ORIGINAL CONTRIBUTION

Use of Advanced Treatment Technologies Among Men at Low Risk of Dying From Prostate Cancer

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Importance The use of advanced treatment technologies (ie, intensity-modulated radiotherapy [IMRT] and robotic prostatectomy) for prostate cancer is increasing. The extent to which these advanced treatment technologies have disseminated among patients at low risk of dying from prostate cancer is uncertain.

Objective To assess the use of advanced treatment technologies, compared with prior standards (ie, traditional external beam radiation treatment [EBRT] and open radical prostatectomy) and observation, among men with a low risk of dying from prostate cancer.

Design, Setting, and Patients Using Surveillance, Epidemiology, and End Results (SEER)-Medicare data, we identified a retrospective cohort of men diagnosed with prostate cancer between 2004 and 2009 who underwent IMRT (n=23 633), EBRT (n=3926), robotic prostatectomy (n=5881), open radical prostatectomy (n=6123), or observation (n=16 384). Follow-up data were available through December 31, 2010.

Main Outcomes and Measures The use of advanced treatment technologies among men unlikely to die from prostate cancer, as assessed by low-risk disease (clinical stage ≤T2a, biopsy Gleason score ≤6, and prostate-specific antigen level ≤10 ng/mL), high risk of noncancer mortality (based on the predicted probability of death within 10 years in the absence of a cancer diagnosis), or both.

Results In our cohort, the use of advanced treatment technologies increased from 32% (95% CI, 30%-33%) to 44% (95% CI, 43%-46%) among men with low-risk disease ($P<.001$) and from 36% (95% CI, 35%-38%) to 57% (95% CI, 55%-59%) among men with high risk of noncancer mortality ($P<.001$). The use of these advanced treatment technologies among men with both low-risk disease and high risk of noncancer mortality increased from 25% (95% CI, 23%-28%) to 34% (95% CI, 31%-37%) ($P<.001$). Among all patients diagnosed in SEER, the use of advanced treatment technologies for men unlikely to die from prostate cancer increased from 13% (95% CI, 12%-14%), or 129.2 per 1000 patients diagnosed with prostate cancer, to 24% (95% CI, 24%-25%), or 244.2 per 1000 patients diagnosed with prostate cancer ($P<.001$).

Conclusion and Relevance Among men diagnosed with prostate cancer between 2004 and 2009 who had low-risk disease, high risk of noncancer mortality, or both, the use of advanced treatment technologies has increased.

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PROSTATE CANCER IS A COMMON and expensive disease in the United States.[1,2] In part because of the untoward morbidity of traditional radiation and surgical therapies, advances in the treatment of localized disease have evolved over the last decade. Chief among these are the development of intensity-modulated radiotherapy (IMRT) and robotic prostatectomy. Although the evidence underlying these technologies is mixed,[3,4] both are generally perceived as being more targeted and less toxic than prior therapies. During a period of increasing population-based rates of prostate cancer treatment,[5,6]

CME available online at www.jamanetworkcme.com and questions on p 2602.

Author Video Interview available at www.jama.com.

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both of these advanced treatment technologies have disseminated rapidly.

However, the rapid growth of IMRT and robotic prostatectomy may have occurred among men with a low risk of dying from prostate cancer.[7,8] Recognizing the protracted clinical course for most of these cancers, clinical guidelines recommend local treatment only for men with at least a 10-year life expectancy.[9,10] Men with low-risk cancer have a particularly favorable prognosis, with a much greater likelihood of dying from other causes even 20 years after diagnosis.[11] Because many older men will die with rather than from prostate cancer, observation (with delayed intervention if needed) has been promoted by some experts,[12] although the extent to which this has gained traction in the community is uncertain. Aggressive direct-to-consumer marketing and incentives associated with fee-for-service payment may promote the use of these advanced treatment technologies.

For these reasons, we performed a study to better understand relationships among the use of advanced treatment technologies (ie, IMRT and robotic prostatectomy), prior standards (ie, traditional external beam radiation treatment [EBRT] and open radical prostatectomy), and observation for men with a low risk of dying from prostate cancer. Understanding patterns of new technology use in this population is particularly important given the growing concerns about overtreatment.

METHODS

We used Surveillance, Epidemiology, and End Results (SEER)-Medicare data to identify patients with newly diagnosed prostate cancer between 2004 and 2009, with follow-up data available through December 31, 2010. SEER represents approximately 26% of the US population.[13] Using the Medicare Provider Analysis and Review (MEDPAR), outpatient, and carrier files, we further identified men aged 66 years or older who were primarily treated with IMRT (Healthcare Common Procedure Coding System [HCPCS] codes 77418, G0174, and 0073T), EBRT (HCPCS codes 77401-77416), robotic prostatectomy (HCPCS code 55866), open radical prostatectomy (HCPCS codes 55840, 55842, 55845), and observation (ie, no treatment) within the first 12 months of diagnosis. We included only fee-for-service beneficiaries who were eligible for both Medicare Parts A and B from 12 months prior to diagnosis to 12 months after diagnosis. Men aged 65 years were excluded to ensure accurate comorbidity estimation using Medicare claims for the 12-month period prior to diagnosis.[14]

Outcomes

The objective of our study was to compare the use of advanced treatment technologies to treat prostate cancer (ie, IMRT or robotic prostatectomy) with prior standards (ie, EBRT or open radical prostatectomy) and observation. Because we were primarily interested in the use of these treatments among men who would least likely benefit from any treatment, we focused on 3 groups of patients: men with low-risk prostate cancer, those with a high risk of noncancer mortality, and those with both low-risk disease and a high risk of noncancer mortality.

We defined low-risk prostate cancer (clinical stage ≤T2a, biopsy Gleason score ≤6, and prostate-specific antigen [PSA] level ≤10 ng/mL), intermediate-risk prostate cancer (clinical stage T2b, biopsy Gleason score=7, or PSA level between 10.1 and 20 ng/mL), and high-risk prostate cancer (clinical stage ≥T2c, biopsy Gleason score ≥8, or PSA level >20 ng/mL) according to the well-established D'Amico classification.[15] Generally speaking, patients with low-risk disease are the least likely to die from prostate cancer.[16] For example, men older than 65 years with low-risk disease have about a 25% chance of dying from prostate cancer 20 years after diagnosis but more than a 60% chance of dying of other causes.[11]

Thus, we also chose to examine treatment among men at high risk of noncancer mortality. Specifically, we assessed the probability of noncancer mortality within 10 years, largely because clinical guidelines recommend active treatment only in men with a life expectancy of at least a decade.[9,10]

We estimated each patient's probability of dying within 10 years in the absence of a cancer diagnosis based on methods established by Gross et al.[17] Briefly, using the 5% random sample of Medicare beneficiaries without cancer, we modeled mortality as a function of demographic data available in the Medicare Surveillance Summarized Denominator (SUMDENOM) file as well as comorbidity measurements extracted from the MEDPAR, outpatient, and carrier files. Specifically, we generated a random sample of patients within the SUMDENOM file (n=5000). Because these patients do not have a cancer diagnosis date, an index date was chosen based on the following 2 criteria: (1) the date had to be prior to December 31, 1999, allowing for the possibility of 10 years of follow-up; (2) patients had to be enrolled in both Medicare Parts A and B for 12 months prior to the index date to ensure accurate comorbidity estimation.[14] Of note, patients who died within this follow-up window were observed and censored at death.

Using this sample, we modeled the probability of dying within 10 years based on age, race, comorbidity, socioeconomic class, area of residence (eg, rural vs urban), and SEER region. This model was internally cross-validated using a bootstrap aggregating technique.[18] The discrimination of the prediction model was high (*C* index=0.90). We applied this model to men diagnosed with prostate cancer as their first and only cancer to estimate their probability of dying within 10 years. We sorted patients into terciles based on this mortality probability.

In addition, we estimated the use of prostate cancer treatments for men least likely and most likely to benefit. When we calculated the percentage of men treated, the numerator was determined by the sum of the number of men least likely to benefit (ie, those with low-

risk disease or a high risk of noncancer mortality) or the number of men most likely to benefit (ie, those with high-risk disease or a low risk of noncancer mortality). The denominator was the total number of Medicare beneficiaries diagnosed with prostate cancer during the study period.

Statistical Analysis

We first compared demographics and clinical characteristics of patients treated with IMRT, EBRT, robotic prostatectomy, open radical prostatectomy, and observation using χ^2 tests. For each of the 3 groups of patients (those with low-risk disease, high risk of noncancer mortality, and both), we fit multinomial logistic regression models.[19] To assess the fit of these models, we used a likelihood ratio test for the null hypothesis that independent variables have no effect on treatment type ($P<.001$). We assessed the use of advanced treatment technologies, prior standards, and observation among men least likely to benefit. We then looked more critically at advanced treatment technologies by examining IMRT and robotic prostatectomy individually. All models were adjusted for age, race, socioeconomic class, comorbidity, tumor grade, year of diagnosis, SEER region, and disease risk, where appropriate.

Race was self-determined by patients and was examined because it has been shown to influence cancer treatment.[20] Socioeconomic class was ascertained at the zip code level using the approach of Diez Roux et al.[21] Because it is difficult to interpret the marginal effect of an independent variable on treatment probabilities directly from a multinomial regression model's coefficient estimates, we back-transformed the model estimates into predicted probabilities. We derived 95% CIs using bootstrapping (n=1000).

We performed several sensitivity analyses to assess the strength of our results. First, to examine the robustness of our predicted model of 10-year mortality, we sorted patients into quartiles, which generated fairly similar mortality probabilities for the lowest and highest groups. Second, because some case records lack the specific staging information to precisely classify disease risk (eg, differentiate T2a from T2b from T2c), we repeated our analyses after excluding these patients. Third, because of the concern that older patients would generally not be considered for surgery, we reran our analyses stratified by age. These additional analyses did not alter our findings, so we present results from our primary analyses only.

All analyses were performed using SAS version 9.2 and R version 2.11.[22] The probability of a type I error was set at .05 and all testing was 2-sided. Because patients cannot be identified, the institutional review board of the University of Michigan exempted this study from review.

RESULTS

Our study population included men who had prostate cancer as their first and only cancer (n=83 191). We then excluded those with metastatic disease (n=2621) and those not receiving one of the designated treatments (n=21 898). Among these men, we further excluded those with missing information needed to classify disease risk (ie, missing stage, Gleason score, or PSA levels; n=1647) or with missing demographic information (n=1078). Using these criteria, our study population consisted of 23 633 IMRT, 3926 EBRT, 5881 robotic prostatectomy, 6123 open radical prostatectomy, and 16 384 observation patients. When we applied our predictive model to our cohort of prostate cancer patients, the predicted mortality rates at 10 years were 19%, 61%, and 91% for patients in low, intermediate, and high terciles, respectively.

As shown in the TABLE, the use of IMRT and observation was more common than EBRT, robotic prostatectomy, and open radical prostatectomy among Medicare beneficiaries with prostate cancer. The use of advanced treatment technologies increased over time, particularly for robotic prostatectomy, while the use of prior standards significantly decreased. Throughout the study period, the overall treatment of prostate cancer was relatively stable. For example, in 2004 and 2009, there were 6556 and 6169 patients, respectively, treated with either surgery or some form of external beam radiotherapy (ie, IMRT or EBRT). Intensity-modulated radiotherapy was a common method of treatment regardless of socioeconomic class and disease risk. Robotic prostatectomy use was more common among younger men, while those undergoing observation tended to have low-risk disease. Many SEER regions that contained a large number of patients treated with advanced treatment technologies also had a relatively large number of patients treated with prior standards or observation (eg, Greater California, New Jersey, Seattle, and Detroit).

We next assessed the treatment of prostate cancer among patients least likely to benefit from treatment because of either nonaggressive cancer biology or competing causes of death (FIGURE 1). The use of advanced treatment technologies was common among men with low-risk disease (an increase from 32% [95% CI, 30%-33%] in 2004 to 44% [95% CI, 43%-46%] in 2009), those with a high risk of noncancer mortality (from 36% [95% CI, 35%-38%] in 2004 to 57% [95% CI, 55%-59%] in 2009), and those with both low-risk disease and a high risk of noncancer mortality (from 25% [95% CI, 23%-28%] in 2004 to 34% [95% CI, 31%-37%] in 2009). For each of these 3 groups of patients, there was greater use of advanced treatments over time, particularly among those with an increased probability of noncancer mortality ($P<.001$ for trend). Conversely, there was a decreased use of prior standards across these 3 groups of patients ($P<.001$ for trend), making the overall use of treatment among men least likely to benefit relatively stable over time.

We next examined the use of IMRT and robotic prostatectomy separately among men who are the least likely to

benefit (FIGURE 2). Use of IMRT increased among men with low-risk disease (from 27% [95% CI, 25%-28%] in 2004 to 33% [95% CI, 32%-35%] in 2009), those with a high risk of noncancer mortality (from 35% [95% CI, 33%-36%] in 2004 to 52% [95% CI, 50%-53%] in 2009), and those with both low-risk disease and high risk of noncancer mortality (from 24% [95% CI, 22%-26%] in 2004 to 32% [95% CI, 28%-34%] in 2009; $P<.001$ for trend). Although less common than IMRT, robotic prostatectomy use increased over time among men with low-risk disease (from 5% [95% CI, 4%-6%] in 2004 to 11% [95% CI, 10%-12%] in 2009), those with a high risk of noncancer mortality (from 2% [95% CI, 1%-2%] in 2004 to 5% [95% CI, 5%-6%] in 2009), and those with both low-risk disease and a high risk of noncancer mortality (from 1% [95% CI, <1%-2%] in 2004 to 3% [95% CI, 2%-4%] in 2009; $P<.001$ for trend).

In addition, we estimated the use of prostate cancer treatments for men least

Table. Demographics and Clinical Characteristics of the Study Population

Characteristics	No. (%)[a] IMRT (n = 23 633)	EBRT (n = 3926)	Robotic Prostatectomy (n = 5881)	Open Radical Prostatectomy (n = 6123)	Observation (n = 16 384)	P Value[b]
Age, y						
66-69	5536 (23)	978 (25)	3334 (57)	3479 (57)	3766 (23)	<.001
70-74	8540 (36)	1409 (36)	2071 (35)	2174 (36)	4557 (28)	
75-79	6670 (28)	1063 (27)	438 (7)	437 (7)	4086 (25)	
>80	2887 (12)	476 (12)	38 (<1)	33 (<1)	3975 (24)	
Race/ethnicity						
White	19 232 (81)	3207 (82)	5056 (86)	5238 (86)	13 236 (81)	<.001
Black	2508 (11)	454 (12)	349 (6)	461 (8)	2044 (12)	
Hispanic	498 (2)	96 (2)	66 (1)	127 (2)	306 (2)	
Asian	700 (3)	100 (3)	152 (3)	114 (2)	412 (3)	
Other	695 (3)	69 (2)	258 (4)	183 (3)	386 (2)	
Socioeconomic class						
Low	6151 (26)	1390 (35)	1289 (22)	1703 (28)	4889 (30)	<.001
Medium	10 305 (44)	1372 (35)	1843 (31)	1930 (32)	5836 (36)	
High	7177 (30)	1164 (30)	2749 (47)	2490 (41)	5659 (35)	
Comorbidity score						
0	14 612 (62)	2415 (62)	4501 (77)	4537 (74)	10 830 (66)	<.001
1	5697 (24)	992 (25)	1048 (18)	1214 (20)	3241 (20)	
2	2019 (9)	324 (8)	243 (4)	265 (4)	1313 (8)	
≥3	1305 (6)	195 (5)	89 (2)	107 (2)	1000 (6)	
Tumor grade						
Well or moderately differentiated	8482 (36)	1260 (32)	1971 (34)	2276 (37)	10 565 (64)	<.001
Poorly differentiated or undifferentiated	15 151 (64)	2666 (68)	3910 (66)	3847 (63)	5819 (36)	
Clinical stage						
T1	13 080 (55)	1923 (49)	3551 (60)	3099 (51)	9611 (59)	<.001
T2	9614 (41)	1809 (46)	2237 (38)	2867 (47)	6571 (40)	
T3/T4	939 (4)	194 (5)	93 (2)	157 (3)	202 (1)	
Disease risk classification						
Low	6266 (27)	785 (20)	1663 (28)	1730 (28)	8871 (54)	<.001
Intermediate	8870 (38)	1427 (36)	3022 (51)	2765 (45)	4618 (28)	
High	8497 (36)	1714 (44)	1196 (20)	1628 (27)	2895 (18)	
Risk of noncancer mortality						
Low	6644 (28)	1015 (26)	3169 (54)	3078 (50)	4113 (25)	<.001
Intermediate	8307 (35)	1417 (36)	2058 (35)	2276 (37)	4977 (30)	
High	8682 (37)	1494 (38)	654 (11)	769 (13)	7294 (45)	
Year of diagnosis						
2004	2990 (13)	1618 (41)	432 (7)	1516 (25)	2624 (16)	<.001
2005	3609 (15)	927 (24)	614 (10)	1219 (20)	2661 (16)	
2006	4237 (18)	613 (16)	906 (15)	1056 (17)	2889 (18)	
2007	4569 (19)	415 (11)	1191 (20)	976 (16)	2893 (18)	
2008	4195 (18)	191 (5)	1345 (23)	775 (13)	2737 (17)	
2009	4033 (17)	162 (4)	1393 (24)	581 (9)	2580 (16)	

(continued)

Table. Demographics and Clinical Characteristics of the Study Population (continued)

Characteristics	No. (%)[a] IMRT (n = 23 633)	EBRT (n = 3926)	Robotic Prostatectomy (n = 5881)	Open Radical Prostatectomy (n = 6123)	Observation (n = 16 384)	P Value[b]
SEER region[c]						
San Francisco	715 (3)	216 (6)	216 (4)	190 (3)	748 (5)	
Connecticut	1766 (7)	196 (5)	303 (5)	187 (3)	1011 (6)	
Detroit (Metropolitan)	2046 (9)	369 (9)	479 (8)	257 (4)	1243 (8)	
Hawaii	470 (2)	35 (1)	137 (2)	47 (1)	186 (1)	
Iowa	1168 (5)	337 (9)	286 (5)	513 (8)	750 (5)	
New Mexico	627 (3)	44 (1)	87 (1)	268 (4)	588 (4)	
Seattle (Puget Sound)	1110 (5)	271 (7)	406 (7)	625 (10)	1338 (8)	
Utah	214 (<1)	250 (6)	121 (2)	421 (7)	653 (4)	<.001
Atlanta (Metropolitan)	1002 (4)	128 (3)	69 (1)	94 (2)	535 (3)	
San Jose	629 (3)	96 (2)	110 (2)	111 (2)	457 (3)	
Los Angeles	1529 (6)	141 (4)	719 (12)	600 (10)	1185 (7)	
Greater California	3733 (16)	630 (16)	1468 (25)	1536 (25)	3423 (21)	
Kentucky	1276 (5)	489 (12)	518 (9)	353 (6)	1187 (7)	
Louisiana	1810 (8)	220 (6)	296 (5)	497 (8)	1094 (7)	
New Jersey	5466 (23)	475 (12)	658 (11)	418 (7)	1948 (12)	

Abbreviations: EBRT, traditional external beam radiation treatment; IMRT, intensity-modulated radiotherapy; SEER, Surveillance, Epidemiology, and End Results.
[a] Percentages might not sum to 100 because of rounding.
[b] *P* values generated from χ^2 tests.
[c] Data not shown for 153 patients in the SEER Rural Georgia registry according to SEER-Medicare guidelines.

likely (FIGURE 3) and most likely to benefit (FIGURE 4). Among Medicare beneficiaries diagnosed with prostate cancer, the use of advanced treatment technologies for men unlikely to die of prostate cancer increased from 13% (95% CI, 12%-14%) in 2004 to 24% (95% CI, 24%-25%) in 2009, a relative increase of 85% ($P<.001$, Pearson χ^2 test). That is, rates of IMRT and robotic prostatectomy use increased from 129.2 per 1000 patients in 2004 to 244.2 per 1000 patients diagnosed with prostate cancer in 2009. At the same time, the use of prior standard treatments for men least likely to benefit decreased from 11% (95% CI, 10%-11%) in 2004 to 3% (95% CI, 2%-3%) in 2009 ($P<.001$, Pearson χ^2 test). For these men, rates of EBRT and open radical prostatectomy use decreased from 106.9 per 1000 patients diagnosed with prostate cancer in 2004 to 27.2 per 1000 patients diagnosed with prostate cancer in 2009. The estimated use of advanced treatment technologies for men most likely to benefit (ie, those with high-risk disease or a low risk of noncancer mortality) increased 11%, while the use of prior standards decreased 10% over the study period (both $P<.001$, Pearson χ^2 test).

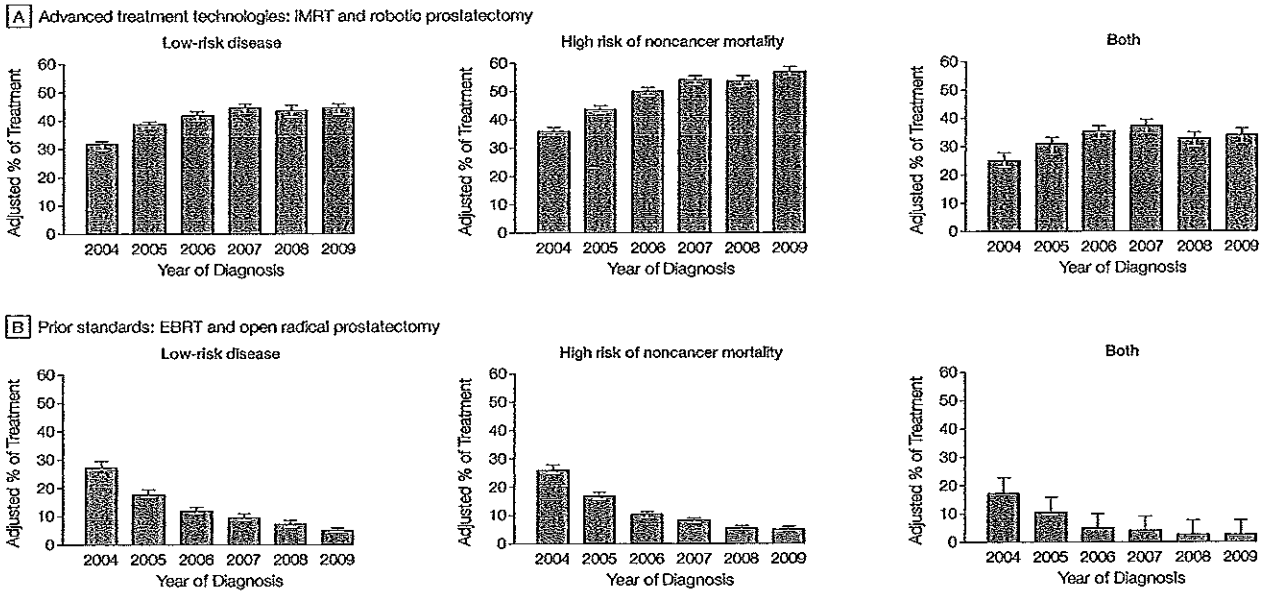
DISCUSSION

The use of advanced treatment technologies for prostate cancer was common among patients with low-risk disease and among those with a high risk of noncancer mortality. The most common treatment modality was IMRT, which accounted for the greatest use among men who stand the least to gain in terms of survival. The increasing use of both IMRT and robotic prostatectomy in populations unlikely to benefit from treatment was largely explained by their substitution for the treatments they aim to replace, namely EBRT and open radical prostatectomy.

The absolute magnitude of the use of advanced treatment technologies in these populations has 2 important implications. First, both treatments are considerably more expensive than the prior standards. Start-up costs for both approach $2 million.[5,7] Further, IMRT is associated with higher total episode payments, which translate into an additional $1.4 billion in spending annually.[23] Thus, the implications of any potential overtreatment with these advanced treatment technologies are amplified in financial terms. Second, and perhaps more important, the implementation of these technologies in populations unlikely to benefit from treatment occurred during a time of increasing awareness about the indolent nature of some prostate cancers and of growing dialogue about limiting treatment in these patients.[11,12] Our findings suggest that, even during this period of enhanced stewardship, incentives favoring the diffusion of these technologies outweighed those related to implementing a more conservative management strategy.

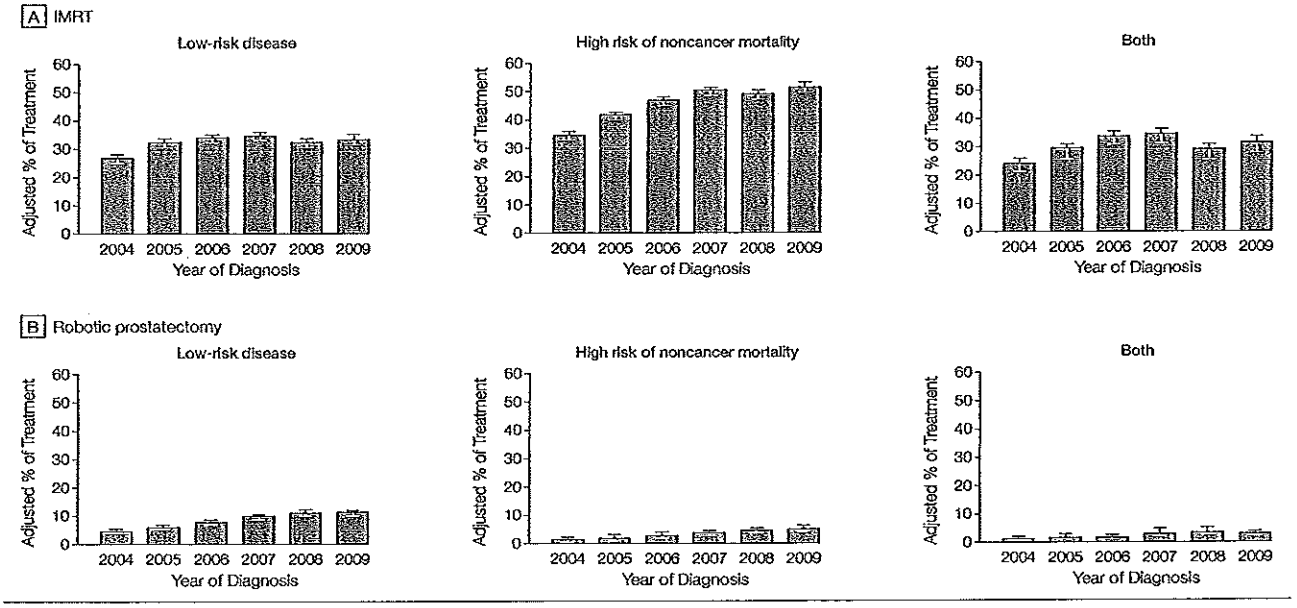
There are several potential explanations as to why this might be the case. First, there is uncertainty about the natural history of prostate cancer. Even for low-risk cancer, patients or physicians may be reluctant to observe when there is a high chance of cure with treatment. Patients who choose observation may live with a high level of anxiety knowing that they have cancer. Further, there is potential to underestimate the severity of disease based on

Figure 1. Treatment of Prostate Cancer Among Men Who Are the Least Likely to Benefit



The percentage of treatment was adjusted for age, race, socioeconomic class, comorbidity, tumor grade, year of diagnosis, and Surveillance, Epidemiology, and End Results region. Use of advanced treatment technologies significantly increased among prostate cancer patients with low-risk disease, high risk of noncancer mortality, and both low-risk disease and high risk of noncancer mortality ($P<.001$ for trend). Conversely, there was a decreased use of prior standards among these patients ($P<.001$ for trend), making the overall use of treatment relatively stable over time. Error bars indicate 95% CIs; EBRT, traditional external beam radiation treatment; IMRT, intensity-modulated radiotherapy.

Figure 2. Use of Advanced Treatment Technologies Among Prostate Cancer Patients Who Are the Least Likely to Benefit

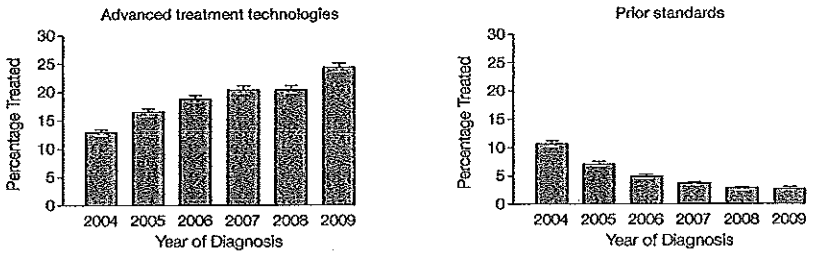


The percentage of treatment was adjusted for age, race, socioeconomic class, comorbidity, tumor grade, year of diagnosis, and Surveillance, Epidemiology, and End Results region. Use of intensity-modulated radiotherapy (IMRT) and robotic prostatectomy both increased among men who stand the least to gain in terms of survival (both $P<.001$ for trend). The majority of these patients were treated with IMRT. Error bars indicate 95% CI.

the prostate biopsy.[24] These concerns aside, the outcomes of men with low-risk disease following conservative management (ie, observation) are fairly well established,[16] causing some to even push for removing the label of cancer from low-risk tumors.[25] Second, a perceived improvement in outcomes compared with prior alternatives may make these advanced treatment technologies seem more palatable. However, comparative studies have shown that the advantages of these newer treatments are marginal at best.[3,4] Third, financial incentives—through ownership opportunities,[7] growing market share,[26] and fee-for-service reimbursement[23]—may be too strong to overcome.

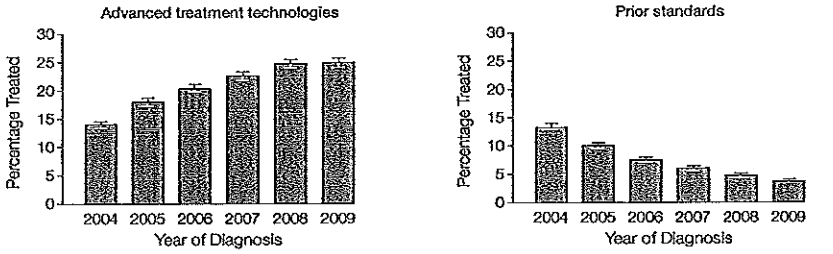
In quantifying the use of advanced treatment technologies among men who are unlikely to benefit from treatment, we rely on 2 measures of patient risk. The first is the risk of death from prostate cancer, which is determined entirely by the biology of the disease itself. It is well established that men with low-risk disease—as assessed by low grade, stage, and PSA level (the criteria used in this study)—have an extremely low chance of dying from prostate cancer, particularly in the elderly population.[16] Because of its protracted course, clinical guidelines recommend treating prostate cancer only in men expected to live at least 10 years,[9,10] which informs our second measure of patient risk, noncancer mortality. For this competing measure of mortality, we calculated the 10-year probability of death in a cohort of patients without prostate cancer. Although our model lacked certain information (eg, baseline functional status), we were able to generate a robust model with high discrimination (C index=0.90) by incorporating several conditions closely associated with mortality.[17,27] Although neither risk assessment is absolute, both are well informed by the expansive knowledge about the natural history of prostate cancer and provide an objective approach for quantifying the potential overtreatment burden.

Figure 3. Estimating the Use of Prostate Cancer Treatments for Men Least Likely to Benefit



Among Medicare beneficiaries diagnosed with prostate cancer, the use of advanced treatment technologies increased from 13% (95% CI, 12%-14%) in 2004 to 24% (95% CI, 24%-25%) in 2009 for men unlikely to die of prostate cancer ($P<.001$, Pearson χ^2 test). At the same time, the use of prior standard treatments for these patients decreased 8% ($P<.001$, Pearson χ^2 test).

Figure 4. Estimating the Use of Prostate Cancer Treatments for Men Most Likely to Benefit



Among Medicare beneficiaries diagnosed with prostate cancer, the use of advanced treatment technologies for men most likely to benefit (ie, those with high-risk disease or a low risk of noncancer mortality) increased 11%, while the use of prior standards decreased 10% over the study period (both $P<.001$, Pearson χ^2 test).

Another limitation of our study is the inclusion of only Medicare beneficiaries 66 years or older. Younger men are frequently diagnosed with prostate cancer. However, nearly two-thirds of men with prostate cancer are older than 65 years.[28] In addition, we are unaware of a biological rationale for why the use of advanced treatment technologies would be different across ages. For these reasons, our findings are informative to the vast majority of men with prostate cancer.

These limitations notwithstanding, the increasing use of advanced treatment technologies among men unlikely to die of prostate cancer carries significant policy implications, particularly in light of the recent US Preventive Services Task Force recommendations. The task force recently recommended against screening asymptomatic men for prostate cancer, largely based on the evidence that PSA screening results in the detection of many cases of indolent cancer that remain insignificant over a person's lifespan.[29] However, by using treatments more selectively, the benefits of screening may become clearer. For instance, in the European Randomized Study of Screening for Prostate Cancer trial, higher-grade cancer was less common in the screened group (as compared with the control group), with a 40% lower incidence of locally advanced and metastatic disease.[30] From our findings, the use of advanced treatment technologies is not much higher in men who would most likely benefit (ie, those with high-risk disease and low risk of noncancer mortality).

There are 2 potential reasons for this observation. First, the ability to risk-stratify patients is imperfect. However, the development of molecular markers and identification of gene signatures are examples of ongoing re-

search that may make it easier to differentiate indolent disease from "bad actors" in the near future. Second, it is difficult for clinicians to evaluate a patient's risk of noncancer mortality.[31,32] For example, clinicians inaccurately predict 10-year life expectancy nearly 20% of the time.[32] With this in mind, clinicians and policy makers could better focus efforts on identifying men who will benefit from screening and subsequent treatment, rather than on eliminating screening efforts altogether.

At the same time, more diligence is needed to reduce the potentially unnecessary treatment of men with a low risk of dying from prostate cancer. Patients with medical conditions that portend poor prognoses are still aggressively treated with radiation or surgery for their prostate cancer.[31] A Swedish study demonstrated that patients diagnosed with indolent prostate cancer account for a substantial and growing part of the increase in radical prostatectomies.[8] Although the majority of physicians consider active surveillance an effective strategy, less than one-third of urologists and radiation oncologists recommend surveillance over treatment for patients with low-risk disease.[33] Understanding the underpinnings of the discrepancy between these physician beliefs and what is occurring in practice will be fundamental to broadening the use of observation among appropriate patients. Furthermore, garnering support for surveillance in an environment that encourages the adoption of novel technologies will remain a challenge.

Research and policy change represent 2 avenues that could affect the current treatment patterns for prostate cancer. The Surveillance Therapy Against Radical Treatment (START) trial is a randomized controlled trial that will provide valuable information regarding the effectiveness of radiation, surgery, and active surveillance for low-risk prostate cancer.[34] However, because of the protracted natural history of prostate cancer, results from this trial are not expected for another 5 to 10 years. In the interim, well-designed observational studies can inform this debate. More immediately, policy change may help curtail the excessive use of advanced treatment technologies among patients least likely to benefit. For example, value-based insurance design encourages the use of services when clinical benefits outweigh the cost and discourages their use when the benefits do not justify the cost.[35] Taken together, efforts in these domains can help eliminate the overuse of advanced treatment technologies when patients stand little to gain.

In conclusion, we found that the use of advanced treatment technologies increased among men diagnosed with prostate cancer between 2004 and 2009 who had low-risk disease, high risk of noncancer mortality, or both. Continued efforts to differentiate indolent from aggressive disease and to improve the prediction of patient life expectancy may help reduce the use of advanced treatment technologies in this patient population.

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Study concept and design: Jacobs, Zhang, Montie, Miller, Hollenbeck.
Acquisition of data: Jacobs, Zhang, Skolarus.
Analysis and interpretation of data: Jacobs, Zhang, Schroeck, Skolarus, Wei, Gilbert, Strope, Dunn, Miller, Hollenbeck.
Drafting of the manuscript: Jacobs, Zhang, Skolarus, Dunn, Hollenbeck.
Critical revision of the manuscript for important intellectual content: Jacobs, Zhang, Schroeck, Skolarus, Wei, Montie, Gilbert, Strope, Miller, Hollenbeck.
Statistical analysis: Jacobs, Zhang, Schroeck, Dunn.
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Online-Only Material: The Author Video Interview is available at http://www.jama.com.

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Michigan

Average treatments per technologist per year

680

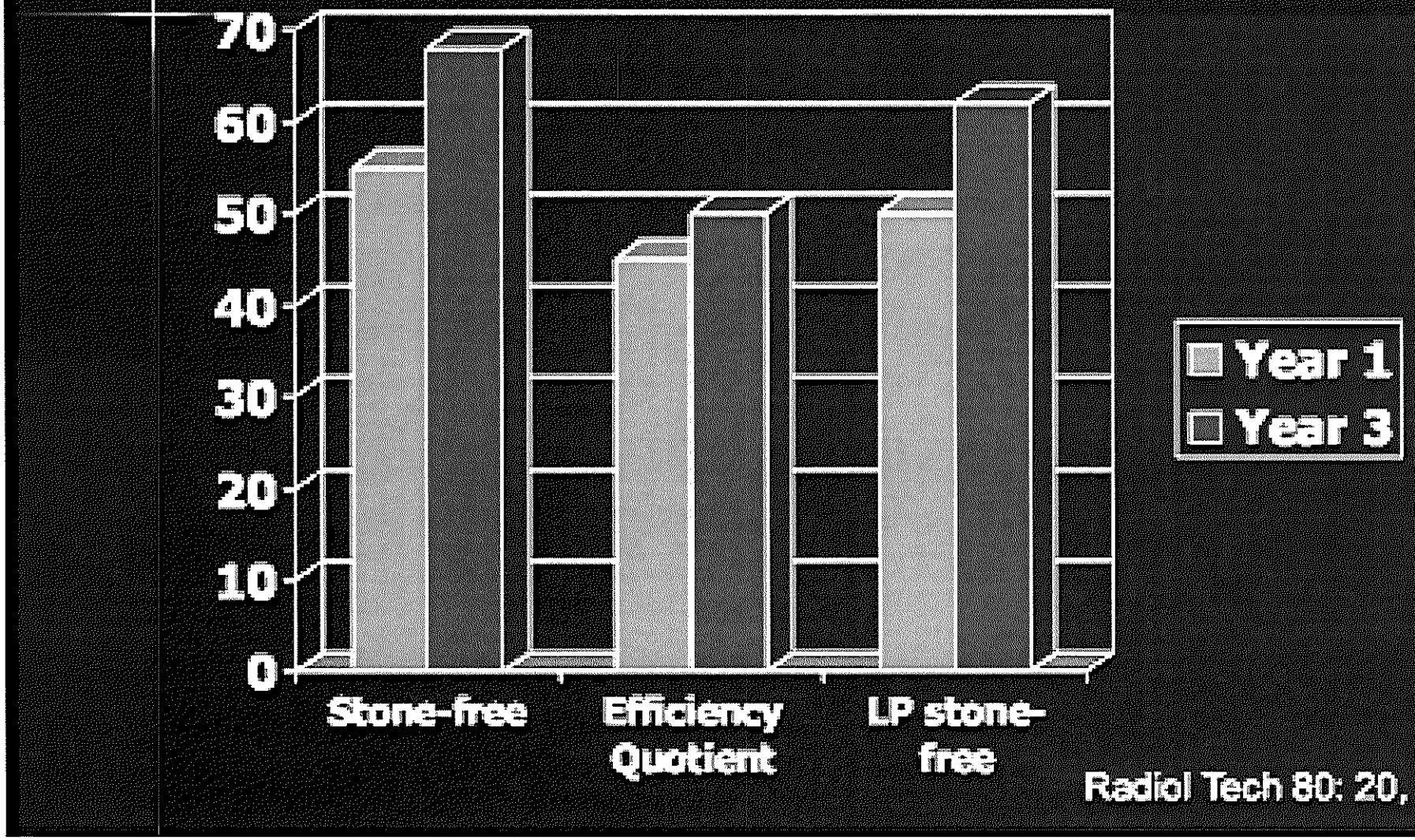
AKSM

Michigan

Average technologist years of experience

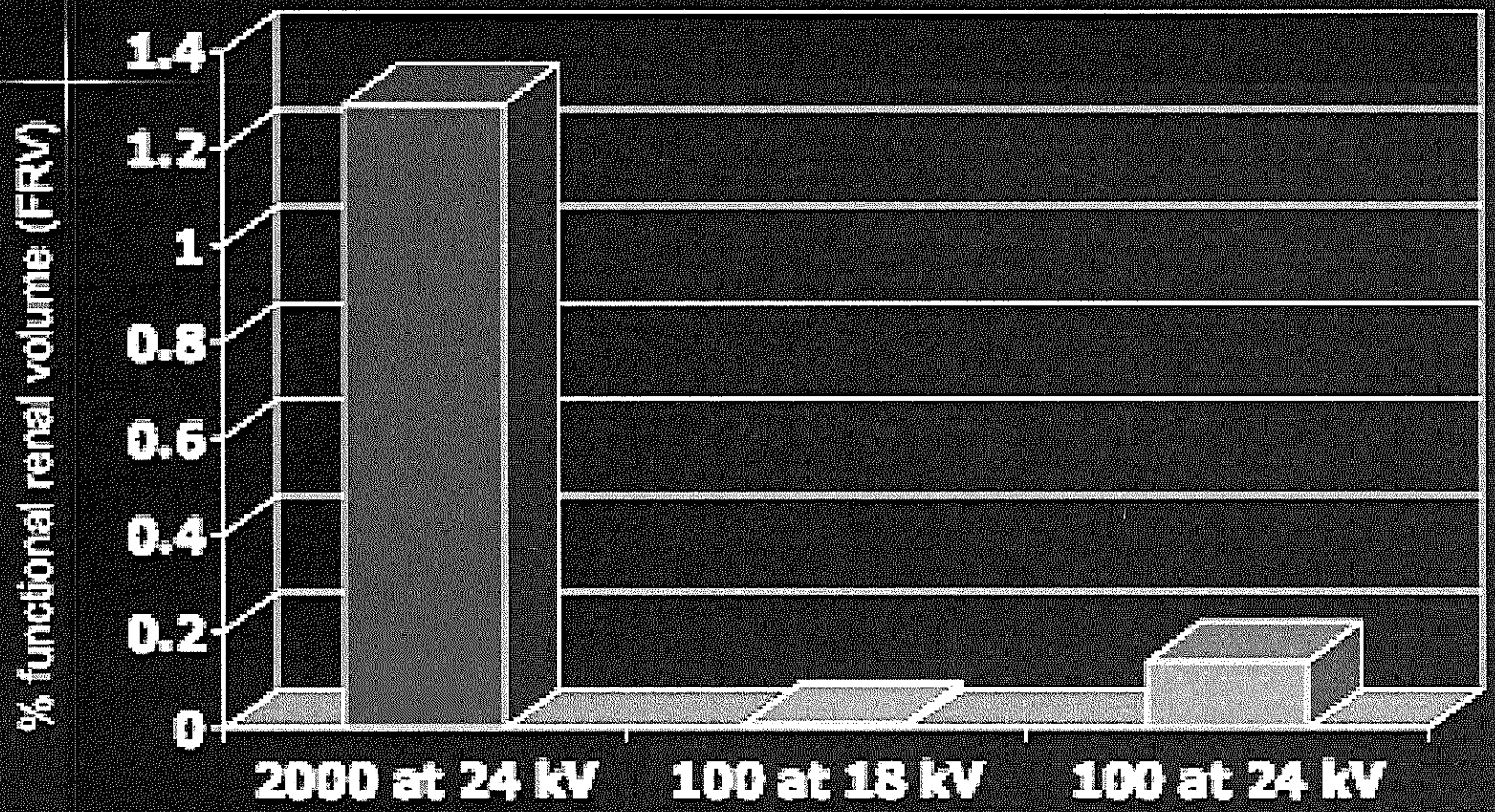
4 years

Litho Tech Learning curve



Radiol Tech 80: 20, 2008

Pause for the Cause



- 3 minute pause between priming shocks and treatment is the key

BJU Int. 2009 Jan;103(1):104-7.

Coupling

- Air pockets in the coupling medium
  - 2% surface area = 40% decrease in fragmentation
    - J Urol. 2006 Dec;176(6 Pt 1):2706-10

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Michigan Department of Community Health

Lithotripsy CON Workgroup – June 27, 2013

Overview:

In the document titled "MDCH Recommendations for CON Standards Scheduled for 2010 Review" on page 4 of 4, there are several data points cited that we feel are incorrect or unclear.

Comments:

Page 4 of 4, "**Reimbursement rates for Lithotripsy have decreased**":

The section states regarding the cost of lithotripsy nationally versus Michigan that "MDCH, however, found that Michigan's costs are very near the national average." In its 2009 Annual Report Form 10K, Healthtronics Inc. (HTRN), at the time the nation's only publicly traded provider of lithotripsy, stated that "we estimate that nationally, on average, our share of the non-physician fee was roughly $2,100, respectively, for both 2009 and 2008." As noted previously, the average cost of UESWL in Michigan is less than $1,500 or more than 25% less than the national average.

Page 4 of 4, "**Reimbursement policies limit physician office use**":

The section states that "The Medicare reimbursement system (as well as certain technological considerations) strongly discourages the provision of lithotripsy services in a physician office setting." Although this may be true, only approximately 20-25% of lithotripsy procedures performed nationally are done on Medicare patients.

In the last paragraph of the document, there are several references to Medicare reimbursement rates and amounts. There appears to be some inaccuracies in the facts noted. There is reference to a 21% decrease in the ASC rate for 2012 when in reality there was a 2.4% increase in the ASC rate. The following table shows the Medicare payment rate for CPT code 50590 under the HOPPS and ASC schedule for the last several years.

Schedule	2010	2011	2012(a)	2013	Avg Chg%
HOPPS	2,788.09	2,891.39	2,886.75	2,838.29	0.6%
ASC	1,656.98	1,626.43	1,665.59	1,592.65	-1.3%

(a) For 2012, CMS originally set the reimbursement for CPT code 50590 at $3,647.00 and $2,102.29 for HOPPs and ASC, respectively. A correction of these two amounts was done on April 24, 2012 retroactive to 1/1/12. The revision was done to correct an error in the calculation of the original rates and the revised rates reflect what the rates should have been from the beginning of the year.

Statements that are predictive in nature, that depend upon or refer to future events or conditions, or that include words such as "will", "would", "should", "plans", "likely", "expects", "anticipates", "intends", "believes", "estimates", "thinks", "may", and similar expressions, are forward-looking statements. The following important factors, in addition to those discussed under "Risk Factors" under Part I, Item 1, could affect the future results of the health care industry in general, and us in particular, and could cause those results to differ materially from those expressed in such forward-looking statements.

- uncertainties in our establishing or maintaining relationships with physicians and hospitals;
- the impact of current and future laws and governmental regulations;
- uncertainties inherent in third party payors' attempts to limit health care coverages and levels of reimbursement;
- the effects of competition and technological changes;
- the availability (or lack thereof) of acquisition or combination opportunities;
- the integration of acquired business; and
- general economic, market or business conditions.

General

We provide healthcare services and medical devices, primarily to the urology marketplace.

Lithotripsy services. We provide lithotripsy services, which is a medical procedure where a device called a lithotripter transmits high energy shockwaves through the body to break up kidney stones. Our lithotripsy services are provided principally through limited partnerships and other entities that we manage, which use lithotripters. In 2009, physicians who are affiliated with us used our lithotripters to perform approximately 50,000 procedures in the U.S. We do not render any medical services. Rather, the physicians do.

We have two types of contracts, retail and wholesale, that we enter into in providing our lithotripsy services. Retail contracts are contracts where we contract with the hospital and private insurance payors. Wholesale contracts are contracts where we contract only with the hospital. The two approaches functionally differ in that, under a retail contract, we generally bill for the entire non-physician fee for all patients other than governmental pay patients, for which the hospital bills the non-physician fee. Under a wholesale contract, the hospital generally bills for the entire non-physician fee for all patients. In both cases, the billing party contractually bears the costs associated with the billing service, including pre-certification, as well as non-collection. The non-billing party is generally entitled to its fees regardless of whether the billing party actually collects the non-physician fee. Accordingly, under the wholesale contracts where we are the non-billing party, the hospital generally receives a greater proportion of the total non-physician fee to compensate for its billing costs and collection risk. Conversely, under the retail contracts where we generally provide the billing services and bear the collection risk, we receive a greater portion of the total non-physician fee.

Although the non-physician fee under both retail and wholesale contracts varies widely based on geographical markets and the identity of the third party payor, **we estimate that nationally, on average, our share of the non-physician fee was roughly $2,100, respectively, for both 2009 and 2008.** At this time, we do not anticipate a material shift between our retail and wholesale arrangements, or a material change in our share of the non-physician fee.

CNBC.com

Robotic Surgery: Growing Sales, but Growing Concerns

BUSINESS FRAUD, COMPANY MISTAKES, BUSINESS NEWS, CNBC, INVESTIGATIONS INC, HEALTH CARE EQUIPMENT, INVESTIGATIONS INC., INTUITIVE SURGICAL INC, FDA, BUSINESS NEWS

CNBC.com | Tuesday, 19 Mar 2013 | 11:04 AM ET

When Intuitive Surgical went public 13 years ago at $9, it dazzled Wall Street with its sizzling story of something that would revolutionize medicine: a surgical robot called the da Vinci.

Born in Silicon Valley, the da Vinci was steeped in technology so advanced that it "overcomes many of the shortcomings" of traditional open surgery, notably less blood loss and a faster recovery, Intuitive boasted in its IPO filing.

Since then, da Vinci hospital robot placements and procedures have skyrocketed. Last year alone, installations rose by 21 percent to 2,585 units worldwide at a cost of more than $1.5 million each. And robotic surgical procedures leaped by 25 percent to 450,000.

While one of the downsides of robotic surgery is a lack of tactile feel, surgeons who sit at a console a few feet from the patients raved about its 3-D vision. "The vision compensated for everything," world-renowned prostate specialist Dr. Ash Tewari of New York Presbyterian Hospital said in a recent interview. He performs as many as four of the two-to-three hour procedures a day, four times a week. "If you look at it from a surgical standpoint, every surgeon's dream is to get to see exactly what he or she is doing and get to do it in a field (of vision) which is not pooled with a lot of blood."

Such testimonials have helped propel Intuitive into what Northland Capital analyst Suraj Kalia calls "the 'Apple' of the medtech sector."

Intuitive, which builds and sells the machines, also collects more than $100,000 in service maintenance agreements for each machine and sells the disposable instruments used by the machines for surgical procedures.

With revenue last year topping $2 billion, its stock has climbed well above $500, propelling its current market valuation to more than $20 billion.

In recent years, as the da Vinci's popularity has grown, so have questions and concerns about its safety, training and the aggressiveness of its marketing.

Intuitive executives declined to be interviewed for this story, and a spokeswoman said the company would not comment on issues of safety, training and marketing because they are "within the context of active litigation."

However, at a recent investment conference, Intuitive dismissed safety concerns, telling analysts that given the number of procedures it does, it believes its safety record is "exemplary."

And in a statement to CNBC, Intuitive said: "In any definitive treatment for complex disease, such as surgery of the cancerous prostate, heart, or other major organs there are risks of complications. Robotic surgery has proven benefits in reducing the risk and complications associated with open surgical procedures thereby extending the benefits of minimally invasive surgery to a broader population of patients. Overall, adverse event rates are very low. Da Vinci surgery has been shown to be safer than the open surgery alternatives in numerous independent large scale, peer reviewed studies."

Many surgeons, including critics, agree that in the right hands the da Vinci is generally safe.

However, a CNBC Investigations Inc. review, which included numerous interviews with surgeons,

lawyers, ex-employees and patients and an extensive review of internal documents, multiple studies, lawsuits and depositions of current employees, shows:

- A sharp rise in lawsuits and complaints about injuries, complications and even deaths following da Vinci procedures. At least 10 have been filed over the past two years, most of them in 2012; many more complaints, plaintiffs attorneys says, are headed toward mediation.
- Surgeons can use the robot to operate on patients after several steps, including at least an hour of online training, four hours watching two full-length procedures online, seven hours operating on a pig and as few as two surgeries, overseen by a more seasoned robotic surgeon. The number of supervised cases can vary by hospital.
- A high-pressure sales culture driven by quarterly "quotas" on surgical procedures has led sales people to lean on surgeons to do more robotic surgeries, according to interviews with former salespeople and internal emails.

On its website, Intuitive promotes the da Vinci as superior to open surgery, with such benefits as less blood loss, faster recovery and less pain.

In some procedures, such as hysterectomies, robotic surgery is being promoted and used as an alternative to laparoscopic surgery, another so-called "minimally invasive" surgical technique. A recent study published in the Journal of the American Medical Association concluded that "To date, robotically assisted hysterectomy has not been show to be more effective than laparoscopy."

And in prostatectomies, while robotic surgery is likely to result in less blood loss and faster recovery than traditional open surgery, the most feared side-effects of all—incontinence and sexual impotence —"are high after both," according to a study released last year by the Journal of Clinical Oncology.

Just last week, in what amounted to a stinging rebuke of robotic surgery, the president of the American Congress of Gynecologists and Obstetricians said: "Many women today are hearing about the claimed advantages of robotic surgery for hysterectomy, thanks to widespread marketing and advertising. Robotic surgery is not the only or the best minimally invasive approach for hysterectomy. Nor is it the most cost-efficient. It is important to separate the marketing hype from the reality when considering the best surgical approach for hysterectomies."

(*Read More:* Gynecologists Urge Caution on Robotic Hysterectomies)

The Food and Drug Administration recently asked surgeons to take part in a voluntary survey asking about complications involving the da Vinci. The FDA told CNBC the surveys are a routine part of its surveillance to help evaluate the device and its performance and to help understand the risk/benefit profile for devices like this.

Injury Complaints

"The robot has a place in surgery," said Dr. Francois Blaudeau, a practicing Alabama gynecologist who also is lead plaintiffs attorney focused on da Vinci-related injuries. Blaudeau, who has been trained on the da Vinci, also cautions that "it is a sophisticated piece of equipment that has its own set of issues." One, he said, is that it can inadvertently cause serious injury.

According to lawsuits, complaints, interviews with alleged victims, plaintiff attorneys and an FDA's database, many of the reported injuries during robotic surgery appear to be burns and other heat-related damage to intestines, ureter, bowels and other organs. Blaudeau and several surgeons interviewed for this story said the injuries can occur beyond the surgeon's range of vision and without the surgeon's knowledge and may only show days after the surgery. This, plaintiff lawyers say, has meant that many of the injuries and complications in the complaints have not been reported to the Food & Drug Administration as a da Vinci issue, resulting in an under-reporting of "adverse events" related to the machine.

Instead patients, unaware of a possible link between robotic surgery and their injuries, have in the past filed malpractice suits against doctors and hospitals, Blauedeau said. Intuitive declined to comment on the specific number of lawsuits and complaints. "Patients and attorneys have a right to make legal claims," a spokeswoman said. "We take any claim seriously, evaluate it on its own merits and trust in

the legal system to resolve these matters."

(**Read More:** What Happens When a Surgical Robot Malfunctions?)

The best official source for medical device "adverse events" is the FDA's Manufacturer and User Facility Device Experience (MAUDE) database. Submissions are voluntary, based only on reported cases and have not necessarily been investigated by the FDA. In fact, the agency cautions that it "is not intended to be used to evaluate" rates of adverse events. And doing so, Intuitive said, would be "factually and contextually inaccurate."

Since 2000, the database shows reports of at least 85 deaths and 245 da Vinci-related injuries. (A complete spreadhseet of 4,600 adverse events, including machine malfunction, filed with the FDA is included in this Intuitive report by Citron Research, which does investment research.)

During the same period, roughly 1.5 million robotic procedures have been performed, suggesting reported problems are statistically insignificant.

But critics like Dr. Marty Makary of Johns Hopkins University Hospital believe the number of injuries and complications are under-reported. A study he co-authored, which is under review by the Journal for Healthcare Quality, cross-referenced the FDA's database with press reports and lawsuits and found eight cases that were either incorrectly or never filed with the FDA.

While that may be a "fraction of procedures that are done," said Makary, the industry has done "a poor job of monitoring the safety profile of certain new technologies, and this is a classic example."

Makary, a pancreatic specialist known for doing complicated procedures—and trained on the robot—prefers straight non-robotic laparoscopy because of its lack "of what we call haptic (tactile) feedback. Because we're working around blood vessels, an inadvertent injury could result in a catastrophic bleed in seconds."

Yet, he added, "we have not even been keeping a national registry of robotic surgery-related complications. And from the ones that we have, we know from our research there is a massive under-reporting."

Blaudeau said after last fall's launch of his website badrobotsurgery.com—and in the wake of several lawsuits he filed—he has received "hundreds" of what he says are "confirmed" complaints involving "ureteral" and other injuries" during da Vinci gynecologic procedures.

And in the three months since advertising robotic injuries for Blaudeau's law firm on television in local markets, "We've probably had over 10,000 calls regarding vascular injuries, bowel, bladder, re-surgical procedures, punctures and tears," said Loni Liss, president of the Legal Communications Group, which conducts advertising campaigns seeking plaintiffs for personal injury lawsuits. "That's a very large response."

Among those who responded was Sonya Melton of Birmingham. Following six weeks in the hospital after what was supposed to be same-day robotic surgery, she said, she was home recovering and watching TV when "I see one of these commercials for attorneys. And they're talking about anyone had any problems with a robotic surgery. I'm like, 'hmmm.' ... I start to do a little bit more research. And I was like, 'Well, is that the name of the robot that they used on me? Yeah, it is.'"

In an interview, she said she had become so sick almost immediately after her surgery to remove uterine fibroids that she thought she was going to die. Her condition, she said, puzzled doctors so much that within days they sliced open her stomach open to find out why she was in excruciating pain and had developed a full-fledged pneumonia. What they found, she said, was a perforation in her small intestine.

Shawn Todd, who lives outside of Mobile, Ala., also contacted Blaudeau's firm. She still breaks down and sobs when she tells how doctors, unable to get anesthesia to work, apologized for what they were about to do as they held her down and stuck needles into her kidneys, which had shut down. Turns out, she said they told her, her ureters, which carry urine from the kidneys to the bladder, had somehow been burned.

Intuitive declined to discuss both cases, which are in mediation.

Blaudeau and other surgeons we spoke with say they believe one reason for the injuries is the da Vinci's use of "monopolar" energy for cauterizing and cutting, which can create excessive heat. If there is a failure in insulation on the instruments, they said, it can cause what is known as a "stray current" or arching—when sparks from an instrument leap elsewhere.

Stray currents can occur in regular laparoscopy as well. However, a 2011 study published in the American Journal of Obstetrics & Gynecology said, "robotic instruments have a significantly higher incidence and prevalence of [insulation failure] compared with laparoscopic instruments."

Intuitive said instruments using monopolar energy have been employed in "open and laparoscopic surgery for decades," and the company is "confident that the da Vinci surgical system deploys monopolar energy in a safe and effective way when used as indicated."

The company said it offers instruments that use various types of energy, and "surgeons determine which energy instruments to use."

Training on a Pig

Surgeons, plaintiffs lawyers and at least one lawsuit cite training as a concern. Typically it involves seven hours of training over a weekend, usually operating on a pig.

Then, based on the hospital's criteria, the surgeon is required to conduct two to five surgeries supervised or "proctored" by an experienced robotic surgeon before doing their first unsupervised operation. The more practice, in general, the better, but that also adds to the cost of training.

"Many surgeons are trained the same way, with no differences made as to their prior knowledge or prior ability prior to entering the robotic training," Bladeau said. "It's not reasonable to believe that every surgeon across the country can be adequately trained with one pig lab and two proctored cases."

It was a lack of training, according to one lawsuit filed in Washington state, that ultimately led to the death of Fred Taylor in 2012, roughly four years after undergoing what was supposed to be a routine prostate surgery.

His was the third robotic case for Dr. Scott Bildsten—his first without a supervisor. Instead of taking a few hours, the lawsuit alleges, the surgery lasted around 13 hours and 26 minutes. Two hours later, Taylor was "intubated in an ambulance" after suffering from a torn rectum, losing 15 cups of blood and undergoing "a consequent hypovolemic shock," a lawsuit filed by Taylor's widow claims.

"The weeks and months to come showed the results of the surgery were devastating," it states. Taylor never fully recovered. The lawsuit alleges he died of complications from the surgery.

Meanwhile, Bildsten, according to his deposition in connection with the lawsuit, "gave up robotics forever" one year after he operated on Taylor, saying:

I was under the initial impression you would get a level of comfort within a certain number of cases. And as .... it went along, it seemed it was going to be much longer than that. ... And after speaking with some other urologists in a similar situation, who attempted to use the ....da Vinci robot prostatectomy, a lot of others have decided not to proceed as well. They found the learning curve so steep and lengthy that the level of comfort just took too long and decided to quit. I was one of those.

Neither Bildsten nor his lawyer returned calls seeking comment. Intuitive, in keeping with its policy, declined comment on the lawsuit.

The Marketing Drive

Underlying all of this, according to former salespeople and internal emails, is a company culture steeped in aggressive marketing techniques, that includes high-pressure sales efforts by Intuitive to hospitals and doctors.

"Our extensive field checks highlighted a story where aggressive marketing drives the message and

true clinical utility seems secondary in nature," wrote Kalia, the Northland Capital analyst.

Intuitive declined comment on Kalia's report.

His comments are supported by our interviews with former Intuitive salespeople and internal documents, including those filed with the Taylor lawsuit. One common theme is an effort to prod surgeons to "convert" previously scheduled non-robotic surgeries to robotic surgeries to meet quarterly sales quotas.

In one email, Intuitive's clinical sales director bemoaned how the "Mountain West team is forecasting about 285 procedures each week. We need to be at 345 procedures/week to close on our goal."

With two days left in one quarter, another sales leader wrote: "Let's bring it home! Be sure to scrub all schedules, identify cases on Thursday and Friday that can be moved up. ... Turn over every stone possible. I know there are 2 out there."

In another email that day, another sales leader wrote: "Guys, it's time to call in favors for these last 2 cases. ... We need to start calling our surgical champions who know our business first thing tomorrow."

Other emails show sales reps trying to persuade hospitals to lower the amount of supervised surgeries required before surgeons can operate solo.

Marketing the robots to the hospitals, the former salespeople said, was just as aggressive. "We would go to hospitals in a local geography and get docs to pledge they would take business away to other hospitals if their hospital didn't get the robot," said one former regional sales director, repeating something several sales reps said.

With Intuitive, the marketing is to doctors, hospitals and something quite unusual for a surgical device: marketing directly to the consumer.

Hospitals proudly display banners and advertise the arrival of the da Vinci. Northwest Medical Center in Margate, Fla, even put up the da Vinci outdoor billboard with slogans like "The Power Performer" and "da Vinci, same name, same genius."

Some hospitals that have the robot, however, have kept it low key. Massachusetts General, for example, has one robot, has never actively promoted it and has capped the doctors who can use it. "We have had a very conservative, cautious and skeptical approach to the use of it," said anesthesiologist Dr. Peter Dunn, who also oversees the hospital's new surgical technology as head of its perioperative operations.

Dunn said that after five years, Mass General, which prides itself on being on the cutting edge of new medical technologies, has determined the robot has not proven to be the best solution for all patients.

And while the hospital continues to consider new uses for the robot, Dunn said, "more important than the device, is the quality of the surgeon."

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