



Evidence-Based Series 17-3 Version 2

A Quality Initiative of the
Program in Evidence-based Care (PEBC), Cancer Care Ontario (CCO)

Guideline for Optimization of Surgical and Pathological Quality Performance for Radical Prostatectomy in Prostate Cancer Management

The Expert Panel on Prostate Cancer Surgery and Pathology

An assessment conducted in January 2024 deferred the review of Evidence-Based Series (EBS) 17-3 Version 2. This means that the document remains current until it is assessed again next year. The PEBC has a formal and standardized process to ensure the currency of each document ([PEBC Assessment & Review Protocol](#))

EBS 17-3 Version 2 is comprised of 4 sections. You can access the summary and full report here:

<https://www.cancercareontario.ca/en/guidelines-advice/types-of-cancer/556>

- Section 1: Surgical and Pathological Guidelines (ENDORSED)
- Section 2: Evidentiary Base
- Section 3: EBS Development Methods and External Review Process
- Section 4: Document Review Summary and Tool

October 13, 2017

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Guideline Document History

GUIDELINE VERSION	SYSTEMATIC REVIEW		PUBLICATIONS	NOTES and KEY CHANGES
	Search Dates	Data		
Original version September 2008	1996- March 2007	Full Report	Can Urol Assoc J. 2010 Feb 1;4(1):13-25. Web publication	N.A.
Current Version 2 October 2017	March 2007 - May 2016	New data found in Section 4: Document Assessment and Review	Updated web publication	2008 recommendations ENDORSED Sections 2 and 3 are unchanged from the original 2008 guideline



Evidence-Based Series #17-3 Version 2: Section 1

Guideline for Optimization of Surgical and Pathological Quality Performance for Radical Prostatectomy in Prostate Cancer Management: Surgical and Pathological Guidelines

The Expert Panel on Prostate Cancer Surgery and Pathology

A Quality Initiative of the Surgical Oncology Program, Cancer Care Ontario
and the Program in Evidence-based Care, Cancer Care Ontario
A Special Project of the Expert Panel on Prostate Cancer Surgery and Pathology

These guideline recommendations have been ENDORSED, which means that the recommendations are still current and relevant for decision making. Please see Section 4: Document Assessment and Review for a summary of updated evidence published between 2007 and 2016 and for details on how this Clinical Practice Guideline was ENDORSED

October 13, 2017

QUESTIONS

Surgical Questions

What are the recommended surgical procedures and outcomes for radical prostatectomy (RP), specifically:

1. What is the recommended extent of resection, and what is an acceptable positive margin rate?
2. What are the reported rates for surgical complications, specifically incontinence, erectile dysfunction, rectal injury, and blood transfusion, and does surgical technique (e.g., nerve sparing, bladder neck preservation) affect complication rates?
3. Under what circumstances should nerve-sparing techniques be used?
4. Which patients should receive pelvic lymph node dissection (PLND), and what is the recommended extent of PLND?

Pathological Questions

1. What are the recommended procedures for handling the RP specimen in the operating room and for handling and processing the RP specimen (with or without lymph nodes) in the pathology lab?
2. What diagnostic and prognostic elements should be included in the pathology report, what format should be used, and what reporting elements should be included?

Target Population

The target population is adult males with potentially curable prostate cancer for whom RP is the preferred treatment option.

- Risk Categories: Patients may be considered “low”, “intermediate”, or “high” risk for treatment failure (e.g., local recurrence, biochemical failure with prostate-specific antigen [PSA] relapse, emergence of metastatic disease) based on disease characteristics using the definitions proposed by D’Amico et al (1).
Patient Risk:
 - Low Risk: PSA <10, Gleason ≤ 6, and clinical stage T1 or T2
 - Intermediate Risk: PSA 10-20, and/or Gleason 7
 - High Risk: PSA >20, Gleason ≥ 8, or clinical stage ≥T3

RECOMMENDATIONS

The following recommendations are based on the expert opinion consensus of members of the Prostate Cancer Surgery and Pathology Expert Panel (For membership, please see Section 2: Appendix 5.) and informed by evidence from case series studies located through a systematic review of the available clinical evidence. The pathological questions are largely addressed by the protocol for invasive carcinomas of the prostate gland developed by the College of American Pathologists (CAP). The 2006 version was endorsed by the CCO Expert Panel on Prostate Cancer Surgery and Pathology during preparation of the original 2008 guideline.

Qualifying Statement - Added to the 2017 Endorsement:

The recommendations for pathology were updated to align with the most recent CAP protocol released in February 2017 (2), based on the International Society of Urological Pathology (ISUP) consensus conferences in 2009 (3-8) and 2014 (9, 10), the (2016) WHO/IARC classification of urological tumours (11) and the seventh edition AJCC cancer staging manual. The eighth edition of the AJCC (12) will come into effect January 1, 2018 and a corresponding version of the CAP protocol was released June 2017 (13) in preparation for this change. The current documents may be obtained from the CAP website: http://www.cap.org/web/home/protocols-and-guidelines?_adf.ctrl-state=an0gly311_54&_afLoop=482850301561693# See Section 4, for additional information.

SURGICAL RECOMMENDATIONS

The main goals of RP are (a) complete eradication of the cancer-containing organ with negative surgical margins, (b) preservation of urinary function, and (c) preservation of erectile function, where appropriate, but, in some cases, it is not possible to achieve all three. Positive surgical margins are associated with higher rates of cancer recurrence, but techniques for the preservation of urinary and erectile function may result in positive margins.

The consensus opinion of the expert panel is that the following techniques and objectives form the basis for good surgical management during RP. In Ontario currently, most RPs are performed via the open retropubic route, but other methods are acceptable.

Radical Prostatectomy

- RP should be offered to low-risk and intermediate-risk patients for whom surgery is the preferred option after full discussion with patient and taking into account patient preferences.
- The decision to offer surgery to high-risk patients should be made with careful consideration. High-risk patients should be offered a referral for radiation consultation or review at a Multidisciplinary Cancer Conference (MCC). The intent of the MCC is to ensure that all appropriate diagnostic tests, all suitable treatment options, and the most appropriate treatment recommendations are generated for each cancer patient and discussed prospectively with a multidisciplinary team with the knowledge and tools to provide a full array of surgical interventions, systemic and radiation treatments, and supportive and palliative care. The incidence of positive margins in this patient group is expected to be higher than in that for pT2 disease.
- Sparing of the neurovascular bundles should be considered the “standard approach” except for high-risk patients.
- In patients with otherwise low or intermediate risk, where there is an increased likelihood of positive margins, based on clinical evidence, or the likelihood of extracapsular tumour extension and risk categorization, wide excision of the neurovascular bundles would be warranted in order to avoid compromising cancer control.
- The panel consensus was that the goals are to achieve rates of <1% mortality, <1% for rectal injury and <10% for blood transfusion in non-anemic patients.
- Radical Prostatectomy should aim at achieving a negative margin, while ensuring a balance between margin rates and functional outcomes

Qualifying Statements - Added to the 2017 Endorsement:

The original 2008 recommendation on positive margin rates was modified in 2017 by the Expert Panel, removing the reference to a specific target and not limiting that patient population to pT2 cases. See Section 4 for additional information.

The original and the revision to the positive margin rate recommendations are based on the expert opinion of the guideline panels. In the updated literature review (to May 2016) no new data were identified to directly inform this recommendation.

Pelvic Lymph Node Dissection

- Standard PLND should be mandatory in high-risk patients and is recommended for the intermediate group. PLND is optional for low-risk patients. (Standard PLND should include all lymphatic tissue along the external iliac vein from the lymph node of Cloquet distally to the bifurcation of the common iliac vein proximally and includes all lymphatic tissue in the obturator fossa.)
- Evidence and opinions on the role of extended PLND in high-risk patients are divided. (An extended PLND entails the removal of lymph nodes medial and lateral to the internal iliac vessels up to and around the bifurcation of the common iliac artery, with the genitofemoral nerve as the lateral limit.)

Technical Considerations for Radical Prostatectomy

- For additional specific details concerning technical considerations for RP refer to Section 2: Appendix 4.a) of this document.

PATHOLOGICAL RECOMMENDATIONS

Handling of the Radical Prostatectomy Specimen in the Operating Room

- Frozen section analysis of the radical prostatectomy specimen (RPS) for margin status is not recommended.
- For routine handling, the RPS should be fixed in 10% neutral buffered formalin or other appropriate fixative. The specimen should be put in an appropriately sized container with a minimum formalin/tissue ratio of 10:1 (i.e., 500 cc formalin for a 50 cc prostate).

Pathology Requisition Information

- The surgical specimen should be accompanied by an appropriate pathology requisition that includes demographic and other identifying information, relevant clinical data (e.g., serum PSA, DRE findings [T1c versus T2], Gleason score on biopsy), and the history of neoadjuvant therapy (e.g., hormones)

Pathology Report

- The surgical pathology report should include the relevant diagnostic and prognostic information as outlined in the CAP Cancer Protocol for Carcinomas of the Prostate Gland (2, 13). CCO has recommended as a minimum standard that all required (core) elements on the CAP checklist be included in the RPS pathology report.

Added to the 2017 Endorsement:

See Section 4, Appendix 2 for the updated checklist.

- It is recommended that the diagnostic and prognostic factors be presented as a synopsis as opposed to a narrative or paragraph form. Data from CCO indicates that synopses are more likely to be complete.

Technical Considerations for Handling and Processing the Radical Prostatectomy Specimen in the Pathology Laboratory

- For additional specific details concerning technical considerations for handling and processing, refer to Section 2: Appendix 4.b) of this document.
- In the Pathology Laboratory, the RPS (with or without lymph nodes) is accessioned in the usual fashion.
- The RPS should be fixed in neutral buffered formalin (minimum 10:1 ratio) for a minimum of 18-24 hours prior to sectioning. A microwave-assisted technique may be used to reduce fixation time.
- The prostate gland should be weighed and measured in three dimensions; seminal vesicles should be measured; accompanying lymph node specimens should also be measured and a record made of the number and size of grossly identified nodes.
- The outer aspects of the RPS should be carefully inked to identify the surgical margins, prior to tissue banking.
- After appropriate fixation and inking, the distal apical segment is transected and then serially sectioned, perpendicular to the inked surface. An en face (shave) technique is to be discouraged at the apex, as this approach can result in false-positive margin interpretation.

- The basal (bladder neck) aspect is commonly doughnut shaped and irregular. It is transected from the main specimen and should also be submitted in a perpendicular fashion to minimize the possibility of a false-positive margin at this location.
- The intervening transverse sections can be either totally or subtotally submitted using regular-sized blocks. The submission protocol should be documented with an appropriate diagrammatic or written block legend.
- For subtotal submissions, a systematic approach to include the posterolateral peripheral zone should be used.
- All lymph nodes accompanying the RPS should be submitted for histological analysis. It is not necessary to submit all perinodal fat, although it is often difficult to distinguish between adipose tissue and fatty lymph nodes.

- ***Updated in the 2017 Endorsement:***

The full CAP checklist and protocol for RP are available from CAP at http://www.cap.org/web/oracle/webcenter/portalapp/pagehierarchy/cancer_protocol_templates.jsp?_adf.ctrl-state=i6f2zyq5p_9&_afLoop=481147013012490#!

RELATED GUIDELINES

For a current listing of guidelines on prostate cancer, please visit the Cancer Care Ontario website at <http://www.cancercare.on.ca>:

- *Multidisciplinary Case Conference Standards*, June 2006
- *Guideline 3-1-2016-1: Brachytherapy for Patients with Prostate Cancer: American Society of Clinical Oncology/Cancer Care Ontario Joint Guideline Update*, March 2017
- *Evidence-Based Series 3-15 Version 2: Systemic Therapy in Men with Metastatic Castration-Resistant Prostate Cancer*, September 2014
- *Evidence-Based Series 3-17 Version 3: Adjuvant Radiotherapy Following Radical Prostatectomy for Pathologic T3 or Margin-Positive Prostate Cancer*, May 2014.

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