Open, laparoscopic and robot-assisted laparoscopic radical prostatectomy for localised prostate cancer

Health technology description

Radical prostatectomy (RP) is a treatment option for men with localised prostate cancer that involves surgical removal of the entire prostate gland and seminal vesicles. RP is traditionally performed by open surgery via an incision in the lower abdomen (retropubic) or, less commonly, in the perineum. A nerve-sparing technique may be used to minimise nerve damage. Laparoscopic radical prostatectomy (LRP) is the same surgical procedure performed using a minimally invasive technique involving insertion of a laparoscope (endoscope) and surgical instruments through small incisions in the abdomen (extraperitoneal) or perineum (transperitoneal) or both locations. While performing laparoscopic surgery the surgeon sees a magnified two-dimensional image of the surgical field on a monitor. Robot-assisted surgery is a further development of minimally invasive surgery. The technology comprises a console, computerised control system, and robotic arms with wrists capable of 360° rotation that hold the endoscope and surgical instruments. The surgeon operates the robotic arms by remote control from the console while viewing the magnified surgical field on the monitor. The computer technology scales down the surgeon’s hand movements to a microscopic level. The da Vinci® Surgical System (Intuitive Surgical Ltd, California) is the only integrated robotic surgical system currently available; the most advanced platform integrates three-dimensional high-definition endoscopy (da Vinci® S HD System).

The potential advantages of LRP over open surgery include reduced blood loss, fewer complications and quicker recovery. The main disadvantages are its technical complexity, and the associated training and learning curve for surgeons to achieve good patient outcomes. The purported advantages of robot-assisted LRP (RALRP) over LRP include better surgical dexterity and depth perception of the surgical field. The main drawbacks are the learning curve required to achieve proficiency, and the additional training required for the entire surgical team. As the operating surgeon is at a distance from the patient and the anaesthetist, and can see only what is in front of the endoscope, all members of the team must be vigilant to problems outside the surgeon’s control. A second surgeon at the patient’s side may assist during the procedure to ensure proper patient care. A large operating room is also needed to accommodate the current size of surgical robots.

Key points

- Laparoscopic prostatectomy takes longer to perform than open surgery but is associated with less intraoperative blood loss, lower blood transfusion rates, fewer complications and a shorter hospital stay.
- Studies comparing laparoscopic prostatectomy with robot-assisted laparoscopic surgery report inconsistent results for perioperative outcomes.
- There is insufficient evidence to conclude that any of the three surgical approaches is superior with regard to functional and oncological outcomes.
- The cost effectiveness of alternative surgical approaches to radical prostatectomy has not been established.
- Robot-assisted surgery may be best suited to high-volume prostatectomy centres to minimise costs associated with the learning curve.
In Scotland, the annual number of RP operations for any indication increased from 175 to 350 between 1997 and 2008. Most operations in Scotland are performed by open surgery. RALRP is currently not available in Scotland.

Epidemiology

Prostate cancer is the most commonly diagnosed cancer in men in Europe and the second most common male cancer worldwide. The incidence of prostate cancer increases with age, with 75% of cases in the UK occurring in men over the age of 65 years and very few in men younger than 50. In Scotland, the incidence of prostate cancer increased by 17.9% between 1997 and 2007, and the estimated lifetime risk of developing the disease is 1 in 128. There were 2,507 new cases diagnosed in Scotland in 2007, and 792 recorded prostate cancer deaths in 2008.

Clinical effectiveness

Six recent systematic reviews have summarised studies comparing open RP, LRP and RALRP for localised prostate cancer. These reviews supersede the evidence sources used to inform the Interventional Procedures Guidance on LRP, including RALRP, published by the National Institute for Health and Clinical Excellence (NICE) in 2006.

Open RP versus LRP

In the only published randomised controlled trial (RCT), the mean operative time for open surgery was significantly shorter for open retropubic RP compared with LRP (-65 minutes, 95% confidence interval (CI) -49.69, -80.31) whereas blood loss (mean 596 ml, 95% CI 465.36, 726.64) and the requirement for transfusion (relative risk (RR) 4.00, 95% CI 2.01, 7.95) were significantly higher. Similar results were obtained from a meta-analysis combining the RCT with 10 non-randomised studies. The meta-analysis of non-randomised studies showed earlier withdrawal of catheters (weighted mean difference (WMD) 6.18 days, 95% CI 0.46, 11.91; four studies) and shorter duration of hospitalisation (WMD 2.46 days, 95% CI 1.54, 3.37; six studies) following LRP compared with open surgery. The RCT showed no significant difference in the rate of positive surgical margins (RR 0.81, 95% CI 0.43, 1.54), as did meta-analysis of the RCT together with 15 non-randomised studies. Similar recurrence-free survival and prostate-specific antigen (PSA) relapse rates were observed in non-randomised studies comparing open with laparoscopic surgery.

Data on functional outcomes were limited. The RCT found a significant difference in pain scores in favour of LRP only on the day after surgery, and a meta-analysis of three non-randomised studies showed no significant difference in post-operative analgesia. Urinary continence at 12 months was not significantly different between open RP and LRP on meta-analysis of eight non-randomised studies, and three non-randomised studies found no difference in post-operative erectile function. A subsequent case series reported that 36.4% of LRP patients were fully continent 6 months after surgery compared to 45.9% of those who underwent open retropubic RP. Four non-randomised studies found no difference in incontinence related or health-related quality of life scores up to 12 months after open RP or LRP.

Open RP versus RALRP

Open RP has not been compared with RALRP in an RCT. Most non-randomised studies reported less blood loss and lower transfusion rates with RALRP. Some studies have also reported statistically significant reductions in operative times (three out of seven studies), catheterisation time (one out of three studies), and hospital stay (six out of seven studies) in favour of RALRP. The mean length of hospital stay in both groups tended to be shorter in studies conducted in the United States. Meta-analysis of six non-randomised studies showed a significantly higher positive surgical margin rate with open RP compared with RALRP (RR 1.58, 95% CI 1.29, 1.94), as did a subsequent case series. Non-randomised studies have reported similar rates of recurrence-free survival and detectable PSA.
Data on functional outcomes were limited to two non-randomised studies that reported higher rates of recovery of urinary continence at 6 months, and one study that reported a shorter median time to recovery of erectile function and sexual intercourse, in favour of RALRP\(^1\)\(^\text{10,12}\). In one study, the return to normal physical component health-related quality of life scores reached statistical significance (5–6 weeks following RALRP versus 6–7 weeks for open RP)\(^1\)\(^\text{10}\).

**LRP versus RALRP**

LRP has not been compared with RALRP in an RCT. A meta-analysis of three non-randomised studies showed no significant difference in operative time, blood loss or rates of transfusion\(^1\)\(^\text{10}\). Subsequent individual studies have reported statistically significant differences in favour of RALRP for operative times (two out of three studies), blood loss (two out of four studies), and transfusion rates (one out of three studies)\(^1\)\(^\text{12}\). Three studies showed no significant difference in catheterisation time or hospital stay\(^1\)\(^\text{10}\). Only one out of six non-randomised studies found a significant difference in the rate of positive surgical margins, which favoured RALRP over LRP\(^1\)\(^\text{10,12}\). One case series reported similar rates of PSA relapse with both techniques\(^1\)\(^\text{12}\). Data from non-randomised studies showed no difference in urinary continence outcomes (three studies) or post-operative erectile function (two studies)\(^1\)\(^\text{10,12}\).

**Safety**

A meta-analysis of one RCT together with 13 non-randomised studies comparing open RP with LRP showed a significantly higher risk of complications with open surgery (RR 1.52, 95% CI 1.17, 1.97)\(^1\)\(^\text{10}\). A meta-analysis of six non-randomised studies showed no difference in complication rates between open surgery and RALRP\(^1\)\(^\text{10}\). Two non-randomised studies that compared complication rates between LRP and RALRP reported conflicting results\(^1\)\(^\text{10,11}\). A meta-analysis of five non-randomised studies showed a higher risk of anastomotic stricture with open RP compared with LRP (RR 2.92, 95% CI 1.97, 4.34), but the difference was no longer statistically significant when only prospective studies were included\(^1\)\(^\text{10}\).

Non-randomised studies comparing RALRP with open RP or LRP showed no difference in anastomotic strictures\(^1\)\(^\text{10}\).

A systematic review of case series concluded that perioperative mortality was rarely associated with open RP, LRP or RALRP (approximate risk 0.4%, range 0–0.7%), and the risk of major complications appeared to be similar (approximately 3–4%)\(^1\)\(^\text{13}\). Case series reported minor perioperative complication rates of between 8% and 9%. Comparative series suggested that the minimally invasive techniques performed by experienced surgeons may be associated with fewer minor complications than open surgery\(^1\)\(^\text{13}\). Case series have reported rates of conversion from LRP or RALRP to open RP of less than 1% overall, although rates as high as 14% have been reported among surgeons who are at an earlier stage of the learning curve\(^1\)\(^\text{13}\).

**Economic implications**

No studies of the cost effectiveness of alternative surgical approaches to radical prostatectomy for localised prostate cancer were identified. A cost-utility model, based on the assumption that the rate of complications is lower with RALRP compared with open RP, showed a gain in quality-adjusted life years of 8 weeks at a lifetime cost saving of US $1,740 (£1,104) for a 65-year-old man with localised prostate cancer\(^1\)\(^\text{13}\). Cost estimates were based on United States Medicare rates and did not take account of differences in equipment acquisition, maintenance or supplies costs between RALRP and open surgery. It must also be remembered that there is currently insufficient evidence to support the assumption of superiority for RALRP on which this analysis was based\(^1\)\(^\text{13}\).

The cost of the da Vinci® Surgical System has been estimated at between €1.83 million and €1.95 million (£1.52 million and £1.62 million) including VAT, and the additional three-dimensional high-definition option at €116,900 (£96,897)\(^1\)\(^\text{15}\). Annual maintenance costs have been reported at between US $100,000 to US $200,000 (£63,414 to £126,839)\(^\text{13,16}\), and as 10% of the purchase price after the first year of
The average instrument cost per RALRP procedure has been estimated at between US $2,000 and US $3,000 (£1,268 and £1,902). On the basis of 200 surgical procedures per year (not only RALRP), the equipment and running costs have been estimated at between €830,000 and €860,000 (£688,911 and £713,894) per annum (€4,150 to €4,300 (£3,446 to £3,570) per procedure) with almost half of this attributable to instruments and consumables. The estimated useful life of the da Vinci® Surgical System is 5 years.

Steinberg et al. constructed a theoretical model of operative time and anaesthesia costs to determine the cost of the learning curve for RALRP. Costs were based on two case series published in the United States. The model did not consider complications, length of hospital stay, blood loss, oncologic outcomes, impotence, incontinence, surgeons’ prior experience with prostatectomy techniques, or confounding factors that could lengthen operative time. The estimated cost of the learning curve ranged from US $95,000 (£60,238) over 24 cases to US $1,365,000 (£865,695) over 360 cases. Estimates of the learning curve in eight published case series ranged from 13 to 200 cases at an average cost of US $217,034 (range US $49,613 to US $554,694 (£137,656, range £31,467 to £351,834)). The authors concluded that RALRP may be best suited to high-volume prostatectomy centres where learning curve associated costs can be minimised.

Note: All reported costs have been converted to GBP using current exchange rates at the time of writing.

Conclusions

The available evidence from comparative studies of open RP, LRP and RALRP for localised prostate cancer is of low quality and clinically heterogeneous. A meta-analysis of non-randomised studies warrants cautious interpretation as pooled estimates of effect may be confounded by imbalances between comparator groups arising from selection bias in the individual studies. Overall, the evidence available suggests that while laparoscopic approaches take longer to perform, they are associated with less intraoperative blood loss and lower transfusion rates than open surgery. There is insufficient robust and consistent evidence to conclude that any surgical approach is superior with regard to functional and oncological outcomes.

The UK National Institute for Health Research Health Technology Assessment programme has funded a new study on the clinical and cost effectiveness of LRP and RALRP for localised prostate cancer, which will involve construction of an economic model capturing the availability of robotic surgery centres in the UK and the training required to master robotic techniques. The study will start in 2010 for a duration of 14 months (http://www.abdn.ac.uk/~wmm077/news/ [accessed 19.4.10]).

Equality and Diversity

NHS QIS is committed to equality and diversity in respect of the six equality groups defined by age, disability, gender, race, religion/belief and sexual orientation.

The Evidence Note process has been assessed and no adverse impact across any of these groups is expected. The completed equality and diversity checklist is available on www.nhshealthquality.org

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For further information about the Evidence Note process, see www.nhshealthquality.org

To propose a topic for an Evidence Note, email evidencenotes.qis@nhs.net

References can be accessed via the internet (where addresses are provided), via the NHS Knowledge Network (formally eLibrary) http://www.knowledge.scot.nhs.uk, or by contacting your local library and information service.
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