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Treatment of a Population Based Sample of Men Diagnosed with Testicular Cancer in the United States

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Abstract

Objectives—Testicular cancer is the most common cancer in men age 25 to 35 years. We examined therapy, compliance with guidelines, and survival in a population based sample of men newly diagnosed with testicular cancer.

Materials and Methods—We analyzed the National Cancer Institute's (NCI) patterns of care data on 702 men diagnosed with testicular cancer in 1999. These studies supplement routine data collection by verifying therapy with the patients' treating physician. Follow-up for vital status was available through December 31, 2004.

Results—The majority of the men with localized seminoma were diagnosed while their cancer was localized and more than 80% of received orchiectomy with radiation. For men with seminoma and nonseminoma (NSGCT) tumors the percent receiving chemotherapy increased markedly as stage increased. More than 90% of men with regional and distant NSGCT received chemotherapy. Less than 25% of men with localized NSGCT received orchiectomy and retroperitoneal lymph node dissection (RPLND), about 40% had surveillance following an orchiectomy alone and the other third received orchiectomy and chemotherapy.

Conclusions—The majority of these patients received therapy consistent with guidelines. While there was no significant difference in the use of RPLND in men with localized NSGCT by geographic region, chemotherapy use varied widely. Over 90% of men with localized or regional disease diagnosed in 1999 were alive at the end of 2004. The excellent survival rates point to the need to monitor for late effects of therapy.

Keywords

Testicular cancer; treatment; surgery; radiotherapy; guideline adherence

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Introduction

The American Cancer Society estimates that 8,090 men will be diagnosed with testicular cancer and 380 will die due to the disease in 2008.[1] Testicular cancer is more common in men age 25 to 35, but it can occur at any age. McGlynn, et al. analyzed data from nine Surveillance, Epidemiology and End Results Program (SEER) registries and found an increasing incidence of this cancer among all men, but especially in African Americans where the rates have doubled between the time period of 1988 to 1992 and 1998 to 2001.[2] Whereas the proportion of tumors diagnosed at localized stages has significantly increased among white men, there has been no change in the distribution of stage at diagnosis among African-Americans.

The treatment of testicular cancer has lead to the significant improvement in patient survival over the past 30 years due to advances in surgery, radiation and chemotherapy. Five year survival rates have improved from 85% (1975-1979) to greater than 96% for men diagnosed in 1997 with an estimated 171,430 testicular cancer survivors in the US [3] and research is now being directed at decreasing the toxicity of treatment in addition to improving survival. Although there has been an overall increase in survival, the survival rates for white and African American men become more disparate. During the period 1975-1977 the 5-year survival rates were 83% and 82% for white men and African American men, respectively. During the time period 1996-2003 these rates increased to 96% for white men, but only 88% for African American men.

We analyzed the National Cancer Institutes' (NCI) patterns-of-care (POC) study of testicular cancer patients diagnosed in 1999. The goal was to describe the therapy being provided to a population based sample of men with testicular cancer treated in the community, compare the treatment to national guidelines, investigate whether there were differences in therapy by age, racial/ethnic group and geographic region and examine the 5-year survival.

Materials and Methods

The NCI SEER program collects detailed data on all cancer cases diagnosed within the population of defined geographic regions of the United States. In addition to data on tumor characteristics, demographics and therapy provided, the registries maintain follow-up of the patients for vital status. Data for the SEER registries are primarily collected from hospitals, surgical centers, and radiation facilities. Because much of the adjuvant therapy is provided in an outpatient setting the NCI annually conducts POC studies to supplement the treatment data for selected cancer sites. Following IRB approval, patients diagnosed with testicular cancer in 1999 were identified through SEER for inclusion in the POC study.

Eligible patients were all males diagnosed in 1999 with germ cell testicular cancer. Patients with primary extragonadal tumors were excluded. Patients were selected by histology, stage and racial/ethnic group. All non-Hispanic black and Hispanic men who were registered in SEER in 1999 with germ cell testicular cancer were included to obtain more stable estimates. All non-Hispanic white men with regional stage (defined as the testicular adnexa and/or regional lymph nodes) or distant stage disease (defined as ulceration of the scrotum, contralateral scrotum, bilateral testis, penis and/or metastasis outside the retroperitonium) were included. [4] Within each registry non-Hispanic white men with localized disease (confined to the tunica albuginea, tunica vaginalis or localized, not otherwise specified) were stratified by histology, seminoma or non-seminoma, and randomly sampled. Patients with in situ disease, those diagnosed at autopsy or on death certificate were ineligible for the study. Men with a previous diagnosis of cancer, other than non-melanoma skin, or with a simultaneous diagnosis of cancer of a second site were excluded. A total of 702 cases, 83% of all cases with testicular

germ cell cancer, were included in the study. Two patients with unknown stage were excluded from the analysis.

Patients' clinical and demographic information were re-abstracted. One of the aims of the study was to obtain complete treatment data including that provided in the outpatient setting. Therefore, each patient's treating physician was contacted to verify treatment provided. The physician was also asked whether other physicians may have treated the patient and if so they were asked to provide the name and address of the physician(s). That physician was then contacted for further verification of therapy. One abstractor from each of the participating registries (the metropolitan areas of San Francisco/Oakland, Detroit, Atlanta, Seattle, San Jose/Monterey and Los Angeles County and the states of Connecticut, Iowa, New Mexico, and Utah) attended a central training to ensure the consistency of data abstraction and coding among registries. Information was collected on whether the hospital where the patient received his most definitive treatment, usually surgery, had an approved residency training program. The specialty of the residency training program was not coded.

We analyzed seminoma and NSGCT patients separately because of differences in recommended therapy. Univariate assessments of the association between seminoma or NSGCT and clinical or non-clinical variables were performed. SEER historic stage was utilized for this report and has been previously described.[4]

All analyses were weighted to reflect the population from which the sample was drawn. The sample weights, calculated as the inverse of the sampling proportion for the each stratum (defined by race/ethnicity and stage), were used to obtain estimates that are representative of all eligible testicular cancer patients in the study areas. All percentages that are presented are the weighted percentages, reflecting the population from which they were sampled. We used the statistical software SUDAAN for all analyses which allows for the use of sample weights and adjusts the standard errors appropriately.[5] The co-variables of age, registry, presence of a residency training program, extent of disease were included in models. Patients were followed through December 31, 2004. The statistical significance tests were assessed using the Wald-type F statistics which tests the statistical significance of each beta coefficient in the model. All p-values were two-sided and the test results were considered to be statistically significant if their associated p-values were less than 0.05.

Results

A total of 702 cases of testicular cancer, 382 cases of seminoma (54.4%) and 320 cases of NSGCT (45.6%) were included. Two cases were excluded, one seminoma and one NSGCT because they were unstaged. The majority of cases of both histologies were non-Hispanic whites: 84.3% of seminoma cases and 78.7% of NSGCT cases (data not shown). Despite including all non-Hispanic black men, they represented only 2.3% of patients. The remaining patients were Hispanic men diagnosed with seminoma, 13.7% and NSGCT, 19%. Seminoma patients were older with a median age of 36 (mean 37.3; range 15 – 81) compared with NSGCT patients who had a median age of 28 (mean 29.2; range 0 – 78) (table 1). Ninety percent of seminoma patients fell between the ages of 23 and 53 compared with NSGCT where 90% of patients fell between the ages of 16 and 47. More than 26% of men with seminoma testis cancer and 31% of men with NSGCT were treated in hospitals with less than 200 beds; while about 42% of men with seminoma and NSGCT were treated in hospitals with more than 300 beds (data not shown).

Seminoma

Seminoma patients were generally diagnosed at an early stage. Slightly more than 82% were diagnosed with localized stage and only 4.3% with distant disease.

Overall, only 3% of seminoma patients underwent RPLND (data not shown). Eighty-five percent of men diagnosed with localized seminomas were treated with orchiectomy and radiation (table 2). Slightly more than 12% were treated with orchiectomy alone. A very small percentage received other therapeutic regimens.

Among patients with regional seminoma the majority, nearly 55%, were treated with orchiectomy and radiation. A larger percentage of patients with regional disease received chemotherapy, 34%, with or without radiation, than did men with localized disease. The percentage of seminoma patients diagnosed with distant disease was less than 6% and the majority of these were treated with chemotherapy in combination with other modalities. Although one patient received no therapy, he died suddenly within six months of his diagnosis.

More than 75% of men who received chemotherapy for seminoma, regardless of stage, were given bleomycin, cisplatin, and etoposide (BEP) (table 4). Of men with distant seminoma who received chemotherapy, 11% received carboplatin and another 11% received cisplatin and etoposide.

Survival declined with advancing stage of disease (table 1). Nearly 99% seminoma patients diagnosis in 1999 with localized disease were alive on December 31, 2004, this figure declined to 95% for regional disease and 65% for distant disease.

Non-seminoma

Approximately 54% of men NSGCT had localized disease at diagnosis and 18% distant disease. Overall, almost a third of NSGCT patients underwent RPLND. Of NSGCT patients undergoing RPLND, the majority had greater than 10 nodes removed for examination (data not shown). NSGCT patients with localized and regional disease were more likely than seminoma patients to have an RPLND (table 1).

In patients with localized NSGCT disease, 41% were treated with orchiectomy alone and another 21% with orchiectomy and RPLND. More than a third of the men with localized disease were treated with adjuvant chemotherapy and orchiectomy. Among men with regional NSGCT, 81% received chemotherapy, 8% underwent orchiectomy alone and 11% underwent orchiectomy plus RPLND without additional chemotherapy. Of advanced disease patients all received chemotherapy.

We performed multivariate analyses of treatment modality in men with localized NSGCT. We examined extent of disease, presence of a residency training program, age at diagnosis, and geographic region. Only extent of disease was associated with surgical treatment of orchiectomy alone vs. orchiectomy with any other treatment, RPLND, chemotherapy or radiation (table 3). After adjusting for age, the presences of a residency training program and geographic region, 52% of patients without vascular or lymphatic received the more aggressive therapy, compared to 72% of patients with vascular or lymphatic invasion. In a model comparing patients who received an orchiectomy, with or without RPLND, to patients who also received chemotherapy, vascular invasion and geographic region were associated with the use of chemotherapy. Those patients with vascular invasion were much more likely to receive chemotherapy after orchiectomy. The predicted probability of receiving chemotherapy after adjusting for age, hospital residency program and geographic area for those without vascular invasion was 23% compared to 58% for men with vascular invasion. Differences were noted in the use of chemotherapy by geographic regions. The range varied from an adjusted high of 73% to a low of 12%.

The choice of chemotherapy was overwhelmingly bleomycin, cisplatin, and etoposide, (BEP), for all stages (table 4). Of men who received chemotherapy more than 88% received cisplatin

and etoposide with or without bleomycin. Carboplatin was given to 1.8% and 2.9% of men with NSGCT, localized or regional disease, respectively, of men who received chemotherapy. Fewer than 10% of men who received chemotherapy also received growth factor support with G-CSF (data not shown).

Survival, based on follow-up through December 31, 2004, was similar for men with NSGCT as for men with seminoma; 99% and 95% for localized and regional disease, respectively (table 1). Survival was slightly better, 72%, for men with distant NSGCT compared to men with distant seminoma.

Discussion

Though still a disease of young men, these data indicate that testicular cancer occurs in older age groups with over 10% occurring in men over the age of 45. As noted by McGlynn, et al, [2] testicular cancer remains predominantly a disease of white males. Despite including all cases of testicular cancer occurring in African American men in the participating SEER regions, they represented only 2.3% of the cases in this study.

The overwhelming majority of seminoma patients continue to be treated with radiation and orchiectomy despite increased use of chemotherapy in early stage NSGCT. Rather than being offered surveillance after surgery, patients with early stage seminoma have typically been offered radiation therapy after orchiectomy with excellent survival results and low toxicity rates. However, nearly 80% of early stage patients would not relapse with orchiectomy alone. [6] Although adjuvant chemotherapy has been proposed by EGCCCG as an alternative to radiation in early stage seminoma[6] and a single does of carboplatin has been shown to be as effective as radiation in the treatment of stage I seminoma[7], very few patients in our data set were treated with this approach. This may be due to the high success of radiation therapy in preventing relapse in early stage seminoma.

Patients with early stage NSGCT historically were offered orchiectomy followed by either RPLND although beginning in 1985, surveillance became more prevalent.[8] While RPLND and surveillance the primary therapies, chemotherapy is being used early stage NSGCT disease. In this study one-third of patients with localized NSGCT received adjuvant chemotherapy and orchiectomy. The rate of adjuvant chemotherapy for early NSGCT reported in our study is higher than rates reported in Steele's POC study of patients diagnosed in 1985 through 1996 and may signal a trend in the increased use of chemotherapy in the treatment of early stage disease.[9] Currently we do not have randomized clinical trials data that directly compares chemotherapy versus RPLND versus surveillance in early stage disease after orchiectomy, though each of these options is recognized as reasonable care by current National Comprehensive Cancer Network (NCCN) guidelines.[10]

NCCN guidelines allow for two cycles of BEP chemotherapy instead of RPLND for patients with stage IB.[10] The European Germ Cell Cancer Consensus Group (EGCCCG) recommended 2 cycles of BEP to prevent relapse in high risk patients and 3 cycles for patients with advance disease and “good” prognosis.[6] Another study reported that men with stage I NSGCT “at a moderate risk of relapse” men who received only one cycle of chemotherapy faired no worse than men who received two cycles.[11] In low-volume stage II NSGCT patients one cycle of BEP plus two cycles of EP was as effective as three cycles of BEP. [12] However, a recent study of men diagnosed with stage I NSGCT reported that adjuvant chemotherapy was significantly more effective in preventing recurrences than an RPLND [13] Although not statistically significant, there was a suggestion that men treated in hospitals with a residency training program were more likely to receive chemotherapy than men treated in hospitals with our such training programs. The observation that chemotherapy use varies by geographic region

suggests that physicians have differing opinions on the value of chemotherapy. In our study, men with NSGCT living in California and Atlanta were given chemotherapy relatively infrequently. Men living in the northern US, Detroit, Iowa Seattle (Puget Sound area) and Connecticut were more often given chemotherapy. Detroit, Iowa and Seattle had significantly higher use of chemotherapy than the San Francsico/Oakland area.

The vast majority (>90%) of chemotherapy agents utilized were standard BEP. Some patients received therapy with bleomycin omitted, a reasonable alternative in good risk individuals to avoid bleomycin toxicity. In patients with good-risk disease, 4 cycles of etoposide and cisplatin (EP) has been suggested as an option to 3 cycles of BEP when bleomycin is contraindicated.[6] Two large trials have demonstrated the inferiority of carboplatin to cisplatin.[14, 15] In our study, carboplatin was utilized in only 7 patients (3% of all chemotherapy patients). Several patients were treated with ifosfamide, an agent that is normally reserved for salvage therapy but currently being investigated as an alternative to bleomycin in high risk disease. Very small numbers of patients were treated with other agents such as doxorubicin, methotrexate and dactinomycin. These agents have been under investigation in poor-risk NSGCT.

Growth factor support with G-CSF was reported in less than 10% of patients receiving chemotherapy, in keeping with published literature and the most recent American Society of Clinical Oncology guidelines.[16] Whereas growth factor use is considered reasonable to maintain dose intensity in patients with curable malignancies, the majority of germ cell patients can receive 3 to 4 cycles of BEP without a need for dose reduction.

Germ cell cancers continue to be a highly curable malignancy with 5-year survival of greater than 90% in men in this data set diagnosed with localized and regional disease. This is comparable to other studies and clinical trials.[9, 14] A meta-analysis of NSGCT patients showed an improvement in survival for those diagnosed in the more recent years compared to the past.[17]

Testicular cancer is relatively rare and is usually diagnosed early therefore the number of cases, especially for the later stages, is limited. We have data from 1 year. However, it is collected from across the country and while treatments for cancer change over time, we do not believe that treatment in 1999 was dramatically different than the year preceding or following. The value of this study is that it is a population-based sample that provides a snapshot of therapies prescribed in communities across the US. With patient follow-up it provides the opportunity to examined subsequent survival of these patients following their treatment in the community.

Conclusions

In this population-based study of testicular cancer, we find that the overwhelming majority of patients are receiving therapy consistent with recommended guidelines. However, the use of chemotherapy in men with localized NSGCT varied widely across geographic regions of the study. This suggests that while there may be a general agreement that the use of chemotherapy in the treatment of localized disease is beneficial, not all physicians convinced of its value.

Survival for testicular cancer remains excellent for those with localized and regional disease even with the increased use of chemotherapy in NSGCT patients. The use of chemotherapy instead of complete RPLND in early stage NSGCT appears to have caused no detriment in short-term survival. We will need to continue to follow this group of patients for longer term survival and, toxicities from chemotherapy and radiation therapy.

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Table 1

Distribution of Clinical and Non-Clinical Characteristics of Men Diagnosed with Testicular Cancer in 1999

	Seminoma			Nonseminoma		
	Localized N = 308 WT %	**Regional n=56 WT %**	**Distant n=17 WT %**	**Localized n=175 WT %**	**Regional n=85 WT %**	**Distant n=59 WT%**
Age						
0-19	1.3	0	0	13.4	9.6	13.8
20-24	7.2	1.6	4.8	20.0	26.3	23.3
25-29	13.4	17.2	6.3	17.6	20.0	24.7
30-34	20.5	12.1	30.2	23.1	21.1	16.5
35-39	24.9	15.5	14.3	10.1	13.0	12.4
40-44	16.2	21.3	9.5	7.2	3.2	0
45-49	8.0	17.8	20.6	6.7	3.4	6.2
50-54	4.2	9.6	9.5	1.2	1.2	1.5
55-59	1.0	3.3	4.8	0	1.1	0
60+	3.2	1.6	0	0.7	1.1	1.5
Race						
NH White	84.0	83.8	90.5	79.8	85.1	66.2
NH Black	1.7	4.7	0	2.7	4.3	0
Hispanic	14.2	11.5	9.5	17.5	10.7	33.8
Residency training program						
No	49.6	34.4	31.7	52.4	49.5	38.2
Yes	50.1	65.6	68.3	47.1	49.2	59.2
Unknown	0.3	0	0	0.5	1.3	2.7
Retroperitoneal Lymph Node Dissection						
No	99.7	85.7	73.0	75.6	42.8	82.0
Yes	0	10.7	15.9	22.6	57.2	16.5
LND, NOS*	0	3.4	0	0.5	0	1.5
Unknown	0.3	0	11.1	1.2	0	0
Nodes positive						
None	1.5	4.1	0	22.1	7.9	4.3
1-4	0	9.2	9.5	0	34.8	4.7
5-9	0	0	0	0	4.6	0
10+	0	0	0	0	3.7	1.5
1+, #unk	0	5.0	11.1	0	7.0	10.5
None exmd	98.5	81.8	68.3	76.7	40.6	78.9
Unknown	0	0	11.1	1.2	1.3	0
Lymph nodes laterality						
No LN exam	100.0	85.9	74.6	75.6	42.8	77.3
Unilat reg LN	0	8.8	4.8	10.9	24.8	7.3
Bilat reg LN	0	0	0	3.4	10.3	5.9
Reg LN, NOS	0	5.3	9.5	8.9	21.1	9.5
Unknown	0	0	11.1	1.2	1.1	0
Vital Status as of 12/2004						
Alive	98.7	95.3	65.1	98.7	94.6	72.2
Dead	1.3	4.7	34.9	1.3	5.4	27.8

*Lymph node dissection, not otherwise specified

Table 2

Treatment Given for Testicular Cancer Patients Diagnosed in 1999 by Histology and Stage at Diagnosis

Treatment summary	Seminoma (n=381)			Non-seminoma (n=319)		
	Localized	Regional	Distant	Localized	Regional	Distant
	n=308 wt%	n=56 wt%	n=17 wt%	n=175 wt%	n=85 wt%	n=59 wt%
Orchiectomy alone	12.2	6.2	0	41.0	7.6	0
Orchiectomy, XRT	83.8	54.7	9.5	3.1	0	0
Orchiectomy, chemotherapy	2.9	18.4	54.0	30.4	32.7	69.3
Orchiectomy, XRT, chemotherapy	0.9	6.5	0	1.2	2.5	7.9
Orchiectomy, RPLND	0	0	0	21.4	10.6	0
Orchiectomy, RPLND, XRT	0	5.0	0	0.6	0	0
Orchiectomy, RPLND, chemotherapy	0	9.2	15.9	2.4	44.3	18.0
Orchiectomy, RPLND, XRT, chemotherapy	0.3	0	4.8	0	2.3	0
XRT, chemotherapy	0	0	6.3	0	0	0
Chemotherapy only	0	0	4.8	0	0	4.7
None	0	0	4.8	0	0	0

XRT = Radiation

Table 3

Predicted Probability of Receiving the More Aggressive Therapy for Localized Non-Seminorma Testicular Cancer

	Orchiectomy alone vs Orchiectomy w other therapy		**Orchiectomy w/wo RPLND vs Any chemo**	
	Predicted Percent	**SEp-value**	**Predicted Percent**	**SEp-value**
Age		0.5		0.3
<30	56%	5%	31%	4%
30-35	57%	8%	43%	7%
35+	66%	7%	36%	6%
Registry		0.3		0.0004
San Francisco	59%	10%	18%	8%
Connecticut	66%	13%	47%	12%
Detroit	58%	11%	**49%**	**10%**
Iowa	88%	8%	**73%**	**11%**
New Mexico	23%	19%	30%	20%
Seattle	69%	11%	**65%**	**11%**
Utah	63%	17%	39%	16%
Atlanta	47%	12%	17%	8%
San Jose	39%	12%	12%	7%
Los Angeles	57%	8%	20%	6%
Extent of Disease *		0.01		<0.0001
No Invasion	52%	5%	23%	4%
Invasion	**72%**	**6%**	**58%**	**6%**
Hospital Residency Training Program		0.3		0.8
Yes	63%	6%	38%	5%
No/Unk	55%	5%	32%	5%

* Vascular or lymphatic invasion

Bold = statistically significant p<0.05

Table 4

Summary of Chemotherapeutic Agents Given for Treatment of Men Diagnosed with Testicular Cancer in 1999 by Histology and Stage at Diagnosis

Summary of chemotherapy agents	Histology					
	Seminoma n=48 *			Nonseminoma n=183 **		
	Localized	Regional	Distant	Localized	Regional	Distant
	n=14	n=19	n=15	n=57	n=67	n=59
	wt%	wt%	wt%	wt%	wt%	wt%
Cisplatin, Etoposide, Bleomycin	78.5	76.3	77.8	74.6	74.1	84.4
Cisplatin, Etoposide	0	23.7	11.1	11.2	11.7	7.7
Carboplatin (in any combination)	0	0	11.1	1.8	2.9	1.5
Other Regimens	21.5	0	0	12.3	11.2	6.4

* 12.6% of all seminoma patients

** 57.4% of all nonseminoma patients