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THE POSITIVE YIELD OF IMAGING STUDIES IN THE EVALUATION OF MEN WITH NEWLY DIAGNOSED PROSTATE CANCER: A POPULATION BASED ANALYSIS

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ABSTRACT

Purpose: We determine the positive yield of imaging studies performed on men with newly diagnosed prostate cancer.

Materials and Methods: A prospective, population based survey was conducted on 3,690 men with prostate cancer diagnosed between October 1, 1994 and October 31, 1995. Cases were identified by the rapid case ascertainment systems used in 6 geographic regions participating in the Surveillance, Epidemiology and End Results Program. Based on information captured in primary medical record reviews we estimated the positive yield of bone scans, computerized tomography (CT) and magnetic resonance imaging.

Results: The positive yield of bone scan and CT was less than 5% and 12%, respectively, for all men with prostate specific antigen (PSA) 4 to 20 ng./ml., and less than 2% and 9%, respectively, for those who also had a Gleason score of 6 or less. Only men with PSA greater than 50 ng./ml. and those with Gleason scores 8 to 10 and PSA greater than 20 ng./ml. had positive yields greater than 10% and 20% for bone scan and CT, respectively.

Conclusions: Imaging studies designed to identify metastases and/or extracapsular extension in men with newly diagnosed prostate cancer frequently have a low positive yield. Wide variations exist in the use of imaging studies and are associated with tumor factors, such as Gleason score and serum PSA, and nontumor factors, such as state of residence. More extensive cost-effectiveness analyses are needed to define appropriate guidelines for ordering imaging studies to optimize the positive yield among men with newly diagnosed prostate cancer.

KEY WORDS: prostatic neoplasms, neoplasm staging, tomography, magnetic resonance imaging, prostate

In 1999 approximately 179,300 American men were diagnosed with prostate cancer.[1] Physicians performed radionuclide bone scans, computerized tomography (CT) and magnetic resonance imaging (MRI) on many of these men as part of the initial staging evaluation to determine whether disease extended beyond the prostate capsule to pelvic lymph nodes or bone. Men with metastatic disease are usually not advised to undergo definitive radiation therapy or surgery.

Several investigators have suggested that serum prostate specific antigen (PSA) can be used to predict the results of imaging examinations. O'Dowd et al suggested that radiographic imaging had a narrow role in the staging of newly diagnosed prostate cancer.[2] A recent report by Kindrick et al suggests that physicians may not need to perform imaging studies, such as bone scans, CT and pelvic MRI, on many men when evaluating newly diagnosed prostate cancer.[3] We analyzed community practice patterns in 6 population based regions in the mid 1990s to quantify the use and outcome of imaging studies among men with newly diagnosed prostate cancer. We assessed the usefulness of imaging studies in the setting of other available pretreatment factors, including Gleason score, disease stage, serum PSA, and patient age, race, education, income and geographic region to identify prostate cancer beyond the prostate capsule in the pelvic lymph nodes or bone.

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MATERIALS AND METHODS

Prostate Cancer Outcomes Study. Data were obtained from the Prostate Cancer Outcomes Study, which is a prospective, population based analysis of men with newly diagnosed disease.[4] A total of 11,137 men were diagnosed with prostate cancer between October 1, 1994 and October 31, 1995 in 6 of the 11 participating regions monitored by the Surveillance Epidemiology and End Results Program (SEER). Cases were identified using rapid case ascertainment systems. After receiving institutional review board approval to contact patients, a random sample was invited to participate in the study. A total of 5,667 men were asked to complete 6, 12 and 24-month surveys concerning health related quality of life. In addition, consent was obtained for office and hospital medical records to be reviewed by trained medical abstractors. The information obtained from these assessments was recorded in a database. Black, Hispanic and white men younger than 60 years were over sampled to obtain more extensive information among these subgroups.

Subjects. Of the 5,667 men sampled approximately 7% could not be located and 2.6% were reported to be too ill or mentally incompetent to complete surveys. Permission to abstract medical records was not granted by the treating

physician or patient for 6.7% of men sampled. Medical records were abstracted in 3,826 cases and information about imaging studies was available in 3,690. Data on the outcome of the imaging study (positive, negative or equivocal for extracapsular or metastatic disease) were obtained from a review of office and/or hospital records. Information was collected on the use of bone scans, CT and MRI. Information was not collected concerning the use of other imaging studies, such as excretory urography or endorectal coil MRI.

Data analysis. Descriptive statistics were calculated for the entire group of 3,690 men. Results of imaging studies and the yield of a positive test were tabulated according to prediagnosis PSA and biopsy Gleason score. The impact of clinical factors on test use was determined by calculating the proportion of subjects stratified by clinical characteristics undergoing each imaging test during the initial staging evaluation. Patients were categorized into groups based on patient and tumor characteristics. In this preliminary analysis the proportions of patients were weighted by the inverses of the sampling fractions to reflect more closely proportions in the actual age and race distribution of the entire set of 11,137 patients diagnosed in the 6 different SEER regions.

In a second analysis multiple logistic regression of the weighted variables was used to determine the independent contribution of each characteristic to variation in the use of imaging studies. Multiple regression was used to assess the difference in the use of staging examinations among patients with different levels of a particular factor but the same profile on all other factors. For example, we compared the use of bone scans for men with different levels of serum PSA at diagnosis while controlling for age, geographic region, race/ethnicity, education, household income and Gleason score. This approach allowed us to assess the extent to which physicians differ in the use of imaging studies among different subgroups of patients and which information is most critical in decisions to order imaging studies. Independent variables tested included patient specific factors (age, geographic region, race/ethnicity and socioeconomic status) and tumor factors (PSA at diagnosis and biopsy Gleason score). The standard error of each coefficient in the logistic regressions was used to determine whether a factor was significant after adjusting for the other variables. Analysis of geographic region and race/ethnicity was limited to situations when there were adequate numbers of patients.

TABLE 1. *Patient and tumor characteristics*

	No. Pts.	Weighted % Diagnosed With Ca (11,137 pts.)
Total No. pts.	3,690	
Pt. age:		
Younger than 45	13	0.2
45–49	76	1.3
50–54	254	4.2
55–59	494	8.3
60–64	625	17.8
65–69	797	21.0
70–74	727	23.3
75–80	436	14.0
Older than 80	268	9.9
Region:		
Connecticut	670	24.1
New Mexico	439	8.3
Seattle	398	6.3
Utah	704	9.2
Atlanta	442	11.2
Los Angeles	1,037	40.9
Race/ethnicity:		
Nonhispanic white	2,502	77.2
Black	651	13.4
Hispanic	537	9.5
Education:		
Did not graduate high school	746	21.3
High school graduate	692	20.1
Some college	802	23.7
College graduate	472	15.8
Advanced/graduate training	617	19.1
Annual household income ($1,000):		
Less than 10	295	8.4
10–20	533	17.7
20–30	531	17.4
30–40	453	15.4
40–50	327	10.9
50–75	409	13.9
Greater than 75	476	16.3
PSA at diagnosis (ng./ml.):		
Less than 4	358	9.2
4–10	1,652	48.5
10–20	743	22.3
20–50	416	11.6
Greater than 50	317	8.5
Gleason score on biopsy/transurethral resection:		
2–4	557	14.5
5	647	18.5
6	884	28.9
7	791	24.7
8–10	438	13.4
Clinical stage:		
T1/T2	3,265	91.9
T3	120	3.2
T4	180	4.9
Bone scan (3,670 pts.)	2,549	69.5
CT (3,644 pts.)	1,099	32.0
MRI (3,652 pts.)	152	5.0

Frequencies do not always total 3,690 because of missing data. Weighted proportions are based on the sample size available for each variable.

RESULTS

Clinical and demographic characteristics of the 3,690 patients with available data are summarized in table 1. Because of the sampling scheme these 3,690 men were slightly younger than the 11,137 diagnosed in the 6 SEER regions, and there were greater proportions of black and Hispanic men. Estimates of the true distributions of the 11,137 men are provided by the weighted proportions shown in table 1. The majority of patients were 60 to 74 years old (range less than 45 to greater than 90). Weighted mean patient age of the study sample was 69 years.

Based on the distribution of patients sampled or weighted distribution nearly 50% had PSA 4 to 10, 10% PSA less than 4 and 40% PSA greater than 10 ng./dl. Most patients had biopsy tumor Gleason score 5, 6 or 7 (19%, 28% and 24%, respectively) with the remainder almost equally divided between high (Gleason 8 to 10) and low (Gleason 2 to 4) scores. Final clinical staging suggested that 92% of the weighted sample had clinically localized (stage T1 or T2), 3% regional (T3) and 5% metastatic (T4) disease. A review of patient symptoms suggests that few had clinical evidence of metastatic disease. Only 63 patients (1.8%) complained of weight loss or anorexia and only 81 (2.2%) had bone pain. Therefore, most studies appear to have been ordered to determine the presence of extracapsular or metastatic disease rather than to confirm the presence of suspected metastatic disease.

We estimated that bone scan was performed in 69% of men, pelvic CT in 30% and pelvic MRI in 4%. Of the cases 40% had bone scan only, 26% bone scan and CT, 1% all 3 studies and 27% no imaging study. Results were located for 2,532 of 2,549 bone scans (99%), 1,066 of 1,099 CTs (97%) and 149 of 155 MRIs (96%). Table 2 shows the positive yield of studies stratified by pre-diagnosis PSA and biopsy Gleason score. Bone scan was positive in 171, equivocal in 208 and negative in 2,153 of 2,532 cases. The positive yield of bone scans was less than 5% for all men with PSA 4 to 20 ng./dl., and less than 2% for those with PSA 4 to 20 ng./ml. and Gleason score 6 or less. Only men with PSA greater than 50 ng./dl., and those with Gleason scores 8 to 10 and PSA greater than 20 ng./ml. had positive yields greater than 10%. The exceptions were men with PSA less than 4 ng./dl. and Gleason scores 8 to 10 but there could be random fluctuations because of the small cell sample sizes on which some percentages were based.

TABLE 2. *Yield of positive bone scans and CT stratified by pre-diagnosis PSA and Gleason score on biopsy or transurethral resection*

Gleason Score	% Yield (No. men)/95% CI					
	PSA Less Than 4	PSA 4–10	PSA 10–20	PSA 20–50	PSA Greater Than 50	All pts.
Bone scan:						
2–4	4 (41)/ 0–20	0 (164)/ 0–4	0 (66)/ 0–5	0 (28)/ 0–20	0 (9)/ 0–50	1 (323)/ 0–3
5	1 (40)/ 0–15	1 (226)/ 0–4	0 (108)/ 0–5	1 (51)/ 0–12	10 (13)/ 0–46	1 (450)/ 0–3
6	0 (39)/ 0–12	0 (271)/ 0–2	2 (126)/ 0–7	10 (82)/ 3–22	32 (35)/ 15–53	4 (567)/ 2–6
7	2 (24)/ 0–21	1 (204)/ 0–4	4 (168)/ 1–9	3 (105)/ 0–9	22 (85)/ 12–34	5 (609)/ 3–8
8–10	11 (20)/ 1–36	2 (70)/ 0–11	5 (75)/ 1–14	18 (73)/ 9–32	51 (101)/ 38–63	21 (355)/ 16–27
All pts.	3 (180)/ 1–8	1 (1,013)/ 0–2	2 (597)/ 1–4	7 (362)/ 4–11	38 (276)/ 31–45	6 (2,532)/ 5–8
CT:						
2–4	5 (17)/ 0–32	0 (62)/ 0–8	0 (23)/ 0–21	10 (14)/ 0–46	15 (4)/ 0–82	3 (126)/ 0–8
5	0 (13)/ 0–29	3 (84)/ 0–10	9 (52)/ 2–23	5 (24)/ 0–29	0 (4)/ 0–71	4 (185)/ 1–9
6	0 (16)/ 0–26	0 (109)/ 0–5	5 (46)/ 1–19	19 (36)/ 6–41	20 (15)/ 3–53	5 (227)/ 2–10
7	18 (12)/ 2–52	4 (90)/ 1–11	1 (75)/ 0–7	14 (44)/ 4–30	21 (41)/ 8–39	7 (269)/ 4–12
8–10	16 (11)/ 1–55	1 (41)/ 0–12	12 (42)/ 3–30	17 (36)/ 5–37	62 (34)/ 40–81	19 (167)/ 13–27
All pts.	8 (77)/ 3–18	2 (420)/ 1–4	5 (251)/ 3–10	14 (162)/ 8–22	36 (111)/ 25–48	8 (1,066)/ 7–11

Yield expressed as a percentage projected to the sampled population, and numbers of men refer to those in the dataset, who underwent the examination and may not add up across rows or columns because data were not always available on PSA and Gleason score.

CT was positive in 88, equivocal in 100 and negative in 878 of 1,066 cases. Men with PSA 4 to 20 ng./dl. had a positive yield of 12% or less with most combinations of PSA and Gleason scores. More than 10% of men with PSA greater than 20 ng./dl. and Gleason score 6 or greater were likely to have CT positive for metastatic disease. For combinations of high Gleason scores and PSA greater than 50 ng./dl. the positive yield was as high as 62%. Findings were similar for pelvic MRI, although the sample sizes were much smaller. Pelvic MRI was positive in 27, equivocal in 14 and negative in 108 of 149 cases.

Variations in the use of bone scan and CT in relation to patient and tumor characteristics are shown in table 3 and figure 1. Percentages were weighted to reflect the actual age/race distribution of the total number of men with prostate cancer diagnosed in the 6 SEER regions sampled. Figure 2 demonstrates the extent to which individual patient and tumor factors influence the use of imaging examinations, even after adjusting for the other factors. Serum PSA was a major predictor of the decision to order an imaging study.

DISCUSSION

Testing for serum PSA during the last decade has resulted in a dramatic increase in the number of incidental cases of prostate cancer in the United States. Prostate cancer has become a significant medical problem and is estimated to account for $4.75 billion in health care expenditures annually.[5] Routine use of PSA testing has identified men with early stage disease and produced a significant shift toward clinically localized disease during the last 5 years.[6] Historically, appropriate staging studies included imaging studies, such as chest x-ray, pelvic CT, bone scan and possibly pelvic MRI. Others have suggested that many of these studies are no longer necessary for men with low serum PSA since results are frequently negative.[2,3,7,8]

Accurate pretreatment staging of newly diagnosed prostate cancer is critical in determining whether patients will benefit from surgery or radiation targeted at localized disease. Under staging may result in ineffective local therapy, while over staging risks withholding therapy that may control or even cure local disease. From the perspective of resource use physicians must balance the need to document the presence or absence of metastatic disease against the cost and morbidity of these studies, and the probability that they will provide information that will alter clinical decision making.

In 1995 physicians ordered bone scans for approximately two-thirds and CT for a third of all new patients. Our findings document that in less than 5% of most of these patients imaging studies yielded positive results. Bone scan or CT was positive in 10% to 20% of men with serum PSA 20 to 50 ng./dl.

TABLE 3. *Use of imaging tests stratified by patient and tumor characteristics*

	% Bone Scan	% CT	% Pelvic MRI
Pt. age:			
Younger than 45	77	38	0
45–49	69	38	5
50–54	77	38	8
55–59	69	33	6
60–64	68	29	6
65–69	73	31	5
70–74	71	33	5
75–80	69	26	3
Older than 80	61	17	1
Region:			
Connecticut	83	61	5
New Mexico	64	23	2
Seattle	58	25	2
Utah	70	17	2
Atlanta	78	41	7
Los Angeles	62	19	6
Race:			
Nonhispanic white	71	32	5
Nonhispanic black	69	28	4
Hispanic	66	26	3
Education:			
Did not graduate high school	73	32	4
High school graduate	69	33	5
Some college	70	28	5
College graduate	70	32	4
Advanced/graduate training	69	31	6
Annual household income ($1,000):			
Less than 10	67	23	3
10–20	69	31	3
20–30	72	31	4
30–40	71	28	7
40–50	73	34	5
50–75	67	30	4
Greater than 75	71	33	8
PSA at diagnosis (ng./ml.):			
Less than 4	50	24	5
4–10	62	30	5
10–20	81	36	5
20–50	87	41	4
Greater than 50	88	35	7
Gleason score on biopsy/transurethral resection:			
2–4	59	23	3
5	70	34	6
6	65	29	4
7	78	36	6
8–10	82	41	5
Clinical stage:			
T1/2	67	30	4
T3	92	60	5
T4	94	48	10

Percentages are weighted to reflect the age-race-region distribution in sampled population.

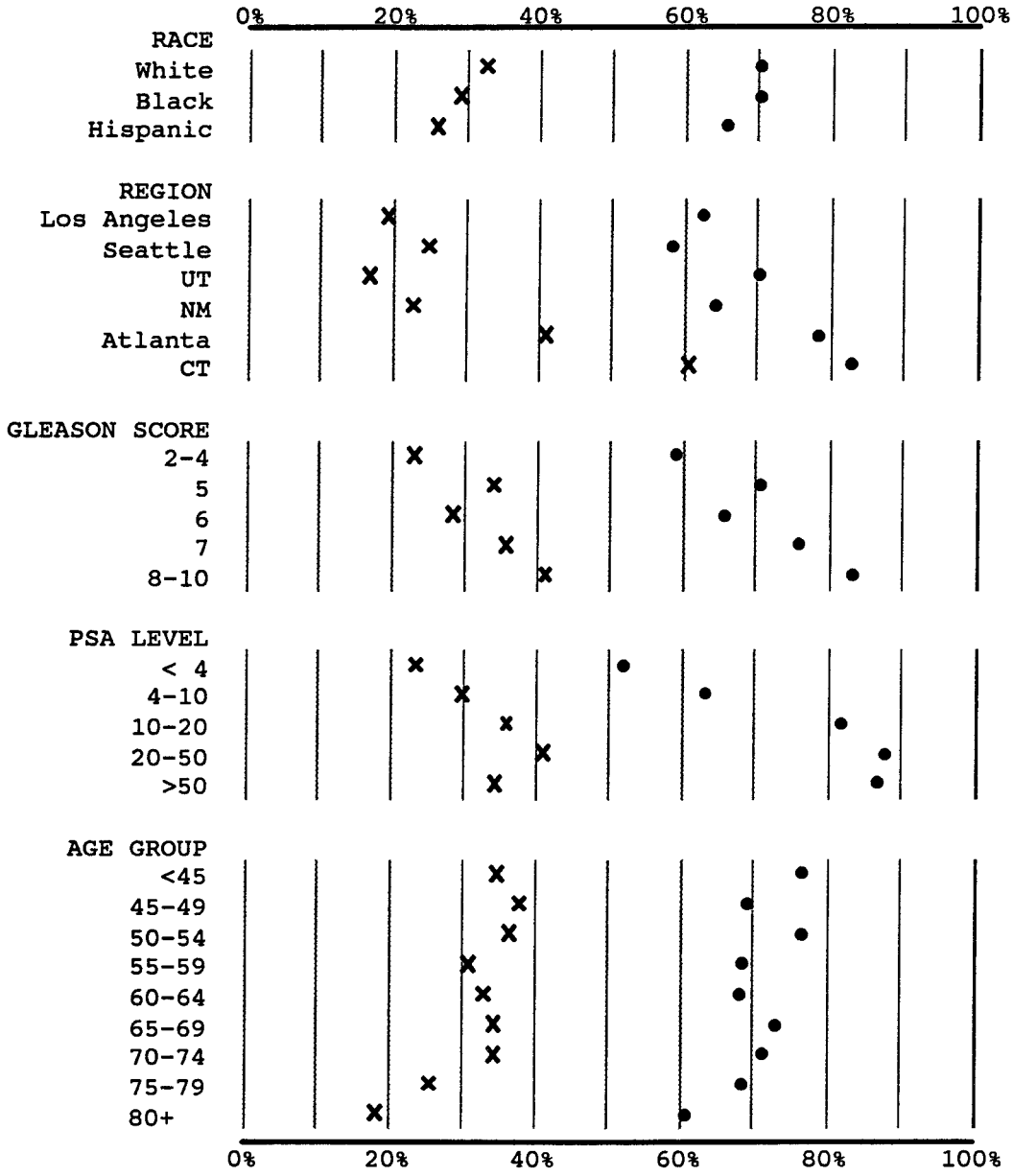

FIG. 1. Variation in use of bone scan (●) and CT (X) in relation to patient and tumor characteristics. Percentages are weighted to reflect actual age/race distribution of total numbers of patients diagnosed in 6 areas combined. *UT*, Utah. *NM*, New Mexico. *CT*, Connecticut.

or biopsy Gleason scores 8 to 10. Imaging studies were positive in more than 20% of men with serum PSA greater than 50 ng./dl. and more than 60% with a high probability of metastatic disease (serum PSA greater than 50 and Gleason scores 8 to 10).

Since physicians sometimes order imaging studies to confirm the absence of extracapsular or metastatic disease, no findings of metastatic disease can also provide valuable information. Patients with a low probability of metastatic disease (PSA less than 20 ng./ml. and Gleason score less than 8) had a 98.6% chance (95% confidence interval [CI] 98 to 99) of having a negative bone scan. Only 136 of 819 men (17%) with a higher risk of metastatic disease (PSA greater than 20 ng./ml. or Gleason score 8 to 10) had evidence of metastatic disease on bone scan. Similar values were found for CT. Patients with a low probability of metastatic disease had a 97.3% chance (95% CI 96 to 98) that CT would not demonstrate such disease. Only 59 of 370 men (16%) with a higher risk of metastatic disease had evidence of such disease on CT.

Although no practice guidelines have been developed to specify an appropriate test yield to justify ordering an imaging study, the high cost of these examinations will likely prompt closer scrutiny in the future. Well designed cost-benefit analyses can help define optimal practice guidelines. In 1995 only 1.0% of bone scans and 2.7% of CTs were positive for extracapsular or metastatic disease for men with PSA less than 10 ng./dl. and Gleason score of 6 or less.

Our analysis also documented wide variations in the use of imaging studies in a community based sample of prostate cancer cases. As expected, our data indicate that in general a greater proportion of patients at high risk for systemic metastases underwent bone scan and CT compared to those at low risk. Pelvic MRI was not frequently used in the initial evaluation of men with clinically localized disease.

In 1995 there appears to have been very little unanimity in the use of imaging studies among practicing clinicians. Our study documents variations in ordering patterns by geographic region, Gleason score, biopsy PSA and age groups. In general physicians ordered bone scans twice as often as CT. This finding was relatively consistent across all variables

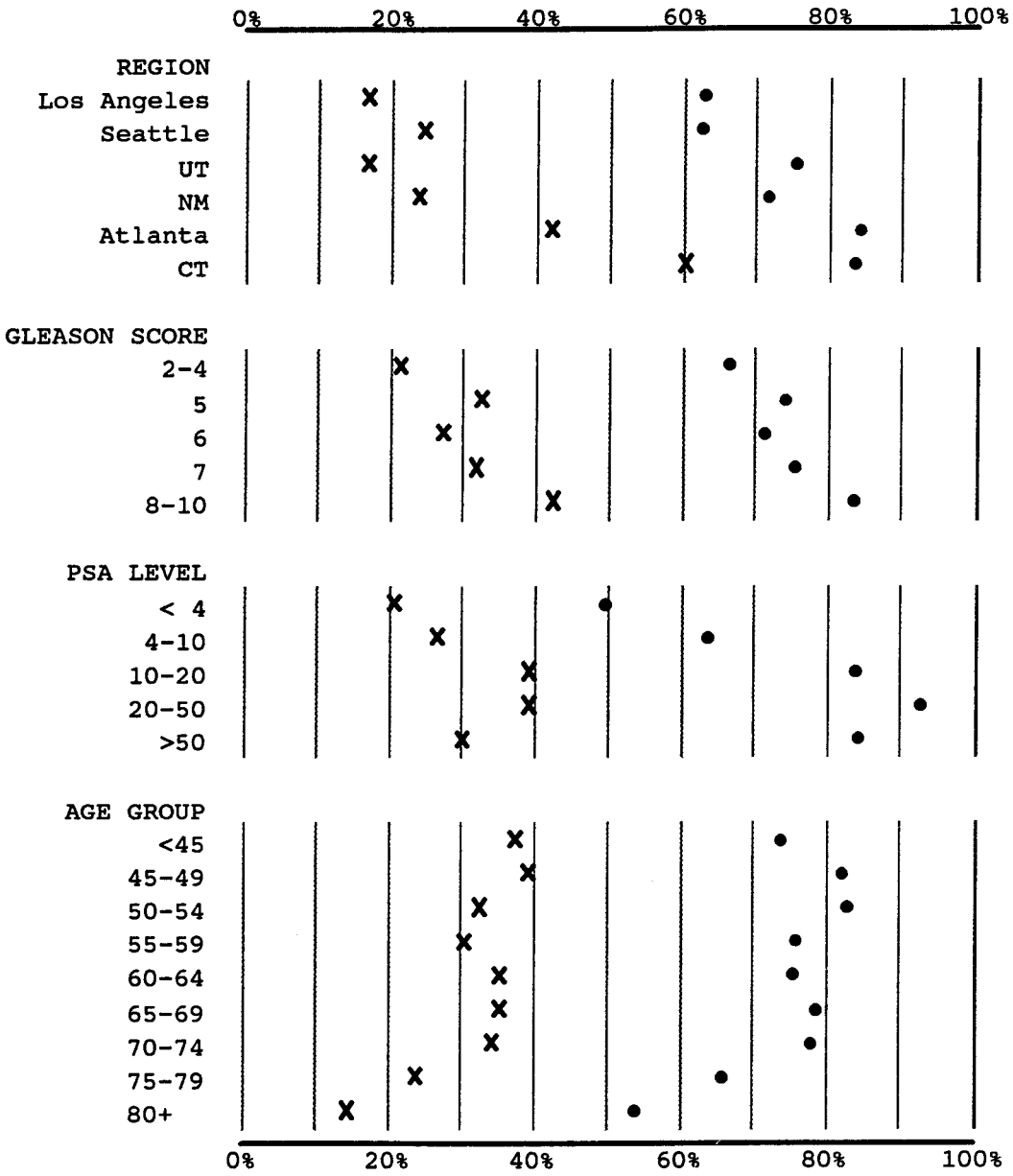

FIG. 2. Extent to which individual patient and tumor factors influence use of bone scans (●) and CT (X) after adjusting for all other factors. Percentages are predicted from multiple logistic regression of weighted data on white men using average value of other variables. *UT*, Utah. *NM*, New Mexico. *CT*, Connecticut.

tested. A possible explanation includes the perceived need for a baseline bone scan so that future metastatic progression can be monitored more accurately. Other possible explanations include a belief that bone scans are more sensitive indicators of metastatic disease compared to CT, that bone metastases precede lymph node metastases or simply because bone scans are less costly and less invasive than CT. As expected, the use of imaging studies was greatest for patients with high PSA and high Gleason scores.

Imaging studies were used much more frequently among practitioners in Connecticut and Atlanta compared to those on the West Coast. This finding may reflect regional practice standards, the impact of managed care or the fact that radiation therapy was performed more frequently in these 2 regions in the East compared to the 4 regions in the West. Radiation therapists often order CT to assist in pretreatment planning. The use of imaging studies positively correlated with the use of radiation therapy as the primary treatment. Radiation therapy was used most frequently in Connecticut (30%) and Seattle (27%) followed by the other 4 regions (16% to 21%). Even after adjusting for these treatment patterns regional differences in the use of imaging studies persisted. Ordering patterns did not vary much by race or age with the exception of men older than 80 years. Imaging studies for these men were ordered less frequently possibly because elderly men were less likely to receive definitive therapy for disease.

Several factors contribute to the strength of our study. The population based study design ensures that our findings are more generalized to community practices than reports originating from tertiary medical centers. Cases were randomly selected to be included in this study by rapid case ascertainment systems operating in large geographic areas. Furthermore, patients were sampled prospectively and during a relatively short time, minimizing the chances of reporting biases and changing practice patterns. Rather than relying on physician surveys, we used primary data collection methods that verified the ordering of imaging studies and eventual clinical outcomes. Therefore, our estimates for positive

yields should be free of response biases that frequently occur in physician surveys.[9–11]

A potential limitation of our study stems from the potential selection bias introduced by incomplete survey responses. Some patients chose not to participate in our study and some physicians did not permit access to patients. Based on information on file with the SEER system, these patients do not appear to differ from those sampled.

CONCLUSIONS

Based on our analysis bone scan and CT should probably only be ordered for men with newly diagnosed prostate cancer with PSA greater than 20 ng./ml. or PSA greater than 10 ng./ml. and Gleason scores 8 to 10. Our data are consistent with previous reports that also document low positive yields of imaging studies.[2,3] To our knowledge only 1 professional organization, the American College of Radiology, has developed guidelines for ordering imaging studies.[12] The guidelines discourage imaging with bone scan and CT for men with low grade disease (Gleason scores 2 to 5) and/or serum PSA 10 ng./ml. or less. Our data suggest that bone scans should be restricted to men with serum PSA greater than 20 ng./dl. or biopsy Gleason scores 8 to 10. These men have a higher risk of extracapsular extension and had positive yields greater than 10% on bone scans. Men in lower risk groups had positive yields that generally range from 0% to 5%. Positive yields for CT were similar but somewhat higher than those for bone scans for all men with PSA greater than 20 ng./dl. or Gleason score 8 to 10. It is noteworthy that positive yields for bone scan and CT were higher for men with PSA less than 4 ng./dl. and Gleason score greater than 6 but these findings may simply reflect small sample sizes in these groups.

Our data also documented wide variations in the use of imaging studies, some of which can be attributed to clinical factors, such as serum PSA and biopsy Gleason scores. However, a considerable portion of the variation can be attributed to different practice patterns by geographic region. More extensive cost-effectiveness studies are needed to define the optimal use of imaging studies in the evaluation of men with newly diagnosed prostate cancer. Until then clinicians should carefully evaluate the potential yield of an imaging study based on serum PSA and Gleason score before recommending testing for men with newly diagnosed prostate cancer.

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