

Advice Statement 003/18

January 2018

What is the clinical and cost-effectiveness of robot assisted laparoscopic partial nephrectomy compared with open or conventional laparoscopic procedures in patients with T1a or T1b renal cancer?



Why is SHTG looking at this topic?

Da Vinci robotic surgical devices are a relatively new technology which is available at three centres in NHSScotland. These devices are currently used predominantly to provide a laparoscopic prostatectomy service. To ensure the devices are optimally employed, NHSScotland is considering expanding the indications for which robotic surgery is available. This work was requested by the West of Scotland Cancer Network and accepted onto the SHTG programme as a priority, to support evidence-informed use of robotic surgery capacity.

Evidence Note 75 was produced by Healthcare Improvement Scotland.

SHTG advises that:

Evidence is of insufficient quality to reach conclusions on the comparative clinical effectiveness and long-term cost effectiveness of robot assisted laparoscopic partial nephrectomy, open partial nephrectomy and conventional laparoscopic partial nephrectomy. Reported benefits for the robotic procedure are based on short-term non-randomised studies which do not report long-term clinical outcomes.

In a single retrospective UK study the robot assisted laparoscopic procedure was associated with a statistically significant reduction in the costs associated with 90-day complication rates and 1-year hospital activity when compared with open partial nephrectomy.

NHS boards are required to consider Scottish Health Technologies Group (SHTG) advice.

Background

- Kidney cancer represents around 3% of all cancer diagnoses in Scotland and is more common in men than in women. In 2015 there were 1,013 diagnoses. Recorded incidence has increased by around 25% in the last decade.
- Partial nephrectomy (nephron sparing surgery (NSS)) which preserves renal function is the gold standard surgical treatment for early kidney cancer (T1a (tumour \leq 4cm) or T1b (tumour $>$ 4cm and \leq 7cm)). In Scotland in 2014 there were 92 cases where the renal cancer was graded as T1a and NSS was appropriate.
- Partial nephrectomy (PN) procedures can be undertaken using either an open (OPN), laparoscopic (LPN) or robot assisted laparoscopic approach (RALPN). At present in Scotland, most procedures are conducted via open surgery.

Clinical effectiveness

No RCTs were identified comparing RALPN with OPN or with LPN. The evidence base consists of meta-analyses of short-term comparative cohort studies, many of which are retrospective. High risk of bias, particularly around patient selection, prevents robust conclusions. In these observational studies:

- RALPN is associated with fewer post-operative complications, less blood loss and shorter length of stay than OPN, with no statistically significant differences between study groups in rate of positive surgical margins or degree of estimated glomerular filtration rate (eGFR) decline.
- RALPN is associated with shorter warm ischaemia time, reduced eGFR decline and a lower rate of conversion to open surgery or radical nephrectomy than LPN, with no statistically significant differences between study groups in positive surgical margin rate or post-operative complications. RALPN is associated with shorter length of stay than LPN.

Long-term outcome data around survival or recurrence was not available.

Safety

- No incidents attributable to robot assisted surgery have been recorded by the NHSScotland Incident Reporting & Investigation Centre (IRIC) database since the introduction of the technology to Scotland in 2015. In the first two years of use to March 2017, 486 procedures have been performed: 442 prostate, 33 kidney or renal pelvis, 7 bladder and 4 relating to other cancers.
- In a retrospective analysis of all the adverse events related to robotic surgical systems, collected by the US FDA MAUDE database between 2000 and 2013 there were 1,565 events associated with urological surgery (most commonly prostatectomy). The estimated injury rate associated with urological, gynaecological and general surgery in this analysis was 71.5 per 100,000 procedures. A range of device malfunctions were identified including system errors, video and imaging problems, broken instruments falling into the patient's body, electrical arcing, sparking or charring of instruments and uncontrolled movements and spontaneous powering on/off of system.

Cost effectiveness

- A cost effectiveness study using hospital administration data from the US measured the rate of peri-operative complications (including mortality) and costs associated with RALPN, LPN and OPN. LPN was superior to OPN resulting in a lower rate of perioperative complications and lower cost, while RALPN had a higher cost than both LPN and OPN but offered a superior complications rate. While RALPN seems to offer better outcomes in the short-term in terms of perioperative complications, no firm conclusions can be made around its long-term cost-effectiveness compared to OPN/LAPN as the impact on long-term survival, quality of life and costs were not modelled in the study. Also, the data comes from the US healthcare system and may not be generalisable to Scotland.
- In a retrospective analysis of routinely collected NHS data RALPN was associated with a statistically significant reduction in the costs associated with 90-day complication rates and 1-year hospital activity when compared with OPN. Differences between LPN and RALPN were not statistically significant.

Patient and social aspects

- The evidence examined did not encompass patient experience of robotic partial nephrectomy.

Context

- Robotic systems (da Vinci®, Intuitive Surgical Inc., California) are installed in three centres in Scotland; Edinburgh, Glasgow and Aberdeen and each are presently used 2 to 3.5 days per week to provide a robotic assisted laparoscopic prostatectomy service. The technology is also used in some centres for renal and bladder cancers and for gynaecological indications. Interest from ear, nose and throat and colorectal surgical teams is currently being explored.
- In 2012 a UK evaluation of robotic surgery detailed the costs associated with each procedure. The consumable costs per procedure were approximately £1,200. Despite being based on the prostatectomy procedure, it is expected that this cost is indicative of RALPN procedure consumable costs. Additional cost data of interest include the cost of the robot, service and contract costs, and the costs of specialist equipment; full utilisation of the robots will reduce the overall average procedure cost. Robotic assisted surgery for specific patients with complex early kidney cancers that are unsuitable for conventional laparoscopic surgery is commissioned in NHS England <https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2016/08/clinical-com-pol-16060p.pdf>

Further research

Randomised controlled trials are required to progress from the evaluation phase to the assessment phase of the IDEAL Framework for surgical innovation <http://www.ideal-collaboration.net/>

Studies should investigate:

- peri-operative outcomes
- long-term outcomes including cancer recurrence rates and mortality
- quality of life and patient experience
- cost effectiveness
- learning curve and volume/outcome relationships.

Advice context:

No part of this advice may be used without the whole of the advice being quoted in full. This advice represents the view of the SHTG at the date noted.

It is provided to inform NHS boards in Scotland when determining the place of health technologies for local use. The content of this Advice Statement was based upon the evidence and factors available at the time of publication. An international evidence base is reviewed and thus its generalisability to NHSScotland should be considered by those using this advice to plan services. It is acknowledged that the evidence constitutes only one of the sources needed for decision making and planning in NHSScotland. Readers are asked to consider that new trials and technologies may have emerged since first publication and the evidence presented may no longer be current. SHTG Advice Statements are intended to inform a decision at a particular point in time. They will however be considered for review if requested by stakeholders, based upon the availability of new published evidence which is likely to materially change the advice given. This advice does not override the individual responsibility of health professionals to make decisions in the exercise of their clinical judgment in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

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Chair
Scottish Health Technologies Group



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