



Prepared by ASERNIP-S

NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Laparoscopic Radical Prostatectomy

Introduction

This overview has been prepared to assist members of IPAC advise on the safety and efficacy of an interventional procedure previously reviewed by SERNIP. It is based on a rapid survey of published literature, review of the procedure by Specialist Advisors and review of the content of the SERNIP file. It should not be regarded as a definitive assessment of the procedure.

Procedure name

Laparoscopic radical prostatectomy

SERNIP procedure number

39

Specialty society

British Association of Urological Surgeons (BAUS)

Executive Summary

The current evidence base regarding the safety and efficacy of laparoscopic radical prostatectomy largely consists of case series from a few specialised centres who have invested the considerable time and effort involved in mastering the required level of laparoscopic technical skill that is necessary to perform this procedure.

There is very little good quality comparative data currently available to compare the laparoscopic radical prostatectomy procedure to standard open retropubic radical prostatectomy. The early comparative results suggest that the laparoscopic technique may result in lower positive surgical margin rates which, in turn, could lead to a decreased rate of disease recurrence following surgery. Patients undergoing laparoscopic radical prostatectomies also appear to require less postoperative pain analgesia.

Surgical conversion rates were low, ranging from 0% to 3.7%. Two studies reported total postoperative complication rates of 17.1% (in which 20% of these complications were considered 'major') and 20% respectively.

In terms of urinary continence and erectile function, case series data report continence rates (defined as either no pads or one pad required daily) ranging from 78.4% at one year to 85% at 3 months.

In terms of erectile function, one study reported that 75% of patients (who were under 70 years of age and had bilateral nerve sparing) were potent at 6 months. Another study reported that only 11% of their sample reported spontaneous erections at 1 year and only 2% reported erectile function sufficient for penetrative intercourse at 1 year.

Indication(s)

Indications for laparoscopic radical prostatectomy are localised prostate carcinoma with little evidence of extraprostatic or systematic metastatic progression of disease (identical to those for the standard radical retropubic prostatectomy).

Summary of procedure

The Montsouris technique¹, as originally pioneered by Vallancien and Guillionneau is described here.

The patient is placed in the dorsal supine position with lower limbs in abduction to provide perineal access. Five trocars are inserted: A 10 mm trocar in the umbilicus, three 5 mm trocars sequentially inserted into the left iliac fossa, midway between the umbilicus and pubis and into the right pararectal fossa. A final 10 mm trocar is inserted into the right iliac fossa above McBurney's point.

The lymph nodes can be removed at this point for frozen section histological analysis. This is followed by the laparoscopic dissection of the vasa deferentia, seminal vesicles and prostatic specimen itself. Sparing of the two neurovascular pedicles is attempted, if oncologically and anatomically possible.

A water-tight anastomosis is then made and the prostatic specimen is extracted with a laparoscopy bag via the orifice located above McBurney's point.

Advantages/ Disadvantages of Procedure

The postulated advantages of laparoscopic radical prostatectomy over the traditional retropubic approach are:

- A reduction of abdominal wall morbidity
- Less blood loss
- Less postop pain
- Quicker convalescence
- Better cosmetic results
- Improved magnification and lighting which aids in the dissection of the narrow pelvis and suturing of the urethrovesical anastomosis, which could theoretically improve continence and facilitate an earlier catheter removal

In terms of disadvantages, Kavoussi *et al.*² have commented that the procedure requires a steep learning curve with an average 'learning curve of

60 cases' compared to other laparoscopic urological procedures, such as laparoscopic nephrectomy, where the learning curve typically is 20 cases for inexperienced laparoscopists.³

A recent development in laparoscopic radical prostatectomy has been the evolution of robotically assisted laparoscopic radical prostatectomies. The literatures searches yielded 13 references⁴⁻¹⁶ on this particular topic.

Literature review

A systematic search of MEDLINE, PREMEDLINE, EMBASE, Current Contents, PubMed, Cochrane Library and Science Citation Index using Boolean search terms was conducted, from the inception of the databases until November 2002. The York Centre for Reviews and Dissemination, Clinicaltrials.gov, National Research Register, SIGLE, Grey Literature Reports, relevant online journals and the Internet were also searched in November 2002. Searches were conducted without language restriction.

Articles were obtained on the basis of the abstract containing safety and efficacy data on the laparoscopic radical prostatectomy procedure in the form of randomised controlled trials (RCTs), other controlled or comparative studies, case series and case reports. Conference abstracts and manufacturer's information were retrieved if they contained relevant safety and efficacy data. The English abstracts from foreign language papers were also retrieved if they contained safety and efficacy data. In the case of duplicate publications, publications with the most safety and efficacy data were retrieved.

List of Studies Included

Total number of studies: 36

| | |
|------------------------------------|----|
| Randomised controlled trials | 0 |
| Non-randomised comparative studies | 1 |
| Case series | 33 |
| Case reports | 2 |

The references for the five papers considered to be most useful are highlighted in bold in the reference list. The one available comparative study was included as well as a series of papers from the Institut Mutualiste Montsouris (pioneers of the Montsouris technique) which contains their most recent data on positive surgical margins, learning curve effect, perioperative complications and postoperative results. One other well-reported series from the USA from a centre reporting upon its initial 70 cases was also included along with two other large case series which focussed upon the quality of life outcomes of postoperative erectile function and continence respectively.

Proposal for a Randomised Controlled Trial in the UK

A randomised controlled trial comparing open retropubic versus laparoscopic radical prostatectomy has been proposed. All the laparoscopic radical prostatectomy procedures would be performed at the North Hampshire Hospital in Basingstoke whilst all the open procedures for the trial would be conducted at the Bristol Royal Infirmary. Start and completion dates for this trial were not known at the time of report writing.

Summary of key efficacy and safety findings

See following tables;

Abbreviations

| | |
|--------|------------------------------------|
| Lap RP | Laparoscopic radical prostatectomy |
| MI | Myocardial infarction |
| pT | Pathological stage |
| RRP | Radical retropubic prostatectomy |

| Authors, date, location, number of patients, length of follow-up, selection criteria | Key efficacy findings | Key safety findings | | | Appraisal/Comments |
|---|---|---------------------|------------|----------------|---|
| Non Randomised Comparative Studies | | | | | |
| Fromont et al.¹⁷ 2002 FRANCE | | Lap RP | RRP | P value | None reported |
| Total N: 278 139 Lap RP pts 139 RRP pts | Positive surgical margins | 13.7% | 25.9% | <0.02 | <i>Potential for bias:</i> Lap RP and RRP procedures performed at differing time periods (but by the same two surgeons when both were experienced in either technique). It is not clear whether they had 100% compliance at follow-up or whether there were losses to follow-up. |
| Follow-up not reported | No. of positive margins in organ confined cancers only | 10% | 20.9% | <0.05 | |
| <u>Selection Criteria</u> Localised prostate cancer amenable to surgery. Pts receiving neoadjuvant therapy were excluded | Median length of margins (mm) | 3 +/- 2.2 | 3 +/- 3.1 | NS | Although no statistical difference measured, the number of Gleason scores of 8 or 9 were higher in the RRP group than the Lap RP group (8.6% vs 4.3%) at baseline. |
| <i>Both groups similarly matched for age, PSA, number of positive biopsies, prostate weight, number of positive lymph nodes, pathological stage and distribution of intraprostatic (pT2) versus extraprostatic cancer (pT3)</i> | Number of surgically induced margins | 2.1% | 2.9% | | Outcome Measures: Specimens were processed using a standardised pathologic method (Stanford procedure) |
| | Apical positive margin | 7.2% | 15.5% | <0.05 | |
| | Level of positive apical margins in localised cancers (pT2) | 7% | 18% | <0.05 | Positive surgical margins were carefully defined ('extension of tumour to the inked surface of the specimen') and all assessments were carried out by the same two pathologists |
| | % Positive Margins - Stratified by Gleason Score | | | | Gleason score is a standardised, well accepted method of assessing the histological grade of the cancer. |
| | Gleason Score | Lap RP | RRP | | |
| | 5 or 6 | 7.8 | 24.3 | | |
| | 7 | 18.8 | 20.7 | | |
| | 8 or 9 | 16.7 | 58.3 | | |

| Authors, date, location, number of patients, length of follow-up, selection criteria | Key efficacy findings | Key safety findings | Appraisal/Comments | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|--|---------------------------|--------------------|-----|---------|-----------|-------|--------|---------|------------------|-------|-------|---------|--------------------------------|--------|--------|--------|--|----------------------|------|----------------------------|---------|-----------------|---------|----|---------|-------------------|---------|--------------------|---------|------------------------|---------|---------------|---------|---|
| <i>Comparative Studies/ Case Series</i> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <p>Dahl et al.¹⁸ 2002 USA</p> <p>70 patients, Minimum 3 months follow-up</p> <p>Case series with a comparison of analgesia use of this lap RP series with the previous 40 RRP patients for the two surgeons involved in the study</p> <p>Selection criteria: Patients who would be appropriate for RRP</p> | <p><u>Mean length of stay:</u> 2.5 days (range 1-6)</p> <p><u>Mean operating time:</u> 274 min (range 165-495)</p> <p>Positive surgical margins: 11.4% (8/70) of patients: 4 – apical 4 – lateral margin 1- at the bladder neck</p> <p><u>Patient reported continence</u> (minimum of 3 months follow-up) 85% of patients used no or only 1 pad per day</p> <p><u>Physician reported continence</u> (At 3 months n=51) 70.6% of patients – used no pads 13.7% of patients – used one (or fewer) pads per day 15.7% of patients – used two or more pads per day</p> <p><u>Mean Analgesia Use</u></p> <table border="1" data-bbox="562 1026 1070 1246"> <thead> <tr> <th>Average Dose of Analgesic</th> <th>Lap RP</th> <th>RRP</th> <th>P value</th> </tr> </thead> <tbody> <tr> <td>Ketorolac</td> <td>86 mg</td> <td>123 mg</td> <td><0.0007</td> </tr> <tr> <td>Morphine sulfate</td> <td>14 mg</td> <td>34 mg</td> <td><0.0005</td> </tr> <tr> <td>Oral hydrocodone acetaminophen</td> <td>3.7 mg</td> <td>6.5 mg</td> <td><0.003</td> </tr> </tbody> </table> | Average Dose of Analgesic | Lap RP | RRP | P value | Ketorolac | 86 mg | 123 mg | <0.0007 | Morphine sulfate | 14 mg | 34 mg | <0.0005 | Oral hydrocodone acetaminophen | 3.7 mg | 6.5 mg | <0.003 | <p><u>Surgical conversion rate:</u> 1.4% (1/70) due to a rectal injury</p> <p><u>Mean estimated blood loss:</u> 449 ml (50-2750)</p> <p>Blood transfusion rate: 5.7% (4/70)</p> <p><u>Intraoperative or immediate postop complication rate:</u> 2.9% 1 small bowel enterotomy 1 rectal injury</p> <p><u>Overall postop complications:</u> 20% (14/70)</p> <table border="1" data-bbox="1115 802 1688 1050"> <thead> <tr> <th>Postop Complications</th> <th>n(%)</th> </tr> </thead> <tbody> <tr> <td>Transient urine leak/ileus</td> <td>6 (8.6)</td> </tr> <tr> <td>Flank haematoma</td> <td>1 (1.4)</td> </tr> <tr> <td>MI</td> <td>1 (1.4)</td> </tr> <tr> <td>Urinary retention</td> <td>2 (2.9)</td> </tr> <tr> <td>Bacterial cystitis</td> <td>2 (2.9)</td> </tr> <tr> <td>Cervical plexus injury</td> <td>1 (1.4)</td> </tr> <tr> <td>Bladder stone</td> <td>1 (1.4)</td> </tr> </tbody> </table> | Postop Complications | n(%) | Transient urine leak/ileus | 6 (8.6) | Flank haematoma | 1 (1.4) | MI | 1 (1.4) | Urinary retention | 2 (2.9) | Bacterial cystitis | 2 (2.9) | Cervical plexus injury | 1 (1.4) | Bladder stone | 1 (1.4) | <p><i>Potential for Bias:</i> Not clear if Lap RP patients are consecutive. Also, the historical comparison is limited in its usefulness. There is also a lack of longer follow-up.</p> <p><i>Outcomes:</i> Patient and physician reported continence rates give similar results</p> <p><i>Other comments:</i> Authors note that ‘operating times, blood loss and complication rates all decrease with experience’.</p> |
| Average Dose of Analgesic | Lap RP | RRP | P value | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Ketorolac | 86 mg | 123 mg | <0.0007 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| Postop Complications | n(%) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Transient urine leak/ileus | 6 (8.6) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Flank haematoma | 1 (1.4) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| MI | 1 (1.4) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Urinary retention | 2 (2.9) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Bacterial cystitis | 2 (2.9) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Cervical plexus injury | 1 (1.4) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Bladder stone | 1 (1.4) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

| Authors, date, location, number of patients, length of follow-up, selection criteria | Key efficacy findings | Key safety findings | Appraisal/Comments | | | | | | | | | | | | | | | | |
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| Comparative Studies/ Case Series | | | | | | | | | | | | | | | | | | | |
| <p>Institut Mutualiste Montsouris Case Series (FRANCE)</p> <p>Guillonneau et al.¹⁹ 2000 (n=120) <i>Comparative study- 120 lap RP (compares three consecutive groups of first, second and third set of 40 patients- Groups 1, 2 and 3) and also compares the 120 patients to the last 100 patients who underwent RRP at Institut Montsouris</i></p> <p>Guillonneau et al.²⁰ 2002 (n=567) <i>Documents perioperative complications</i></p> <p>Vallancien et al.²¹ 2002 (n=841) <i>Provides longest follow-up for this case series of patients (January 1998 to April 2001)</i></p> <p>(Overlap of patients in these three studies)</p> | <p><u>Positive surgical margins</u> (n=120)</p> <p>pT2a 5% pT2b 22.5% pT3a 22.7% pT3b 30%</p> <p><u>Continence</u> Since 1999, 89.2% of all patients (n=841) had regained their continence at 1 year 0.3% required an artificial urinary sphincter (n=841)</p> <p><u>Erectile Function</u> 75% of patients < 70 years of age who had bilateral nerve sparing were potent at 6 months (n= 77 of 120 pts in series)</p> <p><u>Mean operating time:</u> 2 hrs 40 minutes (range: 1hr 30 min to 6 hrs 30 mins) (n=841)</p> | <p><u>Postoperative deaths:</u> 0 (n=841)</p> <p><u>Pulmonary emboli:</u> 0 (n=841)</p> <p><u>Re-operation rate:</u> 3.7% (n=567)</p> <p><u>Surgical conversion rate:</u> 0.9% (n=841)</p> <table border="1" data-bbox="1256 667 1675 970"> <thead> <tr> <th></th> <th>Group 1</th> <th>Group 2</th> <th>Group 3</th> </tr> </thead> <tbody> <tr> <td>Mean operating time (min)</td> <td>282</td> <td>247</td> <td>231</td> </tr> <tr> <td>Mean intraop bleeding (ml)</td> <td>534</td> <td>517</td> <td>277</td> </tr> <tr> <td>Transfusion rate (%)</td> <td>15</td> <td>12.5</td> <td>2.5</td> </tr> </tbody> </table> <p><u>Mean bleeding overall (ml):</u> 402 +/- 293 (range: 50 to 1500 ml) (n=567)</p> <p><u>Overall cost of procedures:</u> (in US dollars) RRP was \$1237 more on average than the lap RP</p> <p>Lap RP series - Complications Perioperative and Short-term (30 days post-op) Complications : Overall rate: 17.1 %</p> | | Group 1 | Group 2 | Group 3 | Mean operating time (min) | 282 | 247 | 231 | Mean intraop bleeding (ml) | 534 | 517 | 277 | Transfusion rate (%) | 15 | 12.5 | 2.5 | <p>Potential for Bias: Case series. Methods for selecting patients not stated Limited historical comparison data</p> <p>In the Guillonneau 2002 series, 11/579 potential patients for the case series were excluded from the study</p> <p>Outcomes: Continence Self report by patient (validated) Also used a complication rating scheme</p> <p>Other Comments: Authors noted that to decrease risk of undiagnosed bleeding due to trocar injury to the epigastric artery, it is wise to reduce insufflation pressure at the end of op and remove trocars under direct visualisation</p> |
| | Group 1 | Group 2 | Group 3 | | | | | | | | | | | | | | | | |
| Mean operating time (min) | 282 | 247 | 231 | | | | | | | | | | | | | | | | |
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|--|-----------------------|--|---------------------|--------------|-------------------|--|---------------------|---------|----------------|---------|-----------------|---------|--------------------|----------|--------------|--|---------------|---------|--------------|----------|----------------|----------|-------|---------|---------------------|--|-------------------------|----------|---------------------|----------|--------------|--|--------------|---------|------------|----------|----------------|----------|-------------------|---------|------------------|---------|------------------------------------|-------------|-------|----|-------|----|--|
| Institut Mutualiste Montsouris Case Series (FRANCE) (continued) | | <u>All Complications: (from Guillonneau <i>et al.</i> 2002)</u> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Guillonneau <i>et al.</i> 2000 (n=120) Guillonneau <i>et al.</i> 2002 (n=567) Vallancien <i>et al.</i> 2002 (n=841) | | <table> <thead> <tr> <th data-bbox="1104 464 1473 488">Complication</th> <th data-bbox="1496 464 1574 488">n (%)</th> </tr> </thead> <tbody> <tr> <td colspan="2">Urological</td> </tr> <tr> <td>Anastomotic fistula</td> <td>57 (10)</td> </tr> <tr> <td>Bladder Injury</td> <td>9 (1.6)</td> </tr> <tr> <td>Ureteral injury</td> <td>3 (0.5)</td> </tr> <tr> <td>Obstructive anuria</td> <td>1 (0.17)</td> </tr> <tr> <td colspan="2">Bowel</td> </tr> <tr> <td>Rectal injury</td> <td>8 (1.4)</td> </tr> <tr> <td>Ileal injury</td> <td>2 (0.35)</td> </tr> <tr> <td>Sigmoid injury</td> <td>1 (0.17)</td> </tr> <tr> <td>Ileus</td> <td>6 (1.1)</td> </tr> <tr> <td colspan="2">Neurological</td> </tr> <tr> <td>Compressive neuropraxia</td> <td>2 (0.35)</td> </tr> <tr> <td>Axonal degeneration</td> <td>1 (0.17)</td> </tr> <tr> <td colspan="2">Other</td> </tr> <tr> <td>Lymphorrhoea</td> <td>2 (0.4)</td> </tr> <tr> <td>Thrombosis</td> <td>2 (0.35)</td> </tr> <tr> <td>Hemoperitoneum</td> <td>5 (0.88)</td> </tr> <tr> <td>Epigastric injury</td> <td>3 (0.5)</td> </tr> <tr> <td>Wound dehiscence</td> <td>4 (0.7)</td> </tr> <tr> <td><u>Total Complications: (n=97)</u></td> <td>105 (17.1%)</td> </tr> <tr> <td>Major</td> <td>21</td> </tr> <tr> <td>Minor</td> <td>83</td> </tr> </tbody> </table> | Complication | n (%) | Urological | | Anastomotic fistula | 57 (10) | Bladder Injury | 9 (1.6) | Ureteral injury | 3 (0.5) | Obstructive anuria | 1 (0.17) | Bowel | | Rectal injury | 8 (1.4) | Ileal injury | 2 (0.35) | Sigmoid injury | 1 (0.17) | Ileus | 6 (1.1) | Neurological | | Compressive neuropraxia | 2 (0.35) | Axonal degeneration | 1 (0.17) | Other | | Lymphorrhoea | 2 (0.4) | Thrombosis | 2 (0.35) | Hemoperitoneum | 5 (0.88) | Epigastric injury | 3 (0.5) | Wound dehiscence | 4 (0.7) | <u>Total Complications: (n=97)</u> | 105 (17.1%) | Major | 21 | Minor | 83 | |
| Complication | n (%) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Urological | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Anastomotic fistula | 57 (10) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Bladder Injury | 9 (1.6) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Ureteral injury | 3 (0.5) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Obstructive anuria | 1 (0.17) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Bowel | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Rectal injury | 8 (1.4) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Ileal injury | 2 (0.35) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Sigmoid injury | 1 (0.17) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Ileus | 6 (1.1) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Neurological | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Compressive neuropraxia | 2 (0.35) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Axonal degeneration | 1 (0.17) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Other | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Lymphorrhoea | 2 (0.4) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Thrombosis | 2 (0.35) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Hemoperitoneum | 5 (0.88) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Epigastric injury | 3 (0.5) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Wound dehiscence | 4 (0.7) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <u>Total Complications: (n=97)</u> | 105 (17.1%) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Major | 21 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Minor | 83 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

| Authors, date, location, number of patients, length of follow-up, selection criteria | Key efficacy findings | | | | Key safety findings | Appraisal/Comments |
|---|--|--------------------|-----------------------------|---|---------------------|---|
| Case Series | | | | | | |
| Katz et al.²² 2002 FRANCE | Erectile Function | | | | None reported | Potential for Bias: Large losses to follow-up Of 143 patients, only 100, 80, 48 and 26 responded at 1,3,6, and 12 month followups. |
| 143 patients (of the 232 total patients in the case series) who were potent preoperatively, Followup at 1,3,6 and 12 months | Time of Follow-up | No. of respondents | % reporting erections | % reporting penetrative intercourse | | Outcomes: Non-validated questionnaire used for patient reported outcomes |
| <u>Selection criteria:</u> Localised prostate cancer amenable to surgical resection | 1 month | 100 | 21 | 8 | | |
| | 3 months | 80 | 31 | 23.7 | | |
| | 6 months | 48 | 29.1 | 22.9 | | |
| | 12 months | 26 | 53.8 | 23 | | |
| | Bilateral sparing patients only (63/143) | No. of respondents | No. (%) reporting erections | No. (%) reporting penetrative intercourse | | |
| | 1 month | 46 | 13 (21) | 7 (11) | | |
| | 3 months | 34 | 14 (22) | 11 (17) | | |
| | 6 months | 24 | 7 (11) | 5 (8) | | |
| | 12 months | 8 | 7 (11) | 1 (2) | | |
| | Positive surgical margins – 25% in bilateral nerve sparing group | | | | | |

| Authors, date, location, number of patients, length of follow-up, selection criteria | Key efficacy findings | Key safety findings | | | | Appraisal/Comments | | | | | | | | | | | | | | | |
|---|--|---------------------|------------------|------------------|----------|--------------------|--|------------------|------------------|------------------|------------------|--------------|-----------------|-----------------|-----------------|-----------------|---|--|--|--|---|
| <p>Olsson <i>et al.</i>²³ 2001 FRANCE</p> <p>228 patients, Follow-up at 1,3,6, and 12 months</p> <p>May 1998 to February 2000</p> <p><i>(Please note: First half of patient sample overlaps with the Katz <i>et al.</i> study documented above for erectile function)</i></p> | <p>Continence</p> <table border="1"> <thead> <tr> <th></th> <th>1 months</th> <th>3 months</th> <th>6 months</th> <th>12 months</th> </tr> </thead> <tbody> <tr> <td>Perfect diurnal urinary control (no pads and no leaks)</td> <td>9.9% (10/109)</td> <td>28.6% (22/77)</td> <td>57.4% (35/61)</td> <td>56.8% (21/37)</td> </tr> <tr> <td>No pads used</td> <td>18.8 19/109)</td> <td>58.4 (45/77)</td> <td>68.9 (42/61)</td> <td>78.4 (29/37)</td> </tr> </tbody> </table> | | 1 months | 3 months | 6 months | 12 months | Perfect diurnal urinary control (no pads and no leaks) | 9.9% (10/109) | 28.6% (22/77) | 57.4% (35/61) | 56.8% (21/37) | No pads used | 18.8 19/109) | 58.4 (45/77) | 68.9 (42/61) | 78.4 (29/37) | <p>No conversion to open RRP</p> <p>Blood transfusion rate: 3%</p> <p>Leaks identified in 19.4% of cases</p> <p>Anastomotic strictures occurred in 1.3% of patients</p> | | | | <p><i>Potential for Bias</i></p> <p>Only 115 of the 228 patients (50%) agreed to answer questionnaires for the study</p> <p>Outcomes:</p> <p>Used their own modified version of the International Continence Society (ICS) standard, validated questionnaire</p> |
| | 1 months | 3 months | 6 months | 12 months | | | | | | | | | | | | | | | | | |
| Perfect diurnal urinary control (no pads and no leaks) | 9.9% (10/109) | 28.6% (22/77) | 57.4% (35/61) | 56.8% (21/37) | | | | | | | | | | | | | | | | | |
| No pads used | 18.8 19/109) | 58.4 (45/77) | 68.9 (42/61) | 78.4 (29/37) | | | | | | | | | | | | | | | | | |
| | <p>Positive surgical margins: 24.6%</p> <p>Median urethral catheter duration (days): 4</p> | | | | | | | | | | | | | | | | | | | | |

King's College Hospital, London 30 cases to date
Southmead Hospital, Bristol 10 cases to date

Issues for consideration by IPAC

None

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ANNEX: Studies that met the inclusion criteria but which were not tabulated.

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