

# ASERNIP/S



Australian Safety  
and Efficacy  
Register of New  
Interventional  
Procedures – Surgical

## Consumer summary

### Laparoscopic radical prostatectomy – [accelerated systematic review](#)

A glossary of medical terms appears on the last page.

- In Word, click on words underlined in blue to link to the glossary definition.
- In the PDF, scroll to the end of the document to access the glossary.

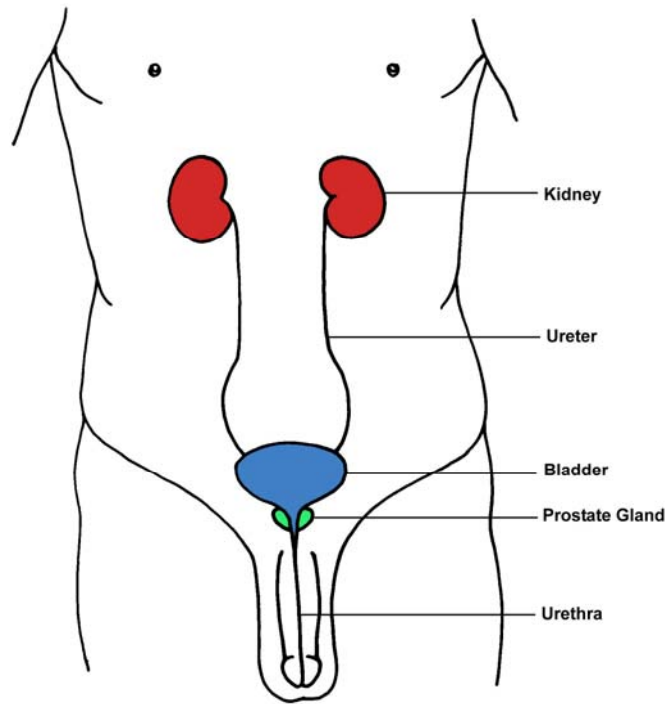
#### Introduction

The following information is about laparoscopic radical prostatectomy (LRP), a new [minimally invasive](#) surgical technique used to treat prostate cancer. ASERNIP-S has reviewed the available published studies (called evidence) to compare the safety and effectiveness of this procedure with open surgery to treat this condition. The review also looked at the learning curve for surgeons first performing LRP.

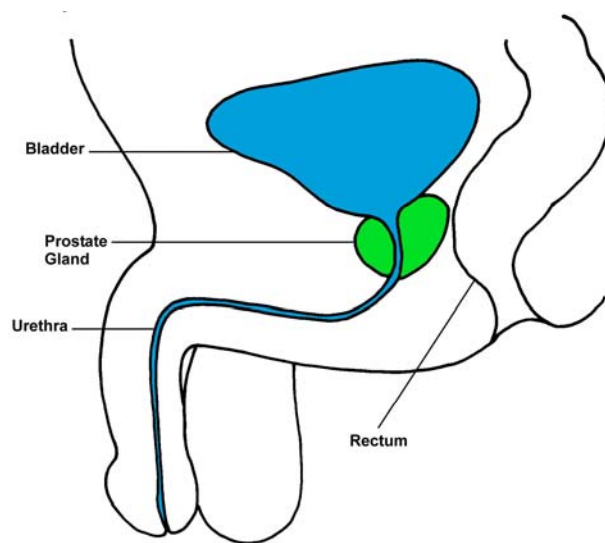
#### What is prostate cancer?

The prostate gland of the male encircles the bladder neck, which is the opening of the bladder to the outflow tube called the [urethra](#) through which urine travels to outside the body (Figures 1 & 2). In most men, the prostate gland slowly gets bigger over time after 40 years of age, and this is very common beyond 60 years of age. This is called benign prostatic hyperplasia (or BHP) and is not a cancer. The reason for this growth of the prostate gland is not known. Prostate cancer (malignant) is the abnormal growth of prostate cells, usually those secreting fluid which becomes part of the semen ejaculated by the male. Prostate cancer usually grows slowly and the patient may not have symptoms for years. As the prostate gets bigger, it may gradually block off the [urethra](#), which can cause urinary symptoms such as difficulty in starting to pass urine; having to pass urine more often, especially during the night; dribbling of urine before and after passing urine; and, rarely, blood in the urine.

**Figure 1: Anatomy of the male urogenital system**



**Figure 2: Side view of the male urogenital system**



Prostate cancer is the most common form of cancer for men (excluding non-melanoma skin cancer) in Australia and around the world, and increases with age in men over 50 years. One in eleven Australian men will have prostate cancer during their lifetime; however, many of these will not have treatment and many will die from another cause.

### **Treatment options**

Treatment options for prostate cancer depend on whether the cancer has spread, the way the tumour cells grow, the presence of prostate specific antigen (PSA) in the blood, and the patient's age, general health and preference with regard to side effects. The options include:

- surgery (recommended for younger men with localised cancer which has not spread to other parts of the body)
- radiation therapy (for patients who can't have surgery)
- watchful waiting (for older men of more than 75 years or those with poor health and short life expectancy).

If a malignant cancer is detected early, the whole prostate may be surgically removed. If the enlargement is not a cancer (BPH), there are a number of options for removing part of the prostate.

### **Surgical techniques**

The removal of the whole prostate of a patient is called radical prostatectomy. The [seminal vesicles](#) and affected [lymph nodes](#) may also be removed. The aim is to cure the cancer while not affecting the patient's [continence](#) or sexual function.

#### ***Open radical prostatectomy***

The prostate may be removed during an [open operation](#) through a large cut made in either:

- *the lower [abdomen](#) (radical retropubic prostatectomy or RRP)* – usual approach
- *the [pelvic floor](#) (radical [perineal](#) prostatectomy or RPP)* – less common.

In both procedures a nerve-sparing technique can be used in which the nerves and vessels near the prostate are separated from the prostate (spared) so as to minimise the effect on the patient's sexual function. After cutting the prostate away, the bladder neck (which previously drained into the top of the urethra) is re-connected to the urethra. A drain is placed and the wound is closed.

Following open radical prostatectomy, up to 95% of patients (i.e. 95 patients in 100) are still alive after 5 years. However, the procedure may lead to complications such as

urinary incontinence (between 5% and 42%) and problems with sexual function (between 22% and 77%). Up to 1 in 3 patients who had the procedure in the United States between 1991 and 1994 experienced at least one complication, including cardiorespiratory failure, damage to the rectum and ureter, [urinary retention](#), infection, bleeding, [haematoma](#) and leaking [anastomosis](#). Patients usually stay in hospital for 2 to 3 days after the procedure in the U.S. and 5 to 7 days in Europe.

[Minimally invasive](#) procedures are expected to reduce the amount of blood lost by the patient and the time needed to recover after the operation. In theory, the [laparoscope](#) should give the surgeon a better view of the patient's anatomy and minimise damage to surrounding organs including those affecting the patient's [continence](#) and sexual function. However, it is not known whether these procedures control cancer as well as open radical prostatectomy. It is also unclear how much experience a surgeon needs (i.e. the number of procedures performed) in order to obtain the best outcomes for patients.

### ***Laparoscopic prostatectomy***

Since 1997 laparoscopic radical prostatectomy (LRP) has been offered as a [minimally invasive](#) alternative to open prostatectomy. The prostate can be approached in several ways, through:

- *the lower [abdomen](#) (extraperitoneal [endoscopic](#) radical prostatectomy or EERP)*. This technique does not cross the [peritoneal](#) cavity, and is similar to the [open procedure](#) RRP (but the surgeon uses [laparoscopic](#) instruments inserted through small cuts rather than accessing the site through a large 'open' cut).
- *the [peritoneum](#) (transperitoneal LRP or TLRP)* –the usual laparoscopic approach. During this procedure, five pointed tubes called trocars are placed in the [abdomen](#), forming access holes. One of these is used to pump air into the space between the inner lining of the [abdomen](#) and the organs so that the surgeon can see and access the site of the operation. Any affected [lymph nodes](#) are cut away, followed by the prostate and [seminal vesicles](#). Nerve-sparing can take place. The urethra is connected to the bladder neck and the prostate tissue is removed through one of the holes.
- *the [peritoneum](#) using a robotic surgical system (robotic-assisted LRP)*, generally the da Vinci surgical robotics system. The approach is similar to TLRP, except the surgeon observes and conducts the operation through a computerised console connected to robotic arms with laparoscopic instruments attached.

### **How do these procedures compare?**

#### ***Laparoscopic versus open radical prostatectomy***

### *Safety*

Total complication rates were similar for laparoscopic and open prostatectomy, although in one study complications were significantly higher for open prostatectomy than for robotic-assisted laparoscopic prostatectomy.

Regarding individual complications:

- complications of the ureter may have been more common after the laparoscopic approach through the peritoneum (TLRP) than the open operation through the lower abdomen (RRP)
- deep vein thrombosis/embolus probably occurred more after the open operation through the lower abdomen (RRP) (with 2 deaths from pulmonary [embolism](#) reported in 2 studies totalling 364 patients) than the laparoscopic approaches.

Regarding other outcomes:

- blood loss and transfusions were less for laparoscopic than open prostatectomy
- the laparoscopic operations took longer than open prostatectomy (except the robotic-assisted laparoscopic procedure was of similar duration)
- no consistent pattern was recorded for pain relief
- length of hospital stay and catheterization was shorter for laparoscopic than open prostatectomy.

### *Effectiveness*

Regarding effectiveness:

- [positive margin rate](#) was similar for laparoscopic and open prostatectomy
- there was no difference in recurrence-free survival between laparoscopic and open prostatectomy but there was little data to judge this.

### *Patient-reported outcomes*

Regarding outcomes reported by patients:

- [continence](#): rates were similar for laparoscopic and open prostatectomy; may have recovered more quickly after laparoscopic prostatectomy through the peritoneum (TLRP) than open; and was faster to recover after the robotic-assisted laparoscopic approach than open prostatectomy (in one study)
- potency (measure of sexual function) after the procedures not well-reported, but appeared to be similar for laparoscopic prostatectomy through the peritoneum or lower abdomen compared to open prostatectomy; one study reported it recovered more quickly after the robotic laparoscopic procedure than the open procedures

- quality of life was rarely reported, but did not differ between the laparoscopic approach through the peritoneum and the open procedure through the lower abdomen.

### ***Comparisons between different laparoscopic approaches***

#### *Safety*

Total complication rate did not appear to differ according to laparoscopic approach. One patient death (without specific cause) was reported after transperitoneal laparoscopic prostatectomy (study of 165 patients) and there were two conversions from laparoscopic prostatectomy through the lower abdomen to the peritoneal approach.

Regarding other outcomes:

- blood loss was similar for the laparoscopic approaches through the peritoneum and the lower abdomen (except for robotic-assisted LRP, which resulted in less blood loss than the trans-peritoneal approach in one study)
- rates of blood transfusion, length of operation, hospital stay and catheterization, and amount of pain relief were similar.

#### *Effectiveness*

Regarding effectiveness:

- [positive margin rates](#) and recurrence-free survival were similar.

#### *Patient-reported outcomes*

Regarding outcomes reported by patients:

- effects on [continence](#) and potency were similar in 3 studies
- quality of life was not reported.

#### ***Learning curve***

As surgeons gained experience with laparoscopic approaches, most clinical outcomes improved, except for the length of time the patient stayed in hospital and the duration of catheterization.

### **What is the recommended procedure for treating the disease?**

Laparoscopic radical prostatectomy is emerging as an alternative to open radical prostatectomy for treating localised prostate cancer. The evidence shows that the laparoscopic procedures are associated with less blood loss and transfusions for the patient, and shorter hospital stay and catheterization. However, there is not enough comparative data regarding [continence](#), potency and survival.

There did not appear to be any clear differences between the laparoscopic approaches with regard to safety and effectiveness. Robotic-assisted prostatectomy is expensive, but offers the promise of shorter operative times than standard laparoscopic approaches and may produce a quicker recovery of [continence](#) and potency than open prostatectomy.

As experience with laparoscopic radical prostatectomy increased, clinical outcomes improved. However, it was not possible to determine how many laparoscopic procedures must be completed to overcome this learning curve.

The review group recommended that a national audit of laparoscopic radical prostatectomy, including robotic-assisted LRP, take place while the technique is being introduced into the Australian healthcare system. The progress of surgeons introducing laparoscopic radical prostatectomy into their practice should be monitored by hospitals. The costs of the procedures in Australia should also be evaluated.

(June 2005)

### **Acknowledgments**

The illustrations were prepared by Ms Beth Chandler.

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**Important note**      The information provided is based on up-to-date research. However, it is not intended to replace the advice of your medical practitioner. Please ask your doctor if you have any further questions about the management of this condition.

### **For further information about ASERNIP-S**

Contact Professor Guy Maddern, ASERNIP-S Surgical Director, PO Box 553, Stepney, SA 5069, ph. (08) 83637513, fax (08) 83622077, or visit the website (<http://www.surgeons.org/asernip-s.htm>). If you would like to provide feedback on this consumer summary, please contact us at [consumer.asernip@surgeons.org](mailto:consumer.asernip@surgeons.org)

ASERNIP-S is a part of the Research and Audit Division, Royal Australasian College of Surgeons (RACS).

## **Laparoscopic radical prostatectomy**

### **Consumer information group members**

#### **ASERNIP-S Director**

Professor Guy Maddern  
Surgical Director  
ASERNIP-S  
PO Box 553 STEPNEY SA 5069

#### **Protocol Surgeon**

Mr Peter Swindle  
Mater Prostate Cancer Research Centre  
Mater Medical Research Institute  
550 Stanley Street SOUTH BRISBANE QLD 4101

#### **Other Specialty Surgeon**

Dr Guy Rees  
Senior Lecturer  
Department of ENT (8C)  
The Queen Elizabeth Hospital  
Woodville Road WOODVILLE SA 5011

#### **Consumer representatives**

Barbara Beacham  
Primary Health Care Research Information Service  
Department of General Practice  
Flinders University, Adelaide BEDFORD PARK SA 5042

Jane Doyle  
Channel Seven Adelaide Pty Limited  
45 Park Terrace GILBERTON 5081

#### **Director, Research and Audit, Royal Australasian College of Surgeons**

Dr Wendy Babidge

#### **ASERNIP-S Senior Research Officer**

Dr Rebecca Tooher

#### **ASERNIP-S Project Officer**

Eleanor Ahern

## Glossary

**Abdomen:** The part of the body between the chest and the pelvis.

**Accelerated systematic reviews (ASR):** are produced in response to a pressing need for a systematic assessment of the available literature for a new or emerging surgical procedure. This need may arise if: the procedure is being introduced into the Australasian healthcare system too quickly or too slowly; the clinical or cost effectiveness of the new procedure needs to be assessed; or there are significant concerns regarding its safety or its use in particular populations. ASRs use the same methodology as full [systematic reviews](#), but the types of studies included may be restricted so that the review can be produced in a shorter time period.

**Anastomosis:** A direct surgical connection formed between two sections of tissue.

**Continence:** The patient is able to hold in his/her gas, fluid or faeces before getting to the toilet.

**Embolism:** Sudden blocking of an artery by solid, semisolid or gaseous material carried in the bloodstream to the site of the blockage. The object, or material, causing the embolism is called an embolus.

**Endoscope:** A tube with a viewing mechanism at the end, used to see inside hollow organs in the body and to perform various surgical procedures.

**Evidence:** The studies included in the review.

**Haematoma:** Pooling of clotted blood in surrounding tissue.

**Laparoscope:** Long thin tube with a telescope on the end, used to see inside the [abdomen](#).

**Lymph nodes:** A small collection of tissue along the lymphatic system which acts as a filter. White cells and cancer cells, in particular, collect in lymph nodes. They are found in the neck, the armpit, the groin and many other places. Lymph nodes are also known as glands.

**Minimally invasive operation:** Operation accessing the site through small cuts using a telescope.

**Open procedure:** Operation in which the surgeon accesses the site through a large surgical cut.

**Pelvic floor:** The muscles which line the bottom of the pelvis and support the uterus, rectum and bladder.

**Perineum:** Pelvic floor or area between the thighs.

**Peritoneum:** Layer of cells lining the space ([peritoneal cavity](#)) between the inner walls of the [abdomen](#) and pelvis and the organs of the body.

**Positive margin rate:** The number of patients with cancer left in the margins of the tumour specimen. It can be an indication of whether the tumour was completely removed or not.

**Seminal vesicles:** Small sac-like structures which, together with the prostate, produce the fluid part of semen.

**Systematic review:** ASERNIP-S conducts literature reviews on the safety and effectiveness of new surgical techniques before they are widely accepted into the health care system. Each review collects all relevant information, or evidence, on new and standard techniques used to treat a medical condition. The quality of evidence is assessed. ASERNIP-S then makes recommendations on the safety and effectiveness of the procedures that are then endorsed by RACS.

**Urinary retention:** Inability to urinate or empty full bladder.