

Prostatectomy vs. Observation for Prostate Cancer: PIVOT

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Posted: 09/10/2012; Journal Watch © 2012 Massachusetts Medical Society

Abstract and Introduction

Abstract

Prostatectomy did not lower 10-year mortality overall; the exception was men with PSA levels >10 ng/mL.

Introduction

Until now, no randomized trial has been designed to compare surgery with "watchful waiting" in patients with primarily prostate-specific antigen (PSA)-detected, localized prostate cancer. PIVOT (Prostate Cancer Intervention versus Observation Trial), conducted in the U.S., fills this gap.

The participants — 731 men with localized prostate cancer and life expectancy of at least 10 years — were randomized to radical prostatectomy or observation. Three quarters of cases were diagnosed through PSA screening, two thirds of men had PSA levels \leq 10 ng/mL, and two thirds had Gleason scores <7. During the study, 10% of men in the observation group crossed over to prostatectomy.

At median follow-up of 10 years, neither all-cause mortality nor prostate cancer–specific mortality was significantly lower in the prostatectomy group than in the observation group. However, among men with PSA levels >10 ng/mL, mortality was lower with prostatectomy (Table). Subgroups with higher-risk cancers (defined by criteria incorporating PSA levels, Gleason scores, and tumor staging) also showed trends toward lower mortality with surgery. Bone metastases occurred in 4.7% of prostatectomy patients and in 10.6% of observation patients ($P<0.001$).

Table

Ten-Year Mortality Among Men in PIVOT

	Prostatectomy	Observation	P Value
Overall 10-year mortality:			
Entire study group	47.0%	49.9%	0.22
Subgroup with PSA levels \leq 10 ng/mL	46.2%	43.6%	0.82
Subgroup with PSA levels >10 ng/mL	48.4%	61.6%	0.02
Prostate cancer–specific 10-year mortality:			
Entire study group	5.8%	8.4%	0.09
Subgroup with PSA levels \leq 10 ng/mL	5.9%	6.2%	0.82
Subgroup with PSA levels >10 ng/mL	5.6%	12.8%	0.02

Comment

Interpretation of these results likely will depend on one's preconceptions. Clinicians predisposed to no intervention will emphasize the overall results, which suggest low probability of benefiting from radical prostatectomy. Clinicians predisposed to aggressive intervention will note that prostatectomy was associated with significantly lower 10-year mortality in prespecified subgroups. Some people will argue that PIVOT was underpowered; indeed, it fell short of its original enrollment goal of 2000 participants. Nevertheless, these findings comprise the best available data and should be used by urologists, oncologists, and primary care physicians to guide clinical decision making. Finally, given that

surgery was ineffective for men with PSA levels ≤ 10 ng/mL, it will be interesting to see whether PSA screening supporters will revise upward their favored PSA thresholds for triggering biopsy.

References

1. Wilt TJ et al. Radical prostatectomy versus observation for localized prostate cancer. *N Engl J Med* 2012 Jul 19; 367:203.