Radical Prostatectomy 2012

Summary Recommendations

Notes on PROSPECT recommendations

PROSPECT provides clinicians with supporting arguments for and against the use of various interventions in postoperative pain based on published evidence and expert opinion. Clinicians must make judgements based upon the clinical circumstances and local regulations. At all times, local prescribing information for the drugs referred to must be consulted.

Grades of recommendation (GoR) are assigned according to the overall level of evidence (LoE) on which the recommendations are based, which is determined by the quality and source of evidence. An explanation of how study quality assessments are performed to determine the LoE and GoR can be found in Appendix A: Levels of evidence and grades of recommendation.

The AGREE II instrument (Brouwers 2010) is used internationally to assess the methodological rigour and transparency of practice guidelines. As far as possible, the methodology of the PROSPECT Radical Prostatectomy review meets the requirements of 'Domain 3: Rigour of development' of the AGREE II instrument:

- Systematic methods were used to search for evidence.
- The criteria for selecting the evidence are clearly described.
- The strengths and limitations of the body of evidence are clearly described.
- The methods for formulating the recommendations are clearly described.
- The health benefits, side effects, and risks have been considered in formulating the recommendations.
- There is an explicit link between the recommendations and the supporting evidence.
- The guideline has been externally reviewed by experts prior to its publication. [The evidence and recommendations will be submitted for peer-review after publication on the PROSPECT website]
- A procedure for updating the guideline is provided. [Methodology is provided so that the systematic review can be updated as required]

Summary recommendations

Interventions that are recommended for radical prostatectomy:

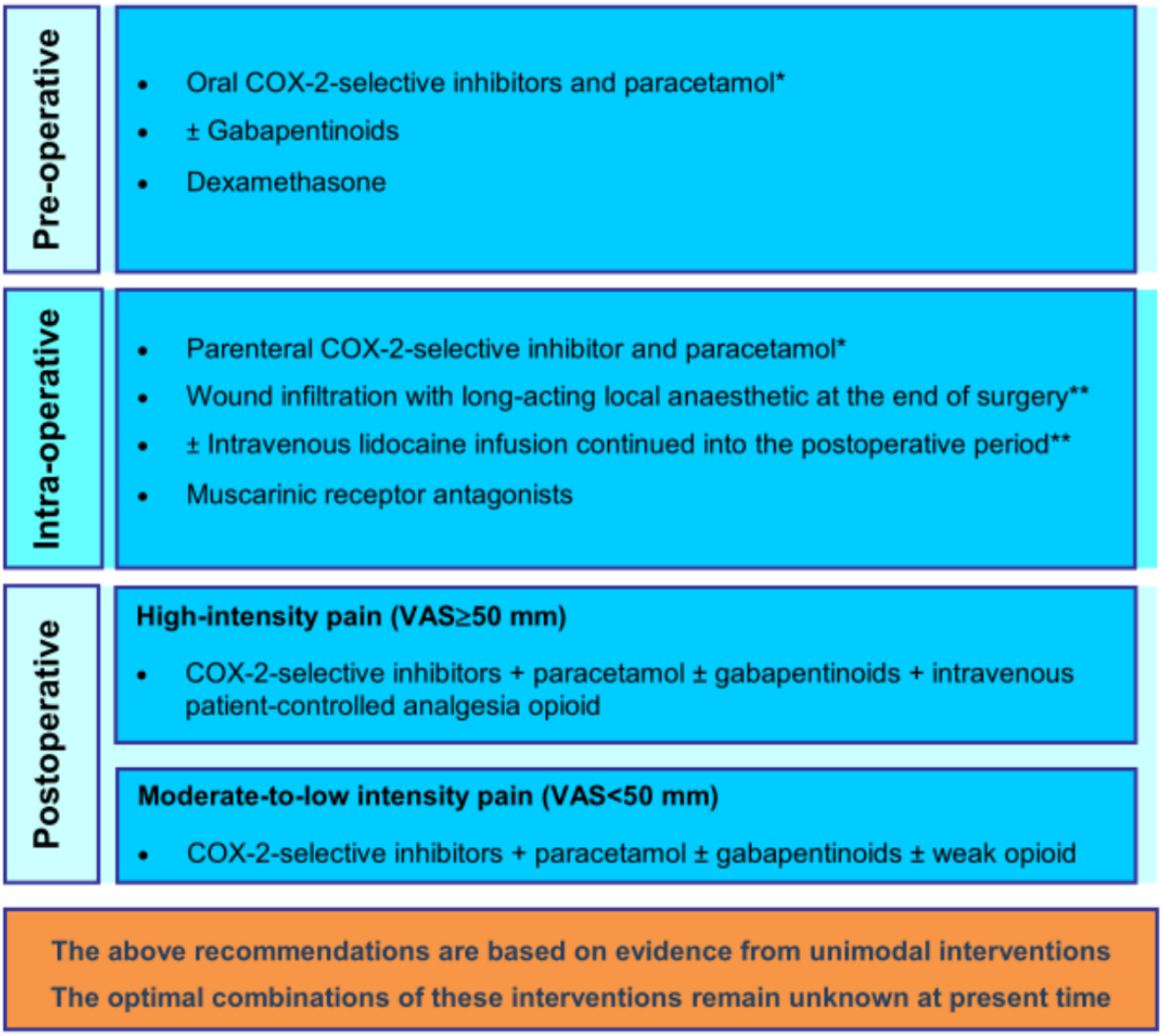
Pre-operative interventions that are recommended for radical prostatectomy Note: Unless otherwise stated, 'pre-operative' refers to interventions applied before surgical incision Note: All analgesics should be administered at the appropriate time (pre- or intra-operatively) to provide sufficient analgesia in the early recovery period	
COX-2-selective inhibitors	• As with all analgesics, COX-2-selective inhibitors should be administered at the appropriate time (pre- or intra-operatively) to provide sufficient analgesia in the early recovery period (GoR B), based on transferable evidence from diverse procedures showing analgesic efficacy (LoE 1)
Dexamethasone	• Pre-operative dexamethasone is recommended both for its analgesic and anti-emetic effects (GoR B), based on transferable evidence from multiple procedures (LoE 1), despite lack of procedure-specific evidence
Gabapentinoids	• Pre-operative gabapentinoids are recommended (GoR B) based on transferable evidence from multiple procedures showing analgesic efficacy (LoE 1), despite lack of procedure-specific evidence
Intra-operative interventions that are recommended for radical prostatectomy Note: Unless otherwise stated, 'intra-operative' refers to interventions applied after incision and before wound closure Note: All analgesics should be administered at the appropriate time (pre- or intra-operatively) to provide sufficient analgesia in the early recovery period Note: All intra-operative anaesthetic and/or analgesic interventions are considered in the postoperative section.	
Postoperative interventions that are recommended Note: 'Postoperative' refers to interventions applied at or after wound closure	
COX-2-selective inhibitors	• COX-2-selective inhibitors are recommended (GoR B) based on transferable evidence from multiple procedures showing analgesic efficacy (LoE 1), despite a lack of procedure-specific evidence

Systemic lidocaine	• Lidocaine infusion is recommended for radical prostatectomy (GoR B), due to transferable evidence from multiple procedures showing analgesic efficacy (LoE 1) despite limited procedure-specific evidence
Systemic strong opioids	• Systemic strong opioids are recommended following prostatectomy (GoR B), based on transferable evidence from multiple procedures, for their efficacy in reducing high-intensity postoperative pain (VAS >/=50 mm) (LoE 1), with the following considerations: • Systemic strong opioids should be used in combination with COX-2-selective inhibitors and paracetamol to reduce opioid use and its associated side-effects (GoR D) • IV PCA strong opioids are recommended (GoR B) based on greater patient satisfaction compared with regular (fixed-interval) or PRN dosing (transferable evidence, LoE 1); however, fixed-interval IV administration titrated to pain intensity is also recognised as an effective mode of administration (LoE 4)
Systemic weak opioids	• Weak opioids are recommended to be used for moderate- or low-intensity pain if non-opioid analgesia is insufficient or is contra-indicated (GoR B), based on transferable evidence (LoE 1) showing analgesic efficacy in multiple surgical procedures • Weak opioids are recommended to be used in combination with non-opioid analgesics (GoR B), based on transferable evidence (LoE 1) showing analgesic efficacy in combination regimens
Paracetamol	• Paracetamol is recommended (GoR B) due to strong transferable evidence from multiple procedures showing analgesic efficacy (LoE 1) despite lack of procedure-specific evidence • Paracetamol should be administered at the appropriate time (pre- or intraoperatively) to provide sufficient analgesia in the early recovery period (GoR D)
Alternative analgesics	• Muscarinic receptor antagonists (oxybutynin, tolterodine) are recommended (GoR B) to prevent bladder discomfort based on procedure-specific (LoE 1) and transferable evidence from various procedures (LoE 2) • For *open prostatectomy* local anaesthetic wound infiltration administered at the end of surgery is recommended (GoR B)

Wound infiltration or infusion	because transferable evidence from hernia repair shows analgesic efficacy (LoE1) and because it is a convenient technique with a favourable safety profile, despite limited procedure-specific evidence • For *video-assisted prostatectomy* local anaesthetic port-site infiltration administered at the end of surgery is recommended (GoR B) because transferable evidence from laparoscopic cholecystectomy shows analgesic efficacy (LoE 1) despite lack of procedure-specific evidence • Long-acting local anaesthetics are recommended in preference to short-acting local anaesthetics (GoR D)

Overall Recommendations: Pain Management for Radical Prostatectomy

Overall recommendations for management of pain associated with radical prostatectomy



* Administered in time to secure analgesia in immediate postoperative period

** Total dose of local anaesthetics should be adjusted to avoid the risk of systemic toxicity

IV lidocaine can be used when other approaches are not adequate or appropriate

VAS = visual analogue scale of 1–100 mm

Interventions that are NOT recommended for radical prostatectomy

Alternative analgesics: Pre-operative belladonna and opium suppository, melatonin, amantadine, or clonidine	Not recommended (GoR D) due to limited procedure-specific evidence
Intra- and postoperative conventional NSAIDs	Not recommended (GoR B) based on limited procedure-specific (LoE 2) and strong transferable evidence from multiple procedures concerning an increased risk of bleeding (LoE 1)
Intra- or postoperative ketamine	Not recommended for routine use (GoR D) because of conflicting procedure-specific evidence (LoE 4), despite favourable transferable evidence from more painful surgical procedures (LoE 1)
Lidocaine patch	Not recommended (GoR B) based on limited procedure-specific evidence
IM strong opioids	Not recommended because of the pain associated with these injections (GoR D)
Transdermal nicotine and intravenous magnesium	Not recommended (GoR D) due to limited procedure-specific and transferable evidence
Epidural analgesia	Not recommended for prostatectomy (GoR D) despite some procedure-specific evidence (LoE 1) of analgesic benefit, due to adverse risk:benefit profile
Paravertebral analgesia	Not recommended (GoR D) due to limited procedure-specific evidence
TAP-blocks	Not recommended (GoR D) due to lack of procedure-specific and limited transferable evidence
Intrathecal opioid anaesthesia and analgesia	Not recommended (GoR B) despite procedure-specific evidence (LoE 1) of analgesic benefit, due to adverse risk:benefit profile (intrathecal anaesthesia is also not recommended). This statement is supported by transferable evidence (LoE 1) from patients undergoing major surgery
Continuous local anaesthetic wound infusion	Not recommended (GoR B) based on procedure-specific evidence (LoE 2) showing lack of analgesic efficacy
Magnesium sulfate wound infiltration	Not recommended (GoR D) due to limited procedure-specific evidence

Evidence review process

PROSPECT Radical Prostatectomy Subgroup and Working Group process

For each review, a Subgroup of the PROSPECT Working Group performs an initial evaluation of the evidence and also drafts clinical practice statements and recommendations, which are then discussed by the whole Working Group before a final consensus is reached.

For the Radical Prostatectomy review, the Subgroup members were:

- Professor Girish Joshi (PROSPECT Working Group member)
- Professor Francis Bonnet (PROSPECT Working Group member)

Dr Thomas Jaschinski (IFOM - Institut für Forschung in der Operativen Medizin, Universität Witten/Herdecke, Köln, Germany) provided support in conducting the literature search, preparing the evidence summary and coordinating the Subgroup and Working Group reviews of the evidence to prepare the final recommendations.

The recommendations for postoperative pain management in Radical Prostatectomy were voted on by eight Working Group members to show the strength of consensus. The results of each vote are indicated within the PROSPECT recommendations sub-folders.

Details of systematic literature review

Literature search

- Systematic review of the literature from 1966–November 2012 using MEDLINE and EmBASE, following the protocol of the Cochrane Collaboration
- Inclusion of randomised/controlled studies assessing analgesic, anesthetic or operative techniques in radical prostatectomy and reporting pain assessment, required analgesia or adverse events
    - Appendix B: Radical Prostatectomy: Inclusion criteria
    - Appendix C: Radical Prostatectomy: Search strategy
- 47 studies included (Appendix D: Radical Prostatectomy: Included studies)
- 49 studies excluded after full-text screening (Appendix E: Radical Prostatectomy: Excluded references)
- The most common reason for exclusion was that the study was not in adult patients with prostate cancer following prostatectomy using open or laparoscopic radicalprostatectomy including computer-assisted laparoscopic radical prostatectomy (CALP) (12 studies)

Appendix

A. Levels of evidence and grades of recommendation

<table>
<tr><td></td><td colspan="5">Study quality assessments</td><td rowspan="2">Level of Evidence (LoE)</td><td colspan="2">Grade of recommendation (based on overall LoE, considering balance of clinical practice information and evidence)</td></tr>
<tr><td>Study type</td><td>Statistical analyses and patient follow-up assessment</td><td></td><td>Allocation concealment</td><td>Jadad scores</td><td>Additional assessment of overall study quality required to judge LoE</td><td>Procedure-specific</td><td>Transferable</td></tr>
<tr><td>Systematic review with homogeneous results</td><td>N/A</td><td></td><td>N/A</td><td>N/A</td><td>N/A</td><td>1</td><td>A</td><td>B</td></tr>
<tr><td rowspan="5">Randomised controlled trial (RCT)</td><td rowspan="5">Statistics reported and >80% follow-up</td><td rowspan="5">AND</td><td>A</td><td>(1-5)</td><td>N/A</td><td rowspan="5">1</td><td rowspan="5">A
(based on two or more studies or a single large, well-designed study)</td><td rowspan="5">B</td></tr>
<tr><td colspan="3">OR</td></tr>
<tr><td>B</td><td>(3-5)</td><td>N/A</td></tr>
<tr><td colspan="3">OR</td></tr>
<tr><td>B</td><td>(1-2)</td><td>Yes</td></tr>
<tr><td rowspan="5">RCT</td><td rowspan="5">Statistics not reported or questionable or <80% follow-up</td><td rowspan="5">AND/OR</td><td>B</td><td>(1-2)</td><td>Yes</td><td rowspan="5">2</td><td rowspan="5">B
(or extrapolation from one procedure-specific LoE 1 study)</td><td rowspan="5">C</td></tr>
<tr><td colspan="3">OR</td></tr>
<tr><td>C</td><td>(1-5)</td><td>N/A</td></tr>
<tr><td colspan="3">OR</td></tr>
<tr><td>D</td><td>(1-5)</td><td>N/A</td></tr>
<tr><td>Non-systematic review, cohort study, case study; (e.g. some adverse effects evidence)</td><td>N/A</td><td></td><td colspan="3">N/A</td><td>3</td><td colspan="2">C</td></tr>
<tr><td>Clinical practice information (expert opinion); inconsistent evidence</td><td>N/A</td><td></td><td colspan="3">N/A</td><td>4</td><td colspan="2">D</td></tr>
</table>

B. Radical Prostatectomy: Inclusion criteria

Inclusion criteria for title/abstract and full text screening

1. Adult patients with prostate cancer following prostatectomy using open or laparoscopic radical prostatectomy including computer-assisted laparoscopic radical prostatectomy (CALP)
2. Comparison of two or more interventions (analgesia, anesthesia, operative techniques) affecting postoperative pain
3. At least one of the following outcomes are reported: pain assessment, required analgesia or adverse events
4. Systematic review or RCT/CCT
5. Patient population comprises at least 80% prostatectomies or the statistical analyses are separately calculated and presented
6. Full text available (including studies only published as abstracts)
7. Full text is published in English
8. No multiple publication

C. Radical Prostatectomy: Search strategy

Literature search in Medline and Embase using Embase as search engine

	syntax
1	(('meta analysis'/exp OR (meta NEAR/1 analy*):ab,ti OR metaanalys*:ab,ti OR (systematic NEAR/1 (review* OR overview*)):ab,ti) OR (cancerlit:ab OR cochrane:ab OR embase:ab OR psychlit:ab OR psyclit:ab OR psychinfo:ab OR psycinfo:ab OR cinhal:ab OR cinahl:ab OR 'science citation index':ab OR bids:ab) OR ('reference lists':ab OR bibliograph*:ab OR ((hand OR manual) NEAR/1 search*):ab OR (relevant NEAR/1 journals):ab) OR (('data extraction' OR 'selection criteria'):ab AND review:pt)) NOT (letter:pt OR editorial:pt OR ('animal'/exp NOT ('animal'/exp AND 'human'/exp)))
2	(‘Clinical trial‘/exp OR ‘Randomized controlled trial‘/exp OR ‘Randomization‘/exp OR ‘Single blind procedure‘/exp OR ‘Double blind procedure‘/exp OR ‘Crossover procedure‘/exp OR ‘Placebo‘/exp OR ‘Randomised controlled trial’:ab,ti OR ‘Randomized controlled trial’:ab,ti OR Rct:ab,ti OR ‘Random allocation’:ab,ti OR ‘Randomly allocated’:ab,ti OR ‘Allocated randomly’:ab,ti OR (allocated NEAR/2 random):ab,ti OR ‘Single blind’:ab,ti OR ‘Double blind’:ab,ti OR ((treble OR triple) NEAR/1 blind):ab,ti OR Placebo*:ab,ti OR ‘Prospective study‘/exp) NOT (‘Case study‘/exp OR ‘Case report’:ab,ti OR ‘Abstract report‘/exp OR ‘letter‘/exp)
3	'prostatectomy'/exp OR 'prostate cancer'/exp OR prostatectomy:ab,ti OR ((resection OR remov*) NEAR/3 prostat*):ab,ti OR (prostat* NEAR/1 (neoplasm* or cancer* or carcinoma* or neoplasia* or tumor* or tumour* or malignan*)):ab,ti
4	'pain'/exp OR 'pain assessment'/exp OR 'postoperative pain'/exp OR pain:ab,ti OR 'analgesia'/exp OR VAS:ab,ti OR anesthesia:ab,ti OR anaesthesia:ab,ti OR 'visual analogue scale':ab,ti OR VRS:ab,ti OR 'verbal rating scale':ab,ti OR NRS:ab,ti OR 'numerical rating scale':ab,ti
5	Limitation: English

D. Radical Prostatectomy: Included studies

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postoperative analgesia after prostatectomy. Urologia Internationalis 1996;57(4):227–229

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assisted laparoscopic radical prostatectomy. Journal of Endourology/Endourological Society 2009;23(11)1843–1849

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E. Radical Prostatectomy: Excluded references

E1: Not adult patients with prostate cancer following prostatectomy using open or laparoscopic radicalprostatectomy including computer-assisted laparoscopic radical prostatectomy (CALP)

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E2: Not comparison of two or more interventions (analgesia, anesthesia, operative techniques) affecting postoperative pain

1. Grass JA, Sakima NT, Valley M, Fischer K, Jackson C, Walsh P, Bourke DL (1993) Assessment of ketorolac as an adjuvant to fentanyl patient-controlled epidural analgesia after radical retropubic prostatectomy. Anesthesiology 78:642-648

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E3: No reporting of at least one of the following outcomes are reported: pain assessment, required analgetica or adverse events

1. Ficarra V, Cavalleri S, Novara G, Aragona M, Artibani W (2007) Evidence from Robot-Assisted Laparoscopic Radical Prostatectomy: A Systematic Review. European Urology 51:45-56

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9. Tikuisis R, Miliauskas P, Samalavicius NE, Zurauskas A, Sruogis A (2009) Epidural and general anesthesia versus general anesthesia in radical prostatectomy. Medicina (Kaunas, Lithuania) 45:772-777

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E4: neither systematic review (of RCT/CCT) nor RCT/CCT

1. Albertsen PC (2005) General versus spinal anesthesia in patients undergoing radical retropubic prostatectomy: results of a prospective, randomized study. The Journal of urology 174:931

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4. Lepor H (2004) Radical prostatectomy: Status and opportunities for improving outcomes. Cancer Investigation 22:435-444

5. Menon M, Shrivastava A, Tewari A (2005) Laparoscopic radical prostatectomy: Conventional and robotic. Urology 66:101-104

E5: patient population does not comprise at least 80% prostatectomies or the statistical analyses are separately calculated and presented

1. Atanassoff PG, Hartmannsgruber MWB, Thrasher J, Wermeling D, Longton W, Gaeta R, Singh T, Mayo M, McGuire D, Luther RR (2000) Ziconotide, a new N-type calcium channel blocker, administered intrathecally for acute postoperative pain. Regional Anesthesia and Pain Medicine 25:274-278

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E6: Full text is not available (including studies only published as abstracts)

1. Bianchi M, Allara A, Panerai AE (1993) A randomized, placebo-controlled study on the efficacy of ketorolac tromethamine in the prevention of postoperative pain. European Journal of Pain 14:10-13

2. De S, Bell D, Launcelott G, Bailly G, Bagnell S, Lawen J, Norman R, Rendon RA (2011) Surgeon-administered regional anesthesia, using the transversus abdominal plane (TAP) block during radical retropubic prostatectomy (RRP): A randomized double blinded, controlled trial. Journal of Urology 185:e253

3. Finnerty O, Carney J, Laffey J, McDonnell J (2011) A comparison of continuous epidural based versus transversus abdominis plane (TAP) block based regimens in patients undergoing retropubic prostatectomy. Anesthesia and Analgesia 112

4. Kitayama M, Hashimoto H, Kudo T, Takada N, Wada M, Hirota K (2010) Plasma concentration of ropivacaine after ultrasound-guided transversus abdominis plane block for open retropubic prostatectomy. British Journal of Anaesthesia 105:712P-713P

5. Kommu S, Crosby A, Hashim Z, Golash A, Luscombe C, Augustine A (2009) Role of Ultrasound Guided Transversus Abdominis Plane (USTAP) Block in analgesic supplementation for Laparoscopic Radical Prostatectomy-preliminary findings. Journal of Endourology 23:A3-A4

6. Smaldone M, Chelly J, Nelson J (2010) A prospective, randomized, double-blind, placebo controlled trial of multimodal anesthesia compared to patient controlled opioid anesthesia in patients undergoing radical prostatectomy. Journal of Urology 183:e605

7. Tetzlaff D, Koss W, Oldenburger A, Glaser T, Werning P, Hammerer P (2009) Pain after Radical Prostatectomy (RP) in Patients with Peridural Catheter (PDC) and Patient-Controlled Analgesia Pumps (PCA). Urology 74:S274-S275

E7: Full text is not published in English

1. Cheng YD, Zhou ZQ, Chen WP, Hu SJ, Guo MZ, Lin DD (2003) Application of morphine analgesia after prostatectomy. Journal of Chinese Physician,

2. Dimirel CB, Kati I, Cem Tuncer Y, Huseyinoglu UA, Silay E (2001) Anaesthetic and hemodynamic effects of continuous spinal anaesthesia versus single dose spinal anaesthesia in elderly patients. Turk Anesteziyoloji Ve Reanimasyon,

E8: multiple publication

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