

OVERVIEW
Radical Prostatectomy

Introduction

Radical prostatectomy has long been an option for the treatment of prostate cancer. The procedure involves the surgical removal of the prostate gland as well as seminal vesicles and, in some cases, lymph nodes. It is typically performed when the cancer is localized to the prostate. Candidates for surgery are typically in good overall health with a life expectancy of at least 10 years. There are 4 major approaches commonly employed in radical prostatectomy:

- **Open Prostatectomy**
 - *Radical retropubic prostatectomy*: the most common form of the procedure, in which the incision begins below the navel and extends to the pubic bone
 - *Radical perineal prostatectomy*: involves an incision from the anus to the base of the scrotum
- **Minimally-Invasive Prostatectomy**
 - *Laparoscopic prostatectomy*: this technique requires several small incisions and is performed with surgical instruments that are inserted through the incisions, using a laparoscopic camera that allows the surgeon to view the surgical field in real time
 - *Robot-assisted prostatectomy*: a type of laparoscopic technique in which the surgeon manipulates a robotic arm to perform the procedure while seated at a viewing console nearby

Modern applications of both open and laparoscopic prostatectomy (with the exception of the perineal approach) also involve the use of “nerve-sparing” techniques to preserve post-surgical erectile function. Utilization of laparoscopic procedures in particular has increased dramatically in the last few years, given the appeal of potentially shorter hospital stays and recovery time with these procedures. In a national survey of radical prostatectomy patterns from 2003 to 2005, utilization of laparoscopic procedures, including robot-assisted surgeries, increased from 6.2% to 21.6% of all prostatectomies. At the same time, retropubic procedures decreased from 86.6% to 72.8%, and perineal procedures decreased from 5.2% to 4.1% of all such surgeries. The rapid change in utilization has not been accompanied by a

robust understanding of differences between these procedures in patient outcomes, resource utilization, and costs. Areas of uncertainty around radical prostatectomy techniques include:

- 1) Differences among the prostatectomy techniques in operating room time, length of stay in hospital, recovery time, and procedure-related complications.
- 2) The impact of variability in physician volume and experience on patient outcomes.
- 3) Clinical and cost-effectiveness of radical prostatectomy relative to other therapy alternatives (e.g., active surveillance, radiation therapy modalities).
- 4) How best to share existing evidence and remaining uncertainties with patients and families to inform decision-making.

Professional Organization and Agency Recommendations

- American Urological Association (2007):
<http://www.auanet.org/content/guidelines-and-quality-care/clinical-guidelines/main-reports/proscan07/content.pdf>
The AUA has concluded that radical prostatectomy is considered one of the viable monotherapy options for clinically localized, low-risk prostate cancer, along with active surveillance, external beam radiotherapy, and interstitial brachytherapy, and that “study outcomes data do not provide clear-cut evidence for the superiority of any one treatment.”
- National Comprehensive Cancer Network (2008):
http://www.nccn.org/professionals/physician_gls/PDF/prostate.pdf
The NCCN Prostate Cancer Panel Members determined that radical prostatectomy is appropriate for “any patient with clinically localized prostate cancer that can be completely excised surgically, who has a life expectancy of 10 years or more and no serious co-morbid conditions that would contraindicate an elective operation.” It is also stated that laparoscopic and robot-assisted procedures are common and that results can be similar to the open surgical procedure in experienced hands.
- National Institute for Health and Clinical Excellence (2008):
<http://www.nice.org.uk/nicemedia/pdf/CG58NICEGuideline.pdf>
NICE released official guidelines on radical prostatectomy in which it was recommended that radical prostatectomy should be offered to patients with localized prostate cancer at intermediate or high risk. It was stated that while laparoscopic and robotically-assisted techniques resulted in lower blood loss and shorter inpatient stays, no evidence exists that benefits any treatment over another.

- European Association of Urology (2007):
http://www.uroweb.org/fileadmin/user_upload/Guidelines/07_Prostate_Cancer_2007.pdf
 Patients with a T1b, T1c, or T2 stage tumors and life expectancy of over 10 years can be recommended to undergo radical prostatectomy. Laparoscopic and robot assisted laparoscopic procedures seem to have similar short-term outcomes as compared to high volume centers for open radical prostatectomy; however, long term outcomes are unknown.

Recent Technology Assessments

- California Technology Assessment Forum (2008):
<http://www.ctaf.org/content/assessment/detail/872>
 Robotic assisted laparoscopic radical prostatectomy did not meet CTAF criteria, as it was deemed that evidence was insufficient to conclude any of the following:
 1. The technology must improve net health outcomes.
 2. The technology must be as beneficial as any established alternatives.
 3. The improvement must be attainable outside of the investigational setting.
- Medical Services Advisory Committee (MSAC, Australia) (2006):
<http://www.msac.gov.au/internet/msac/publishing.nsf/Content/app1091-1>
 Robotic-assisted laparoscopic radical prostatectomy is at least as safe as and possibly safer than open radical prostatectomy. It is as effective as open surgery and may have additional advantages. The cost-effectiveness compared to open surgery is unknown.
- Agency for Healthcare Research and Quality (2008):
<http://effectivehealthcare.ahrq.gov/healthInfo.cfm?infotype=rr&ProcessID=9&DocID=79#section4>
 In an analysis of the comparative risks, benefits, and outcomes of therapeutic options for clinically-localized prostate cancer, including radiation therapy, radical prostatectomy, and active surveillance, AHRQ concluded that “no one therapy can be considered the preferred treatment for localized prostate cancer due to limitations in the body of evidence as well as the likely tradeoffs an individual patient must make between estimated treatment effectiveness, necessity, and adverse effects.”
- Canadian Agency for Drugs and Technologies in Health (CADTH, Canada):
 CADTH has not recently reviewed open, laparoscopic, or robot-assisted radical prostatectomy.

Coverage Policies

- Centers for Medicare and Medicaid Services (CMS): CMS does not have a national coverage decision on radical prostatectomy (open, laparoscopic, or robot-assisted). Local coverage decisions indicate that robot-assisted laparoscopic prostatectomy is a covered service, and that reimbursement is identical to that for general laparoscopic prostatectomy.
- CIGNA: Radical prostatectomy is covered for the treatment of prostate cancer. CIGNA stipulates that no additional reimbursements are provided for the use of robotic-assisted surgical techniques.
- United Healthcare: "Laparoscopic radical prostatectomy is proven for the treatment of localized prostate cancer. Robotic-assisted radical prostatectomy is proven non-preferentially as a form of laparoscopic radical prostatectomy for the treatment of localized prostate cancer. Coverage for robotic-assisted radical prostatectomy is not differentiated from laparoscopic radical prostatectomy."
- Blue Cross/Blue Shield of Massachusetts: Robot-assisted laparoscopic radical prostatectomy is covered for treatment of prostate cancer; no additional reimbursements are provided for use of the robotic technique.

Ongoing Research (from www.clinicaltrials.gov)

Trial Sponsor /Title	Design	Primary Outcomes	Populations	Variables	Comments
Dep. of Veterans Affairs, NCI, AHRQ (NCI high priority trial) NCT00007644 "PIVOT Trial"	RCT	<ul style="list-style-type: none"> ▪ All cause mortality ▪ CAP mortality ▪ Survival – disease free and progression free ▪ Quality of life ▪ Cost effectiveness 	<ul style="list-style-type: none"> ▪ N = 1,050 ▪ Age < 75 	Radical prostatectomy vs. Palliative expectant management	Final data collected November 2009.
National Cancer Institutes of Canada and United States NCT00499174 "START Trial"	RCT	<ul style="list-style-type: none"> ▪ Disease-specific survival ▪ QOL ▪ Overall survival ▪ Progression after radical intervention ▪ ADT initiation ▪ Biomarkers and PSA doubling-time 	<ul style="list-style-type: none"> ▪ N=2,130 ▪ Age ▪ PSA level of 10 ng/mL or less and Gleason score 6 or less 	Standard treatment (surgery, brachytherapy, EBRT, vs. active surveillance)	Final data collection 2023
Oxford Radcliffe Hospital NCT00632983 "ProtecT Study"	RCT	<ul style="list-style-type: none"> ▪ Survival ▪ Disease progression ▪ Complications ▪ Quality of life 	<ul style="list-style-type: none"> ▪ N=2050 	Watchful waiting vs. radical prostatectomy vs. radiation	Multi-center study. Final data collection 2013.
Memorial Sloan-Kettering, NCT00578123	RCT	<ul style="list-style-type: none"> ▪ Potency after 2 years ▪ Recovery of continence 	<ul style="list-style-type: none"> ▪ N=450 ▪ Clinical stage T1-3a, NX or N0, Mx or M0 	Open vs. robot assisted vs. laparoscopic prostatectomy	Final data to be collected July 2010.
William Beaumont Hospital NCT00442000	Retrospective Observational	<ul style="list-style-type: none"> ▪ Perioperative outcomes ▪ Postoperative outcomes 	<ul style="list-style-type: none"> ▪ N=1000 ▪ Age > 18 	Robotic, Retropubic, and Perineal Prostatectomy	Ongoing, but no longer recruiting. Final data collection was November 2008.
Lawson Health Research Institute NCT00292019	Retrospective observational	<ul style="list-style-type: none"> ▪ Operative outcome ▪ Quality of life ▪ Details of procedure 	<ul style="list-style-type: none"> ▪ N=20 ▪ Age 40-65 ▪ Stage T1a, T2a or T2b prostate cancer 	Robotic laparoscopic radical prostatectomy	Study began in March 2004.
European Organization for Research and Treatment of Cancer NCT00027794	Interventional, Open Label	<ul style="list-style-type: none"> ▪ Success rate for locally advanced pts ▪ Toxic event rates ▪ pN status of patients ▪ 2-year PSA survival ▪ Surgical morbidity 	<ul style="list-style-type: none"> ▪ N = 32 to 74 ▪ Age <70 ▪ Locally advanced cancer 	Radical prostatectomy	Study began in 2001. This is multicenter study.