

March 4, 2010

Active Surveillance/Radical Prostatectomy: Analysis of New Evidence
Original Review Release Date: September 11, 2009

New Evidence

- (1) Hu JC, Gu X, Lipsitz SR, et al. Comparative effectiveness of minimally invasive vs. open radical prostatectomy. *JAMA* 2009;302:1557-64.
- (2) Lowrance WT, Elkin EB, Jacks LM, et al. Comparative effectiveness of prostate cancer surgical treatments: a population based analysis of postoperative outcomes. *J Urol* 2010;183:1366-72.

In order to aid decision-makers in applying the results of its reviews, ICER analyzes important new evidence that emerges following the release of a final appraisal document. ICER seeks to give perspective on this evidence in light of the original conclusions of the appraisal.

Overview

Prior studies comparing outcomes between minimally-invasive (laparoscopic and robot-assisted) and traditional open prostatectomy have been criticized for their use of administrative databases that lacked data on the clinical characteristics and tumor pathology of study subjects.^{1,2} The new studies listed above linked Medicare claims data to clinical findings from the Surveillance, Epidemiology, and End Results (SEER) population-based cancer registry to address such concerns. Study timeline, duration of follow-up, and definitions of key outcomes differed somewhat between these studies; however, both included detailed clinical information and employed statistical techniques to control for differences between patients undergoing minimally-invasive vs. open prostatectomy.

In both studies, minimally-invasive surgery was associated with reduced hospital length of stay (median, 2 vs. 3 days) as well as a lower rate of bladder neck obstruction or anastomotic stricture. Rates of subsequent cancer therapy did not differ between groups in either study. Small differences in the rates of peri-operative complications were observed in both studies, with no consistent direction

¹ Blute ML. Radical prostatectomy by open or laparoscopic/robotic techniques: an issue of surgical device or surgical expertise? *J Clin Oncol* 2008;26:2248-9.

² Tewari AK, Jhaveri JK, Serasi K, et al. Benefit of robotic assistance in comparing outcomes of minimally invasive versus open radical prostatectomy. *J Clin Oncol* 2008;26:4999-5000.

by surgical approach. The study by Hu et al., which also examined rates of diagnosed incontinence and erectile dysfunction at 18 months post-procedure, reported higher rates of these diagnoses among those receiving minimally-invasive surgery; however, when receipt of procedures to address incontinence and erectile dysfunction was assessed, no significant differences were observed by surgical approach.

Analysis

ICER's original rating of the comparative clinical effectiveness of robot-assisted laparoscopic vs. open prostatectomy was "unproven with potential", which indicates a net clinical benefit that is at least comparable, and possibly incremental, to the comparator; however, the evidence base is judged to be inconclusive on the presence and magnitude of the possible benefit. The findings of these two recent retrospective cohort studies draw essentially similar conclusions – while the use of minimally-invasive prostatectomy is associated with reductions in certain clinical outcomes and resource utilization, rates of other key outcomes do not differ by surgical approach or are inferior for minimally-invasive surgery. ICER therefore sees no compelling reason to change its original rating.

Future Analyses

As mentioned in ICER's appraisal of active surveillance and radical prostatectomy, several randomized controlled trials of these management options are underway. The Prostate cancer Intervention Versus Observation Trial (PIVOT), which randomized 731 U.S. men to receive radical prostatectomy or watchful waiting,³ was recently completed. It is expected that ICER will publish a subsequent analysis when the results of this trial are reported.

³ Wilt TJ, Brawer MK, Barry MJ, et al. The Prostate cancer Intervention Versus Observation Trial:VA/NCI/AHRQ Cooperative Studies Program #407 (PIVOT): design and baseline results of a randomized controlled trial comparing radical prostatectomy to watchful waiting for men with clinically localized prostate cancer. *Contemp Clin Trials* 2009;30:81-7.