Quality of Surveillance for Stage I Testis Cancer in the Community

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ABSTRACT

Purpose

Patients with clinical stage I testicular germ cell tumors have been managed with adjuvant radiotherapy, chemotherapy, or retroperitoneal lymph node dissection (RPLND). The use of surveillance-only strategies at referral centers has yielded survival outcomes comparable to those achieved with adjuvant therapy. We evaluated compliance with follow-up protocols developed at referral centers within the community.

Methods

We identified patients with stage I testis cancer within a large private insurance claims database and calculated compliance of follow-up test use with guidelines from the National Comprehensive Cancer Network.

Results

Surveillance was widely used in the community. Compliance with surveillance and postadjuvant therapy follow-up testing was poor and degraded with increasing time from diagnosis. Nearly 30% of all surveillance patients received no abdominal imaging, chest imaging, or tumor marker tests within the first year of diagnosis. Patients who elected RPLND were most compliant with recommended follow-up testing within the first year. Recurrence rates were consistent with previously reported literature, despite poor compliance.

Conclusion

Surveillance is a widely accepted strategy in clinical stage I testicular cancer treatment in the community. However, follow-up care recommendations developed at referral centers are not being adhered to in the community. Although recurrence rates are similar to those of reported literature, the clinical impact of noncompliance on recurrence severity and mortality are not known. Further prospective work needs to be done to evaluate this apparent quality of care problem in the community.

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INTRODUCTION

Due to the risk of undetected micrometastatic disease, patients with stage I testicular germ cell tumors are offered adjuvant surgery, chemotherapy, or radiation therapy (XRT), depending on histology. Men with nonseminomatous germ cell tumors (NSGCTs) undergoing either chemotherapy or retroperitoneal lymph node dissection (RPLND) and men with seminomas undergoing XRT have an excellent chance of cure; 5-year survival is approximately 98%. However, a similar survival benefit is available for men who choose a surveillance-only strategy, despite the fact that 20% to 30% of these men have undetectable micrometastatic retroperitoneal disease. The success of surveillance protocols has been attributed to rigorous schedules of regular imaging and laboratory studies that presumably

allow early clinical detection and treatment of occult disease.¹

Reports of the oncologic efficacy of surveillance strategies from academic settings have not addressed whether these protocols result in effective cancer control in the community. Severities of recurrences and mortality in surveillance-only series reported by academic centers have differed between studies with lower versus higher rates of noncompliance with surveillance.²⁻⁴ Little is known about how frequently men elect surveillance-only strategies or about the quality of adherence with recommended follow-up protocols. A survey of North American radiation oncologists showed that approximately 80% offered surveillance to patients with stage I seminoma and that approximately 20% of patients chose this option.⁵ A study of Canadian urologists estimated that two thirds offered this option and 42% of patients elected it.⁶ Given the reportedly high compliance

rate within the Netherlands, more than 90% of their patients with stage I NSGCT undergo surveillance.¹ Additionally, little is known about when surveillance should stop. Although most recurrences occur largely within the first year after diagnosis, late seminoma recurrences are more common, with one pooled analysis of 638 patients with stage I disease showing that 6% of relapses occurred after 5 years.⁷

Given the possibility that surveillance-only strategies may be offered to the majority of men in the community and that noncompliance with recommended surveillance protocols may affect clinical outcome, we undertook a community-based study to examine adherence to surveillance protocols generated in academic settings. We hypothesized that, in the absence of strict study protocol enforcement and process of care, adherence within the community would be lower than that reported in academic series. We aimed to provide descriptions of the prevalence of surveillance as a strategy in the community and compliance with follow-up protocols, as well as the duration of its use. Finally, we wished to report cancer recurrence rates associated with initial treatment choices in the community.

METHODS

Cohort Definition

We identified subjects using the i3 Innovus database, which contains private insurance claims for approximately 30 million individuals with continuous insurance eligibility through 2007. Incident cases of stage I testicular cancer occurring between 2002 and 2007 were identified using administrative codes for testicular cancer and radical orchiectomy. Because this database does not contain pathologic or stage data, we were unable to distinguish between men who received chemotherapy for distant disease versus those who chose adjuvant chemotherapy for apparently stage I disease. Thus men with claims for chemotherapy before or within 4 months of radical orchiectomy were excluded, as were men who had claims for other radical resections, bone marrow transplantation, or required ureteral stenting within 4 months of radical orchiectomy, as these interventions suggest metastatic disease at diagnosis.

We used claims for medical and surgical services to define three primary treatment cohorts. Individuals were assigned to the adjuvant RPLND or adjuvant XRT cohorts if claims for these services occurred within 4 months after radical orchiectomy. Individuals were assigned to the surveillance cohort if they had no claims for RPLND, XRT, or chemotherapy within 4 months of orchiectomy. We defined subjects as having pathologic stage II disease if they had claims for chemotherapy less than 4 months after the claim for RPLND. The 4-month cut point was chosen based on our clinical experience with the timeframe during which men elect adjuvant chemotherapy. Sensitivity analyses showed that a 2-month cut point resulted in apparent post-RPLND recurrence rates of 25%, which is inconsistent with literature on the topic.¹

Definition of Disease Recurrence

Recurrences after failure of primary treatment were defined in RPLND or XRT patients by claims for chemotherapy or XRT $\geq$ 4 months after primary treatment. Surveillance patients who experienced disease progression were defined by chemotherapy or XRT $\geq$ 4 months after orchiectomy.

Measurement of Compliance

We identified follow-up test use after primary therapy using administrative codes for abdominal imaging, chest imaging, and laboratory tests. Abdominal imaging included computed tomography (CT), positron emission tomography CT, and magnetic resonance imaging. Chest imaging included chest x-ray, CT, positron emission tomography CT, and magnetic resonance imaging. Laboratory tests included chemistries, CBC, liver function tests, and tumor markers. Claims for tests within the same category occurring within 1 week of one another were considered duplicates. Tests occurring within 30

days of adjuvant therapy (RPLND, XRT, or radical orchiectomy in surveillance patients) were considered part of initial diagnostic work-up and excluded as part of follow-up testing.

Compliance rates were calculated for patients with continuous insurance eligibility for up to 5 years of follow-up based on guidelines established by the National Comprehensive Cancer Network (NCCN) for follow-up after RPLND, XRT, and during surveillance-only care.⁸ Our database does not identify histology, so for patients choosing surveillance only, we produced parallel analyses for both NSGCT and seminoma-based NCCN follow-up protocols. The surveillance protocol for NSGCT is more stringent than that for seminoma. Therefore, calculated compliance rates using the NSGCT protocol are necessarily lower than those using the seminoma protocol. Using the NCCN recommendation as the denominator, yearly compliance was categorized into three groups: 100% compliant if all the recommended number of tests were obtained, $\geq$ 50% compliant if at least half of all recommended tests were obtained (including those with 100% compliance), and 0% compliant if none of the recommended tests were performed. Greater than or equal to 50% compliance rates were equivalent to 100% compliance rates when only one test was recommended in a given year. Patients diagnosed in 2006 and 2007 who had less than 12 months of eligibility were not included in this analysis; only the average number of tests and mean follow-up are reported.

Data Analysis

Subject age and benefit structure were compared between cohorts using analysis of variance and χ^2 tests, respectively. Times to adjuvant treatment and recurrence rates after adjuvant treatment were divided and analyzed according to age and insurance type and compared using analysis of variance. χ^2 analyses compared subjects whose insurance benefit structure included a primary "gatekeeper" (health maintenance organizations and point of service plans) with those without such a control (preferred provider organizations) and exclusive provider organizations). Compliance rates were separately analyzed by year after orchiectomy, age, and insurance type. One hundred percent and less than 100% compliance rates among cohorts were compared using χ^2 tests, using the NSGCT guidelines for the surveillance cohort. All tests were performed using SAS 9.1.3 (SAS Institute, Cary, NC) and were two-sided with a significance level of .05.

RESULTS

We identified 739 adult men who underwent radical orchiectomy between 2002 and 2006. All had continuous insurance coverage and were present in the database until 2007. Seventy-two patients underwent RPLND, 388 underwent XRT, and 279 were managed with surveillance (Table 1). Respective mean ages were 30.6, 38.3, and 37.3 years ($P < .0001$). Mean length of follow-up for RPLND, XRT, and surveillance was 30, 28.6, and 29.9 months, respectively ($P = .39$). Mean time to treatment was 1.5 and 1 month for RPLND and XRT; F tests showed no significant differences between age groups. Although 77% to 83.3% of patients within the three treatment groups had a gatekeeper, differences in compliance rates and times to treatment were not statistically different between the groups when separately analyzed based on benefit structure.

Tables 2 to 4 show compliance with follow-up for men with continuous insurance eligibility for up to 5 years after primary treatment, as well as median number of tests per patient per year. We wished to demonstrate the highest, intermediate, and lowest rates of compliance, because there is no generally accepted definition of "compliant." We chose to use 50% as an intermediate level that patients might reasonably be expected to achieve. Those who complied between 1% and 49% were not shown, as this range represents a low level of compliance that can be inferred from the percentage of patients who were not included in the 100%, 50%, or 0% groups. During

Table 1. Patient Characteristics

Characteristic	Total	RPLND	XRT	Surveillance	P
No. of patients	739	72	388	279	NA
Age, years					< .0001
Mean	37.2	30.6	38.3	37.3	
SD	10.1	8.9	8.4	11.9	
Range	18-85	18-53	19-67	18-85	
Follow-up, months					.39
Mean	29.2	30	28.6	29.9	
SD	13.4	13.5	13.1	13.9	
Range	12.0-62.8	12.6-62.6	12-62.8	12-62.3	
Benefit structure, %					.36
HMO/POS (gatekeeper)	79.5	83.3	80.6	77	
PPO/EPO (no gatekeeper)	20.5	16.7	19.4	23	
Stage II after RPLND, %	NA	31.6	NA	NA	NA

Abbreviations: RPLND, retroperitoneal lymph node dissection; XRT, external beam radiation; NA, not applicable; HMO, health maintenance organization; POS, point of service; PPO, preferred provider organization; EPO, exclusive provider organization.

the first year, 0% compliance with NCCN guidelines for the three test categories were lowest among men who underwent RPLND (2.8% to 27.8%), compared with those who had XRT (25.8% to 36.1%) or surveillance (28.3% to 29.7%). Zero percent compliance generally worsened with time in all test categories. The exception was for post-RPLND abdominal imaging, where the only recommended study occurs in the first year. A total of 8.3% of patients who underwent surveillance and XRT and 7.5% of patients who underwent RPLND received no follow-up tests of any kind during the second-year. First

year 100% and less than 100% compliance rates with RPLND, XRT, and NSGCT surveillance protocols were compared using Pearson χ^2 analyses, which showed that patients who underwent RPLND had the highest degree of complete compliance with follow-up testing (Table 5).

From 2006 to 2007, 26 patients who underwent RPLND, 152 patients who underwent XRT, and 126 patients who underwent surveillance had less than 1 year of continuous insurance eligibility after primary treatment. The mean lengths of follow-up for these men were

Table 2. Stage I Testis Cancer Compliance With Surveillance and Post-Treatment Abdominal Imaging

NCCN Follow-Up Guideline*	Follow-Up Year	No. of Patients	% of Patients			Median No. of Tests per Patient per Year
			100% Compliant†	≥ 50% Compliant†	0% Compliant†	
Surveillance for seminoma	1	279	36.9	52.3	29.7	2
	2	156	21.8	41.0	39.7	1
	3	85	2.4	25.9	48.2	1
	4	38	10.5	39.4	60.5	0
	5	11	0	54.5	45.5	1
Surveillance for NSGCT	1	279	16.1	52.3	29.7	2
	2	156	8.3	41.0	39.7	1
	3	85	2.4	25.9	48.2	1
	4	38	10.5	39.4	60.5	0
	5	11	54.5	54.5	45.5	1
Post-RPLND	1	72	72.2	72.2	27.8	1
	2	40	NA	NA	NA	1
	3	22	NA	NA	NA	1
	4	10	NA	NA	NA	1
	5	2	NA	NA	NA	0.5
Post-XRT	1	388	7.0	26.6	36.1	1
	2	206	26.7	59.7	40.3	1
	3	112	44.6	44.6	55.4	1
	4	41	39.0	39.0	61.0	0
	5	6	0	0	100.0	0

Abbreviations: NCCN, National Comprehensive Cancer Network; NSGCT, nonseminomatous germ cell tumor; RPLND, retroperitoneal lymph node dissection; NA, not applicable (no tests recommended); XRT, radiotherapy.

*Histology cannot be distinguished among surveillance patients; compliance with both NSGCT and seminoma guidelines are presented.

†Compliance after 30 days after RPLND, XRT, or radical orchiectomy (surveillance patients).

Table 3. Stage I Testis Cancer Compliance With Surveillance and Post-Treatment Chest Imaging

NCCN Follow-Up Guideline*	Follow-Up Year	No. of Patients	% of Patients			Median No. of Tests per Patient per Year
			100% Compliant†	≥ 50% Compliant†	0% Compliant†	
Surveillance for seminoma	1	279	54.5	70.6	29.4	2
	2	156	45.5	62.2	37.8	1
	3	85	23.5	51.7	48.2	1
	4	38	44.7	44.7	55.3	0
	5	11	63.6	63.6	36.4	1
Surveillance for NSGCT	1	279	12.9	39.4	29.4	2
	2	156	3.8	28.2	37.8	1
	3	85	4.7	23.5	48.2	1
	4	38	5.3	21.1	55.3	0
	5	11	18.2	63.7	36.4	1
Post-RPLND	1	72	48.6	83.3	2.8	3
	2	40	37.5	70.0	15.0	3
	3	22	22.7	45.5	27.3	2
	4	10	20.0	40.0	30.0	1.5
	5	2	0	0	100.0	0
Post-XRT	1	388	23.2	46.4	25.8	1
	2	206	38.8	68.4	31.6	1
	3	112	55.4	55.4	44.6	1
	4	41	63.4	63.4	36.6	1
	5	6	50.0	50.0	50.0	1

Abbreviations: NCCN, National Comprehensive Cancer Network; NSGCT, nonseminomatous germ cell tumor; RPLND, retroperitoneal lymph node dissection; XRT, radiotherapy.

*Histology cannot be distinguished among surveillance patients; compliance with both NSGCT and seminoma guidelines are presented.

†Compliance after 30 days after RPLND, XRT, or radical orchiectomy (surveillance patients).

8.2, 7.8, and 7.8 months, respectively. The median number of laboratory tests and chest imaging obtained by patients who underwent RPLND or XRT exceeded the median number of tests obtained by surveillance patients, despite less stringent follow-up protocols.

Recurrences occurred in 5.5% of patients who underwent RPLND, 2.8% of patients who underwent XRT, and 14.3% of patients who elected surveillance. Times to recurrence treatments occurred at medians of 4.4, 4.1, and 6.1 months of follow-up after primary therapy,

Table 4. Stage I Testis Cancer Compliance With Surveillance and Post-Treatment Laboratory Tests/Tumor Markers

NCCN Follow-Up Guideline*	Follow-Up Year	No. of Patients	% of Patients			Median No. of Tests per Patient per Year
			100% Compliant†	≥ 50% Compliant†	0% Compliant†	
Surveillance for seminoma	1	279	43.0	52.0	28.3	2
	2	156	37.8	48.7	33.3	2
	3	85	28.2	47.0	41.2	2
	4	38	36.8	52.6	50.0	1
	5	11	36.4	63.7	36.4	1
Surveillance for NSGCT	1	279	20.4	43.0	28.3	2
	2	156	16.7	37.9	33.3	2
	3	85	14.1	47.0	41.2	2
	4	38	18.4	36.8	50.0	1
	5	11	36.4	63.7	36.4	1
Post-RPLND	1	72	48.6	66.7	20.8	3
	2	40	37.5	57.5	25.0	3
	3	22	27.3	40.9	27.3	1
	4	10	20.0	40.0	40.0	1.5
	5	2	50.0	100.0	0	3
Post-XRT	1	388	32.5	50.8	27.6	2
	2	206	46.6	69.4	30.6	2
	3	112	58.9	58.9	41.1	1
	4	41	53.7	53.7	46.3	1
	5	6	50.0	50.0	50.0	1

Abbreviations: NCCN, National Comprehensive Cancer Network; NSGCT, nonseminomatous germ cell tumor; RPLND, retroperitoneal lymph node dissection; XRT, radiotherapy.

*Histology cannot be distinguished among surveillance patients; compliance with both NSGCT and seminoma guidelines are presented.

†Compliance after 30 days after RPLND, XRT, or radical orchiectomy (surveillance patients).

Table 5. First Year Complete Compliance With Post-Treatment and Surveillance Follow-Up Protocols

NCCN Follow-Up Guidelines	% of Patients					
	Abdominal Imaging		Chest Imaging		Labs/Tumor Markers	
	100%	< 100%	100%	< 100%	100%	< 100%
Surveillance for NSGCT	16.1	83.9	12.9	87.1	20.4	79.6
Post-RPLND	72.2	27.8	48.6	51.4	48.6	51.4
Post-XRT	7.0	93.0	23.2	76.8	32.5	67.5
<i>P</i>	< .0001		< .0001		< .0001	

Abbreviations: NCCN, National Comprehensive Cancer Network; Labs, laboratory tests; NSGCT, nonseminomatous germ cell tumor; RPLND, retroperitoneal lymph node dissection; XRT, radiotherapy.

respectively. A total of 31.6% of patients who underwent RPLND had stage II disease after surgery, with mean time to chemotherapy of 1.1 months.

DISCUSSION

The frequencies at which clinicians offer surveillance and actual acceptances of this strategy by patients have varied widely across studies and differ significantly based on geography and clinician type.^{1,5,6} The i3 database contains data that describe practice patterns across the United States, reflecting patient care for privately insured individuals in the community as well as at some referral centers. Although we cannot calculate the prevalence of surveillance use as a result of the exclusion of patients who underwent chemotherapy, nearly 40% of patients captured in this study underwent surveillance.

Compliance with NCCN surveillance protocols for both seminoma and NSGCT is poor, even within the first year after diagnosis. Higher recurrence rate among patients with NSGCTs⁹ necessitates a more stringent follow-up protocol than those with seminomas. It is therefore alarming to find that, at best, only approximately 40% of surveillance patients are obtaining all the recommended abdominal imaging and laboratory tests that are recommended within the first year; these two tests are responsible for detecting the vast majority of recurrences, and most recurrences are detected within the first year.^{2,3,10-13} Many men are not receiving any follow-up test of any kind after the first year of surveillance. A possible explanation could be that after a year of being disease-free, these otherwise healthy young men feel that they have been cured and no longer require intensive medical follow-up. With time, this feeling of invulnerability may be augmented by repeated negative surveillance tests, leading to worsening compliance with time. Physician and health care system factors may also contribute to compliance problems as well. Community-based physicians might not see the same volume of patients with testis cancer as those at academic centers and may be less familiar with current follow-up recommendations. It is also possible that community practices do not have the resources to monitor and remind patients about follow-up visits for these rigorous protocols.

Compliance within the first year was highest among men undergoing RPLND. Although the RPLND follow-up protocol is less stringent than that for NSGCT surveillance and requires only one follow-up abdominal imaging, it still requires more frequent chest imaging and laboratory studies than the seminoma surveillance protocol. Patients who underwent RPLND may be more compliant because of selection, as they have demonstrated willingness to take on the

relatively large and immediate risks of surgery and are highly invested in the success of their treatment strategy.

We found that recurrence rates after RPLND and XRT in the community are similar to those reported in the literature. Our surveillance recurrence rate of 14.3% is similar to the recurrence rates reported for surveillance for seminoma.⁹ Although it would be expected that this rate would be higher, given that our cohort contains patients with seminoma and NSGCT undergoing surveillance, this finding may suggest that a large proportion of those patients have seminomas or that actual recurrence rates in the community are no different from, if not lower than, those reported at academic centers. We are unable to report recurrences after primary chemotherapy. The percent of apparent stage II disease after RPLND is consistent with that of the reported literature.

Others have studied compliance in men with stage I testicular cancer and found low compliance with recommended follow-up. The definition of compliance has varied in the limited numbers of studies in this area. Studies from the Netherlands, where 90% of patients live within 60 minutes of a university hospital or cancer center, reported 95% compliance with follow-up during the first 2 years.¹ A chart review of 76 patients with NSGCT undergoing surveillance used a strict definition of noncompliance as missing two or more consecutive clinic visits, chest x-rays, or marker measurements or missing one or more abdominal CTs within the first 2 years.⁴ Compliance rates with clinical evaluations/chest x-rays/markers in years 1 and 2 were approximately 60% and approximately 40%, respectively, and with abdominal imaging were 25% and 12%. A retrospective review of 197 patients from seven Canadian centers used the same criteria, and compliance ranged from 68% to 94% for clinical visits and 32% to 100% for CT scanning.² However, A Danish study of 695 men with seminoma and NSGCTs reported that only 3.3% of their patients did not respond to follow-up reminders.¹⁴ This may be related to improved access to physicians as a result of proximity to clinics or a more systematic approach toward patient reminders. Another study of 248 patients with NSGCT showed that 12% did not follow planned clinic visits,¹⁵ which is similar to our study. Although not quantified, an Italian study of 85 men undergoing NSGCT surveillance reported that in addition to travel burden, some patients had poor compliance as a result of psychological discomfort with repeated tests. The tests may serve as reminders of their illness and the related anxiety may cause resistance toward further testing. The psychological impact of follow-up deserves further study as a potential barrier to care that may be ameliorated by counseling or education.³ Generally, reports of compliance rates from other countries may differ from those reported here for several reasons, including definitions of compliance, health care infrastructure

differences, or differences in cultural beliefs and expectations in patients and physicians. Our study is the first to evaluate practice patterns within a large, community-based population in the United States.

Mortality and chart data for this cohort are unavailable, and therefore the impact of poor compliance on survival or recurrence severity cannot be determined. Some reports have suggested that a relationship exists between poor compliance, subsequent cancer recurrence, and mortality. However, the only studies describing these issues are nonrandomized studies. In the largest studies of men with NSGCTs, three with 197, 85, and 76 patients each reported that poor patient compliance was associated with relapses with bulky disease.²⁻⁴ Two of these studies had a 3% death rate. Hao et al⁴ reported a relapse rate of 37% and 3% mortality, which is higher than relapse and mortality rates in nine other studies of NSGCT patients on surveillance that reported better compliance or did not report compliance problems. Relapse rates in those studies ranged from 26% to 35%, and mortality rates ranged from 0% to 2%.¹⁰⁻¹⁸ In the Netherlands, where there is 95% compliance with clinical visits, the reported relapse rates were 26% to 27%, with 1% mortality.^{10,11} These published data suggest that poor compliance may adversely affect clinical outcome. However, variations in follow-up protocol designs and definitions of compliance preclude definitive conclusions.

Our study has limitations. First, all analyses of claims data are dependent on the completeness and accuracy of coding, which have been shown to have varying degrees of sensitivities for identifying diagnoses in large secondary data sources.¹⁹ This database includes only privately insured patients, who constitute a socioeconomic group that is not representative of the entire population. Compliance may differ for individuals without insurance. Race and socioeconomic data were not available for analysis, and these patient characteristics may influence compliance. We do not have access to pathologic or staging data, which limits our ability to distinguish those patients who receive chemotherapy for stage I disease from those with stage II or III disease at presentation. Additionally, some practitioners may not be familiar

with the NCCN guidelines; however, these are widely accepted among urologic and medical oncologists, and similarly intensive protocols were used in studies that supported the use of surveillance as a safe treatment strategy for testis cancer.

To our knowledge, this study provides the first description of compliance with recommended stage I testis cancer follow-up in the community. Although surveillance only as a strategy has been embraced in the community setting, compliance with follow-up testing is generally poor when compared with that reported from academic centers. The large deviations in the community from the clinical protocols that established surveillance as a strategy raise the concern that in community settings, surveillance may be associated with more severe recurrences or lower survival than with active therapy. Alternatively, if mortality in men choosing surveillance in the community is no different from those treated under academic protocols, those protocols themselves may be unnecessarily strict, resulting in needless exposure to radiation, anxiety, and increases in health care costs. Further prospective population-based work is needed to resolve these critical issues.

AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

The author(s) indicated no potential conflicts of interest.

AUTHOR CONTRIBUTIONS

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