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Changes in Initial Treatment for Prostate Cancer Among Medicare Beneficiaries, 1999-2007

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Abstract

Purpose—In the absence of evidence from large clinical trials, optimal therapy for localized prostate cancer remains unclear; however, treatment patterns continue to change. We examined changes in the management of patients with prostate cancer in the Medicare population.

Methods and Materials—We conducted a retrospective claims-based analysis of the use of radiation therapy, surgery, and androgen deprivation therapy in the 12 months after diagnosis of prostate cancer in a nationally representative 5% sample of Medicare claims. Patients were Medicare beneficiaries 67 years or older with incident prostate cancer diagnosed between 1999 and 2007.

Results—There were 20,918 incident cases of prostate cancer between 1999 and 2007. The proportion of patients receiving androgen deprivation therapy decreased from 55% to 36%, and the proportion of patients receiving no active therapy increased from 16% to 23%. Intensity-modulated radiation therapy replaced 3-dimensional conformal radiation therapy as the most common method of radiation therapy, accounting for 77% of external beam radiotherapy by 2007. Minimally invasive radical prostatectomy began to replace open surgical approaches, being used in 49% of radical prostatectomies by 2007.

Conclusions—Between 2002 and 2007, the use of androgen deprivation therapy decreased, open surgical approaches were largely replaced by minimally invasive radical prostatectomy, and intensity-modulated radiation therapy replaced 3-dimensional conformal radiation therapy as the predominant method of radiation therapy in the Medicare population. The aging of the population and the increasing use of newer, higher-cost technologies in the treatment of patients with prostate cancer may have important implications for nationwide health care costs.

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Keywords

Prostatic Neoplasms; Prostatectomy; Radiotherapy; Intensity-Modulated; Androgen Antagonists; Medicare; Physician's Practice Patterns

Introduction

Prostate cancer is the most common type of cancer and is the second leading cause of cancer-related deaths among men in the United States. Management options include active surveillance, radical prostatectomy, external beam radiation therapy, and interstitial brachytherapy. A recent systematic review concluded that there is limited evidence concerning the relative effectiveness of localized treatment modalities.[1] Previous studies have observed geographic variations and temporal changes in the treatment of patients with localized prostate cancer.[2] In the absence of large comparative trials, the optimal treatment strategy for these patients remains unclear, leading some to suggest that changes in treatment patterns may reflect changes in reimbursement the availability of new technology, or the belief that new approaches will benefit patients even though evidence from randomized trials is not available.[3]

The relative impact of prostate cancer in the United States will likely grow in coming years as demographic trends lead to greater incidence of the disease. Costs associated with prostate cancer were an estimated $7 billion in 2005, placing it among the 4 most costly malignancies.[4] Most patients with prostate cancer are enrolled in Medicare, which both directly and indirectly influences the coverage policies of private insurers and Medicaid programs.

The introduction of new technologies also drives increases in health care costs. In 2005 US dollars, the average cost of treating patients with prostate cancer increased from $8900 in 1993 to $10,700 in 2003, largely as a result of the expanded use of androgen deprivation therapy (ADT) and radiation therapy. Minimally invasive radical prostatectomy (MIRP) and intensity-modulated radiation therapy (IMRT) emerged in the early 2000s, with MIRP being used in one-quarter of radical prostatectomies by 2005.[5] A recent study of the use of MIRP and IMRT using Surveillance Epidemiology and End Results (SEER)-Medicare linked data found rates of IMRT as high as 80% by 2005.[6] The SEER-Medicare data come from a combination of cancer registries in 15 states that are disproportionately concentrated among urban, nonwhite, affluent populations with relatively high enrollment in health maintenance organizations and low cancer mortality.[7] Significant geographic variation has been observed in the diagnosis, evaluation, and management of prostate cancer.[2,8] In this study, we used Medicare claims data to examine changes in the management of prostate cancer in a nationally representative 5% sample of Medicare beneficiaries and extend this analysis to patients diagnosed through 2007.

Methods and Materials

We obtained administrative claims data for a nationally representative 5% sample of Medicare beneficiaries from 1997 through 2008 from the US Centers for Medicare & Medicaid Services (CMS). The inpatient files include claims covered under Medicare Part A for institutional facility services. The outpatient files include claims covered under Medicare Part A for institutional outpatient providers such as hospital outpatient departments and ambulatory surgery centers. The carrier files contain provider claims for services covered under Medicare Part B. The denominator files contain beneficiary identifiers, sex, race/ethnicity, birth dates, dates of death, zip codes, and information about program eligibility

and enrollment. Medicare beneficiaries report race/ethnicity at the time of enrollment. In this analysis, we used the categories “black” and “other.” The institutional review board of the Duke University Health System approved this study.

Study Population

Consistent with methods developed in previous research,[9,10] the study population included Medicare beneficiaries living in the United States for whom a diagnosis of prostate cancer (*International Classification of Diseases, Ninth Revision, Clinical Modification* [*ICD-9-CM*] code 185) was listed on an inpatient, outpatient, or carrier claim between 1999 and 2007. We used claims data from 2008 for ascertainment of initial therapy for prostate cancer only. We defined the date of disease onset as the date of the earliest observed cancer claim. To be considered a new-onset or incident case, we required beneficiaries to be 67 years or older, to be enrolled in fee-for-service Medicare for at least 2 years before the first diagnosis of prostate cancer, and to have no claims for any type of cancer during that 2-year period. In addition, we required that beneficiaries have at least 1 additional claim containing a diagnosis of prostate cancer within 60 days after the first claim and a prostate biopsy within 12 months after diagnosis. Using these criteria to identify diagnoses of prostate cancer, we selected the first diagnosis for each patient for the analysis. We applied these criteria to ensure that we selected incident cases rather than metastatic or recurrent disease. Inclusion in the analysis was conditional on survival for at least 60 days after the date of disease onset.

Initial Therapy

We identified the therapies for prostate cancer received by each patient by examining Current Procedural Terminology codes on claims in the year after the initial diagnosis. We organized claims for treatment into 3 non–mutually exclusive categories according to whether the patient received each treatment type: ADT, radiation therapy, and surgery. Androgen deprivation therapies included leuprolide and goserelin. Radiation therapies included conventional 2-dimensional radiation therapy, 3-dimensional conformal radiation therapy (3-D CRT), intensity-modulated radiation therapy (IMRT), brachytherapy (low or high dynamic range), stereotactic body radiation therapy (SBRT), and proton therapy. Surgical therapies included retropubic radical prostatectomy, radical perineal prostatectomy, and MIRP. Patients receiving neither ADT, radiation, nor surgery were categorized as “no active therapy,” which could include no therapy, active surveillance, or watchful waiting. We limited the analysis to treatments received (vs treatments planned) on the basis of Healthcare Common Procedure Coding System (HCPCS) codes. For patients who received radiation therapy, we did not distinguish among radiation alone, radiation in addition to surgery (ie, as adjuvant treatment), and radiation in combination with hormones.

Statistical Analysis

For characteristics of patients in the incident cohorts, we present categorical variables as frequencies with percentages. We identified comorbid conditions by using validated coding algorithms[10] to search all inpatient, outpatient, and carrier claims for 365 days before the date of disease onset for cerebrovascular disease, chronic obstructive pulmonary disease, congestive heart failure, coronary heart disease, dementia, diabetes mellitus, hypertension, peripheral vascular disease, and renal disease.

We tested for associations between each categorical variable and year of diagnosis using Cochran-Mantel-Haenszel χ^2 tests (row mean score statistic). We compared overall trends in treatment patterns by plotting the total proportion of patients receiving each treatment modality by year of diagnosis between 1998 and 2007. In a sensitivity analysis, we examined the effect of examining treatment using claims within 1 year vs 2 years after

diagnosis. We used SAS version 9.2 (SAS Institute Inc, Cary, North Carolina) for all analyses, and we considered $P < .001$ to be statistically significant.

Results

There were 20,918 incident cases of prostate cancer between 1999 and 2007 that met the study criteria. Approximately 60% of the study population was aged 67 to 75 years. The percentage of black patients was approximately 10% throughout the study period. Rates of most comorbid conditions remained unchanged during the study period, including cerebrovascular disease, chronic obstructive pulmonary disease, congestive heart failure, and dementia. However, the rates of diabetes mellitus, hypertension, peripheral vascular disease, and renal disease increased substantially from 1999 to 2007 (Table 1). Median age in all years of the study was 74 years.

The proportion of patients who received ADT alone or in combination with other therapies decreased from 55% to 36% between 1999 and 2007 (Figure 1 and Table 2). During the same period, ADT monotherapy decreased from 25% to 14%, and the proportion of patients who received no active therapy increased from 16% to 23%. The proportion of patients who underwent definitive surgical or radiation-based therapy remained at roughly 60% during the study period.

Although overall rates of surgery and radiation therapy did not change, the types of surgery and radiation therapy changed beginning in 2002. The overall proportion of patients who underwent radical prostatectomy remained steady at 12% to 16% between 1999 and 2007. A shift from open surgical techniques to MIRP began in 2002 and continued through 2007. In 2001, all radical prostectomies were performed using open approaches. By 2007, half of all radical prostatectomies were perfomed using minimally invasive techniques (all $P < .001$; Figure 1 and Table 2).

Among patients who underwent radiation therapy, IMRT largely replaced 3-D CRT by 2007. In 1999, 36% of patients underwent 3-D CRT and none underwent IMRT. By 2007, 9% of patients underwent 3-D CRT and 31% underwent IMRT. Proton therapy remained a rare treatment modality, used in less than 1% of patients in 2007. Stereotactic body radiation therapy for prostate cancer was essentially unused in the Medicare population in 2007.

Patients aged 67 to 76 years were more likely to undergo definitive treatment (75% vs 40%), including surgery (22% vs 1%), brachytherapy (24% vs 12%), or external beam radiation therapy (40% vs 32%), compared with older patients, who were instead more likely to undergo ADT monotherapy (37% vs 11%) or no active therapy (24% vs 13% ; all $P < .001$). The use of ADT monotherapy persisted among older beneficiaries, with 39% of beneficiaries older than 80 years receiving ADT monotherapy as late as 2007, compared with less than 7% of beneficiaries aged 67 to 75 years. Patients with multiple comorbid conditions were slightly less likely to undergo any treatment, compared with patients who had no comorbid conditions (18.6% vs 16.2%; $P < .001$), but were much less likely to undergo surgery (10.4% vs 19.1%; $P < .001$).

In a sensitivity analysis, we examined the effect of analyzing treatment using 1 year vs 2 years of claims data after a diagnosis of prostate cancer. The effect of examining treatment out to 2 years varied by treatment modality but increased the proportion of patients treated by less than 10% regardless of modality. The proportion of patients who underwent no active therapy during the entire study period was 19% vs 17%, respectively, when we used 1 year vs 2 years of follow-up data. Claims for surgery and brachytherapy occurred within the first 12 months in more than 95% of patients who received either treatment. Patterns of use were qualitatively and quantitatively similar in the primary and sensitivity analyses.

Discussion

The treatment of patients with prostate cancer in the Medicare population changed dramatically between 1999 and 2007. We observed a significant decrease in the use of ADT early in the study period. Although overall rates of surgery and radiation therapy remained constant, MIRP became the dominant form of radical prostatectomy, and IMRT largely replaced 3-D CRT. These rapid changes in clinical practice occurred during a period when the evidence available from large clinical trials and clinical practice guidelines did not change.[1]

Our observation of decreased use of ADT from 2003 through 2007 extends previous studies that observed decreases through 2005.[5] The use of ADT monotherapy persisted for a subgroup of patients. Although wait times and access to intravenous chemotherapy did not change after 2003,[10] previous reports have speculated that reduced rates of overall ADT use in prostate cancer occurred in response to the Medicare Modernization Act of 2003 (MMA), which reduced Medicare reimbursement rates for chemotherapy.[11] Another possibility is that the results of randomized trials have led to restricting ADT to patients who are most likely to benefit.[12] Taken as a group, prostate cancer nationwide is a relatively low-risk disease for which decreased use of ADT may have decreased over time as knowledge regarding the natural course of early-stage prostate cancer has evolved. The decreased use of ADT has important financial implications, because the average annual cost of ADT was $7200 in 2005.[13]

The increasing use of MIRP has been previously observed between 2003 and 2005.[5,6] Our study extends these observations through 2007, at which time the use of MIRP captured almost 50% of the surgery market. Compared with estimates from the predominantly urban SEER-Medicare population, we found substantially lower rates of IMRT adoption in the general Medicare population. Medicare payment for radical prostatectomy does not vary by surgical method, and evaluations of robotic prostatectomy have demonstrated decreased hospital profit margins without clear evidence of improved clinical outcomes.[14] In the context of negative financial incentives and unclear clinical benefit, the increasing use of these technologies may be driven instead by patient and physician demand.[15]

Our study demonstrates that IMRT has largely replaced external beam radiation therapy for the initial treatment of patients with prostate cancer in the Medicare population. This change has significant financial implications. Medicare reimburses more than twice as much for IMRT than for 3-D CRT.[16] As with MIRP, the adoption of IMRT has occurred in the absence of large randomized trials comparing IMRT to conventional therapy.[2] High-level evidence supports decreased toxicity with IMRT compared with 3-D CRT in patients with head and neck cancer[17]; however, no large trial has definitively examined the safety or efficacy of these therapies in patients with prostate cancer. The accuracy of the estimates presented here are supported by a previous analysis using SEER data that found rates of approximately 30% for external beam radiation therapy and 50% overall for radiation therapy in 2004, similar to the rates we observed.[18]

The results of our study may have profound implications for US health care policy. Our finding that IMRT and MIRP have replaced older treatment modalities contrasts with findings from other areas of developing medical technology, such as imaging and diagnostic testing, where increasing use is typically additive rather than a substitute for conventional methods.[9] Although the relative proportion of patients undergoing surgical or radiation-based therapy remained unchanged, a higher incidence of prostate cancer in the later years of our study translated to higher overall rates of patients undergoing therapy. We found that patients were only slightly less likely to undergo therapy if they had multiple vs zero

comorbid conditions, despite recommendations to avoid aggressive treatment in these populations.[19] Unlike reimbursement for other emerging technologies, Medicare reimbursement for radiation therapy is not guided by national coverage determinations and is instead guided by region-specific local coverage determinations. The current local coverage determinations date back to 2002 for IMRT, 2007 for SBRT, and 2009 for proton therapy. In this study, the use of both IMRT and MIRP increased through the last year of available data, suggesting that their use in the Medicare population had not plateaued by 2007.

Our study has some limitations. First, some cases we identified in the claims data as incident may have been recurrent cases. To mitigate this concern, we required patients in the analysis to have had a recent biopsy and no diagnosis of prostate cancer in the preceding 2 years. Second, Current Procedural Terminology codes for radiation therapy are not specific to cancer site, so some radiation therapy procedures included in the analysis may represent uses for indications other than prostate cancer. These cases likely represent a small proportion of study population, because we excluded patients who had claims for any other cancer in the 2 years before their diagnosis of prostate cancer. Alternative treatments, including orchiectomy or chemotherapy, were not included in this study but were likely infrequent. Third, only treatments reimbursed by Medicare are represented in the study; treatment in the Veteran's Administration system and treatments covered entirely by private insurance or the patient were not included. Finally, the data lacked clinical information, such as disease severity, that would have allowed assessment of outcomes. Clinical information, including disease severity, is available through the SEER-Medicare linked data. However, by using Medicare claims data exclusively, we were able to extend our analysis to patients diagnosed through 2007. Stage migration during the era of prostate-specific antigen screening may have affected clinical decisions whether or not to treat early-stage disease.[20] However, no guidelines or recommendations currently exist that would suggest a change in MIRP or IMRT use as a result of stage migration. Recent work by Nguyen et al[6] also found little impact of disease stage on the use IMRT vs 3-D CRT. Nevertheless, it is possible that the changes in treatment patterns we observed were influenced by unmeasured changes in disease severity. Finally, in this study, we were unable to differentiate between no therapy, active surveillance, and watchful waiting.

Conclusion

Management of patients with prostate cancer in the Medicare population has changed dramatically in recent years. Between 2002 and 2007, the use of ADT decreased, open surgical approaches were largely replaced by MIRP, and IMRT replaced 3-D CRT as the predominant method of radiation therapy. The aging of the population together with the increasing use of newer, higher-cost technologies in the treatment of patients with prostate cancer may have significant implications for nationwide health care costs.

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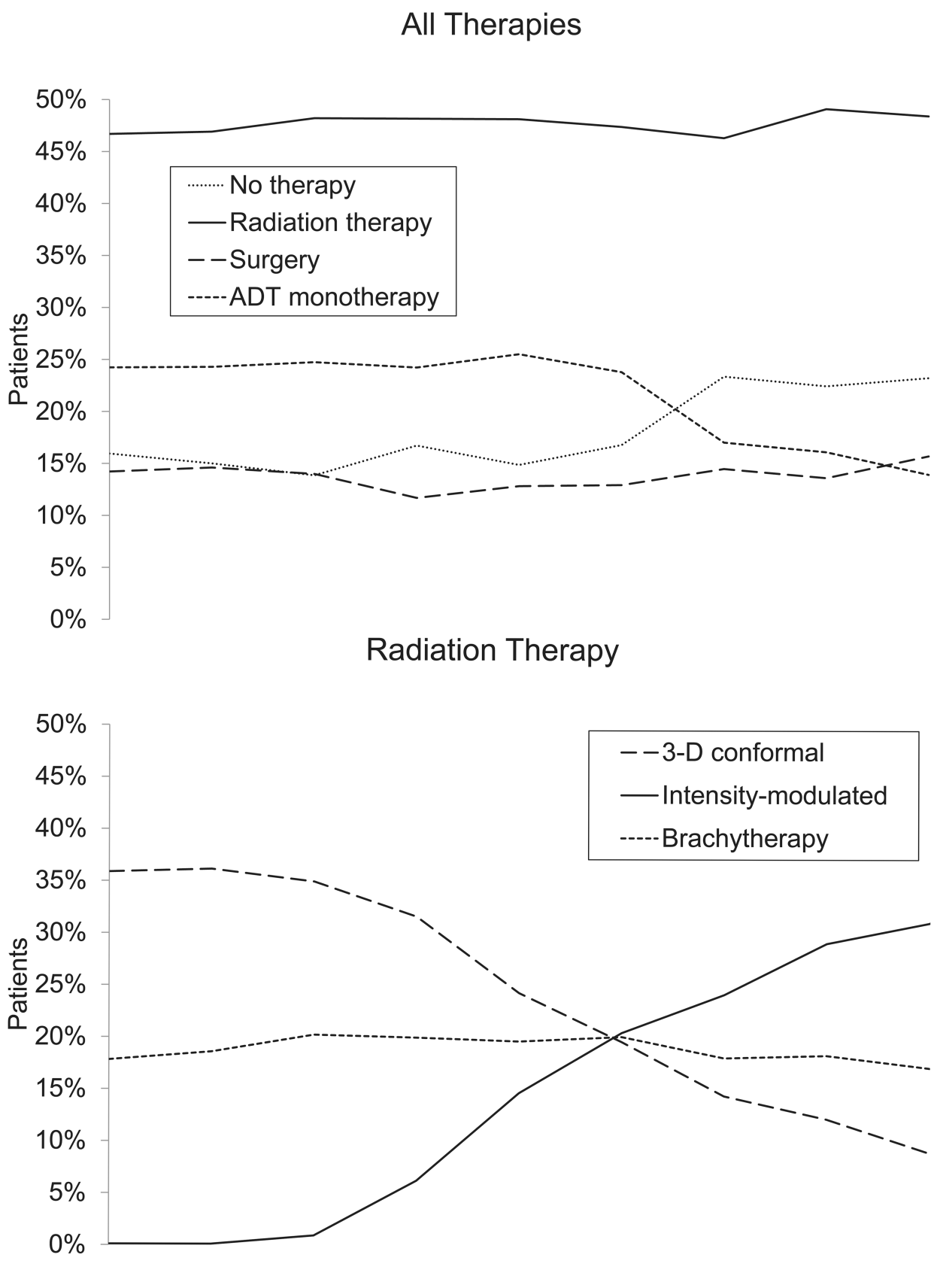

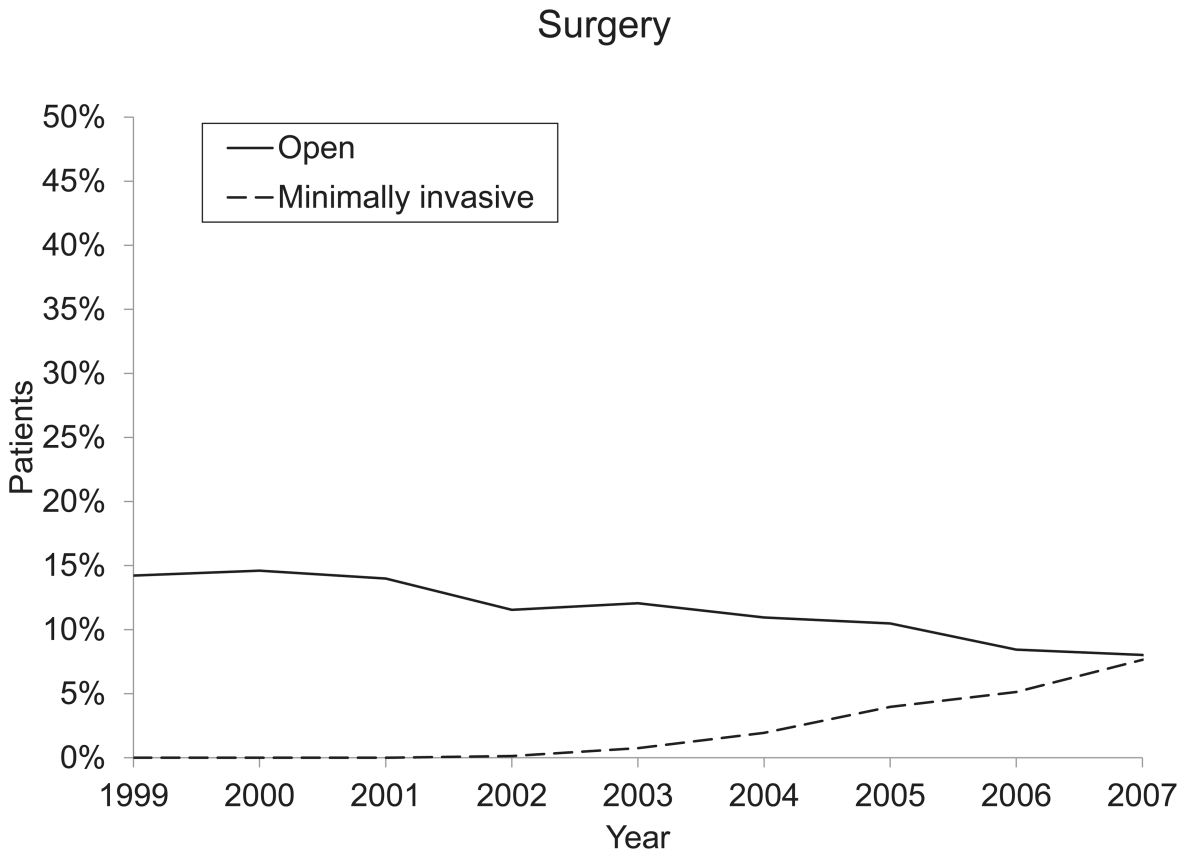

Figure. Changes in the Treatment of Patients With Prostate Cancer in the Medicare Population, 1999-2007

The vertical axes indicate the percentage of patients who had 1 or more claim for the procedure within 1 year after diagnosis. The horizontal axes indicate the year of diagnosis. Abbreviation: ADT, androgen deprivation therapy.

Table 1

Baseline Characteristics of the Study Population

Characteristics	Year of Diagnosis									*P* Value*
	1999 (n = 2151)	2000 (n = 2106)	2001 (n = 2150)	2002 (n = 2448)	2003 (n = 2345)	2004 (n = 2349)	2005 (n = 2380)	2006 (n = 2538)	2007 (n = 2451)	
Age group, No. (%)										.004
67-75 y	1239 (57.6)	1238 (58.8)	1231 (57.3)	1442 (58.9)	1368 (58.3)	1330 (56.6)	1425 (59.9)	1540 (60.7)	1512 (61.7)	
76-80 y	539 (25.1)	511 (24.3)	541 (25.2)	606 (24.8)	550 (23.5)	576 (24.5)	572 (24.0)	588 (23.2)	538 (22.0)	
≥ 81 y	373 (17.3)	357 (17.0)	378 (17.6)	400 (16.3)	427 (18.2)	443 (18.9)	383 (16.1)	410 (16.2)	401 (16.4)	
Race, No. (%)										.10
Black	230 (10.7)	213 (10.1)	205 (9.5)	233 (9.5)	250 (10.7)	212 (9.0)	261 (11.0)	227 (8.9)	221 (9.0)	
Other	1921 (89.3)	1893 (89.9)	1945 (90.5)	2215 (90.5)	2095 (89.3)	2137 (91.0)	2119 (89.0)	2311 (91.1)	2230 (91.0)	
Comorbid conditions, No. (%)										
Cerebrovascular disease	262 (12.2)	250 (11.9)	255 (11.9)	281 (11.5)	319 (13.6)	314 (13.4)	277 (11.6)	338 (13.3)	278 (11.3)	.66
COPD	406 (18.9)	390 (18.5)	413 (19.2)	479 (19.6)	482 (20.6)	453 (19.3)	446 (18.7)	486 (19.1)	433 (17.7)	.46
Coronary heart disease	673 (31.3)	663 (31.5)	653 (30.4)	788 (32.2)	737 (31.4)	804 (34.2)	736 (30.9)	830 (32.7)	746 (30.4)	.69
Congestive heart failure	216 (10)	195 (9.3)	213 (9.9)	233 (9.5)	253 (10.8)	223 (9.5)	221 (9.3)	215(8.5)	203 (8.3)	.02
Dementia	27 (1.3)	28 (1.3)	45 2.1)	43 (1.8)	40 (1.7)	46 (2)	42 (1.8)	48 (1.9)	38 (1.6)	.28
Diabetes mellitus	418 (19.4)	436 (20.7)	437 (20.3)	499 (20.4)	502 (21.4)	565 (24.1)	576 (24.2)	632 (24.9)	625 (25.5)	<.001
Hypertension	1136 (52.8)	1219 (57.9)	1238 (57.6)	1532 (62.6)	1472 (62.8)	1567 (66.7)	1638 (68.8)	1781 (70.2)	1749 (71.4)	<.001
Peripheral vascular disease	221 (10.3)	211 (10)	219 (10.2)	290 (11.8)	311 (13.3)	334 (14.2)	286 (12)	345 (13.6)	334 (13.6)	<.001
Renal disease	61 (2.8)	53 (2.5)	82 (3.8)	64 (2.6)	88 (3.8)	107 (4.6)	113 (4.7)	131 (5.2)	161 (6.6)	<.001

Abbreviation: COPD, chronic obstructive pulmonary disease.

*From Cochran-Mantel-Haenszel tests for associations between characteristic and year of diagnosis.

Table 2

Selected Treatments for Prostate Cancer With 1 Year After Diagnosis*

Characteristics	Year of Diagnosis									*P* Value†
	1999 (n = 2151)	2000 (n = 2106)	2001 (n = 2150)	2002 (n = 2448)	2003 (n = 2345)	2004 (n = 2349)	2005 (n = 2380)	2006 (n = 2538)	2007 (n = 2451)	
No active therapy, No. (%)	345 (16.0)	313 (14.9)	296 (13.8)	394 (16.1)	344 (14.7)	382 (16.3)	534 (22.4)	544 (21.4)	551 (22.5)	<.001
Radiation therapy, No. (%)	998 (46.4)	982 (46.6)	1037 (48.2)	1185 (48.4)	1130 (48.2)	1114 (47.4)	1112 (46.7)	1266 (49.9)	1197 (48.8)	.05
Brachytherapy	380 (17.7)	388 (18.4)	428 (19.9)	491 (20.1)	464 (19.8)	467 (19.9)	438 (18.4)	471 (18.6)	425 (17.3)	.43
External beam										
2-D	52 (2.4)	38 (1.8)	36 (1.7)	26 (1.1)	24 (1.0)		12 (0.5)	14 (0.6)	11 (0.4)	<.001
3-D conformal	767 (35.7)	755 (35.8)	756 (35.2)	775 (31.7)	561 (23.9)	466 (19.8)	354 (14.9)	319 (12.6)	221 (9)	<.001
IMRT			20 (0.9)	151 (6.2)	345 (14.7)	482 (20.5)	574 (24.1)	747 (29.4)	761 (31.0)	<.001
Surgery, No. (%)	<310 (<13.0)	<310 (<13.0)	<310 (<13.0)	<310 (<13.0)	298 (12.7)	304 (12.9)	339 (14.2)	343 (13.5)	386 (15.7)	.16
Open	299 (13.9)	305 (14.5)	295 (13.7)	283 (11.6)	281 (12.0)	259 (11.0)	246 (10.3)	214 (8.4)	197 (8.0)	<.001
Minimally invasive					17 (0.7)	45 (1.9)	93 (3.9)	129 (5.1)	189 (7.7)	<.001
ADT, No. (%)	1187 (55.2)	1140 (54.1)	1184 (55.1)	1345 (54.9)	1265 (53.9)	1267 (53.9)	1030 (43.3)	1093 (43.1)	880 (35.9)	<.001
ADT monotherapy, No. (%)	531 (24.7)	522 (24.8)	539 (25.1)	602 (24.6)	601 (25.6)	567 (24.1)	419 (17.6)	414 (16.3)	345 (14.1)	<.001

Abbreviation: ADT, androgen deprivation therapy; IMRT, intensity-modulated radiation therapy.

*Where cells had 10 or fewer observations, data have been suppressed to protect patient confidentiality.

†From Cochran-Mantel-Haenszel tests for associations between characteristic and year of diagnosis.