease the tumor volume [11]. To date, studies have not yet examined whether debulking actually reduces the need for urological procedures at the end of life.

The frequency of urologic procedures that cancer patients undergo in the final years of life is one contributing factor to the quality of life. Notably, the limited studies to date are based on single institutional data making an accurate assessment of the generalizability of procedural and surgical interventions difficult [12]. In addition, the identification of clinicopathologic factors placing patients at risk for these procedures is unknown. In this population-based study, we reported on the number and type of urological procedures that were required in the last 3 years of life in men who died from PCa. Furthermore, we compared urological

procedures and surgical interventions rates in men who had a history of primary therapy (either prostatectomy or radiation) to those who did not undergo primary therapy.

Methods

Data Source and Study Population

This study was conducted using the population from the Marshfield Clinic (MC), one of the largest multispecialty clinics in the United States, serving 385,000 unique patients in Wisconsin and Michigan. This includes the Marshfield Epidemiological Study Area (MESA) database clinic tumor registry, which was initiated in 1991 as a dynamic, population-based cohort for disease surveillance and epidemiological research [13]. The MC maintains an electronic medical record system including computerized diagnostic files dating back to 1963. Within the area surveyed for this study approximately 90% of the population receives their entire health care from this system. It represents a geographically stable population with granular capture of residents, hospital discharges, outpatient visits, and deaths.

The database was queried between the years 1991–2009 for patients with a cause of death identified as PCa by death certificate. Data was collected on patients that had no local therapy, radical prostatectomy, or radiation treatment (external beam radiation, brachytherapy, or a combined modality). The distribution of the years in which patients were treated was similar across all groups.

Electronic chart abstraction was performed to determine age at diagnosis, age at death, stage, grade, presence of metastatic disease at the time of diagnosis, as well as number and type of procedures. The electronic medical record was queried using ICD9 codes for specific urologic conditions and procedures including insertion of a nephrostomy tube (55.02, 55.03), replacement of a nephrostomy tube (55.93), foley catheter insertion (57.94, 57.95), TURP (60.29), suprapubic tube placement or replacement (57.17, 57.18, 59.94), ureteral stent placement (59.8), cystoscopy with clot evacuation (57), cystoscopy with fulguration (57.4), and urinary diversion (56.71, 56.6). Data collection for procedures was limited to the last three years of life. We chose a three-year follow up based on the data that the median time from castrate-resistance to death is approximately three years and that complications rarely occur before becoming castrate-resistant [14, 15].

Statistical Analysis

The t-test, Chi-square test, and univariate and multivariate multinomial logistic regression were used to compare patients with a history of radiation or surgery against patients without primary therapy. For multinomial logistic regression, radiation and surgery were outcomes of interest. Odds ratios and confidence intervals were reported for only variables that were statistically different between groups. The t-test, Chi-square test, and univariate and multivariate binomial logistic regression were used to test the association between patient characteristics and the need for a urologic procedure. For binomial logistic regression, requiring a subsequent procedure was the outcome of interest. Analysis of variance (ANOVA) test was used to determine whether having primary therapy influenced the mean

number of each type of urological procedure. When Levene's test for homogeneity of variances was significant at the $p < 0.05$ level, nonparametric statistics (Kruskal-Wallis) were used to confirm the results of the ANOVA. Kaplan-Meier analysis was performed to compare the proportion of patients who remained procedure-free among groups. All data were analyzed using SPSS Version 20.

Results

There were a total of 3770 patients diagnosed with PCa in the tumor registry, with 1303 recorded deaths in this population. The query identified 280 (7.4%) of patients with PCa recorded as the primary cause of death. Complete data was available for 96.68 % of PCa patients (only 125 of 3770 individuals were not seen by a database provider within the 3 years of the censor date). The mean follow-up period was 2.7 years. For the population that died of PCa, the average age at diagnosis and death was 73.7 and 78 years, respectively (Table 1). At the time of diagnosis, 47% had poorly differentiated disease, and 46% had metastatic disease.

The patients who died from PCa were divided into three groups: no primary therapy, surgery, and radiation. Among the 280 patients, 29 (10%) of patients had undergone radical prostatectomy and 70 (25%) of patients had undergone radiation as primary therapy. There were 181 patients who had no record of primary therapy in the registry. When the clinical and pathologic characteristics at diagnosis were examined between these groups, we found several significant differences. Men that got surgery or radiation at diagnosis were younger ($p < 0.001$ and $p = 0.004$, respectively) than those not receiving primary therapy (Table 1). A lower incidence of metastases at diagnosis and longer length of survival after diagnosis was identified ($p < 0.0001$ and $p < 0.0001$, respectively) reflecting earlier stage disease in patients receiving primary therapy. There were no differences in the age at death or grade between primary and no primary therapy groups.

We assessed whether clinicopathologic features at the time of diagnosis could predict the need for a urological procedure in the terminal stages of the disease. Among patients who died from PCa, 52 (19%) underwent a urological procedure or surgery during the last three years of life. There were 228 (81%) patients who did not require a procedure. Using univariate and multivariate analyses, we found no statistical differences in the age at diagnosis, age at death, survival after diagnosis, stage, grade, or presence of metastatic disease at diagnosis between patients who subsequently underwent a urological procedure and patients who did not (Table 2). The t-test and Chi-squared test were also performed and confirmed no differences between these groups. Thus, clinical and pathologic parameters at the time of PCa diagnosis did not predict the need for a subsequent urological procedure.

The number of procedures per patient gradually increased approaching death, with the highest frequency (0.35) in the last year of life. However, patients were also at marked risk for undergoing a procedure in the second (0.16) and third (0.08) years prior to death (Figure 1). Among the 52 (19%) patients who required a procedure during the last three years of life, 153 procedures were performed. Of the 52 patients, 25 (48%) of patients required 1 procedure, 19 (37%) of patients required 2–5, and 8 (15%) of patients required 5+.

The most common urological procedure was nephrostomy tube replacement (38%), followed by foley insertion (24%), nephrostomy tube insertion (18%), TURP (10%), suprapubic tube insertion (8%), and ureteral stent placement (3%) (Figure 2). Nephrostomy tube replacement was included since these patients required a hospital-based procedure with recovery. The query did not reveal any patient who required cystoscopy with clot evacuation, fulguration, or urinary diversion. Our analysis included office-based procedures. We found that for patients undergoing a procedure, the frequency was highest for nephrostomy tube replacement (1.11) followed by foley insertion (0.71) (Table 3).

We then evaluated procedures individually and grouped by lower tract (foley, TURP, and suprapubic tube) or upper tract (stent and nephrostomy tube). An argument for the primary treatment of advanced disease is a decrease in the need for lower urinary tract procedures, such as TURP [8]. There were 33 (12%) patients who required an upper tract procedure and 41 (15%) that required a lower tract procedure. We did not find a statistical difference in the mean number of urological procedures per patient when comparing surgery and radiation groups versus the no primary therapy group ($p=0.512$). No difference between groups was observed when procedures were grouped according to upper or lower urinary tract procedures ($p=0.556$ and $p=0.508$, respectively) (Table 3). Although radiation therapy patients might be expected to undergo TURP more frequently, TURP was generally a rare procedure in all groups at the end of life.

Since some men survived less than 36 months after diagnosis, we performed a Kaplan-Meier analysis to account for censored data. Consistent with previous results, there were no differences among groups in the proportion of patients who remained procedure-free in the final 36 months of life ($n=280$, Log-rank $p=0.179$) (Figure 3).

Discussion

Quality of life is a major consideration for patients with terminal prostate cancer. The quality of life decreases in the final 12 months of life in men dying of this disease [16–19]. The number of urological procedures is an important measure of morbidity and costs in men dying from PCa. To date, few studies have attempted to characterize the number of men who required urological procedures at the end of life (Table 4). The current study represents the first population-based analysis to describe specific urological procedure rates in the final years of life in men who died from PCa. There were no clinicopathologic factors that predicted the need for a urological procedure in patients dying of PCa. In addition, we specifically demonstrate that a history of prostate radiotherapy or surgery (e.g. primary therapy) did not influence the need for more interventions in patients dying of PCa.

In this study, we demonstrated that the number of urological procedures increases toward the end of life. This increase in urological interventions is likely a reflection of complications and the clinical sequela of advanced PCa at the end of life. However, the number of procedures required in these patients is not insignificant in the years prior to death. We found that a substantial number of procedures (37%) occurred prior to the final year of life. Most studies to date have focused on the final year of life and have only evaluated the percentage of men affected by procedures, rather than specific urological

procedural rates [6, 10, 17]. Even though the current study examined a longer time period, we found even fewer patients (19%) who required a urological intervention than seen in previous studies (Table 1). For example, Khafagy *et al.* found 25% required intervention [10]. In the current study, nephrostomy tube procedures were among the most common, as well as foley and suprapubic tube insertion similar to other studies.

Previous single institution data has suggested that prostatectomy may have benefits when compared to more conservative measures in men with advanced disease and is associated with extremely low morbidity and mortality rates [12]. Tomlinson *et al.* in 1977 compared patients with cT3 PCa treated by perineal prostatectomy to TURP or simple prostatectomy [20]. They found that 75% of the latter group eventually developed bladder outlet obstruction and were more likely to develop ureteric obstruction (40%), infection (80%), and gross hematuria (45%) compared to the former group (4%, 26%, and 9%, respectively). Other research has found that men with untreated PCa seem to be more affected by physical symptoms than expected from the aging process alone [21]. Our study is important in that we capture both hospital-based and out-patient procedures within a mean follow-up period of 2.7 years prior to death. There is a small possibility that a selection bias exists since men with primary therapy were diagnosed younger and lived longer with the disease. We minimized this potential bias by examining procedures during the final 3 years of life across all groups and find the number of procedures increases uniformly during this time. We found that primary therapy with either prostatectomy or radiation had no influence on overall procedure rates and when procedures were stratified according to upper and lower tract procedures. In addition, there was no difference in the proportion of men requiring procedures. Compared to previous studies, we provide a longer follow-up period and account for censored data (due to death) using Kaplan-Meier analysis. Although our survival analysis may be underpowered to detect a small difference, the study does capture a large study area encompassing 385,000 residents. Our study questions the assumption that patients with advanced PCa should undergo a prostatectomy or radiation simply as a debulking therapy to prevent the morbidity of local tumor progression.

There are inherent weaknesses with any claims research. We may not have captured all men that died from PCa or all urologic procedures for which the database was queried. However, the MC has a remarkably stable medical population with complete medical follow up making it unique [13]. The MESA database is periodically validated and captures 97% of residents, 95% of discharges, 90% of outpatient visits, and 99% of deaths. We have not captured factors that may influence resource utilization, such as income, education, marital status, and geographic density. There may be practice patterns regionally that may not apply to other populations across the country. However, the population-based approach used does have distinct advantages compared to single institution studies in that it limits bias in the treatment and follow up of patients.

In conclusion, the prevalence of urologic procedures at the end of life in men who died from PCa is lower in our study than others have reported. In this population-based study with granular follow up, men who had a history of a radical prostatectomy or radiation underwent a similar number of procedures compared to men who had no definitive primary therapy.

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Figure 1. The Number of Urological Procedures Per Patient Increases in the Last Three Years of Life

The total number of procedures in 99 patients who died from prostate cancer was analyzed during the last 3 years of life. The number of procedures was normalized to the number of patients at risk for each year.

Figure 2. Type of Urological Procedures required during the last 3 years of life

Of procedures that were performed in patients prior to death, the percentage for each one was calculated. The most common procedure performed was nephrostomy tube replacement. In combination with nephrostomy tube insertion these generated over half the procedures required.

Figure 3. Kaplan-Meier analysis comparing time-to-procedure among surgery, radiation, and no primary groups

There was no difference in the proportion of patients who were procedure-free among surgery, radiation, and no primary therapy groups (Log-rank $p=0.179$). The mean follow-up period was 2.7 years (32.2 months).

Table 1

Treatment Group Clinicopathologic Features at Diagnosis

	All patients (N=280)	No Primary Therapy (N=181)	Surgery (N=29)	Odds Ratio	CI 95%	p-value*	Radiation (N=70)	Odds Ratio	CI 95%	p-value*
Average age at diagnosis	73.7	75.3	69.0	0.93	0.90–0.97	<0.001	71.4	0.96	0.93–0.99	0.004
Average age at death	78.0	78.5	77.2			0.49	77.0	0.98	.96–1.01	0.26
Years survival after diagnosis	4.3	3.2	8.2	1.51	1.33–1.72	<0.001	5.6	1.27	1.16–1.72	<0.001
Clinical Stage						0.057	0.55	0.48	0.35–0.67	<0.001
I	10 (4%)	7 (4%)	0 (0%)				3 (4%)			
II	43 (15%)	18 (10%)	5 (17%)				20 (29%)			
III	33 (12%)	7 (4%)	8 (28%)				18 (26%)			
IV	139 (50%)	110 (61%)	9 (31%)				20 (29%)			
Unknown	55 (20%)	39 (22%)	7 (24%)				9 (13%)			
Gleason Grade						0.24		0.73	0.54–0.97	0.16
< 6	4 (1%)	2 (1%)	0 (0%)				2 (3%)			
6	98 (35%)	60 (33%)	8 (28%)				30 (43%)			
7	129 (46%)	80 (44%)	19 (66%)				30 (43%)			
8–10	2 (1%)	2 (1%)	0 (0%)				0 (0%)			
Unknown	47 (17%)	37 (20%)	2 (7%)				8 (11%)			
Metastasis				0.11	0.04–0.32	<0.001		0.20	0.10–0.37	<0.001
Yes	129 (46%)	109 (60%)	4 (14%)				16 (23%)			
No	151 (54%)	72 (40%)	25 (86%)				54 (77%)			

* Chi-square test, t-test, and multinomial logistic regression

Table 2

Predictors of a Subsequent End-Of-Life Urological Procedure

	Urological Procedure (N=52)	No Procedure (N=228)	p-value[*]
Average age at diagnosis	74.3	73.5	0.56
Average age at death	78.5	77.9	0.59
Years survival after diagnosis	4.2	4.3	0.86
Clinical Stage			0.70
I	3 (6%)	7 (3%)	
II	7 (13%)	36 (16%)	
III	5 (10%)	27 (12%)	
IV	22 (42%)	117 (51%)	
Unknown	15 (29%)	41 (18%)	
Grade			0.27
< 6	0 (0%)	4 (2%)	
6	16 (31%)	82 (36%)	
7	21 (40%)	108 (47%)	
8–10	2 (4%)	0 (0%)	
Unknown	13 (25%)	34 (15%)	
Metastasis			>0.99
Yes	20 (39%)	104 (46%)	
No	15 (29%)	75 (33%)	
Unknown	17 (33%)	49 (8%)	

^{*}
Chi-square test and t-tests

Table 3

Mean Number of Procedures Per Patient

Mean Procedures Per Patient (SD)	Total (N=280)	No Primary Therapy (N=181)	Surgery (N=29)	Radiation (N=70)	p-value [*]
Any Procedure	0.55 (1.8)	0.63 (2.0)	0.52 (1.5)	0.34 (1.1)	0.512
Upper Urinary Tract	0.32 (1.5)	0.36 (1.7)	0.45 (1.5)	0.16 (0.7)	0.556
Nephrostomy Tube Replacement	0.21 (1.3)	0.27 (1.5)	0.34 (1.2)	0 (0)	0.265
Nephrostomy Tube Insertion	0.10 (0.5)	0.07 (0.3)	0.10 (0.3)	0.16 (0.7)	0.416
Ureteral stent	0.014 (0.1)	0.022 (0.1)	0 (0)	0 (0)	0.332
Lower Urinary Tract	0.23 (0.9)	0.27 (1.0)	0.07 (0.3)	0.19 (0.8)	0.508
Foley catheter	0.13 (0.6)	0.14 (0.5)	0.07 (0.3)	0.13 (0.7)	0.813
TURP	0.05 (0.2)	0.07 (0.3)	0 (0)	0.03 (0.2)	0.158
Suprapubic tube	0.04 (0.5)	0.05 (0.6)	0 (0)	0.24 (0.2)	0.827

* Analysis of Variance (ANOVA) and non-parametric Kruskal-Wallis test

Table 4**Urological Procedures in Men Dying from Prostate Cancer***

	Aus et. al (1995)	Khafagy et. al (2007)	Current study
Study Population	301 who died from PCa	228 who died from PCa	280 who died from PCa
Source	Swedish cancer registry	Single institution	Regional registry
Follow-up	Diagnosis until death (~5 yrs)	Last year of life	Last 3 years of life
Patients Who Underwent Urological Procedure			
Upper Urinary Tract	55 (17%)	6 (2.7%)	33 (11.8%)
Lower Urinary Tract	-	17 (7.5%)	41 (14.6%)
TURP	123 (41%)	32 (14.2%)	15 (5.4%)
Urological Procedures Performed	255	85	153

* Manuscripts that evaluated urologic procedures in men dying from PCa