American trends in expectant management utilization for prostate cancer from 2000 to 2009

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Abstract

Introduction: The overtreatment of early prostate cancer has become a major public health concern. Expectant management (EM) is a strategy to minimize overtreatment, but little is known about its pattern of use. We sought to examine national EM utilization over the preceding decade.

Methods: We examined prostate cancer treatment utilization from 2000 to 2009 using the National Cancer Database. EM use was analyzed in relation to other treatments and by cancer stage, age group, Charlson score, and hospital practice setting.

Results: Overall, 109 997 (8.2%) men were managed initially with EM. EM usage remained stable at 7.6% to 9.5% from 2000 to 2009 with no appreciable increase for low-stage cancers. Usage was only slightly higher in elderly patients and in patients with multiple comorbidities. Veterans Affairs and low-volume hospitals had a much higher and increasing EM rate (range: 18.8%-29.8% and 15.1%-24.2%, respectively), compared to community hospitals, comprehensive cancer centres, and teaching hospitals, which showed no increased adoption. On further analysis, EM use remained high for low-stage cancers at Veterans Affairs and low-volume hospitals (24.0% and 19.1%, respectively), regardless of age or comorbidity, a pattern not shared by other practice settings.

Conclusions: EM utilization remained low and stable last decade, regardless of disease or patient characteristics. Conversely, Veterans Affairs and low-volume hospitals led the trend in national EM adoption, particularly in men with low-stage cancers and limited life expectancies. The limitations of this dataset preclude any determination of the appropriateness of EM utilization. Nonetheless, further study is needed to identify factors influencing EM adoption to ensure its proper use in the future.

Introduction

An estimated 23% to 42% of patients with early-detected prostate cancer are overdiagnosed.[1] Most of these men receive active treatment as a result of the diagnosis.[2] This overtreatment offers limited survival benefit and exposes patients unnecessarily to treatment-related harms.[3-5] To minimize overtreatment, the US Preventive Services Task Force recently recommended against prostate cancer screening.[6] While their recommendation avoids the harms associated with overdiagnosis, it introduces a significant risk of undertreatment.[7]

Alternatively, the overtreatment associated with early detection may be mitigated and its life-saving benefits preserved through the judicious use of expectant management (EM).[8] EM is a strategy to minimize prostate cancer overtreatment by withholding or deferring definitive local therapy in well-selected patients. The future of prostate cancer diagnosis may depend on the successful integration of EM into clinical practice.

During the last decade, little was known about EM uptake in the United States. Prior to 2000, only 5.5% of American men underwent EM.[9] In the new millennium, there was renewed enthusiasm in EM given the acceptance of watchful waiting as an option for men with limited life expectancies and the formal introduction of active surveillance.[10,11]

We sought to better understand how this changing climate influenced EM adoption in the United States. To answer this question, we investigated historical trends in EM utilization from 2000 to 2009 in a large national sample of American men.

Methods

The National Cancer Database (NCDB) was established in 1989 as a joint project of the American Cancer Society and the Commission on Cancer (CoC) of the American College of Surgeons. It captures 70% of all newly diagnosed malignancies in the United States annually and has been validated previously against the Surveillance, Epidemiology, and End Results (SEER) registry with good congruity.[12] Treatment information is limited to "first course treatment," defined as all treatments, including no treatment, administered to the patient or documented in their treatment record within 4 months of diagnosis and before disease progression or recurrence. Since patients may receive care at more than one hospital, only the facility initiating treatment is credited with the case to avoid duplicate records for the same patient. In accordance with its data use agreements, the NCDB only collects de-identified data using a standardized, electronic data abstraction format.

Using the Louis Stokes Cleveland VA Medical Center license, aggregate data from the NCDB was accessed through the Hospital Comparison Benchmark Reports, a web-based application on the CoC's Datalinks portal.[13] At the time of retrieval, data were only available through 2009. Despite the statistical limitations of summary data, this dataset was chosen for its inclusion of data from a variety of facilities, including federal hospitals, which are excluded from the complete NCDB dataset. Specific disease classification variables, including Gleason grade, prostate-specific antigen (PSA), and TMN staging, were unavailable.

Patients diagnosed with prostate cancer from 2000 to 2009 (N=1 344 656) were identified for analysis. EM was defined as no first course treatment. Active treatment was defined as radical prostatectomy (RP), radiation with or without androgen deprivation therapy (ADT), ADT alone, or other specified treatment combinations (other), which included multiple treatment modalities that individually account for <3% of all cases.

Five potential predictors of EM utilization were investigated: (1) the use of other first course treatments, (2) American Joint Committee on Cancer (AJCC) staging classification, (3) patient age, (4) Charlson score, and (5) hospital type. Disease staging information followed the AJCC stage classifications, 5th (2000-2002) and 6th (2003-2009) editions: Stage I (T1a, N0, M0), Stage II (T1-T2, N0, M0), Stage III (T3, N0, M0), and Stage IV (T1-T4, N0-N1, M0-M1).[14] Due to uncertain clinical significance, patients with AJCC stage 0 (n = 59) or stage "not applicable" or "unknown" (n = 94 029) and patients younger than 40 years (n = 994) were excluded from subgroup analysis. Charlson scores were only available after 2002. Using the classification system employed by the CoC, approved hospitals were categorized as: community cancer programs; comprehensive community cancer programs; teaching/research programs; Veterans Affairs (VA) cancer programs; and "other" low-volume cancer programs, which typically report fewer than 100 cases annually to the NCDB. Due to unexpectedly high EM utilization at VA and low-volume hospitals, we decided to analyze these systems by stage, age, and Charlson score to determine if their practice patterns could be explained by differences in their patient populations. Based on evidence of increasing RP usage with time, we decided to perform similar time-trend and subgroup analyses of RP utilization.

Treatment utilization was defined as the percentage of patients who received a given treatment over the total number of eligible patients for that treatment. Data were plotted with treatment utilization as the dependent variable and diagnosis year as the independent variable to confirm linear relationships. Time trends were assessed by linear regression analyses using the least-squares method to produce the line of best fit. Goodness of fit was assessed by the coefficient of determination (R^2) with R^2 values >0.8 considered indicative of a strong association. Analysis of variance (ANOVA) was used to calculate the significance of the regression with p values <0.05 considered statistically significant.[15]

Results

Overall, 8.2% (109 997/1 344,656) of patients were managed initially with EM. In total, 1 234 679 received some form of active treatment: RP (n = 546 608), radiation with or without ADT (n = 507 005), ADT alone (n = 65 255), or other (n = 115 811). EM utilization was low and stable throughout the study period without any particular time trend ($p = 0.89$) (Fig. 1). RP utilization (range: 34.7%-47.9%) increased over time ($p < 0.001$), while utilization of radiation (range: 31.1%-40.0%), ADT (range: 4.0%-5.8%), and other therapies (range: 7.5%-10.6%) decreased ($p < 0.001$).

On subgroup analysis, EM utilization remained low across AJCC stage, patient age, and Charlson score (Table 1). On average, usage was highest for stage IV cancer at 11.0% (7404/67 189), age ≥70 years at 11.8% (57 152/483 408), and Charlson score ≥2 at 13.1% (3063/23 338). Aside from a small but significant decline in EM utilization with time for stage III prostate cancer ($p = 0.001$; $R^2 = 0.80$), EM use was unchanged.

RP utilization was highest (range: 55.9%-68.6%) and increasing ($p < 0.001$) for stage III prostate cancer, but its use was rising fastest for stage II prostate cancer ($p < 0.001$) (Table 1). RP use also increased across all patient age groups ($p < 0.001$), though its use was highest for men <70 years (range: 46.4%-57.5%). Lastly, RP use increased for Charlson score <2 ($p < 0.001$), but remained stable for Charlson score ≥2.

By hospital type, most patients were treated at comprehensive community care programs, and the least number

of patients at VA hospitals (Table 2). VA hospitals exhibited the highest overall rate of EM utilization at 22.6% (14 786/65 286), followed by low-volume hospitals at 18.1% (18 127/100 123). Over the course of the entire study period, only a weak increase in EM utilization was noted at VA hospitals ($p = 0.05$; $R^2 = 0.41$); however, for the 2004-2009 interval a statistically significant association was apparent ($p < 0.01$; $R^2 = 0.92$) (Fig. 2a). On the contrary, RP use at VA hospitals remained stable ($p = 0.87$; $R^2 < 0.01$) (Fig. 2b). Low-volume hospitals exhibited a similar trend of increasing EM utilization overall ($p = 0.02$; $R^2 = 0.52$), especially from 2004 to 2009 ($p < 0.001$; $R^2 = 0.91$), but stable RP usage ($p = 0.69$; $R^2 = 0.02$). EM use was low and stable at community cancer programs, comprehensive community cancer programs, and teaching/research programs, while a strong and significant increase in RP use was noted for comprehensive community cancer programs ($p < 0.001$; $R^2 = 0.95$) and teaching/research programs ($p < 0.001$, $R^2 = 0.98$).

On further analysis of the VA hospitals, EM utilization was highest for stage I and II cancers at 24.0% (12 788/53 302), and it remained high regardless of patient age or Charlson score (Table 2). A similar trend was seen at low-volume hospitals. In contrast, at community cancer programs, comprehensive community care programs, and teaching/research programs, EM utilization rates for low-stage cancer, age <70 years, and Charlson score <2 were lower than their respective overall EM rates, with a trend toward higher utilization for stage IV prostate cancer, age ≥70 years, and Charlson score ≥2.

Discussion

Our study provides a time-trend analysis of American EM and RP utilization for prostate cancer from 2000 to 2009. We found that overall EM utilization comprised less than 10% of treatments, confirming previous mid-decade results from the CaPSURE database.[16] EM use was highest among men with advanced age and competing comorbidities. EM utilization was higher for localized (T1-T2) and lymph-node-positive (N1) disease (stages I, II, and IV) than for stage III (T3) disease (<2%). We also observed increasing RP utilization, corroborating previously reported trends.[16] These patterns occurred at most hospital types, except for VA and low-volume hospitals, which demonstrated a 2- to 3-times higher and rising EM utilization and stable RP utilization. At these facilities, EM was used more frequently for localized disease (T1-T2) and in men with limited life expectancies.

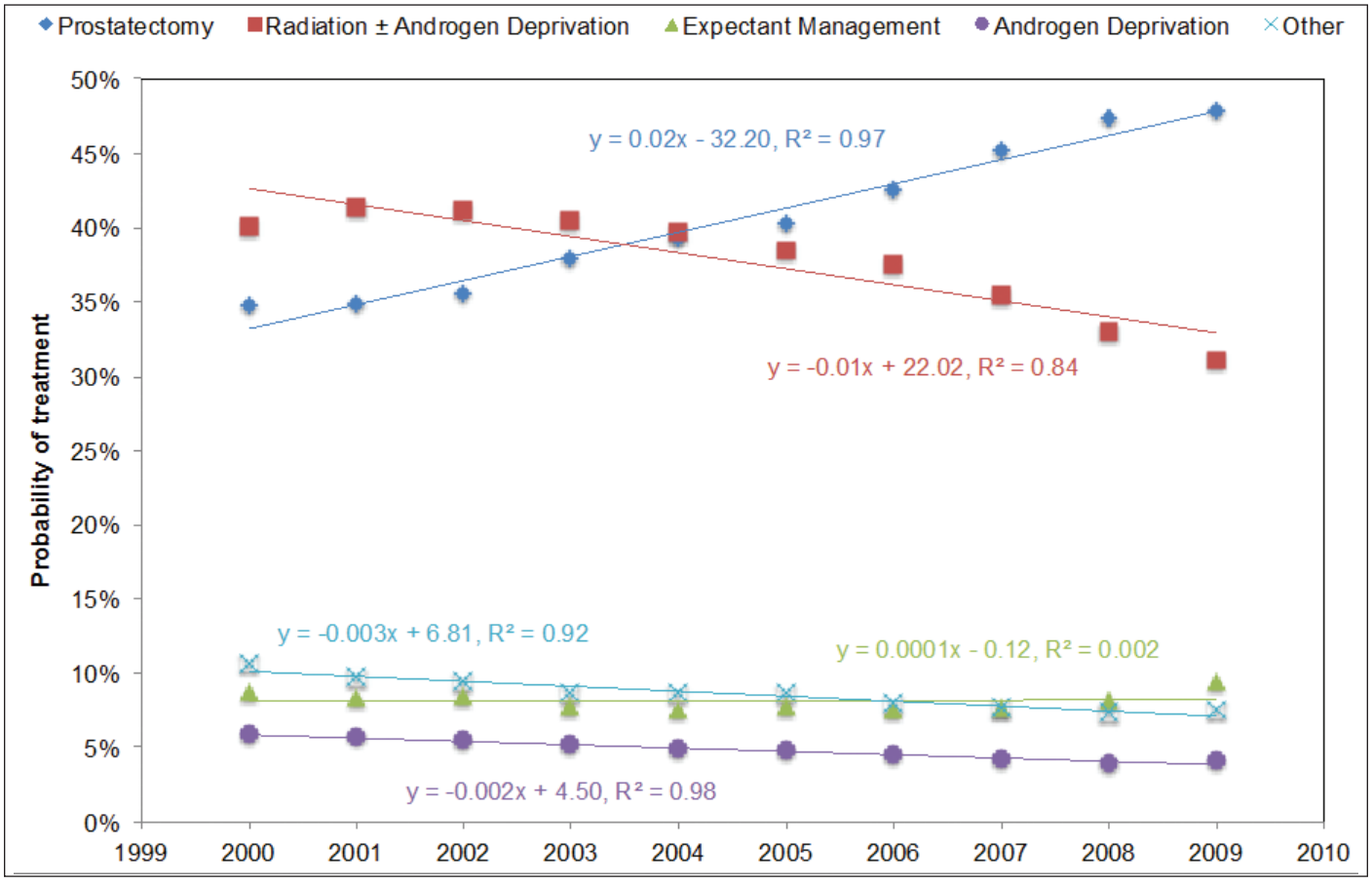

Fig. 1. First course treatment utilization for prostate cancer by diagnosis year.

Table 1. Percentage of prostate cancer diagnoses, 2000-2009, treated with RP and EM according to the AJCC staging classification,[a] age, and Charlson score

	Treatment	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	R^2 value[b]	*p* value[c]
Stage I	RP	43.2%	43.9%	47.5%	49.4%	48.7%	46.6%	47.2%	46.2%	49.3%	41.7%	<0.01	0.87
	EM	9.8%	9.5%	9.4%	8.6%	8.9%	8.6%	9.4%	9.4%	10.4%	9.4%	0.03	0.65
Total (n)		3414	3027	2455	2003	1690	1634	1708	1573	1392	1984		
Stage II	RP	34.5%	34.6%	35.2%	37.6%	38.7%	39.8%	42.3%	44.8%	47.5%	48.3%	0.96	<0.001 (I)
	EM	7.9%	7.4%	7.7%	6.9%	6.9%	7.4%	7.0%	7.3%	8.2%	9.7%	0.20	0.20
Total (n)		101800	108476	110195	100047	95830	97267	106932	115639	112221	107357		
Stage III	RP	55.9%	56.9%	57.1%	60.7%	61.5%	61.8%	63.1%	66.4%	68.2%	68.6%	0.97	<0.001 (I)
	EM	1.9%	1.3%	1.2%	1.4%	1.0%	1.2%	1.0%	0.7%	0.7%	0.7%	0.80	<0.001 (D)
Total (n)		11211	10824	10568	9731	9643	9545	10654	11103	11511	11935		
Stage IV	RP	14.4%	14.5%	14.0%	12.8%	12.4%	12.4%	12.2%	12.1%	12.2%	12.6%	0.69	<0.01
	EM	11.3%	11.8%	11.5%	11.6%	11.3%	11.2%	10.1%	9.8%	10.9%	10.8%	0.44	0.04
Total (n)		6936	6766	6523	6269	6038	6364	6579	6751	7265	7698		
Age <70 years	RP	46.4%	46.8%	46.9%	49.3%	50.4%	51.0%	53.5%	56.1%	57.5%	56.7%	0.95	<0.001 (I)
	EM	6.0%	5.8%	6.0%	5.6%	5.5%	6.0%	5.8%	5.9%	6.5%	8.0%	0.36	0.07
Total (n)		75875	80183	83064	77724	79300	81507	90935	99249	96856	95561		
Age ≥70 years	RP	18.5%	17.7%	17.8%	19.3%	19.8%	20.9%	21.5%	22.8%	25.0%	26.3%	0.91	<0.001 (I)
	EM	12.6%	12.1%	12.2%	11.3%	11.1%	11.2%	11.1%	11.3%	12.1%	13.2%	<0.001	0.99
Total (n)		54667	55753	53348	48071	45925	45524	47686	49093	43801	39540		
Charlson score <2	RP				37.9%	39.3%	40.4%	42.7%	45.3%	47.6%	48.2%	0.98	<0.001 (I)
	EM				7.7%	7.5%	7.7%	7.5%	7.6%	8.1%	9.3%	0.49	0.08
Total (n)					123426	122671	124230	135124	144611	136811	131310		
Charlson score ≥2	RP				36.6%	35.9%	34.7%	36.5%	37.4%	39.1%	37.5%	0.44	0.11
	EM				12.5%	12.1%	12.8%	12.6%	11.7%	13.8%	15.6%	0.46	0.09
Total (n)					2473	2629	2907	3587	3844	3969	3929		

RP: radical prostatectomy; EM: expectant management; AJCC: American Joint Committee on Cancer; (I): increasing trend; (D): decreasing trend.

[a]AJCC, 5th (2000-2002) and 6th (2003-2009) editions. Stage I: Gleason score 2-4 organ-confined disease incidentally detected in <5% of resected tissue (T1a, N0, M0, G1). Stage II: Gleason score 2-10 organ-confined disease (T1-T2, N0, M0). Stage III: Extracapsular extension and/or seminal vesicle invasion in the absence of local or distant metastases (T3, N0, M0). Stage IV: Locally advanced disease with/without regional lymph node metastases and with/without distant metastases (T1-T4, N0-N1, M0-M1).

[b]Goodness of fit was assessed by the coefficient of determination, R^2. R^2 values >0.8 were considered indicative of a strong association.

[c]*p* values <0.05 for the trend were considered significant.

Table 2. Expectant management utilization by hospital type

Community hospitals (n = 455)	Patients treated	Total patients	Percent
Stage I	229	2853	8.0%
Stage II	9322	98137	9.5%
Stage III	164	8366	2.0%
Stage IV	1057	8004	13.2%
Age <70 years	5534	70058	7.9%
Age ≥70 years	7886	56596	13.9%
Charlson score <2	8311	81829	10.2%
Charlson score ≥2	316	2431	13.0%
Overall	13431	126704	10.6%
Comprehensive community hospitals (n = 808)	**Patients treated**	**Total patients**	**Percent**
Stage I	828	11456	7.2%
Stage II	30220	555756	5.4%
Stage III	507	54526	0.9%
Stage IV	3830	32827	11.7%
Age <70 years	18579	433300	4.3%
Age ≥70 years	25392	268575	9.5%
Charlson score <2	28144	475796	5.9%
Charlson score ≥2	1028	11011	9.3%
Overall	43995	702271	6.3%
Teaching/research hospitals (n = 261)	**Patients treated**	**Total patients**	**Percent**
Stage I	759	5670	13.4%
Stage II	26152	321966	8.1%
Stage III	375	37303	1.0%
Stage IV	2034	20334	10.0%
Age <70 years	19063	293940	6.5%
Age ≥70 years	15335	121118	12.7%
Charlson score <2	23878	293403	8.1%
Charlson score ≥2	563	5312	10.6%
Overall	34424	415558	8.3%
Veteran Affairs hospitals (n = 58)	**Patients treated**	**Total patients**	**Percent**
Stage I	57	201	28.4%
Stage II	12731	53101	24.0%
Stage III	104	3747	2.8%
Stage IV	367	4457	8.2%
Age <70 years	8214	41127	20.0%
Age ≥70 years	6568	24146	27.2%
Charlson score <2	10118	44428	22.8%
Charlson score ≥2	1060	4043	26.2%
Overall	14786	65286	22.6%
Low-volume hospitals (n = 132)	**Patients treated**	**Total patients**	**Percent**
Stage I	138	901	15.3%
Stage II	15285	79905	19.1%
Stage III	124	6530	1.9%
Stage IV	483	6024	8.0%
Age <70 years	9582	62956	15.2%
Age ≥70 years	8539	37119	23.0%
Charlson score <2	12230	67155	18.2%
Charlson score ≥2	1156	4584	25.2%
Overall	18127	100123	18.1%

In contrast to our study, Loeb and colleagues found that EM utilization was much higher (30%-60%) and increasing for low- and intermediate-risk prostate cancer in Sweden over the same time period.[17] The apparent lag in EM use in the United States may reflect both the novelty of this approach and cultural differences between the United States and Sweden. In the early 2000s, the optimal treatment for early prostate cancer was uncertain without clear evidence of the relative efficacy and safety of observation compared to aggressive treatment.[3,18] In fact, the first prospective validation of active surveillance was not published until 2010, after the conclusion of our study period.[18] Furthermore, watchful waiting and active surveillance were not included in clinical practice guidelines until 2003 and 2007, respectively.[10,19] For these reasons, treatment decisions relied heavily on physicians' clinical judgment, with Swedish urologists preferring watchful waiting and American urologists favouring active treatment.[20,21]

The failure of academic centres to adopt EM, relative to VA and low-volume hospitals, may be due to lacking evidence, as described previously. However, the concurrent rise in RP usage at academic hospitals seems less evidenced-based, possibly influenced by the rapid adoption of robotic technology.[2] Consistent with our findings, Cooperberg and colleagues reported that patients at VA hospitals are more likely to undergo EM.[22] There are several explanations for this practice pattern. Since these patients are predisposed to higher-risk disease and greater comorbidity,[21] it can be argued that clinical differences may explain differences in EM utilization. However, we observed the highest EM usage among lower stage cancers, regardless of age or comorbidity, which argues against this theory. On the other hand, sociodemographic differences among VA patients, for which we could not control, have been linked to increased EM use and may have influenced our results.[22-25] For example, black men, who are disproportionately represented in VA hospitals, are less likely to receive aggressive treatment.[22,23,26] Alternatively, VA providers may favour less aggressive treatment for prostate cancer, as they do for other diseases.[27] The lack of financial incentive to deliver excess care at VA hospitals offers another possible explanation for increased EM use.[23] Lastly, limited access to robotic technology at VA hospitals for much of the decade may have insulated them from the national RP surge, and in turn, boosted EM adoption. The higher EM use among patients at low-volume hospitals is a new finding. This practice may reflect the

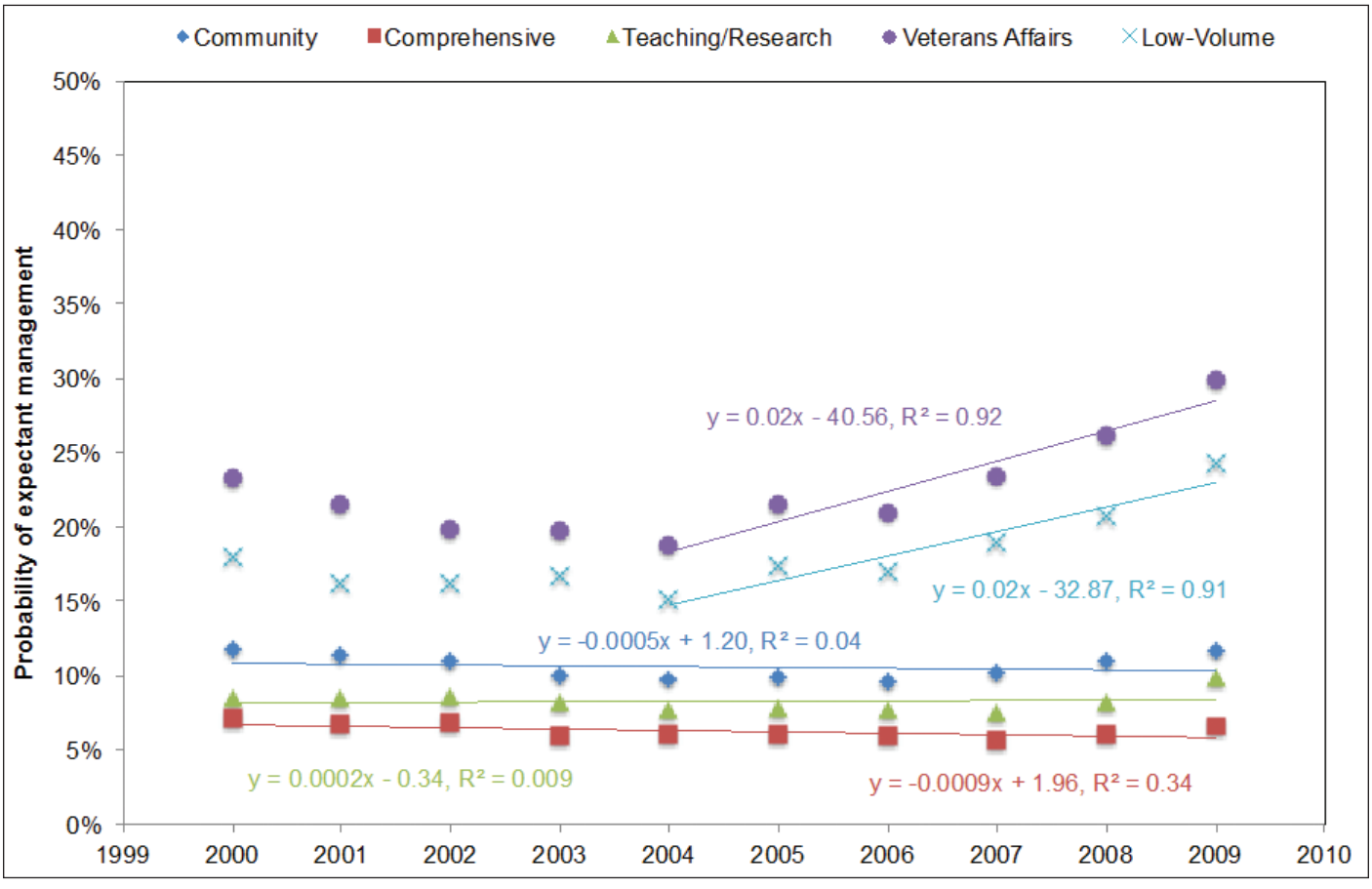

Fig. 2a. Expectant management utilization for prostate cancer by hospital type and diagnosis year.

ongoing centralization of American health care, with fewer RPs being performed on average at low-volume hospitals.[28,29] Urologists at these low-volume hospitals may prefer non-operative management to RP.

Patient preference, a critical driver of treatment selection, also may have caused differential EM use at the various hospitals.[21] Although the data precluded this analysis, the role of patient preference on EM selection is an important topic for future research.

A clear strength of our study is the comprehensiveness of the NCDB, which captures over 70% of incident cancers in the United States, regardless of age, and distinguishes EM from hormonal therapy. Another strength is our analysis of EM utilization by hospital type.

Our study also has several shortcomings. Firstly, watchful waiting and active surveillance cannot be differentiated. Secondly, AJCC staging data lacks information on PSA levels, Gleason grading, or specific TNM staging, precluding analysis in terms of traditional risk classifications. Furthermore, we were unable to exclude locally advanced or metastatic disease from our analyses of stage IV prostate cancer. Lastly, our aggregate dataset precluded multivariate analysis of the factors influencing EM utilization.

Conclusion

Overall EM utilization remained stable over the last decade, regardless of disease or patient factors. Alternatively, VA and low-volume hospitals exhibited high and rising EM usage, particularly in patients well-suited for this approach. The underlying causes may be multifactorial. EM adoption is likely ongoing, but this possibility needs to be reexamined to ensure future progress in the reduction of prostate cancer overtreatment.

Competing interests: Dr. Maurice, Dr. Abouassaly and Dr. Zhu declare no competing financial or personal interests.

This paper has been peer-reviewed.

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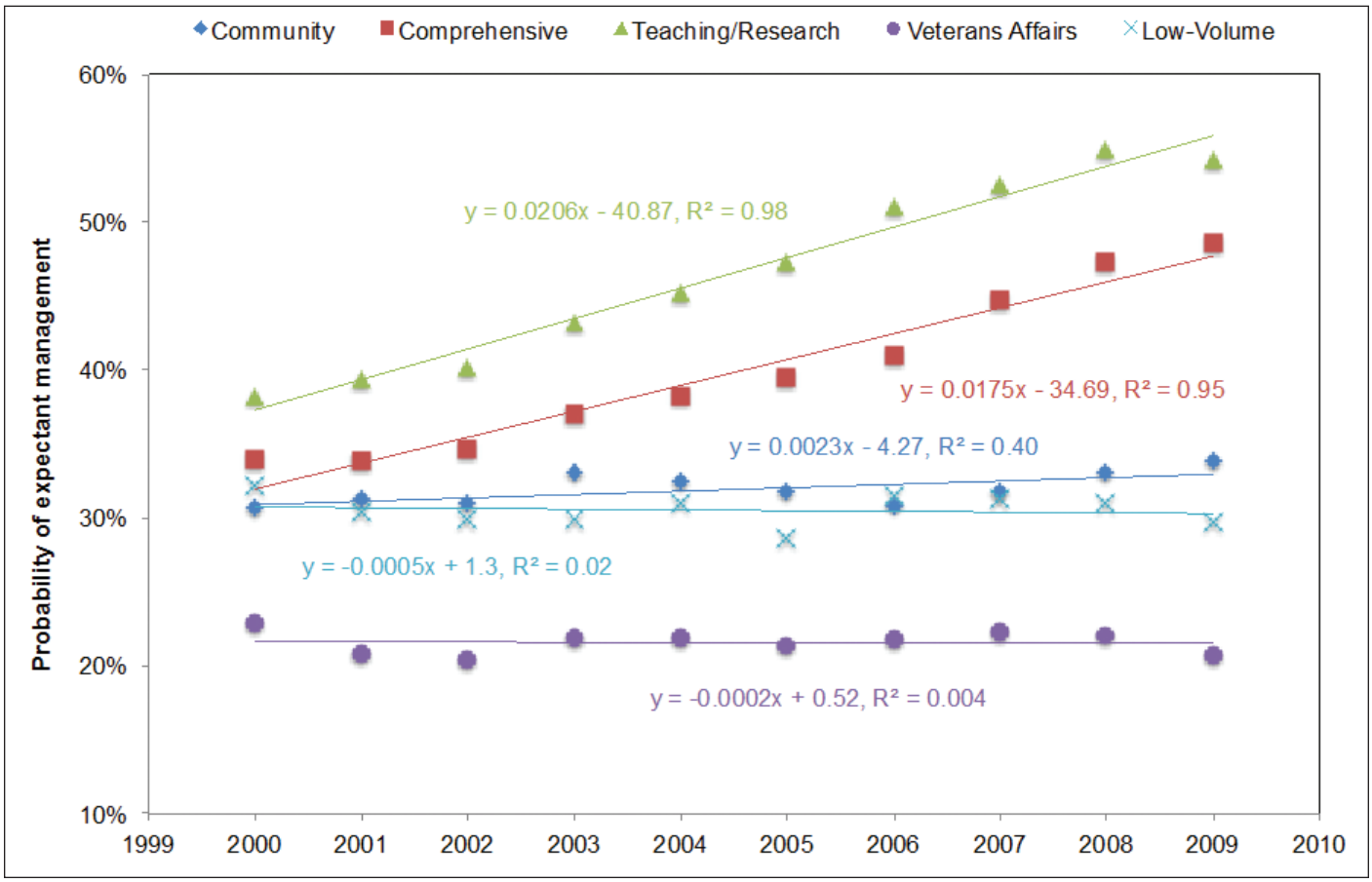

Fig. 2b. Radical prostatectomy utilization for prostate cancer by hospital type and diagnosis year.

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