Active Surveillance Compared With Initial Treatment for Men With Low-Risk Prostate Cancer
A Decision Analysis

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Context In the United States, 192,000 men were diagnosed as having prostate cancer in 2009, the majority with low-risk, clinically localized disease. Treatment of these cancers is associated with substantial morbidity. Active surveillance is an alternative to initial treatment, but long-term outcomes and effect on quality of life have not been well characterized.

Objective To examine the quality-of-life benefits and risks of active surveillance compared with initial treatment for men with low-risk, clinically localized prostate cancer.

Design and Setting Decision analysis using a simulation model was performed: men were treated at diagnosis with brachytherapy, intensity-modulated radiation therapy (IMRT), or radical prostatectomy or followed up by active surveillance (a strategy of close monitoring of newly diagnosed patients with serial prostate-specific antigen measurements, digital rectal examinations, and biopsies, with treatment at disease progression or patient choice). Probabilities and utilities were derived from previous studies and literature review. In the base case, the relative risk of prostate cancer–specific death for initial treatment vs active surveillance was assumed to be 0.83. Men incurred short- and long-term adverse effects of treatment.

Patients Hypothetical cohorts of 65-year-old men newly diagnosed as having clinically localized, low-risk prostate cancer (prostate-specific antigen level ≤10 ng/mL, stage ≤T2a disease, and Gleason score ≤6).

Main Outcome Measure Quality-adjusted life expectancy (QALE).

Results Active surveillance was associated with the greatest QALE (11.07 quality-adjusted life-years [QALYs]), followed by brachytherapy (10.57 QALYs), IMRT (10.51 QALYs), and radical prostatectomy (10.23 QALYs). Active surveillance remained associated with the highest QALE even if the relative risk of prostate cancer–specific death for initial treatment vs active surveillance was as low as 0.6. However, the QALE gains and the optimal strategy were highly dependent on individual preferences for living under active surveillance and for having been treated.

Conclusions Under a wide range of assumptions, for a 65-year-old man, active surveillance is a reasonable approach to low-risk prostate cancer based on QALE compared with initial treatment. However, individual preferences play a central role in the decision whether to treat or to pursue active surveillance.
prostate cancer morbidity and mortality from those who will die with but not because of their cancer. Active surveillance is an alternative to initial treatment for men with low-risk, clinically localized disease that has the potential to mitigate overtreatment. 

Active surveillance is a strategy of close monitoring for carefully selected patients with low-risk prostate cancer. The intent of active surveillance is to avert treatment unless disease progression occurs or a patient chooses treatment, in which case case treatment with curative intent is undertaken. The results of several observational cohorts of active surveillance have been promising, but follow-up has been relatively short.9-13

We performed a decision analysis to assess the quality-adjusted life expectancy (QALE) of active surveillance compared with initial definitive treatment with radical prostatectomy, intensity-modulated radiation therapy (IMRT), or brachytherapy.

METHODS

We constructed a state transition model analyzed using Monte Carlo simulation with TreeAge Pro Suite 2009, version 1.0.2,14 to estimate health benefits (QALE) accruing to men with low-risk, clinically localized prostate cancer (PSA/H1102110 ng/mL, stage/H11349T2a disease, and Gleason score/H113496).15 In the model, men are treated at diagnosis or undergo active surveillance. Men enter the model at age 65 years and exit at time of death due to prostate cancer or another cause. The decision tree structure is shown in eFigure 1 (available online at http://www.jama.com).

Initial Treatment

Men in this cohort undergo treatment with IMRT, brachytherapy, or open retropubic nerve-sparing radical prostatectomy. Once treated, men are at risk of recurrence as evidenced by an increase in PSA (biochemical recurrence). If a man develops biochemical recurrence, he is at risk of progression to metastatic disease and death due to prostate cancer or another cause.
Active Surveillance
The active surveillance protocol includes regular physical examinations, PSA measurement, and rebiopsy 1 year following diagnosis and every 3 years thereafter. Treatment is triggered by progression to a Gleason score of 7 or higher, other evidence of progression (eg, PSA doubling time), or patient preference. In the base case, all men who are treated receive IMRT because the majority of men older than 65 years are eligible for IMRT, whereas men with shorter life expectancies or large prostate tumors may not be candidates for radical prostatectomy or brachytherapy, respectively.16 Men with Gleason score progression receive IMRT with 6 months of androgen deprivation therapy.

The structure of the active surveillance model is identical to that of initial treatment from the point of treatment forward; however, men under surveillance may develop metastases prior to treatment.

Model Inputs
Model inputs were estimated from a systematic literature review; probabilities used in the model were generated by random-effects meta-analysis3-7 (Table 1, eAppendix, eFigure 2, eFigure 3, and eTable 1). All initial treatments were assumed to have equivalent disease-related outcomes.5-7 Men treated initially were assumed to have a relative risk of prostate cancer-specific death of 0.83 compared with men in active surveillance, and threshold analysis was performed to identify the relative risk of prostate cancer-specific death at which the optimal strategy changed. The relative risk of 0.83 was derived from a randomized controlled trial comparing radical prostatectomy to watchful waiting, in which radical prostatectomy was associated with a relative risk of death of 0.65 compared with watchful waiting.24 This trial included men with more advanced disease than those considered eligible for active surveillance, and only palliative treatment was offered to men in the watchful waiting group whose disease progressed. In the base case, the assumption was made that half of the benefit of treatment seen in this study would be maintained in men undergoing active surveillance.

Age-specific risks of death due to causes other than prostate cancer were based on 2006 US life tables.25

Table 1. Model Inputs for Disease-Related and Treatment-Related Probabilities (continued)

<table>
<thead>
<tr>
<th>Development of genitourinary symptoms</th>
<th>Annual Probabilities</th>
<th>Base-Case Estimate (SD)a</th>
<th>Range Used in Sensitivity Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Erectile dysfunction22</td>
<td>Baseline probability at age 65 y = 0.3 (0.075)</td>
<td>Not varied</td>
<td></td>
</tr>
<tr>
<td>Development of symptoms (increases with age)</td>
<td>0.015 (0.004)</td>
<td>0.0075-0.03</td>
<td></td>
</tr>
<tr>
<td>Urinary obstruction23</td>
<td>Baseline probability at age 65 y = 0.3 (0.075)</td>
<td>Not varied</td>
<td></td>
</tr>
<tr>
<td>Development of symptoms (increases with age)</td>
<td>0.011 (0.003)</td>
<td>0.0055-0.022</td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: DRE, digital rectal examination; IMRT, intensity-modulated radiation therapy; PSA, prostate-specific antigen.

With one exception, where standard deviations are provided the parameter was varied (range, 0-1) in probabilistic sensitivity analysis. Parameters a and b were derived from the mean and standard deviation in TreeAge Pro using the following formulas: a=mean x (1−mean)/(SD2); b=mean x (1−mean)/(SD2)−a. The exception was the probability of developing metastatic disease prior to treatment while undergoing active surveillance, which was estimated in probabilistic sensitivity analysis using a uniform distribution.

Major complications include major bleeding, deep vein thrombosis/pulmonary embolus, myocardial infarction/stroke, bowel injury, and major/systemic infection.5

Minor complications represent outcomes not typically requiring reexploration or invasive intervention (eg, urinary tract infection, hematoma, ileus).

Sensitivities include irritative voiding symptoms and incontinence.

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Sensitivity analysis. Parameters a and b were derived from the mean and standard deviation in TreeAge Pro using the following formulas: a=mean x (1−mean)/(SD2); b=mean x (1−mean)/(SD2)−a. The exception was the probability of developing metastatic disease prior to treatment while undergoing active surveillance, which was estimated in probabilistic sensitivity analysis using a uniform distribution.

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Men receiving brachytherapy are also at risk of acute urinary retention. Secondary malignancy risks emerge 10 years after radiation and persist for life.26-30 Men treated with IMRT with androgen deprivation therapy experience erectile dysfunction for the year following androgen deprivation therapy administration.31

Complications and Adverse Effects
Radical Prostatectomy. Complications of radical prostatectomy occur within 30 days of surgery and include perioperative mortality, major complications, and minor complications (Table 1).5-7 Adverse effects include erectile dysfunction and urinary incontinence and are defined as short-term (occurring and resolving within 90 days of treatment) or long-term (occurring or continuing 90 days to 12 months after surgery and remaining stable after 1 year).

Radiation Therapy. For men undergoing radiation therapy, short-term adverse effects occur and resolve within 90 days of treatment; long-term adverse effects occur within 2 years of treatment and remain stable after 2 years. Adverse effects meet or exceed grade 2 on the Radiation Therapy Oncology Group or Common Toxicity Criteria scales and include short- and long-term urinary symptoms (including irritative voiding symptoms and incontinence), bowel disturbances, and long-term erectile dysfunction (Table 1).26,27

Utilities
A utility is a weight assigned to an individual’s preference for a particular health state, with a range between 0 (death) and 1 (perfect health). Quality-adjusted life-years (QALYs) are generated when this weight is applied to a year of life in the health state described; ie, a higher QALY reflects a year of life in a preferred health state. In the
base case, utilities were elicited from men without a diagnosis of prostate cancer using the time–trade-off method, in which individuals are asked to define the amount of time they would be willing to sacrifice to be in a better health state vs a poorer health state (Table 2). Sensitivity analyses were conducted using patient-derived utilities. In the model, patients maintain posttreatment utilities until death, with the exception of utilities related to short-term adverse effects and erectile dysfunction attributed to androgen deprivation therapy.

**Sensitivity, Threshold, and Probabilistic Sensitivity Analyses**

We conducted 1-way and multiway sensitivity analyses around key variables (ranges are given in Table 1 and Table 2). Threshold analyses were performed to identify probability and utility values at which the optimal strategy (as defined by the highest QALE) changed. Sensitivity analysis was also performed to assess the effect of discounting on model results (eTable 2).

Probabilistic sensitivity analysis was performed and effectiveness calculated for each strategy from 500 samples consisting of 100,000 individual trials run with unique sets of draws from independent distributions around 45 parameters, including probability of prostate cancer–specific death during active surveillance, complications and adverse effects of treatment, and utilities. Uncertainty around event probabilities and utilities was represented using β distributions (Table 1) except for uncertainty around the probability of developing metastatic disease prior to treatment during active surveillance, which was estimated using a uniform distribution.

**RESULTS**

**Base Case**

In men aged 65 years, active surveillance, with IMRT for progression, was the most effective strategy (defined as the strategy associated with the highest QALE) producing 11.07 QALYs. Brachytherapy and IMRT were less effective at 10.57 and 10.51 QALYs, respectively. Radical prostatectomy was the least effective treatment, yielding 10.23 QALYs. The difference between the most and least effective initial treatment was 0.34 QALYs, or 4.1 months of QALE. In contrast, active surveillance provided 6.0 additional months of QALE compared with brachytherapy, the most effective initial treatment.

In the base case, 61% of men initially followed up with active surveillance underwent definitive treatment during their lifetimes because of progressive disease or patient choice at a median of 8.5 years after diagnosis, similar to recent published experience.

**Active Surveillance: Evaluation of Key Model Parameters**

The results of sensitivity and threshold analyses in which active surveillance yielded a lower QALE than an initial treatment are reported herein. Analyses using patient-derived utilities (eTable 3 and eTable 4) and which varied the probability of disease progression during active surveillance (eTable 5), developing symptoms of disease during active surveillance (eTable 5), adverse effects of treatment (eTable 6), and the utilities associated with symptoms during active surveillance (eTable 7) resulted in QALE estimates favoring active surveillance.

**Risk of Prostate Cancer–Specific Death**

We conducted a threshold analysis to identify how much greater the risk of prostate cancer–specific death would have to be under active surveillance compared with initial treatment for the 2 approaches to be associated with equal QALE. For QALE to be equal, 15% of men undergoing active surveillance would have to die of prostate cancer as opposed to 9% who received initial treatment, a lifetime relative risk of
death of 0.6 for initial treatment vs surveillance.

Analyses of Utilities. The utility or value assigned by individuals to a particular health state is of central importance in the analysis of QALE. Two utilities were key to determining the favored strategy in the base case: (1) the utility for undergoing active surveillance and being at risk of cancer progression (living under active surveillance) and (2) the utility for having been treated and being at risk of recurrence but not experiencing adverse effects of treatment (posttreatment without adverse effects) (eTable 7 and eTable 8).

Figure 1 demonstrates this dependence. The line on the graph represents the points at which the QALE of active surveillance was equal to initial treatment with brachytherapy; the shaded area to the right and below the line represents values of the utility for living under active surveillance at which active surveillance produced higher QALE than initial treatment. For example, if the utility for active surveillance was 0.83 (the base-case value), the posttreatment utility had to be less than 0.88 for active surveillance to remain associated with higher QALE. If the posttreatment utility was 0.8 (the base-case value), the utility for living under active surveillance had to be greater than 0.77 for active surveillance to be favored.

When deciding whether to undergo active surveillance, patients and clinicians must weigh the psychological burden of living with prostate cancer and the disease-specific risk of doing so. We therefore performed a threshold analysis simultaneously varying the utility for active surveillance and the incidence of prostate cancer–specific death to identify at which values of each active surveillance would continue to be favored over initial treatment. Figure 2 represents the values of utility for active surveillance and incidence of prostate cancer–specific death at which the QALE generated by the model is equal to initial treatment (with brachytherapy). For example, if the utility for active surveillance was 0.9, active surveillance produced a higher QALE than initial treatment even with a risk of prostate cancer–specific death of up to 19%.

Probabilistic Sensitivity Analysis. Given the considerable uncertainty surrounding the model inputs, we performed a probabilistic sensitivity analysis (Table 3). These results reflect the uncertainty surrounding each parameter in the model, including utilities, adverse effects of treatment, and risk of prostate cancer–specific death during active surveillance. Although the confidence interval for each strategy is wide, the ranking of strategies and the magnitude of effect difference between the strategies was unaltered when uncertainty was incorporated. Moreover, there was no statistical advantage of any initial treatment over active surveillance.

COMMENT

Men aged 65 years at diagnosis followed up with active surveillance received an additional 6.0 months of QALE compared with treatment with brachytherapy, the most effective initial treatment, in the base-case results. This analysis demonstrates that when a broad spectrum of possible disease- and quality of life–related outcomes associated with active surveillance and treatment is taken into account, active surveillance is a reasonable approach to consider in 65-year-old men with clinically localized, low-risk prostate cancer.

However, in the United States, active surveillance is used infrequently for management of prostate cancer. Although 16% to 40% of men newly diagnosed as having prostate cancer meet criteria for active surveillance, less than 10% of eligible men elect this approach.40,41 Barriers to its use have included concerns about long-term disease outcomes, the perception that most men will ultimately undergo treatment, and concerns about the quality of life of men who elect active surveillance.42,43 The long-term outcomes of men who undergo active surveillance are poorly characterized. Prospective studies of active surveillance have differing eligibility criteria for active surveillance, less than 10% of eligible men elect this approach.40,41 Barriers to its use have included concerns about long-term disease outcomes, the perception that most men will ultimately undergo treatment, and concerns about the quality of life of men who elect active surveillance.42,43

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bility criteria and triggers for treatment, complicating the interpretation of results\(^9\). The relative merits of one set of eligibility criteria and treatment triggers over another for capturing clinically significant disease and minimizing overtreatment have not been established. Recently, Klotz et al\(^9\) published results on the cohort with the longest median follow-up to date, 6.8 years. Thirty percent of the cohort progressed to definitive treatment; outcomes were favorable after short follow-up, with 97.2% 10-year prostate cancer–specific survival and 78.6% overall survival.

Given the uncertainty surrounding long-term outcomes with active surveillance, we analyzed the effect on the results of varying the estimates of prostate cancer–specific death and progressive disease during active surveillance. In the base case, we assumed that the relative risk of prostate cancer–specific death after initial treatment compared with active surveillance was 0.83, half that of radical prostatectomy compared with watchful waiting as reported in a randomized controlled trial.\(^24\) In that trial, men were not screen-detected and in general had higher-risk disease than patients typically followed up with active surveillance, who are offered potentially curative treatment. The relative risk of prostate cancer–specific death was 0.65 (95% confidence interval, 0.45-0.94) for treatment vs watchful waiting in men of all ages; in men older than 65 years, the relative risk was 0.87 (95% confidence interval, 0.51-1.49) and was not significant. We chose 0.83 as the base case assumption of relative risk to approximate a conservative but reasonable risk of prostate cancer–specific death in the absence of a randomized controlled trial comparing treatment to active surveillance. We then performed sensitivity analyses to assess the point at which the QALE advantage of active surveillance could be overcome by a higher risk of prostate cancer–specific death. For active surveillance and initial treatment to be associated with equal QALE, the relative risk of prostate cancer–specific death after initial treatment vs active surveillance would have to be 0.6. Even if choosing active surveillance places men at a substantially higher risk of dying of prostate cancer or the risk of progressive disease on active surveillance is doubled, active surveillance is associated with higher QALE.

Few studies of quality of life in men undergoing active surveillance have been performed, and even fewer have measured utilities for active surveillance health states. However, anxiety in men who have chosen active surveillance or watchful waiting has not been shown to be higher than in men who elect initial treatment.\(^46\-47\)

In this analysis, active surveillance was favored over initial treatment for low-risk disease in men aged 65 years at diagnosis, but this result was highly dependent on the utility individuals place on living under active surveillance compared with having been treated.\(^46\) In the base case, the utility for living under active surveillance was 0.83; having been treated without adverse effects of therapy but at risk of recurrence carried a utility of 0.80.2 values taken from the same population.\(^36\) If these values are varied, the results of the model change significantly. If the utility for active surveillance is raised above 0.94, active surveillance is favored no matter the utility assigned to the posttreatment health state. If the utility for the posttreatment health state is 0.80 (the base-case value), the utility for active surveillance must be greater than 0.77 for active surveillance to be favored. To place this utility in context, a utility of 0.77 is assigned to living with both impotence and urinary difficulty (Table 2). However, there is no posttreatment utility at which initial treatment is favored independent of the utility for living under active surveillance. Figure 1 demonstrates the importance of utilities in the model results but also reflects the central role of patient preference in the decision-making process.

These findings challenge the perception that active surveillance is a reasonable approach only if the risk of prostate cancer–specific death is equal to that seen with initial treatment. We found that as the utility for living under active surveillance increases, the minimal risk of prostate cancer–specific death associated with active surveillance necessary for initial treatment to be favored increases as well (Figure 2). This analysis simulates the decision-making process experienced by patients and physicians, who must weigh disease-specific and psychological risks of active surveillance.

Probabilistic sensitivity analysis indicates the degree to which uncertainty surrounding each variable affects the results as a whole. The uncertainty surrounding the probabilities and utilities used in the model reflects the gaps in the published literature from which we generated the model inputs. We have been conservative in modeling, assuming a high degree of uncertainty in the distribution parameters and no correlation between events, thereby exaggerating the uncertainty in the results. The overlapping confidence intervals seen in this analysis are therefore not unexpected. However, the ranking of strategies and the magnitude of benefit of active surveillance compared with other strategies mirror the base-case results. The contribution of the probabilistic sensitivity analysis, and of this analysis as a whole, lies in the finding that despite substantial uncertainty surrounding this clinical question, active surveillance appears to be a reasonable alternative to initial treatment.

To our knowledge, this is the first decision analysis comparing active surveillance with initial treatment for low-risk prostate cancer. Previous decision analyses have compared watchful waiting with initial treatment.\(^18,48-52\) The most recent decision analysis\(^68\) used probabilities derived from Bill-Axelson et al\(^29\) for the watchful waiting cohort and found that, in contrast to our study, initial treatment was associated with a benefit in QALE for men with low- and medium-risk disease aged 70 years when average, patient-derived preferences were used. How-
ever, as in our study, individual patient preferences were critical in determining the optimal treatment for patients with low-risk disease.

This decision analysis modeled outcomes only for 65-year-old men; therefore, interpretation of these results must be limited to this population. Most studies performed to date in younger men have demonstrated disease-specific outcomes equivalent to older men.54-58 However, given the uncertainty surrounding long-term outcomes in men followed up with active surveillance, presenting results including younger men would have required extensive sensitivity analysis and discussion surrounding this issue. In addition, this model does not incorporate comorbidities common in older men. Including analyses of younger or older men would have limited the ability to consider the importance of utilities in the outcomes in healthy 65-year-old men, the focus of this analysis.

Additional limitations of this study reflect those in the literature on which model inputs were based. The results of randomized studies comparing active surveillance with initial treatment are expected to emerge over the next few years. A more comprehensive catalog of prostate cancer health states is needed, as is an assessment of the disutility associated with uncertainty among men who choose not to be actively treated.37 In addition, the use of adjuvant and salvage radiation therapy after radical prostatectomy was not modeled. In this low-risk population, the use of subsequent radiation therapy is relatively rare, and given the magnitude of QALE benefit of active surveillance compared with radical prostatectomy, it is unlikely that including a small survival benefit from subsequent radiation would substantively alter these conclusions.59-62 The quality-of-life advantage associated with active surveillance is robust in this model of treatment alternatives for men with clinically localized, low-risk prostate cancer. This benefit reflects the deferred and substantially lower incidence of adverse effects of treatment experienced by men under active surveillance. Active surveillance is associated with significant improvements in QALE even in analyses in which the probability of dying of prostate cancer or of developing progressive disease during active surveillance is increased. However, the finding that the optimal strategy is sensitive to utility weights is evidence that the decision whether to pursue active surveillance must be individualized. Models that incorporate individual patient utilities should be developed to assist patients and their caregivers to estimate the risks and potential benefits of active surveillance before making this decision.

**Author Contributions:** Dr Hayes had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. Study concept and design: Hayes, Ollendorf, Pearson, Barry, Stahl, McMahon. Acquisition of data: Hayes, Ollendorf, Pearson, Stewart, Bhatnagar, McMahon. Analysis and interpretation of data: Hayes, Ollendorf, Pearson, Barry, Kantoff, Stewart, Sweeney, Stahl, McMahon. Drafting of the manuscript: Hayes, Ollendorf, Pearson, Barry, Sweeney, Stahl, McMahon. Critical revision of the manuscript for important intellectual content: Ollendorf, Pearson, Barry, Kantoff, Stewart, Bhatnagar, Stahl, McMahon. Statistical analysis: Hayes, Ollendorf, Pearson, McMahon. Obtained funding: Hayes, Ollendorf, Pearson, Stahl. Administrative, technical, or material support: Ollendorf, Pearson, Sweeney, McMahon. Study supervision: Pearson, Barry, Kantoff, Stahl.

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**Online-Only Material:** The eAppendix, eFigures 1 through 3, and eTables 1 through 9 are available online at http://www.jama.com.

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