

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of laparoscopic radical prostatectomy

Prostate cancer is a common cancer in men. Laparoscopic radical prostatectomy is a type of surgery in which the prostate (and other tissues) is removed without the need for large incisions into the body. Robotic arms controlled by a surgeon can be used to assist with the operation.

Introduction

This overview has been prepared to assist members of the Interventional Procedures Advisory Committee (IPAC) in making recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This overview was prepared in April 2006

Procedure name

- Laparoscopic radical prostatectomy

Specialty societies

- British Association of Urological Surgeons (BAUS)

Description

Indications

Localised prostate cancer (i.e. prostate cancer confined to the prostate gland, and with no distal metastases).

Current treatment and alternatives

There are several treatment options for localised prostate cancer. These include: active monitoring (also termed “watchful waiting”); open radical prostatectomy; external beam radiotherapy; low dose brachytherapy;

combined external beam radiotherapy with high dose brachytherapy; high impact frequency ultrasound therapy; and cryotherapy. The current state of the comparative evidence between different treatment options is poor. There is no consensus on the best treatment option (or options) and/or selection criteria.

What the procedure involves

The patient is placed in the dorsal supine position with the lower limbs in abduction to provide perineal access. Six trocars are inserted through different points of the lower abdomen in order to undertake the laparoscopic procedure. Prior to the prostatectomy phase of the operation, lymph nodes can be removed for intra-operative staging (frozen section histology). Subsequently the vas deferens, the seminal vesicles and the prostate gland are dissected. Sparing of the two neurovascular pedicles is attempted, if this is technically possible. The dissected prostate gland is then extracted using a laparoscopy bag via one of the orifices.

The approach can be either trans- or extra-peritoneal. A recent development has been the evolution of robotically assisted laparoscopic radical prostatectomy. This allows for increased precision in the manipulation of instruments used for the resection, with scaled operator movement, and tremor dampening.

Efficacy

Biochemically-assessed tumour recurrence

- A systematic review of non-randomised controlled studies reported that biochemical recurrence free survival ranged between
 -84% - 99% following transperitoneal laparoscopic radical prostatectomy
 -81% - 91% following extraperitoneal laparoscopic radical prostatectomy, and
 -92% - 95% following robotic assisted laparoscopic radical prostatectomy.

None of these outcomes was statistically different from those among patients undergoing open radical prostatectomy who acted as controls¹.

- One case series study assessed 5-year biochemical recurrence rate in 1,740 patients who underwent laparoscopic radical prostatectomy (out of a total of 5,824 such patients included in the study in total). It reports 5-year prostate specific antigen (PSA) recurrence rates of 9% in patients with pT2 and 18% in patients with pT3a tumours².

Completeness of tumour resection

Laparoscopic (approach not specified) vs. open radical prostatectomy.

Pooled data from 6 case series studies and 2 databases indicate a tumour positive resection margins in 20% of 1,439 patients treated with laparoscopic radical prostatectomy and 24% of 22,164 patients treated with open radical prostatectomy³.

One case series study including 5,824 patients treated with laparoscopic radical prostatectomy reports positive margin rates of 11% in patients with pT2 and 33% in patients with pT3a tumours².

Transperitoneal laparoscopic vs. open radical prostatectomy

In a systematic review¹ of non-randomised controlled trials including data from eight relevant studies

- Six studies reported no significant difference in rates of tumour positive resection margins between the two groups.
- One study reported a significantly higher rate in the laparoscopic radical prostatectomy treated group 50% vs. 29% ($p=0.03$).
- One study, conversely, reported a significantly higher rate with open surgery 14% vs. 26% ($p=0.02$).

Extraperitoneal laparoscopic vs. open radical prostatectomy

In a systematic review¹ of non-randomised controlled trials including data from three relevant studies

- Two studies reported no significant difference in rates of positive margins.
- One study reported a significantly lower rate of positive resection margins in the laparoscopic radical prostatectomy group 26% vs. 40% ($p=0.0001$).

Robotically-assisted laparoscopic vs. open radical prostatectomy

Pooled data from 6 case series studies and 2 databases indicate positive surgical margins in 15% of 373 patients undergoing robotically-assisted laparoscopic radical prostatectomy compared with 24% of 22,164 patients treated with open radical prostatectomy³.

In a systematic review¹ of non-randomised controlled trials including data from four relevant studies

- One study reported a significantly lower positive margin rates among the robotically-assisted laparoscopic groups compared to the open 6% Vs 23% ($p<0.005$).
- Three other relevant studies did not report significance levels for this outcome.

Extraperitoneal vs. transperitoneal vs. open radical prostatectomy

One non-randomised controlled study reported positive surgical margin rates of:

- 20% (8/41) in the extraperitoneal laparoscopic radical prostatectomy group
- 26% (10/39) in the transperitoneal laparoscopic radical prostatectomy group
- 20% (8/41) in the open radical prostatectomy group.

There was no statistically significant difference in the above rates between groups⁴.

Quality of Life

One non-randomised controlled trial including 116 patients reported no difference between scores among men treated with open laparoscopic radical prostatectomy, laparoscopic radical prostatectomy, or low dose rate brachytherapy in any of the SF-36 domains. In this study there was no significant difference in UCLA prostate cancer index scores between laparoscopic and open radical prostatectomy groups⁵.

Safety

Urinary incontinence

In a systematic review of 10 non-randomised controlled studies, five studies reported no significant differences in post-operative continence rates, one study reported a significant difference favouring the laparoscopic group, and four studies did not report the significance of this outcome¹.

Impotence

Definitions of impotence varied between studies included, making comparison of results difficult. In studies that did report this outcome, among men who were potent at baseline and who underwent either unilateral or bilateral nerve-sparing laparoscopic radical prostatectomy potency was retained in between 53%² and 62%³. Preserved potency rates of 82% were reported in patients treated with robotically-assisted laparoscopic radical prostatectomy³.

In a systematic review of non-randomised controlled studies, three studies did not report a significant difference in potency rates between laparoscopic and open radical prostatectomy groups. Two studies did not report the significance of this outcome.¹

In a review of pooled data³, among studies where this outcome was examined, potency (defined as spontaneous erection) at final follow up of variable length was reported to be between:

- 45% - 62% following laparoscopic radical prostatectomy
- 22% - 82% following robotically-assisted laparoscopic radical prostatectomy, and

- 44% -75% of men after open radical prostatectomy.

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to laparoscopic radical prostatectomy. Searches were conducted via the following databases, covering the period from 2004 to 18-04-06: Medline, PreMedline, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches. (See Appendix C for details of search strategy.)

The following selection criteria (Table 1) were applied to the abstracts identified by the literature search. Where these criteria could not be determined from the abstracts the full paper was retrieved.

Table 1 Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies were included. Emphasis was placed on identifying good quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising methodology.
Patient	Patients with localised prostate cancer
Intervention/test	laparoscopic radical prostatectomy, including surgery with robotic assistance.
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

List of studies included in the overview

This overview is based on one systematic review, one review of pooled data, three non randomised controlled trials and one case series.

Other studies that were considered to be relevant to the procedure but were not included in the main extraction table (Table 2) have been listed in Appendix A.

Existing reviews on this procedure

A review of the evidence by the Australian Safety and Efficacy Register of New Interventional Procedures Surgical Programme has been produced and is included in the summary of evidence in Table 2, Toohar (2005).

Related NICE guidance

Below is a list of NICE guidance related to this procedure. Appendix B details the recommendations made in each piece of guidance listed below.

Interventional procedures:

Laparoscopic radical prostatectomy (October 2003)
High-intensity focused ultrasound for prostate cancer (March 2005)
Cryotherapy for recurrent prostate cancer (May 2005)
Low dose rate brachytherapy for prostate cancer (July 2005)
Cryotherapy as a primary treatment for prostate cancer (November 2005)
High dose rate brachytherapy for localised prostate cancer (in combination with external beam radiotherapy) (May 2006 TBC)

Technology appraisals:

None applicable

Clinical guidelines:

Cancer service guidance Improving outcomes in urological cancers (September 2002)

Public health:

None applicable

Table 2 Summary of key efficacy and safety findings on laparoscopic radical prostatectomy

Abbreviations: NR - not reported, NS - not significant, TLRP – transperitoneal laparoscopic radical prostatectomy, ELRP - extraperitoneal laparoscopic radical prostatectomy			
Study details	Key efficacy findings	Key safety findings	Comments

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<p>Toohar R (2005)¹</p> <p>Systematic review – non randomised controlled studies</p> <p>Australian review of international studies</p> <p>Studies published 1996 to December 2004</p> <p>n=2,060 from 21 controlled studies</p> <p>21 studies found comparing laparoscopic radical prostatectomy to open surgery. 13 transperitoneal (n=1351), 3 extraperitoneal (n=249), and 5 robotic assisted (n=460)</p> <p>Demographic and clinical characteristics of patients varied between studies. Inclusion into review required that studies included patients with localised prostate cancer diagnosed by any method.</p> <p>Clinical inclusion criteria varied between studies, but was largely consistent with those for radical retropubic prostatectomy.</p> <p>Follow-up to 1.3 years</p> <p>Disclosure of interest: Not stated</p>	<p>Survival</p> <p>Biochemical recurrence free survival (PSA >0.2 µg/l on more than one evaluation)</p> <table border="1"> <thead> <tr> <th>Study</th> <th>lap</th> <th>open</th> <th>p=</th> <th>FU month)</th> </tr> </thead> <tbody> <tr> <td colspan="5">Transperitoneal laparoscopic radical prostatectomy</td> </tr> <tr> <td>Salomon</td> <td>84.1%</td> <td>75.0 to 85.2%</td> <td>NR</td> <td>36</td> </tr> <tr> <td>Rassweiler</td> <td>99.1%</td> <td>97.2%</td> <td>NR</td> <td>30</td> </tr> <tr> <td colspan="5">Extraperitoneal endoscopic radical prostatectomy</td> </tr> <tr> <td>Roumeguere</td> <td>91.3%</td> <td>93.0%</td> <td>NS</td> <td>12</td> </tr> <tr> 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The quality of included studies was generally average.</p> <p>No published or in progress RCTs were identified, allowing potential selection bias in results from controlled trials included, although in most controlled trials groups were similar at baseline</p> <p>12 of 18 studies that described case accrual confirmed that consecutive cases were included which should have minimised selection bias.</p> <p>2 studies that estimated the effect of the learning curve for this technique, found less conversion to open surgery in the later experience, and no conversions in later patients were reported in one study.</p>
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Only 1 of 4 studies comparing robotically assisted surgery with open prostatectomy found that operative time was significantly longer (368 vs. 242 minutes (p not stated))</p> <p>Length of stay Mean or median length of stay in days</p> <table border="1"> <thead> <tr> <th>Study</th> <th>lap</th> <th>open</th> <th>p=</th> </tr> </thead> <tbody> <tr> <td colspan="4">Transperitoneal laparoscopic radical prostatectomy</td> </tr> <tr> <td>Bhayani</td> <td>3.0</td> <td>3.0</td> <td>0.53</td> </tr> <tr> <td>Martorana</td> <td>5.0</td> <td>6.9</td> <td>NR</td> </tr> <tr> <td>Brown</td> <td>2.8</td> <td>3.0</td> <td>NR</td> </tr> <tr> <td>Salomon</td> <td>7.4</td> <td>15.2</td> <td><0.05</td> </tr> <tr> <td>Atallah</td> <td>7.9</td> <td>10.8</td> <td><0.001</td> </tr> <tr> <td>Bickert</td> <td>1.4</td> <td>4.9</td> <td>NR</td> </tr> <tr> <td>Rassweiller</td> <td>12</td> <td>16</td> <td><0.05</td> </tr> <tr> <td colspan="4">Extraperitoneal endoscopic radical prostatectomy</td> </tr> <tr> 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<p>Soderdahl (2005)^o</p> <p>Non randomised controlled trial</p> <p>USA</p> <p>Studies period: 2001 to 2005</p> <p>n=116 (laparoscopic cases)</p> <p>Patients treated by open prostatectomy, laparoscopic prostatectomy, or brachytherapy.</p> <p>Patients with localised prostate cancer (not defined)</p> <p>Laparoscopic patients Age = 61 years, Clinical stage T1c = 82%, T2 = 18%, Gleason score ≤5 = 5%, 6 = 74%, 7 = 17%, 8 to 10 = 3%</p> <p>Pathological stage T0 =1%, T2 =79%, T3 to 4 20%</p> <p>Baseline PSA = 5.71</p> <p>Follow-up to 15 months</p> <p>Disclosure of interest: Not stated</p>	<p>Quality of life</p> <p>Outcomes were assessed using three survey instruments, the SF-36 health survey, the UCLA prostate cancer index (PCI), and the American urological association (AUA) symptom index.</p> <p>Patients were followed up at 1, 3, 6 and 12 months</p> <p>SF-36</p> <p>There was an initial drop off in general domain scores with a return to baseline score over time. There was no difference between groups in scores over time.</p> <table border="1"> <thead> <tr> <th>Domain</th> <th>P value</th> </tr> </thead> <tbody> <tr> <td>Physical functioning</td> <td>0.26</td> </tr> <tr> <td>Emotional</td> <td>0.57</td> </tr> <tr> <td>Vitality</td> <td>0.46</td> </tr> <tr> <td>Metal health</td> <td>0.35</td> </tr> <tr> <td>Bodily pain</td> <td>0.46</td> </tr> <tr> <td>General health</td> <td>0.92</td> </tr> <tr> <td>Health transition</td> <td>0.55</td> </tr> <tr> <td>Physical limitations</td> <td>0.052</td> </tr> <tr> <td>Social functioning</td> <td>0.06</td> </tr> </tbody> </table> <p>PCI scores</p> <p>The proportion of patients returning to baseline scores at 12 months was significantly lower for open or laparoscopic surgery than brachytherapy for sexual and urinary function, and for sexual bother (p<0.001) for each. There was no significant difference between open surgery and laparoscopic scores.</p> <p>AUA symptom scores.</p> <p>Patients undergoing brachytherapy had worse general urinary function over time compared to those undergoing either surgical procedures (p<0.001).</p>	Domain	P value	Physical functioning	0.26	Emotional	0.57	Vitality	0.46	Metal health	0.35	Bodily pain	0.46	General health	0.92	Health transition	0.55	Physical limitations	0.052	Social functioning	0.06	<p>Potency</p> <p>At 1 months follow up sexual function and bother score were uniformly poor in all groups however there was some improvement by 12 months, although there was no significant difference between groups.</p>	<p>Prospective study</p> <p>Groups compared using a linear model with a correlation structure to account for unequal time sampling, to provide an expected score for a given treatment in time</p> <p>Analysis based on patient self reported questionnaires</p> <p>Complete data to 12 months follow up is available from 46.2% of men who had open prostatectomy, 80.2% of men who had laparoscopic prostatectomy, and 47.3% of men who had brachytherapy. The higher response rate in the laparoscopic group may reflect a proactive approach of surgeons to stress the importance of participation.</p> <p>Patients in the Brachytherapy group were significantly older than those in the open and laparoscopic prostatectomy groups at baseline. Low dose rate brachytherapy employed in the brachytherapy group.</p> <p>Two surgeons undertook all the laparoscopic radical prostatectomy treatments.</p> <p>Outcomes only measured to 1 year and authors confirm that improvements in function may occur in the next 2 to 5 years.</p>
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<p>Remzi M (2005)⁴</p> <p>Non randomised controlled study</p> <p>Austria</p> <p>Study period January 2002 to October 2003</p> <p>n=80 (trans / extra- peritoneal laparoscopic radical prostatectomy)</p> <p>Patients undergoing radical surgical treatment for adenocarcinoma of the prostate with histological confirmation and clinical stage \leqT2. Organ confined cancer was determined by rectal examination, PSA <10ng/ml, Gleason score <7, and negative bone scan imaging.</p> <p>Treatment by open prostatectomy, transperitoneal or extraperitoneal laparoscopic radical prostatectomy.</p> <p>All bar 2 patients undergoing laparoscopic surgery had a staging lymphadenectomy of the obturator fossa, while only 71% of open surgery patients had a staging lymphadenectomy.</p> <p>All patients began walking with 24 hours, and fluids given. On the 2nd postoperative day wound drains were removed, laxatives given and feeding started. 50-100mg tramadol given upon demand.</p> <p>Mean Follow-up 14.9 months</p> <p>Disclosure of interest: Not stated</p>	<p>Operative parameters</p> <p>Mean operating time for the TLRP group (279 \pm70 mins) was significantly longer, than for the ELRP (217 \pm51 mins) and open prostatectomy (195 \pm 72 mins) groups (p<0.001).</p> <p>Conversion to open surgery was required in one TLRP procedure, 1% (1/80) conversion rate for all laparoscopic procedures.</p> <p>Length of stay following laparoscopic surgery (7 \pm2 days) was significantly shorter than with open surgery (10 \pm 4 days)(p<0.001)</p> <p>Pathological parameters</p> <table border="1"> <thead> <tr> <th>Outcome</th> <th>ELRP</th> <th>TLRP</th> <th>Open</th> </tr> </thead> <tbody> <tr> <td>Positive surgical margins</td> <td>20% (8/41)</td> <td>26% (10/39)</td> <td>20% (8/41)</td> </tr> </tbody> </table> <p>No statistical difference between groups.</p>	Outcome	ELRP	TLRP	Open	Positive surgical margins	20% (8/41)	26% (10/39)	20% (8/41)	<p>Perioperative complications</p> <p>Mean blood loss was lower with the laparoscopic approaches ELRP (189\pm140 ml) and TLRP (290\pm254 ml) compared with open surgery (385\pm410 ml) (p=0.0049 and 0.021 respectively vs open)</p> <table border="1"> <thead> <tr> <th>outcome</th> <th>ELRP n=41</th> <th>TLRP n=39</th> <th>Open n=41</th> <th>p=</th> </tr> </thead> <tbody> <tr> <td>Rectal injury</td> <td>0%</td> <td>3% (1/39)</td> <td>2% (1/41)</td> <td>NR</td> </tr> </tbody> </table> <p>P values for comparison between all groups</p> <p>Postoperative complications</p> <table border="1"> <thead> <tr> <th>outcome</th> <th>ELRP n=41</th> <th>TLRP n=39</th> <th>Open n=41</th> <th>p=</th> </tr> </thead> <tbody> <tr> <td>Continenence 1 month</td> <td>27% (11/41)</td> <td>26% (10/39)</td> <td>20% (8/41)</td> <td>0.02</td> </tr> <tr> <td>Continenence 12 months</td> <td>88% (36/41)</td> <td>85% (33/41)</td> <td>80% (33/41)</td> <td>0.02</td> </tr> <tr> <td>Ileus</td> <td>0%</td> <td>3% (1/39)</td> <td>0%</td> <td>NR</td> </tr> <tr> <td>Anastomotic stricture</td> <td>2% (1/41)</td> <td>5% (2/39)</td> <td>10% (4/41)</td> <td>NS</td> </tr> </tbody> </table> <p>P values for comparison between all groups</p> <p>Postoperative pain scores as measured by a visual analogue scale from day 1 to day 5 were lower for in the ELRP group than the TLRP group (p<0.001) and the open surgery group (p=0.008).</p> <p>No difference in analgesic consumption in the first postoperative week was seen between ELRP and open surgery (p=0.555)</p>	outcome	ELRP n=41	TLRP n=39	Open n=41	p=	Rectal injury	0%	3% (1/39)	2% (1/41)	NR	outcome	ELRP n=41	TLRP n=39	Open n=41	p=	Continenence 1 month	27% (11/41)	26% (10/39)	20% (8/41)	0.02	Continenence 12 months	88% (36/41)	85% (33/41)	80% (33/41)	0.02	Ileus	0%	3% (1/39)	0%	NR	Anastomotic stricture	2% (1/41)	5% (2/39)	10% (4/41)	NS	<p>Prospective study.</p> <p>Selection for laparoscopic or open surgery made on the basis of preference of the performing surgeons, or referring institution.</p> <p>Laparoscopic surgery represents a series of 39 patients treated by the transperitoneal approach (following a period of 33 cases to allow for the learning curve) and then a subsequent 41 operations with a extraperitoneal approach.</p>	
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<p>Rassweiler J (2006)²</p> <p>Case series</p> <p>Europe – 18 centres – 50 surgeons</p> <p>Study period March 1999 to August 2004</p> <p>n=5824</p> <p>Treatment by laparoscopic radical prostatectomy, by a transperitoneal descending approach n=2701, a transperitoneal ascending approach n=1234, a extraperitoneal descending approach n=1814, or a extraperitoneal ascending approach n=75.</p> <p>Robotic assistance was routinely used in 2 centres (number of cases not stated). Lymph node dissection was either carried out in each case or on EAU guidelines depending on the participating centre.</p> <p>Mean age = 64 years, All tumours were T1c or T2 clinical assessment, Pathological examination revealed pT2 = 61%, pT3a = 27%, pT3b 11%, pT4 =2%.</p> <p>Mean Follow-up not stated, up to 5 years for PSA evaluation at some centres.</p> <p>Disclosure of interest: Not stated</p>	<p>Operative parameters</p> <p>Mean operating time was 196 minutes. There was a significantly shorter duration with the extraperitoneal approach than the transperitoneal descending or ascending technique (176 Vs 211 Vs 232 mins respectively (p value not presented).</p> <p>Conversion to open surgery was required in 2.4% of patients, although this figure was only 0.9% when only patients treated in the final year of the study period were analysed separately.</p> <p>Oncological outcomes</p> <p>Positive margins were evaluated according to the Stanford protocol</p> <p>Positive margins were reported in 10.6% of patients who had pT2 tumours and in 32.7% of those with p3Ta tumours.</p> <p>5 year PSA recurrence rates (threshold not stated) were 8.6% in patients who had pT2 tumours and 17.5% in those with pT3a tumours. This analysis was based on data from 3 centres, n=1740.</p>	<p>Perioperative complications</p> <table border="0"> <tr> <td>Complication</td> <td>Rate</td> </tr> <tr> <td></td> <td>(n=5824)</td> </tr> <tr> <td>All complications</td> <td>8.9%</td> </tr> <tr> <td>Bleeding</td> <td>2.2%</td> </tr> <tr> <td>Rectal lesion</td> <td>1.7%</td> </tr> <tr> <td>Extravasation</td> <td>2.4%</td> </tr> <tr> <td>Thrombo-embolism</td> <td>0.6%</td> </tr> <tr> <td>Re-intervention rate</td> <td>2.7%</td> </tr> <tr> <td>Requiring open surgery</td> <td>1.4%</td> </tr> </table> <p>Postoperative complications</p> <table border="0"> <tr> <td>Complication</td> <td>Rate</td> </tr> <tr> <td></td> <td>(n=?)</td> </tr> <tr> <td>Continence</td> <td>84.9%</td> </tr> <tr> <td>Sexual intercourse (in those who were active at baseline and underwent bilateral nerve preserving surgery)</td> <td>52.5%</td> </tr> </table>	Complication	Rate		(n=5824)	All complications	8.9%	Bleeding	2.2%	Rectal lesion	1.7%	Extravasation	2.4%	Thrombo-embolism	0.6%	Re-intervention rate	2.7%	Requiring open surgery	1.4%	Complication	Rate		(n=?)	Continence	84.9%	Sexual intercourse (in those who were active at baseline and underwent bilateral nerve preserving surgery)	52.5%	<p>Retrospective study</p> <p>Three participating centres selected patients having small prostate and T1c tumours.</p> <p>Not all participating centres contributed data for all outcomes. Absolute figures are not provided for most outcomes. Cases included in analysis of perioperative complications is not explicitly stated, and assumed to be the whole study cohort.</p> <p>Data on continence and potency were only taken from centres with adequate follow up and validated questionnaires</p> <p>Experience at each participating centre ranged from 65 to 1126 cases, the minimum number of cases undertaken by any one surgeon is not stated.</p> <p>All surgeons participated in hands-on training sessions and live or video demonstrations.</p> <p>Authors highlight the need for step by step learning starting as second assistant and finishing with the entire operation under an experienced laparoscopist</p> <p>Potential overlap of cases with (Tooher 2005)</p>
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Validity and generalisability of the studies

- No randomised controlled trials comparing this procedure to other treatment strategies have been published to date, with potential selection bias in other controlled study designs
- Some variation in surgical technique both within and between studies
- Concomitant treatment not well described or standardised

Specialist advisors' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College.

Mr C Eden, Mr S Harrison

- Advisors were divided in their opinion of the status of this procedure. One thought it to be established, and one that it is a novel procedure of uncertain safety and efficacy.
- The benefits of laparoscopic radical prostatectomy may include low positive surgical margin rates, good biochemical-free survival, and improved safety profile in terms of continence and potency
- Reported adverse events are similar to those with open radical prostatectomy
- Additional theoretical adverse events may include longer operative time, gas embolus, bowel damage, haemorrhage, and incontinence.
- Advisors stressed the importance of training in open radical prostatectomy, and advances laparoscopic surgery before undertaking this procedure.
- Laparoscopic equipment suitable for the procedure must be available.
- Significant additional data is being presented at scientific meetings.
- The BAUS oncology complex procedures database collects data on radical prostatectomy including laparoscopic procedures.
- One advisor suggested that robotic assistance offers no additional benefits to patients over laparoscopic techniques.
- There is a strong patient demand for laparoscopic surgery
- It was thought that this procedure would be used in the minority of hospitals if considered safe and efficacious.
- Audit criteria should include factors relating to operative data, rates of conversion, duration of catheterisation, complications, and rates of positive surgical margins, survival, rectal injuries, re-intervention rates, transfusion requirement, wound complications, deep vein thrombosis, and bladder neck stenosis.

Issues for consideration by IPAC

- Non English language studies were not selected for inclusion in the overview, as significant data in the English language was available

- Literature searches were undertaken from the earliest point in electronic databases, but only studies from 2004 onwards were selected owing to the weight of data available.
- Some studies include patients treated both with and without robotic assistance, without separate reporting of outcomes for the two subgroups.
- Only one reviewed study reports outcomes beyond 5 years, and in this study, cure rates were assessed with biochemical surrogates.

References

- 1 Toohar R, Swindle P, Woo H et al. (2005) Laparoscopic Radical Prostatectomy - Accelerated systematic review. 1-118.
- 2 Rassweiler J, Stolzenburg J, Sulser T et al. (2006) Laparoscopic radical prostatectomy - The experience of the german laparoscopic working group. *European Urology* 49: 113-119.
- 3 Tewari A, El Hakim A, and Leung RA. (2006) Robotic prostatectomy: a pooled analysis of published literature. [Review] [57 refs]. *Expert Review of Anticancer Therapy* 6: 11-20.
- 4 Remzi M, Klingler HC, Tinzi MV et al. (2005) Morbidity of laparoscopic extraperitoneal versus transperitoneal radical prostatectomy versus open retropubic radical prostatectomy. *European Urology* 48: 83-89.
- 5 Soderdahl DW, Davis JW, Schellhammer PF et al. (2005) Prospective longitudinal comparative study of health-related quality of life in patients undergoing invasive treatments for localized prostate cancer. *Journal of Endourology* 19: 318-326.
- 6 Webster TM, Herrell SD, Chang SS et al. (2005) Robotic assisted laparoscopic radical prostatectomy versus retropubic radical prostatectomy: a prospective assessment of postoperative pain. *Journal of Urology* 174: 912-914.

Appendix A: Additional papers on laparoscopic radical prostatectomy not included in summary Table 2

2

The following table outlines the studies that are considered potentially relevant to the overview but were not included in the main data extraction table (Table 2). It is by no means an exhaustive list of potentially relevant studies.

Article title	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in Table 2
Bhandari A, McIntire L, Kaul SA, Hemal AK, Peabody JO, Menon M. Perioperative complications of robotic radical prostatectomy after the learning curve. <i>Journal of Urology</i> 2005; 174(3):915-918.	Case series n=300 FU=7 days	No operative mortality and no conversions to open surgery	Larger case series are included in table 2
Chang CM, Moon D, Gianduzzo TR, Eden CG. The impact of prostate size in laparoscopic radical prostatectomy. <i>European Urology</i> 2005; 48(2):285-290.	Non randomised controlled trial n=400 FU=?	Larger prostates were associated with significantly longer operating time (p<0.001) but had fewer positive surgical margins (p=0.01)	Outcomes comparing effect of prostate size rather than efficacy Vs open surgery
Chien GW, Mikhail AA, Orvieto MA, Zagaja GP, Sokoloff MH, Brendler CB et al. Modified clipless antegrade nerve preservation in robotic-assisted laparoscopic radical prostatectomy with validated sexual function evaluation. <i>Urology</i> 2005; 66(2):419-423	Case series n=56 FU=6 months	Return to baseline potency in 69% of patients at 12 months	Larger case series are included in table 2
Costello AJ, Haxhimolla H, Crowe H, Peters JS. Installation of telerobotic surgery and initial experience with telerobotic radical prostatectomy. <i>BJU International</i> 2005; 96(1):34-38	Case series n=122 FU to 6 months	No conversions to open surgery Complications equivalent to open surgery	Larger case series are included in table 2
Curto F, Benijts J, Pansadoro A, Barmoshe S, Hoepffner JL, Mugnier C et al. Nerve sparing laparoscopic radical prostatectomy: Our technique. <i>European Urology</i> 2006; 49(2):344-352	Case series n=425 FU=1 year	Continence rate 95% at 6 months Potency rate 59% at 12 months	Larger case series are included in table 2
Gonzalzo ML, Pavlovich CP, Trock BJ, Link RE, Sullivan W, Su LM. Classification and trends of perioperative morbidities following laparoscopic radical prostatectomy. <i>Journal of Urology</i> 2005; 174(1):135-139	Case series n=250 FU=13.7 months	20 grade II, 12 grade III and 2 grade IV complications reported Mean length of stay was 2 days	Larger case series are included in table 2
Joseph JV, Rosenbaum R, Madeb R, Erturk E, Patel HR. Robotic extraperitoneal radical prostatectomy: an alternative approach. <i>Journal of Urology</i> 2006; 175(3 Pt 1):945-950	Case series n=325 FU=6 months	Mean operating time was 130 minutes No conversion to open surgery	Larger case series are included in table 2

Link RE, Su L-M, Sullivan W, Bhayani SB, Pavlovich CP. Health related quality of life before and after laparoscopic radical prostatectomy. <i>Journal of Urology</i> 2005; 173(1):175-179	Case series n=122 FU=12 months	93% Continence at 12 months 79% of men undergoing bilateral nerve sparing engaging in sexual intercourse	Larger case series are included in table 2
Menon M, Shrivastava A, Tewari A. Laparoscopic radical prostatectomy: conventional and robotic. [Review] [40 refs]. <i>Urology</i> 2005; 66(5 Suppl):101-104	Non randomised controlled trial n=615 Lap FU=18 months	Operative time blood loss, postoperative pain, and complications lower with robotic assistance than open or laparoscopic surgery	Potentially some cases are included in El-Hakim (2006)
Namiki S, Egawa S, Baba S, Terachi T, Usui Y, Terai A et al. Recovery of quality of life in year after laparoscopic or retropubic radical prostatectomy: a multi-institutional longitudinal study. <i>Urology</i> 2005; 65(3):517-523	Non randomised controlled trial n=45 Lap. FU=1 year	Laparoscopic patients tended to have more delayed recovery in urinary function and bother than open surgery	Larger non randomised controlled trials are included in table 2
Namiki S, Egawa S, Terachi T, Matsubara A, Igawa M, Terai A et al. Changes in quality of life in first year after radical prostatectomy by retropubic, laparoscopic, and perineal approach: Multi-institutional longitudinal study in Japan. <i>Urology</i> 2006; 67(2):321-327	Non randomised controlled trial n=65 Lap. FU=1 year	No significant differences between groups at 6 months.	Larger non randomised controlled trials are included in table 2 Different cases to Namiki (2005)
Patel VR, Tully AS, Holmes R, Lindsay J. Robotic radical prostatectomy in the community setting--the learning curve and beyond: initial 200 cases. <i>Journal of Urology</i> 2005; 174(1):269-272.	Case series n=200 FU to 2 weeks	Mean operative time 141 minutes. Positive margin rate =10.5%	Larger case series are included in table 2
Poulakis V, Ferakis N, Dillenburg W, De Vries R, Witzsch U, Becht E. Laparoscopic radical prostatectomy using an extraperitoneal approach: Nordwest hospital technique and initial experience in 255 cases. <i>Journal of Endourology</i> 2006; 20(1):45-53.	Case series n=255 FU=1 year	Mean operative time 136 minutes The first three cases were converted to open surgery One case of myocardial infarction	Larger case series are included in table 2
Rassweiler J, Schulze M, Teber D, Marrero R, Seemann O, Rumpelt J et al. Laparoscopic radical prostatectomy with the Heilbronn technique: oncological results in the first 500 patients. <i>Journal of Urology</i> 2005; 173(3):761-764.	Case series n=500 FU = 40 months	Positive margins in between 7% and 42% depending on pathological stage PSA recurrence rate 11%	Larger case series are included in table 2
Rozet F, Galiano M, Cathelineau X, Barret E, Cathala N, Vallancien G. Extraperitoneal laparoscopic radical prostatectomy: a prospective evaluation of 600 cases. <i>Journal of Urology</i> 2005; 174(3):908-911.	Case series n=600 FU = 12 months	Mean operative time =173 minutes Reoperations rate 1.7% positive margin rate 18 to 26%	Larger case series are included in table 2

<p>Stolzenburg JU, Rabenalt R, Do M, Ho K, Dorschner W, Waldkirch E et al. Endoscopic extraperitoneal radical prostatectomy: oncological and functional results after 700 procedures.[see comment]. Journal of Urology 2005; 174(4 Pt 1):1271-1275.</p>	<p>Case series n=700 FU= to 6 months</p>	<p>Mean operating time 151 minutes. There were no conversions to open surgery 4 patients had intraoperative rectal injuries</p>	<p>Larger case series are included in table 2</p>
<p>Tewari A, Kaul S, Menon M. Robotic radical prostatectomy: a minimally invasive therapy for prostate cancer. Current Urology Reports 2005; 6(1):45-48.</p>	<p>Case series n=750 FU up to 18 months</p>	<p>Potency rate of 82% in men <60 years, and 75% in those >60 years</p>	<p>Larger case series are included in table 2 Potentially some cases are included in El-Hakim (2006)</p>
<p>Tobias-Machado M, Lasmar MT, Medina JJ, Forseto PH, Jr., Juliano RV, Wroclawski ER. Preliminary experience with extraperitoneal endoscopic radical prostatectomy through duplication of the open technique. International Braz J Urol 2005; 31(3):228-235.</p>	<p>Case series n=28 FU=18 months</p>	<p>Mean surgical time was 280 minutes No conversion to open surgery 2 rectal lesions reported</p>	<p>Larger case series are included in table 2</p>
<p>Yamada Y, Nakamura K, Aoki S, Taki T, Kokubo H, Matsubara H et al. Endoscope-assisted minilaparotomic radical retropubic prostatectomy. International Journal of Urology 2006; 13(2):111-115.</p>	<p>Non randomised controlled study n=30 lap FU for perioperative period</p>	<p>Time before ambulation duration of incontinence was significantly shorter with endoscope assisted mini-lap prostatectomy than open prostatectomy</p>	<p>Larger non randomised controlled trials are included in table 2</p>

Appendix B: Related published NICE guidance for laparoscopic radical prostatectomy

Guidance programme	Recommendation
Interventional procedures	<p>IPG016 Laparoscopic radical prostatectomy.</p> <p>Current evidence on the safety and efficacy of laparoscopic radical prostatectomy does not appear adequate to support the use of this procedure without special arrangements for consent and for audit or research. Clinicians wishing to undertake laparoscopic radical prostatectomy should inform the clinical governance leads in their trusts. They should ensure that patients offered it understand the uncertainty about the procedure's safety and efficacy and should provide them with clear written information. Use of the Institute's <i>Information for the Public</i> is recommended. Clinicians should ensure that appropriate arrangements are in place for audit or research. Publication of safety and efficacy outcomes will be useful in reducing the current uncertainty. NICE is not undertaking further investigation at present.</p> <p>Patients should be informed that radical prostatectomy by any technique can control local symptoms of prostate cancer, but that it can also have significant complications. They should be informed that there is no reliable evidence showing whether or not radical prostatectomy improves survival</p> <p>Laparoscopic radical prostatectomy requires specialist training before it is undertaken. The British Association of Urological Surgeons has agreed to produce training standards.</p> <p>IPG118 High-Intensity focused ultrasound for prostate cancer</p> <p>Current evidence on the safety and efficacy of high-intensity focused ultrasound (HIFU), as measured by reduction in prostate-specific antigen (PSA) levels and biopsy findings, appears adequate to support the use of this procedure for the treatment of prostate cancer provided that the normal arrangements are in place for consent, audit and clinical governance.</p> <p>The effects of HIFU for prostate cancer on</p>

quality of life and long-term survival remain uncertain. Clinicians should therefore ensure that patients understand the uncertainties and the alternative treatment options. Use of the Institute's *Information for the public* is recommended.

Interpretation of the data was difficult because it was not clear from the literature when the procedure was used for primary or for salvage treatment. Further research and audit should address clinical outcomes, long-term survival and indications for treatment (differentiating between the use of the procedure for primary and for salvage treatment).

IPG119 Cryotherapy for recurrent prostate cancer

Current evidence on the safety and efficacy of cryotherapy, as measured by a reduction of prostate-specific antigen (PSA) levels and biopsy findings, appears adequate to support the use of this procedure in patients with recurrent prostate cancer provided that the normal arrangements are in place for consent, audit and clinical governance.

The effects of cryotherapy for recurrent prostate cancer on quality of life and long-term survival remain uncertain. Clinicians should therefore ensure that patients understand the uncertainties and the alternative treatment options. Use of the Institute's *Information for the public* is recommended.

Further research and audit should address quality of life, clinical outcomes and long-term survival.

IPG 132 low dose rate brachytherapy for prostate cancer

Current evidence on the safety and short- to medium-term efficacy of low dose rate brachytherapy for localised prostate cancer appears adequate to support the use of this procedure, provided that the normal arrangements are in place for consent, audit and clinical governance.

Most of the evidence on the efficacy of low dose rate brachytherapy for localised prostate cancer relates to the reduction of prostate-specific antigen (PSA) levels and to biopsy findings. The effects on quality of life and long-term survival remain uncertain. Clinicians should ensure that patients understand these uncertainties and the alternative treatment options. Use of the Institute's *Information for the public* is

	<p>recommended.</p> <p>A multidisciplinary team should be involved in the planning and use of this procedure. The Institute has issued a cancer service guideline on <i>Improving Outcomes in Urological Cancers</i> (www.nice.org.uk/csguc).</p> <p>Further research and audit should address quality of life, clinical outcomes and long-term survival.</p> <p>IPG 145 Cryotherapy as a primary treatment for prostate cancer</p> <p>Current evidence on the safety and efficacy of cryotherapy, measured by reduction of prostatespecific antigen (PSA) levels and biopsy findings, appears adequate to support the use of this procedure as a primary treatment in patients with prostate cancer provided that normal arrangements are in place for consent, audit and clinical governance.</p> <p>The effects of cryotherapy as a primary treatment for prostate cancer on quality of life and long-term survival remain uncertain. Clinicians should therefore ensure that patients understand the uncertainties and the alternative treatment options. They should provide them with clear written information and, in addition, use of the Institute's <i>Information for the public</i> is recommended.</p> <p>Further research and audit should address quality of life, clinical outcomes and long-term survival.</p> <p>IPG XXX high dose rate brachytherapy for localised prostate cancer (in combination with external beam radiotherapy)</p> <p>Current evidence on the safety and efficacy of high dose rate (HDR) brachytherapy in combination with external-beam radiotherapy for localised prostate cancer appears adequate to support the use of this procedure provided that the normal arrangements are in place for consent, audit and clinical governance.</p> <p>A multidisciplinary team should be involved in the planning and use of this procedure</p>
Technology appraisals	None applicable
Clinical guidelines	Improving outcomes in urological cancers

	<p>Early (organ-confined) prostate cancer The prostate cancer service should be capable of providing active monitoring, radical surgery, radiotherapy, or hormone treatment for men whose cancer is believed to be confined to the prostate. All possible management options should be discussed with patients.</p> <p>There is no consensus on the optimum form of management for these patients. Although observational studies suggest that radical treatment can improve long term survival rates in particular patient groups, this evidence is by its nature subject to bias. In addition, the uncertain benefits of radical interventions must be balanced against the risk of lasting adverse effects. Research – both randomised controlled trials and audit of outcomes outside the context of clinical trials – is essential to clarify the role of each form of treatment and should be supported.</p> <p>Different men vary greatly in the value they ascribe to potential outcomes. The treatment each patient receives should be tailored to fit his individual values and situation, so it is essential that patients are actively involved in decision-making. This requires that they receive adequate and accurate information, both through meetings with members of the MDT, and in published forms that they can study at home. Patients should be given sufficient time to consider all the options available to them.</p> <p><u>Surgery</u> Radical prostatectomy should be discussed with men whose tumours are confined to the prostate and who would be expected to live for more than 10 years if they did not have prostate cancer.</p> <p>Patients for whom surgery is being considered should be treated by specialist multidisciplinary urological cancer teams, normally based at cancer centres. (See Topic 1, The urological cancer network and multidisciplinary teams.) Ideally, all radical prostatectomies undertaken in each network should be carried out by a single team. Radical prostatectomy should not be carried out by teams which carry out fewer than 50 radical operations (prostatectomies and cystectomies) for prostate or bladder cancers per year.</p> <p>This level of work-load is currently unusual in the UK and a transition period is likely to be required for re-organisation of services before the criterion of 50 operations can be met. In the meantime, surgeons who currently carry out fewer than five radical prostatectomies per year should refer patients to designated surgeons who will become more specialised in this type of surgery.</p> <p>Laparoscopic prostatectomy is not recommended outside the context of well-designed clinical trials supervised by experienced surgeons. Proficiency in this</p>
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	procedure requires considerable practice and inexperienced surgeons can cause serious harm.
Public health	None applicable

Appendix C: Literature search for laparoscopic radical prostatectomy

IP: 353 Laparoscopic radical prostatectomy		
Database	Date searched	Version searched
Cochrane Library	18.04.06	Issue 1: 2006
CRD databases	“	-
Embase	“	1980 – week 16 2006
Medline	“	1966 – April week 1 2006
Premedline	“	- April week 1 2006
CINAHL	“	1982 – April week 1 2006
British Library Inside Conferences	19.04.06	-
NRR	“	Issue 1: 2006
Controlled Trials Registry	“	-

The following search strategy was used to identify papers in Medline. A similar strategy was used to identify papers in other databases.

1. Laparoscopy/
2. lapraoscop\$.tw.
3. laparoscop\$.tw.
4. exp Endoscopy/
5. endoscop\$.tw.
6. exp Surgical Procedures, Minimally Invasive/
7. or/1-6
8. exp Prostatectomy/
9. prostatectom\$.tw.
10. montsouris.tw.
11. vallancien\$.au.
12. guillonneau\$.au.
13. or/8-12
14. (prostat\$ adj3 (cancer\$ or neoplasm\$ or carcinom\$ or adenocarcinom\$ or malig\$ or tumor\$ or tumour\$ or gerinom\$)).tw.
15. prostatic neoplasms/
16. 14 or 15
17. 7 and 13 and 16
18. animal/
19. human/
20. 18 not 19
21. 17 not 20
22. limit 21 to english language