Adherence to National Comprehensive Cancer Network® Guidelines for Testicular Cancer

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Abbreviations and Acronyms

BEP = bleomycin, etoposide and cisplatin

GCT = germ cell tumor

GDC = guideline directed care

IGCCCG = International Germ Cell Cancer Collaborative Group

NCCN® = National Comprehensive Cancer Network®

NGDC = nonguideline directed care

NSGCT = nonseminomatous germ cell tumor

PET = positron emission tomography

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Purpose: Testicular cancer is the most common malignancy among young men and well established treatment guidelines exist to optimize outcomes. We characterized errors in the management of testicular cancer observed among patients seen at 3 referral centers in the United States.

Materials and Methods: We retrospectively reviewed data from 593 patients presenting with testicular cancer to 3 academic medical centers from 2007 to 2016. Nonguideline directed care was defined as management differing from National Comprehensive Care Network guideline recommendations. Cases of nonguideline directed care were systematically described. Patient and tumor characteristics were compared between guideline directed care and nonguideline directed care. Multivariable logistic regression was used to identify predictors of nonguideline directed care, and Cox regression modeling was used to assess the association between nonguideline directed care and relapse-free survival.

Results: Nonguideline directed care was identified in 177 of 593 (30%) patients. Inappropriate imaging (44%) and overtreatment (40%) were the most common classifications. Misdiagnosis (24%) and under treatment (16%) occurred relatively frequently, while inappropriate treatment (6%) was rare. Multivariable Cox regression modeling controlling for race, tumor stage and tumor histology identified nonguideline directed care as a significant predictor of relapse (HR 2.49, 95% CI 1.61–3.85, $p < 0.01$).

Conclusions: Nonguideline directed care of patients with testicular cancer is common, most frequently in the form of inappropriate imaging and overtreatment. Nonguideline directed care leads to delayed definitive therapy, unnecessary morbidity and higher rates of relapse.

Key Words: testicular neoplasms, guideline adherence, seminoma, nonseminomatous germ cell tumor

TESTICULAR cancer is the most common cancer diagnosis for men 15 to 35 years old and the 5-year survival rate is 95%.[1,2] Even for patients with metastases the cure rates are relatively high, with 5-year survival rates ranging from 73% for IGCCCG poor risk to more than 90% for IGCCCG good risk disease.[1,3,4] Timely and effective treatment of patients with testicular cancer requires complex and often multimodal

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treatment most commonly involving chemotherapy, radiation and surgery. To standardize and disseminate evidence-based treatment, multiple guidelines and risk stratification tools have been created, including the NCCN guidelines and the IGCCCG risk stratification system for metastatic disease.[5,6]

Even with established guidelines, outcomes differ among institutions. Several studies have demonstrated improved overall survival for patients with testicular germ cell tumors seen at high volume institutions, a difference that is more pronounced in the setting of advanced disease.[7–9] A recent study found that patients referred to an academic center later in their treatment had lower recurrence-free survival compared to patients referred earlier during their treatment (61% vs 79%), although this was likely influenced by referral patterns.[10] Similarly, a study evaluating second opinions from large volume centers found discrepancies between the original treatment plan and the second opinion in 32% of cases.[11] Management errors can result in diagnostic delays, higher clinical stage at presentation and unnecessary treatment related morbidity.[12–17]

Variability in management and outcomes may reflect NGDC. A German study found that the implementation of evidence-based guidelines decreased the rate of therapeutic errors from 28% to 8%.[18] There have been few studies characterizing NGDC and, to our knowledge, none based in the United States. In this study we review a large cohort from 3 geographically distinct referral centers in the United States to define and characterize NGDC, identify predictors of NGDC and evaluate rates of relapse among these patients.

MATERIALS AND METHODS

We retrospectively reviewed an institutional review board approved database including 705 consecutive patients presenting with testicular cancer (any stage) to the University of Chicago Medical Center (209) and University of Southern California (422) from 2007 to 2016, and the Johns Hopkins Hospital (74) from 2013 to 2015. Patients were identified based on ICD-9 and ICD-10 codes for a principal diagnosis of testicular cancer (186.9 and C62.90, respectively). Patients with nongerm cell primary testicular tumors, benign testicular tumors and testicular metastases from nontesticular primary tumors were excluded from analysis (76). Patients were also excluded if the medical records were insufficient to compare treatment to NCCN guidelines (36), leaving 593 patients for analysis. Diagnosis (ie orchiectomy or tissue biopsy) was performed elsewhere in 80% and at a study site in 20%.

Patient demographics, clinical presentation, cancer characteristics, management (surgical, medical and radiotherapy), followup length and relapse rates were evaluated. Presentation was classified as testicular enlargement/mass, testicular pain, metastatic symptoms (including symptoms secondary to retroperitoneal metastases as well as nonregional metastases) or incidental findings on imaging. If a patient presented with multiple symptoms, the symptom recorded as the patient's main complaint was used in analysis. However, if a patient noted a testicular mass or enlargement at any point during the initial encounter, this was recorded as the presenting symptom regardless of other symptoms. For multivariate logistic regression and relapse analyses, tumor stage was defined as stage I or metastatic (stage II and III) disease. NGDC was defined as management differing from the 2015 NCCN guidelines for testicular cancer management and categorized as overtreatment, under treatment, misdiagnosis or inappropriate treatment. Misdiagnosis was defined as NGDC that led to delayed diagnosis or inaccurate disease classification. If there were multiple differences between the care received and NCCN guidelines, a case could be placed in multiple categories. However, each case only counted once toward the overall mismanagement rate. NGDC was further classified into more specific subcategories (eg unnecessary biopsy, misinterpreted imaging). Research staff at the 3 study locations reviewed all cases to ensure standardized classification.

Patient and tumor characteristics, including age, race, presenting symptoms, tumor stage, location of diagnostic orchiectomy or biopsy and seminoma vs nonseminoma, were compared between GDC and NGDC. T-tests were used for continuous variables and chi-squared tests were used for categorical variables. A multivariable logistic regression model for predictors of NGDC was developed including factors found to be significant on univariate analysis. Relapse-free survival was compared between GDC and NGDC using a Cox proportional hazard model, and an additional subanalysis was performed comparing relapse-free survival by NGDC classification. A $p < 0.05$ for 2-tailed tests was the threshold for statistical significance.

RESULTS

Of the 593 patients 296 (50%) presented with stage I disease, 192 (32%) with stage II disease, 101 (17%) with stage III disease and 4 (less than 1%) had disease of unknown stage. Seminoma was diagnosed in 166 (28%) patients and median age at diagnosis was 29 years old (IQR 23–36). Median followup from the time of diagnosis was 18 months (IQR 7–40). NGDC was identified in 177 (30%) patients. Patients who received NGDC were more likely to be Hispanic (28% vs 14%, $p < 0.01$), receive initial pathological diagnosis (eg orchiectomy or biopsy) elsewhere (93% vs 74%, $p < 0.01$) and have metastatic disease at diagnosis (71% vs 40%, $p < 0.01$). In addition, patients who received NGDC were more likely to present with testicular pain (19% vs 13%) or metastatic symptoms (22% vs 4%) as opposed to

a testicular mass or enlargement (51% vs 69%, p <0.01, table 1). These associations were significant at all 3 study sites (data not shown) and there was no significant difference in NGDC rate based on study site (25% to 33%, p=0.10).

Of the 177 patients who received NGDC, inappropriate imaging was the most common discrepancy, occurring in 77 (44%) (table 2). Specifically, 56 (32%) patients underwent unnecessary PET (eg PET for nonseminoma), 21 (12%) had unnecessary brain imaging and 8 (5%) had unnecessary bone scans (eg bone scan with no clinical indication of metastases).

Overtreatment also occurred frequently, affecting 70 (40%) patients. Overall 41 (23%) patients underwent unnecessary biopsies of possible metastases (eg biopsy of retroperitoneal lymph node) and 33 (18%) received unnecessary chemotherapy in the form of too many cycles (eg BEP × 4 cycles for IGCCCG good risk) (27, 15%) or an inappropriate drug regimen (eg BEP for stage I seminoma) (6, 3%).

Misdiagnosis occurred in 42 (24%) patients, most commonly misread imaging (12, 7%) or delay to diagnosis (20, 11%). Of the delayed diagnosis cases 14 (74%) were due to initial diagnosis of infection followed by antibiotic treatment without a proper evaluation for testicular tumor. The remaining cases of delay to diagnosis involved improper evaluations and observations of testicular masses. There were 4 cases (2%) in which the original pathology was read incorrectly. One patient had lymph node tissue originally identified as metastatic renal cell carcinoma but later diagnosed as metastatic NSGCT after he was referred to a study site. Of the other 3 patients with misread pathology, 1 had orchiectomy read incorrectly as seminoma when it was NSGCT, and the other 2 had reports incorrectly identifying lymphovascular invasion.

Under treatment was identified in 28 (16%) NGDC cases, with the majority being too few cycles of chemotherapy (eg BEP × 3 for intermediate risk NSGCT) (21, 12%). Delay to intervention, defined as significant delay (more than 1 month) to treatment after the diagnosis of testicular cancer, was observed in 3 cases (range 1 to 6 months) (2%). These cases included delay to orchiectomy, delayed referral for retroperitoneal lymph node dissection and delay to treatment for stage IS NSGCT following orchiectomy. Inappropriate treatment (ie transscrotal orchiectomy) occurred in 5 patients (3%).

Multivariate logistic regression demonstrated that NGDC was associated with metastatic disease (OR 2.17, p <0.01), presentation with testicular pain (OR 1.89, p=0.02), presentation with metastatic symptoms (OR 4.60, p <0.01) and diagnosis elsewhere (OR 3.46, p <0.01, supplementary table, http://jurology.com/). There was a significant association between NGDC and Hispanic race on univariate analysis but this was not significant on multivariate analysis. However, Hispanic race was significantly associated with metastatic disease at diagnosis (70% vs 46%, p <0.01), initial presentation with metastatic symptoms (19% vs 7%, p <0.01) and diagnosis elsewhere (88% vs 78%, p <0.01) compared to Caucasian patients.

With a median followup of 18 months the overall relapse rate was 17% (98). Multivariable Cox regression modeling controlling for race, tumor stage and tumor histology identified NGDC as a

Table 1. *Patient and tumor characteristics*

	GDC	NGDC	p Value
Median age at diagnosis (IQR)	29 (24–35)	30 (23–39)	0.07
% Race (No.):			<0.01
Caucasian	78 (326)	68 (120)	
African American	Less than 1 (2)	Less than 1 (1)	
Hispanic	14 (57)	28 (49)	
Asian	2 (7)	Less than 1 (1)	
Unknown	6 (24)	3 (6)	
% Presentation (No.):			<0.01
Mass/enlargement	69 (289)	51 (91)	
Testicular pain	13 (53)	19 (33)	
Metastatic symptoms	4 (15)	22 (39)	
Incidental imaging findings	1 (6)	1 (2)	
Unknown	13 (53)	7 (12)	
% Stage (No.):			<0.01
I	60 (248)	27 (48)	
II	28 (116)	43 (76)	
III	12 (51)	28 (50)	
Unknown	Less than 1 (1)	2 (3)	
% Tumor histology (No.):			0.07
Seminoma	31 (128)	21 (38)	
Nonseminoma	69 (285)	78 (137)	
Unknown	Less than 1 (3)	1 (2)	
% Orchiectomy location (No.):			<0.01
Study site	26 (108)	7 (13)	
Elsewhere	74 (308)	93 (164)	

Table 2. *Nonguideline directed treatment characteristics*

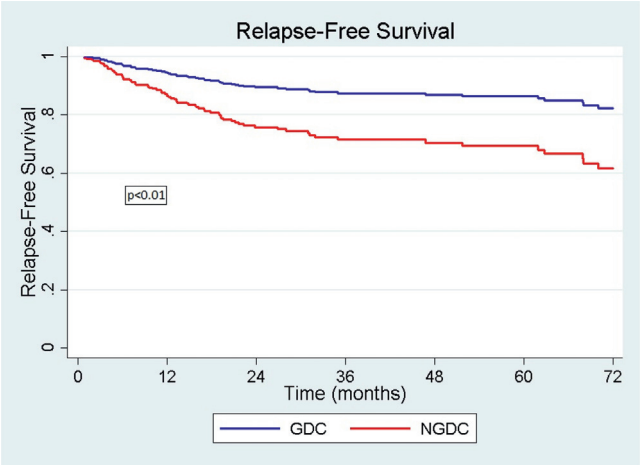
	No. (%)
Inappropriate imaging:	77 (44)
PET	56 (32)
Brain imaging	21 (12)
Bone scan	8 (5)
Overtreatment:	70 (40)
Unnecessary biopsy at diagnosis	41 (23)
Chemotherapy cycles	27 (15)
Inappropriate chemotherapy drug regimen	6 (3)
Misdiagnosis:	42 (24)
Delay to diagnosis	19 (11)
Misread imaging	12 (7)
Incomplete serum tumor markers	9 (5)
Misread pathology	4 (2)
Under treatment:	28 (16)
Chemotherapy cycles	21 (12)
Observation of post-chemotherapy retroperitoneal lymph node larger than 1 cm	3 (2)
Radiation underdosing	2 (1)
Delay to intervention	3 (2)
Inappropriate treatment:	5 (3)
Transscrotal orchiectomy	5 (3)
Overall	177 (100)

significant predictor of relapse (HR 2.49, 95% CI 1.61–3.85, p <0.01, see figure). Subanalysis by classification of NGDC showed that under treatment was the strongest predictor of relapse (HR 3.36, 95% CI 1.79–6.31, p <0.01), although overtreatment was also identified as a predictor (HR 2.25, 95% CI 1.29–3.90, p=0.01, table 3). Race was also a significant predictor of relapse, particularly for Hispanic patients (1.83, 95% CI 1.09–3.06, p=0.02) and Asian patients (13.93, 95% CI 4.88–39.98, p <0.01). These findings remained true when the regression was stratified by stage of disease and under treatment remained the strongest predictor of relapse (HR 3.38, 95% CI 1.09–3.79, p <0.01).

DISCUSSION

Using data collected from 3 geographically distinct referral centers in the United States we identified a relatively high rate of NGDC, particularly overtreatment and inappropriate imaging, which was more common in patients with advanced disease, less typical symptom presentation and diagnosis at a hospital with a low volume of patients with testicular cancer. NGDC, and particularly under treatment, was found to significantly predict disease relapse.

The NGDC rate of 30% is similar to the rates found in European studies evaluating second opinion discrepancies and mismanagement before the implementation of standardized guidelines (32% and 28%, respectively).[11,18] However, it is significantly higher than the 8% error rate reported after the implementation of standardized guidelines.[18]



Multivariate Cox regression model for relapse-free survival controlling for race, tumor stage and tumor histology between GDC and NGDC.

Table 3. *Multivariate Cox regression model subanalysis by NGDC classification*

	HR (95% CI)	p Value
Under treatment	3.36 (1.79–6.31)	<0.01
Overtreatment	2.25 (1.29–3.90)	0.01
Imaging	1.48 (0.84–2.61)	0.18
Misdiagnosis	0.78 (0.33–1.83)	0.56

Because of the small number of patients with mismanagement classified as inappropriate treatment, a full Cox model could not be run for NGDC classified as inappropriate treatment.
Controlled for stage and histology of disease.

Similar to prior studies, overtreatment (40%) was one of the most common forms of NGDC. All cases of overtreatment were due to inappropriate chemotherapy or unnecessary biopsy. Inappropriate imaging was also common (44%). Interestingly, inappropriate imaging and unnecessary biopsy (23%) were not reported in the European studies. The incidence of misdiagnosis (24%) and under treatment (16%) was significantly lower. However, they were still relatively common. Inappropriate treatment (5%) was rare. Of the 177 patients who received NGDC 53 (30%) had multiple aspects of care that differed from NCCN guidelines, highlighting the increased risk of subsequent NGDC after an initial nonguideline treatment.

Our study also identifies multiple patient and tumor characteristics associated with these discrepancies. Similar to the European data, we found that more advanced disease was associated with NGDC, likely due to the increased complexity of these cases. Patients diagnosed with NSGCT were also significantly more likely to receive NGDC. However, this finding is likely due to presentation with more advanced disease and the association did not remain significant when controlling for stage. Patients who presented with a testicular mass had a significantly lower rate of NGDC compared to those who presented with pain or metastatic symptoms, potentially due to inadequate physical examination and evaluation.

In addition, NGDC had a significant association with low volume, nonreferral medical centers. Overall only 2 patients received NGDC at a study institution. Both of these patients underwent unnecessary biopsies for retroperitoneal masses without a proper testicular cancer evaluation. The urology service was not involved in the initial diagnosis and treatment of either patient. This finding, combined with the high rate of NGDC associated with imaging and pathology in our study, highlights the importance of a multidisciplinary approach to following standardized protocols, regardless of treatment center size or volume.

The predilection for NGDC at nonreferral centers is consistent with prior research demonstrating

higher rates of NGDC and inferior outcomes at low volume centers.[8,19,20] Based on the association between center volume and patient survival, even when controlling for tumor and patient characteristics, several authors have recommended further centralization of treatment for patients with testicular cancer.[21–23] Our findings provide additional support for the early referral of patients with testicular cancer to high volume, tertiary centers, particularly those patients with advanced disease.

There was also a significant association between NGDC and Hispanic race on univariate analysis, likely due to a higher stage of disease at presentation for these patients. These findings are consistent with prior data suggesting that Hispanic patients present with larger tumors and are more likely to present with metastatic disease.[24,25] Racial and ethnic disparities in care access exist, although to our knowledge this issue has not been studied specifically in patients with testicular cancer.[26] Potential racial disparities in testicular cancer treatment are further evidenced by the significant association between Hispanic and Asian race and disease relapse even when controlling for stage, histology and the presence or absence of NGDC. This issue warrants further evaluation, particularly because of the disproportional increase observed in the incidence of testicular cancer among Hispanic males during the last 20 years.[27–29]

We also found a significant association between NGDC and worse patient outcomes. Specifically, NGDC was a predictor of disease relapse. Not surprisingly, among classifications of NGDC under treatment was the strongest predictor of relapse. However, overtreatment was also paradoxically associated with relapse. This association may be more representative of underlying confounding variables related to the quality of care associated with NGDC and not necessarily specific overtreatment interventions. The connection between NGDC and disease relapse highlights the benefits of following standardized guidelines and the direct impact that deviations have on patient outcomes. Due to the overall high cure rate of patients with testicular cancer, the potential morbidity associated with inappropriate treatment or disease relapse is of particular importance as these patients often live an additional 40 to 50 years after treatment.[1,2,16]

Limitations of the current study should be noted. As with all retrospective studies we were limited by the accuracy and detail of primary medical documentation. In addition, there is certainly a referral bias and a true population based incidence of nonguideline care cannot be determined. The NGDC rate of 30% is likely an overestimation due to this bias for patients with more advanced disease, although underestimation is also possible. However, the rate of NGDC was relatively constant across the 3 geographically distinct study institutions and, therefore, may be an accurate representation of the incidence of NGDC for patients presenting to academic referral centers in the United States. In addition, due to significant differences in patient characteristics as well as sample size between the GDC and NGDC groups, comparisons between the 2 groups must be interpreted with caution as outcomes may be biased. However, we attempted to account for these differences with multivariate and Cox regression modeling. Lastly, the study period was not the same at the 3 centers, which may have introduced additional bias. However, the rate of NGDC was not significantly different based on study location.

Recognition of common forms of NGDC, predictors of NGDC and potential negative outcomes of NGDC may help urologists, oncologists, radiologists and pathologists treating patients with testicular cancer become more cognizant of common errors or refer earlier to high volume centers. GDC optimizes cancer specific outcomes and minimizes treatment related morbidity.

CONCLUSIONS

Nonguideline directed care of patients with testicular cancer, particularly overtreatment and inappropriate imaging, is common in the U.S. and associated with higher rates of relapse. This likely leads to increased treatment related morbidity and may ultimately compromise cure rates.

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EDITORIAL COMMENT

In this study the authors use data from 3 tertiary medical centers to show that nearly a third of patients with testis cancer received NGDC, which involved overtreatment and under treatment, and inappropriate imaging, among others. Two findings are particularly striking. Receipt of NGDC was associated with increased relapse risk. In addition, nearly all patients who received NGDC, save 2, received it at referring hospitals.

Some have suggested that streamlining patients with urological cancer to high volume centers of excellence may improve cancer specific outcomes, and these data may support that model for men with testis cancer. However, efforts to regionalize care must acknowledge that certain at risk patients (based on lower socioeconomic status) can be left on the outside, looking in.[1] Thus, any effort toward the regionalization of testis cancer care must work in parallel to disseminate high quality care to historically disadvantaged patient populations unable to access high volume tertiary care centers.

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