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Underutilization of Surgical Standard of Care for Insured Men with Invasive Penile Cancer

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Abstract

Purpose: Prior studies of mixed insurance populations have demonstrated poor adherence to surgical standard of care (SOC) for penile cancer. We used data from the Surveillance, Epidemiology and End Results (SEER) cancer registry linked to Medicare to calculate SOC adherence to surgical treatment of penile cancer in insured men over the age of 65, focusing on potential social and racial disparities.

Methods: This is an observational analysis of patients with T2–4 penile cancer of any histologic subtype without metastasis in the SEER-Medicare database (2004–2015). SOC was defined as penectomy (partial or radical) with bilateral inguinal lymph node dissection (ILND) based on the National Comprehensive Cancer Network guidelines. We calculated proportions of those receiving SOC and constructed multivariate models to identify factors associated with receiving SOC.

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Results: A total of 447 men were included. Of these men, 22.1% (99/447) received SOC while 18.8% (84/447) received no treatment at all. Only 23.3% (104/447) had ILND while 80.9% (362/447) underwent total or partial penectomy. Race and socioeconomic status (SES) were not associated with decreased SOC. Increasing age (OR 0.93, 95% CI:0.89–0.96), Charlson Comorbidity Index score ≥ 2 (OR 0.53, 95% CI:0.29–0.97), and T3-T4 disease (OR 0.34, 95% CI:0.18–0.65) were associated with not receiving SOC on adjusted analysis.

Conclusions: Rates of SOC are low among insured men 65 years of age or older with invasive penile cancer, regardless of race or SES. This finding is largely driven by low rates of ILND. Strategies are needed to overcome barriers to SOC treatment for men with invasive penile cancer.

Keywords

penile cancer; standard of care; inguinal lymph node dissection; healthcare disparities; penectomy

Introduction

Studies show that getting guideline-concordant, standard of care (SOC) treatment for penile cancer is critical for optimizing cancer outcomes.^{1–3} Since 2012, the National Comprehensive Cancer Network (NCCN) has recommended that men with T2-T4 penile cancer should receive a penectomy (partial or radical) with a bilateral inguinal lymph node dissection (ILND).⁴ The European Association of Urology (EAU) has also recommended this since at least 2004.⁵ Despite these recommendations, many men in the United States (US) do not receive SOC for invasive penile cancer in accordance with clinical guidelines. The primary limiting factor impacting the likelihood of getting SOC of penile cancer care is the morbidity of the ILND surgery, as penectomy (including both radical and partial) rates are higher (>90%).^{6–9}

Previous studies suggest that race and socioeconomic status (SES) impact penile cancer incidence and survival. Black men present at younger ages with higher stage disease and have worse overall survival.¹⁰ Slopnick et al showed that Black men are less likely to undergo surgical management of their disease which correlates with worse survival.¹¹ Socioeconomic factors such as uninsured status, lower education, and nonmetropolitan residence have also been found to be poor prognostic factors for men with penile cancer.^{10,12,13} Studies in other urologic cancers, such as bladder and prostate cancer, have shown that Black men are less likely to get SOC for localized disease.^{14,15}

Other studies of penile cancer care have used databases of mixed insurance populations, such as the National Cancer Database (NCDB) or Surveillance, Epidemiology and End Results (SEER). Insurance status is a strong confounder when studying disparities based on social determinants of health.¹⁶ To date, there are no studies that have studied adherence to SOC for penile cancer in an insured population. Therefore, we used the linked SEER-Medicare dataset, which connects two large population-based sources of data about insured elderly patients with cancer. We hypothesized that the receipt of SOC therapy would be higher in an insured older population as compared to published rates in variably insured cohorts, and that access to insurance would mitigate treatment-related racial and social disparities.

Methods

Study population

This is an observational cohort study utilizing SEER-Medicare data from 2004–2015. We chose the SEER-Medicare database for the following reasons: (a) All patients are insured under Medicare; (b) Patient clinical stage could be determined; (c) Type of treatment could be elucidated; and (d) the overwhelming majority of penile cancer patients are of Medicare age. Inclusion criteria were men with penile cancer of any histology that were stage T2 or above with no evidence of metastasis. Patients had to have 12 months of Medicare coverage prior to the diagnosis date to allow for comorbidity assessment. Patients with managed care coverage were excluded. Current Procedural Terminology (CPT) and International Classification of Diseases, 9th and 10th Revision, Clinical Modification (ICD 9/10-CM) codes were used to determine which procedures patients received (supplemental tables). This study was exempted by the institutional review board.

Variables and Outcomes

Our primary outcome was receipt of surgical SOC therapy. We defined SOC based on the most recent recommendations given by the NCCN (published January 2020): men with non-metastatic T2 or greater penile cancer who received a partial or radical penectomy with a bilateral ILND.¹⁷ This recommendation has not changed since the NCCN guidelines for penile cancer were introduced in 2012. Secondary outcomes assessed the rates of individual therapies for invasive penile cancer including partial penectomy, radical penectomy, and ILND.

The primary independent variables were race (White, Black, Hispanic, other) and income (i.e., percentage of population in patient's residence who were in poverty). Potential confounding variables considered included age, year of diagnosis, education (characterized by % of population graduated high school and/or college within resident census tract), location (urban vs non-urban), Charlson Comorbidity Index (CCI), T stage, clinical node status, penile cancer grade, and lymphovascular invasion (LVI) status.

Statistical analysis

Descriptive statistics were calculated with univariate tests with chi-squared analysis. Multivariable logistic regression models were constructed to identify factors independently associated with receiving SOC. Variables that were significantly associated ($p < 0.05$) with the outcome in the univariate setting and/or clinically relevant were included in the multivariable model. These included age, race, marital status, CCI, T stage, node status, penile cancer grade and lymphovascular invasion. Variables considered but not found to significantly alter risk estimates included SES, year of diagnosis, urban/rural status, and education level. All statistical analyses were conducted using SAS version 9.4 (SAS Institute Inc., Cary, NC).

Results

We identified 447 men with T2-T4 non-metastatic penile cancer. Of these men, 99 (22.1%) received SOC including partial or radical penectomy with ILND. Adherence to SOC did not improve after the introduction of the NCCN guidelines in 2012 (Table 1, $p=0.56$). Census-tract based income estimates did not affect the rates of SOC; patients living in higher income areas had similar rates of SOC as patients living in impoverished areas (Table 1, $p=0.40$). There was no difference in SOC rates when stratified by race or SES (Table 1 and Table 2). In the multivariate analysis, increasing age, CCI 2 or greater, and T3–4 disease were associated with lower likelihood of getting SOC. Men with clinical positive nodes and poorly differentiated disease were more likely to get SOC (Table 2).

Table 1 also demonstrates that 18.8% men received no treatment. Race and SES were not associated with lack of receipt of any treatment. Men with more aggressive local disease based on T stage, grade, or lymphovascular status were less likely to receive any form of treatment (all $p<0.01$). Among those treated, increasing age was the only factor related to receipt of non-SOC vs SOC ($p<0.01$). Table 3 displays the utilization of various treatments for penile cancer. A total of 362 men underwent partial or radical penectomy (81.0%) and 104 men underwent ILND (23.3%).

Discussion

We demonstrate that less than one-fourth of all patients in our Medicare cohort with invasive penile cancer received SOC as defined by NCCN guidelines. Despite being insured, men in this cohort demonstrated low adherence to SOC treatment. There were no differences in the utilization of SOC treatment by race and SES. The main cause of low adherence to standard therapy in this group is the lack of ILND. Even more worrisome, 18.8% of men in our study received no surgery.

Although the patients in our study are insured, our low utilization of SOC is consistent with previous literature from mixed insurance populations. A retrospective study using the NCDB showed that, of 1689 men diagnosed with T1b-T3 penile cancer and clinically negative nodes, only 25.3% of men underwent surgical staging of inguinal lymph nodes with either ILND or dynamic sentinel lymph node biopsy.⁶ Campbell, et al demonstrated that 36.8% of patients with penile cancer with T1 high grade or greater disease, regardless of node status, underwent ILND.⁷ European centers, on the other hand, have a much higher guideline adherence rate, more than doubling the rate of ILNDs in patients who may need it.^{2,3} Many European countries have a national equal access healthcare system which may lead decreased disparities and more solidified referral networks that allow patients to be connected to the appropriate sub-specialist.¹⁸ For example, the United Kingdom (UK) has a supraregional network for management of penile cancer which helps centralize care to centers of excellence.¹⁹ In addition, there is more legislative oversight to promote guideline-concordant care in places like the UK under their National Institute of Healthcare and Clinical Excellence as evidenced by the Health and Social Care Act in 2012.²⁰ In these types of equal access systems, reimbursements can also be linked to adherence to guideline-based care, which may improve guideline utilization.

In the US, rates of ILND have not increased since the 1980s.⁹ Our study demonstrates that adherence to SOC (23.4% from 2013–2015) has not improved despite guideline recommendations by the NCCN in 2012.⁴ Our study also suggests that being insured does not necessarily lead to getting SOC. With that being said, there is significant room for improving the use of standard therapies in the management of invasive penile cancer in the US. This is particularly important as multiple studies have shown that getting guideline-concordant care is critical to optimizing cancer outcomes.^{1,2,21} The reason for the lack of SOC for invasive penile cancer in the US is likely multifactorial reflecting a multitude of both patient and surgeon factors.³ Our study demonstrates that men with more medical comorbidities and high clinical T stage were less likely to receive SOC. It is possible that after a discussion with the surgeon, a patient decides to avoid the morbidity of ILND, especially in the older and potentially sicker population that comprises penile cancer patients. Surgeon factors may include lack of comfort or training in providing appropriate therapy, given the rarity of penile cancers. Building stronger referral networks and centers of excellence for penile cancer care could provide community urologists who do not manage penile cancer with access to specialty care for these patients.

Multiple studies demonstrate Black and Hispanic men have a worse overall prognosis from penile cancer. Possible reasons why men from these racial groups do worse are that they present with higher stage cancers and/or are not offered the necessary treatment.^{12,13} We demonstrate that race and SES did not impact SOC rates in this cohort of Medicare beneficiaries. This finding is different from a previous study using a mixed insurance population which suggested that Black men were less likely to receive surgical therapy.¹¹ Nevertheless, although there were no statistically significant differences in the use of SOC treatment by race or income despite some absolute differences, it is important to note that our cohort is underpowered to determine if the absolute differences noted are meaningful.

Black and Hispanic men's worse prognosis in penile cancer could be due to a delayed presentation. Although there are limited studies that investigate why specifically Black and Hispanic men have delays in presentation, there are studies suggesting that delays in diagnosing penile cancer affect all men. Skeppner et al showed that 39% of men had a delay in presentation for more than 6 months due to the embarrassment of a genital issue. The remaining men who had a delay in presentation felt they had a lack of knowledge, thought the symptoms were going to resolve on their own, or were afraid. Gao et al similarly showed that men with penile cancer present late because they think symptoms will resolve on their own (28%) or are embarrassed (23%). In this study, 25% of patients were delayed 6 months or more, which led to worse prognosis.²² In addition, 25–34% of men with penile cancer were inappropriately referred to dermatologists instead of urologists, which inevitably delayed their care.^{23,24} Therefore, increasing patient outreach, education and access to care to decrease delays in presentation may pay dividends in improving outcomes, especially with regards to disparities in outcomes. Improving and establishing partnerships between primary care physicians and urologists may also help patients with penile cancer be referred appropriately and not have a delay in care.

Limitations of this study include retrospective design, limited number of patients which affected our power, the subjective nature of penile cancer staging, missing data, and an

inability to account for patient preferences given the sensitive nature of penile cancer surgery. Given that this is a Medicare population, our patients are older and therefore our results may not be generalizable to younger patients with penile cancer. We know that younger patients that do not qualify yet for Medicare are more likely to receive ILND.⁹ With that being said, the overwhelming majority of penile cancer patients are of Medicare age. Additionally, even the younger men in our cohort, aged 66–70 received SOC at a very low rate (30.7%). Our data also does not fully elucidate why patients did not receive certain treatments, as it unclear whether it was a patient factor, surgeon factor, or both. This is something that needs to be studied further to help us better understand how to improve penile cancer care. Also, many of our subjects were diagnosed and treated before 2012, which was the year the NCCN guidelines for penile cancer were first introduced, therefore it might be unfair to expect that these subjects should have received what we consider SOC. Nevertheless, even after 2012, for our patients diagnosed 2013–2015, there was no increase in receiving SOC. In addition, the benefit of penectomy with ILND was relatively well-known prior to 2012 as the EAU guidelines have been recommending penectomy (partial or total) with ILND for men with T2 or greater disease since at least 2004.⁵ Lastly, we did not include chemotherapy utilization, primarily because the percentage of patients who received chemotherapy was so small that the ability to report our results would have been significantly limited by the CMS cell suppression policy. We acknowledge that there are certain patients whose disease is so advanced that SOC for them would be chemotherapy after penectomy without ILND. We see this trend in our data as patients with more advanced disease are less likely to receive surgical SOC. Nevertheless, this topic of chemotherapy utilization for penile cancer is something that our group is currently investigating.

Conclusions

Less than a quarter of insured men with T2–4 penile cancer receive surgical SOC, based on the NCCN guidelines, with the main limiting factor being ILND utilization. The rate of SOC for penile cancer remains equally low for all patients, irrespective of race or SES. A multi-faceted approach is needed to understand the reasons for low adherence, including both patient and surgeon factors that drive low utilization of guideline-concordant therapy.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Abbreviations and Acronyms

CCI	Charlson Comorbidity Index
CPT	Current Procedural Terminology
ICD 9/10-CM	International Classification of Diseases, 9 th and 10 th Revision, Clinical Modification
ILND	inguinal lymph node dissection
NCCN	National Comprehensive Cancer Network
NCDB	National Cancer Database
SEER	Surveillance, Epidemiology and End Results
SES	socioeconomic status
SOC	standard of care
US	United States

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Table 1 –
Patient Characteristics and Rates of Receiving Standard of Care

Characteristic	p value	Total	SOC	Non-SOC	No Treatment
All		447	22.1%	59.1%	18.8%
Race	0.93				
Non-Hispanic White		343	21.3%	59.8%	19.0%
Black		46	<35% *	>60% *	<35% *
Hispanic		40	<35% *	>50% *	<35% *
Other		18	>25% *	>50% *	>10% *
Income	0.4				
0%–<5% poverty		91	23.1%	64.8%	12.1%
5% to <10% poverty		97	26.8%	53.6%	19.6%
10% to <20% poverty		148	18.2%	61.5%	20.3%
20% to 100% poverty		111	22.5%	55.9%	21.6%
Age	0.003				
66–70		101	30.7%	55.4%	13.9%
71–75		100	27.0%	50.0%	23.0%
76–80		93	23.7%	53.8%	22.6%
81+		153	12.4%	70.6%	17.0%
Relationship Status	0.595				
Married/Partnered		261	21.5%	58.2%	20.3%
Divorce/Widow/Sep		123	26.8%	56.1%	17.1%
Single		41	<35% *	>60% *	<35% *
Unknown		22	<70% *	>60% *	<70% *
Urban	0.74				
No		131	27.8%	59.5%	16.8%
Yes		316	27.8%	58.9%	19.6%
Year of diagnosis	0.4				
2004–2006		87	21.8%	62.1%	16.1%
2007–2009		112	16.1%	61.6%	22.3%
2010–2012		124	26.6%	56.5%	16.9%
2013–2015		124	23.4%	57.3%	19.4%
Charleston CI	< 0.001				
0		188	26.6%	48.4%	25.0%
1		104	23.1%	64.4%	12.5%
2+		155	16.1%	68.4%	15.5%
Clinical T stage	< 0.001				
T2		321	24.3%	58.6%	17.1%
T3–T4		126	21.2%	60.3%	23.0%
Node Status	< 0.001				
Negative		321	17.8%	64.5%	17.8%

Characteristic	p value	Total	SOC	Non-SOC	No Treatment
Positive		114	36.0%	42.1%	21.9%
Unknown		12	100%*	100%*	100%*
Grade	< 0.001				
Well differentiated		72	12.5%	73.6%	13.9%
Moderately		195	24.1%	59.0%	16.9%
Poorly diff		139	26.6%	57.6%	15.8%
Unknown		41	<40%*	<40%*	46.3%
LVI	0.02				
Positive		106	29.2%	59.4%	11.3%
Negative		76	26.3%	59.2%	14.5%
Unknown		265	18.1%	58.9%	23.0%

* Exact percentages not provided to comply with Centers for Medicare & Medicaid Services cell size suppression policy

Table 2 –
Multivariate Analysis of Factors Contributing to Receiving Surgical Standard of Care

Characteristic	Unadjusted OR	(95% CI)	Adjusted OR	(95% CI)
Race				
Non-Hispanic White	Ref		Ref	
Hispanic	1.07	0.49–2.36	1.58	0.65–3.85
Black	1.31	0.64–2.65	1.75	0.80–3.82
Other	1.42	0.49–4.12	1.58	0.58–6.23
Age	<i>0.93</i>	<i>0.90–0.96</i>	<i>0.93</i>	<i>0.89–0.96</i>
Relationship Status				
Married/Partnered	Ref		Ref	
Single	0.63	0.25–1.57	0.51	0.19–1.38
Divorce/Widow/Sep	1.34	0.82–2.21	1.36	0.77–2.38
Unknown	0.81	0.27–2.50	0.65	0.19–2.28
Charlson CI				
0	Ref		Ref	
1	0.83	0.47–1.45	0.92	0.5–1.71
2+	<i>0.53</i>	<i>0.31–0.91</i>	<i>0.53</i>	<i>0.29–0.97</i>
Clinical T stage				
T2	Ref		Ref	
T3-T4	<i>0.62</i>	<i>0.37–1.06</i>	<i>0.34</i>	<i>0.18–0.65</i>
Node Status				
Negative	Ref		Ref	
Positive	<i>2.6</i>	<i>1.61–4.20</i>	<i>2.85</i>	<i>1.63–5.00</i>
Unknown	0.42	0.05–3.33	0.81	0.10–6.79
Grade				
Well differentiated	Ref		Ref	
Moderately	1.98	0.95–4.16	1.99	0.90–4.39
Poorly diff	<i>2.42</i>	<i>1.14–5.15</i>	<i>2.79</i>	<i>1.24–6.32</i>
Unknown	0.87	0.30–2.58	0.88	0.28–2.75
LVI				
Negative	Ref		Ref	
Positive	0.86	0.45–1.67	0.68	0.32–1.47
Unknown	<i>0.54</i>	<i>0.32–0.90</i>	<i>0.31</i>	<i>0.17–0.57</i>

Table 3 –
Rates of Receiving Different Guideline-Concordant Surgical Treatment Options for Penile Cancer

Characteristics	Total	Total Penectomy	Partial penectomy	ILND
All	447	24.8%	56.2%	23.3%
Race				
Non-Hispanic White	343	26.8%	54.2%	22.2%
Hispanic	40	<40% *	60.0%	<40% *
Black	46	<40% *	63.0%	<40% *
Other	18	<70% *	<70% *	<70% *
Age				
66–70	101	31.7%	51.5%	32.7%
71–75	100	30.0%	46.0%	28.0%
76–80	93	16.1%	60.2%	25.8%
81+	153	22.2%	63.4%	12.4%
Income				
0%–<5% poverty	91	22.0%	63.7%	23.1%
5% to <10% poverty	97	27.8%	55.7%	27.8%
10% to <20% poverty	148	25.0%	52.7%	20.3%
20% to 100% poverty	111	24.3%	55.0%	23.4%

* Exact percentages not provided to comply with Centers for Medicare & Medicaid Services cell size suppression policy