Dr. Timothy Wilt On The PIVOT Study

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Last week we posted Dr. Mack Roach's comments on the PIVOT Study. We also had the opportunity to discuss the PIVOT trial with the lead investigator himself, Dr. Timothy Wilt of the Veterans Affairs Medical Center.

Wilt says, "I originated the PIVOT study back in 1992. I was trying to address the question: in men with clinically localized prostate cancer, compared to observation, does surgery reduce mortality and help men live longer and live better?

PIVOT showed that compared to observation, radical prostatectomy did not significantly reduce all-cause mortality or prostate cancer specific mortality through twelve years. In particular, there was no reduction in men with low risk disease or low PSA, that is ten or under. There may be a benefit for individuals with intermediate or higher risk disease or higher PSA.

When asked what does the trial say about screening, I'll say that these men were diagnosed in the early PSA era, but only about half of them had PSA-detected prostate cancer. Men diagnosed today have lower PSA values and smaller volume tumors than men enrolled in PIVOT. Any benefit from treatment would likely be smaller in absolute terms and take longer should it occur. Our findings support the US Preventive Services Task Force's conclusions. But PIVOT was a treatment, not a

screening, study, was not the data the Task Force used to make their recommendations. The Task Force based its recommendations primarily on the benefit assessment from the randomized controlled screening trials that demonstrated that PSA screening resulted in small to no reduction in prostate cancer mortality through 14 years and led to screening, diagnostic testing and treatment harms that they assessed to be small to moderate."

When asked how he would respond to the criticism that the PIVOT trial was underpowered, Dr. Wilt answered:

"A larger study would be beneficial. Our study provides accurate information through at least 12 years of the estimated potential benefit of surgery versus observation. Interested men could estimate the plausible benefit by looking at what we call the confidence intervals. That it is unlikely that surgery reduces overall mortality by more than 10% points and may increase mortality by as much as up to a 4%. That's what's called confidence intervals.

I would also say it was the largest treatment trial ever conducted in men with early stage prostate cancer. We need additional treatment trials of similar patients and interventions. One, called the ProTECT study, is ongoing and should be reporting in the next couple of years.

One of the criticisms was that the number of men dying of prostate cancer was low. I say that that's informative. If we know that through a follow-up of about 12 years, the chance of dying of prostate cancer with observation is only about 7%, that's valuable information for men. Longer follow-up may change some of those results, but then what we'd know is that it takes just that much longer to find out. I think the onus really is on others to conduct new research or for us to get additional information from them. This study provides valuable information for patients, their providers and policy-makers."