Clinical Commissioning Policy: Robotic assisted surgery for early kidney cancers that are unsuitable for conventional laparoscopic surgery

Reference: NHS England: 16060/P

NHS England INFORMATION READER BOX		
Directorate		
Medical	Operations and Information	**Specialised Commissioning**
Nursing	Trans. & Corp. Ops.	Commissioning Strategy
Finance		

Publications Gateway Reference:	**05527s**
Document Purpose	Policy
Document Name	Clinical Commissioning Policy 16060/P
Author	Specialised Commissioning Team
Publication Date	26 August 2016
Target Audience	CCG Clinical Leaders, Care Trust CEs, Foundation Trust CEs , Medical Directors, Directors of PH, Directors of Nursing, NHS England Regional Directors, NHS England Directors of Commissioning Operations, Directors of Finance, GPs, NHS Trust CEs
Additional Circulation List	
Description	Routinely Commissioned - NHS England will routinely commission this specialised treatment in accordance with the criteria described in this policy.
Cross Reference	This document is part of a suite of policies with Gateway Reference 05527s.
Superseded Docs (if applicable)	N/A
Action Required	N/A
Timing / Deadlines (if applicable)	**N/A**
Contact Details for further information	england.specialisedcommissioning@nhs.net

Document Status

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Clinical Commissioning Policy: Robotic assisted surgery for early kidney cancers that are unsuitable for conventional laparoscopic surgery

First published: August 2016

Prepared by NHS England Specialised Services Clinical Reference Group for Specialised Urology

Published by NHS England, in electronic format only.

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Policy Statement

NHS England will commission robotic assisted surgery for early kidney cancers that are unsuitable for conventional laparoscopic surgery in accordance with the criteria outlined in this document. In creating this policy NHS England has reviewed this clinical condition and the options for its treatment. It has considered the place of this treatment in current clinical practice, whether scientific research has shown the treatment to be of benefit to patients, (including how any benefit is balanced against possible risks) and whether its use represents the best use of NHS resources. This policy document outlines the arrangements for funding of this treatment for the population in England.

Equality Statement

Promoting equality and addressing health inequalities are at the heart of NHS England's values. Throughout the development of the policies and processes cited in this document, we have:

- Given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it; and
- Given regard to the need to reduce inequalities between patients in access to, and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities

Plain Language Summary

About kidney cancer

Most people have two kidneys which are located on either side of the body, just underneath the ribcage. The main role of a kidney is to filter out waste products from the blood and to produce urine.

In 2013, kidney cancer was the eighth most common cancer affecting adults in the United Kingdom (UK) - making up around 3% of all cancer cases (Public Health England, 2015). Usually, only one of the kidneys is affected by cancer.

There are many different types of kidney cancer, however Renal Cell Carcinoma (RCC) is the most common and accounts for about 90% of all kidney cancers.

Typically kidney cancer:

- affects more men than women
- is more common as you get older.

The main risk factors for kidney cancer include:

- smoking
- being overweight
- having kidney disease or long-term kidney dialysis (Cancer Research UK, 2016).

The rate of new diagnoses (incidence) of kidney cancer has risen significantly in England since 2011, however when kidney cancer is diagnosed at an early stage, treatment is easier and survival rates are significantly better.

About current treatments

Treatment options for kidney cancer are determined by both the size and spread of the cancer, however surgery is the mainstay option. Unlike most other cancers, chemotherapy is not usually effective in treating kidney cancer; however radiotherapy treatments are available.

Surgery involves the removal of the kidney (called a 'nephrectomy procedure'). There are three types of nephrectomy:

- simple (removal of just the kidney)
- radical (removal of the kidney and other nearby tissue and organs)
- partial (removal of just the tumour and surrounding tissue).

These operations can be carried out in three ways:

- open (through an open cut in the tummy)
- laparoscopic (this is done using a thin tube inserted through a small cut in the skin)
- robotic assisted laparoscopic (this is the same as the laparoscopic procedure, but assisted by a robot controlled by the surgeon).

About the new treatment

Robotic Assisted Surgery (RAS) is a form of minimally invasive surgery that is increasingly used in a number of complex surgical procedures internationally.

What we have decided

NHS England has carefully reviewed the evidence to treat early-stage kidney cancers that are unsuitable for conventional laparoscopic surgery. We have concluded that there is enough evidence to make the treatment available at this time.

1 Introduction

This document describes the evidence that has been considered by NHS England in formulating a proposal to routinely commission robotic assisted partial nephrectomy for the treatment of early-stage kidney cancers that are unsuitable for conventional laparoscopic intervention, in accordance with the criteria outlined in this document.

Renal cell carcinoma is the eighth most common cancer in the United Kingdom (UK) (Public Health England, 2015). It is more common in men than women and typically affects adults over the age of 50.

The mainstay treatment for kidney cancer is surgical removal, or partial removal, of the kidney (nephrectomy or partial nephrectomy). Unlike most other cancers, chemotherapy isn't generally very effective at treating kidney cancer, however radiotherapy techniques are available.

Robotic Assisted Surgery (RAS) is a form of minimally invasive surgery that is increasingly used in a number of complex surgical procedures internationally. Within England, this technique has developed primarily within the field of urological cancer treatment and, alongside laparoscopic techniques, has been replacing traditional open surgical procedures.

The gold standard surgical treatments for kidney cancer are those that preserve renal function. This is called 'nephron sparing surgery' (NSS) or 'partial nephrectomy' (PN). This is because chronic kidney disease (<60 mL/min/1.73 m(2)) developed more frequently in radical nephrectomy (RN) patients than in PN patients (75.6% vs. 41.5%, p<0.001) (Kyung et al KJU 55(7) 2014). Given the relatively positive survival rates from early-stage kidney cancer, the preservation of kidney function is, therefore, of importance.

Minimally invasive surgical approaches are also considered to be gold-standard, however, due to the complexity of the surgery required for small tumours and/or that are 'hard to reach', it is often not possible to undertake PN procedures using conventional laparoscopic approaches.

Both RN and PN procedures can be undertaken using either open or laparoscopic approaches. Current practice in England does differ from that seen internationally,

whereby the majority (>60%) of procedures for early-stage kidney cancer are RN's, albeit these are performed laparoscopically. This is because conventional laparoscopic is not always possible and patients prefer the benefits of laparoscopic RN because this is less invasive and has a shorter, less painful recovery period.

Robotic-assisted laparoscopic partial nephrectomy will enable more patients to benefit from partial nephrectomy for two-reasons: (i) confers the benefits of laparoscopic approaches to PN procedures; and (ii) enables more patients to be considered for PN.

2 Definitions

There are three types of nephrectomy:

- **Partial nephrectomy** is defined as the removal of part of the kidney and is used to treat small accessible tumours which have not metastasized. It is sometimes called 'nephron sparing surgery' (NSS).
- **Simple nephrectomy** which involves the removal of the whole kidney. It is mainly used to treat benign renal disease.
- **Radical nephrectomy** which involves removal of the whole kidney, the adrenal gland, local lymph nodes and surrounding tissue. It is used to treat renal cancer confined to the kidney but unsuitable for partial nephrectomy, and sometimes for more advanced renal cancer.

Nephrectomy can be carried out in three different ways:

- **Open radical or partial nephrectomy** is where the kidney is removed through a large incision. The procedure is carried out under direct vision.
- **Laparoscopic radical or partial nephrectomy** is where the surgeon inserts a laparoscope and other surgical instruments through small incisions in the abdominal wall, and uses them to remove the kidney.

- **Robot-assisted laparoscopic partial nephrectomy** is a variant on the laparoscopic approach.

Tumour, Nodes, Metastases (TNM) system is a way of classifying malignant tumours. In the context of renal cancer, early-stage cancer is defined as 'T1', which is where the tumour is completely inside the kidney. 'T1' cancers are further sub-divided into 'T1a', where the tumour is ≤4cm, and 'T1b', where the tumour is >4 and ≤7cm.

Exophytic tumours are defined as tumours which grow outwards from the surface of the kidney.

3 Aims and Objectives

This policy considers: robotic assisted surgery (RAS) for the treatment of kidney cancer.

The objectives were to: establish whether RAS should be routinely commissioned to treat kidney cancer, and if so, to identify any appropriate commissioning criteria, such as stage or procedure sub-group (i.e., simple, radical or partial nephrectomy).

4 Epidemiology and Needs Assessment

Renal cell carcinoma represents 2-3% of all cancers. Worldwide its incidence is increasing annually by approximately 2%. In the UK there were over 11,000 new cases in 2013, with around 4,300 patients dying of kidney cancer, making it the eighth most common malignancy in the UK.

Renal cell carcinoma is the most common form of kidney cancer, accounting for 90% of all renal malignancies. There is a 1.5:1 predominance in men over women, with peak incidence occurring between 60 and 70 years of age (Public Health England, 2015).

In 2012 and 2013 there were 1,970 partial nephrectomies for malignancy recorded on the British Association of Urological Surgeons (BAUS) audit (about 14% of all nephrectomies). Of these, 18% were recoded as being robotically-assisted.

The BAUS audit data also demonstrated:

- That there was no significant difference in the age of patients undergoing RAS partial nephrectomy compared to the laparoscopic or open approach with 54% of robotically-assisted procedures occurring were in those aged 50-69 (24% 50-59; 29% 60-69); and
- That there is a trend towards the increased use of RAS for partial nephrectomy in the UK. In 2012, 13 trusts recorded robot-assisted partial nephrectomies for malignancy with a median of 6 procedures, a minimum of one and a maximum of 22. In 2013, 18 trusts recorded robot-assisted partial nephrectomies for malignancy with a median of 12 procedures, a minimum of one and a maximum of 37.

In the absence of a clinical commissioning policy, the number of RAS partial nephrectomies performed in the UK would be expected to increase by 10% per annum.

5 Evidence base

The evidence base for the policy has been established following (i) evidence review; and (ii) targeted interrogation of national clinical audit data held by the British Association of Urological Surgeons (BAUS). The evidence review indicates that there is a lack of compelling evidence that robot-assisted approaches for the treatment of kidney cancer are associated with lower mortality or morbidity, lower recurrence risk, longer survival or any durable patient advantage when compared to laparoscopic or open approaches, as demonstrated through results from three systematic reviews of controlled studies (Zhang et al. 2013, Wu et al. 2014, MacLennan et al. 2012). However, the review of BAUS data coupled with more recent evidence indicates that there are clinical and patient advantages associated with the use of robotic assisted partial nephrectomies in the treatment of early-stage kidney cancers.

Evidence review

There was limited evidence of some clinical advantages from robot-assisted nephrectomy/partial nephrectomy when compared with laparoscopic procedures.

These include: shorter warm ischaemia time, reduced blood loss, lower re-admission rates and a reduced need for secondary procedures (Zhang et al. 2013, MacLennan et al. 2012, Kalifeh et al. 2013). However, these could be the result of confounding and patient selection within the studies. There is limited evidence that shorter warm ischaemic time in robotic surgery leads to better long term preservation of overall renal function compared with standard laparoscopy.

The technical difficulty of laparoscopic partial nephrectomy may limit its use in complex renal lesions. There is evidence that robotic partial nephrectomy may allow more complex lesions, such as endophytic and hilar tumours, to be treated using nephron sparing surgery (Volpe et al 2014, Kim et al 2014, Wu et al 2014), and thereby offering the long term benefits of NSS to more patients. This is significant given the impact of radical nephrectomy on longer-term clinical outcomes, in particular related to the preservation of kidney function.

There was limited evidence of some clinical advantages from robot-assisted nephrectomy when compared with open procedures. These include reduced blood loss and shorter inpatient stay. In some series the robot-assisted operations took longer to perform, although other series report shorter operative time using the robotic approach compared to standard laparoscopy (Kim et al 2015). There were also fewer complications after robot-assisted procedures (Wu et al. 2013, Wu et al 2015).

There was no clear evidence of improved safety associated with robotic approaches, though some studies do indicate that RAS procedures are associated with lower complications (Wu et al.2013). However this was not consistently reported.

There was some evidence that robotic partial nephrectomy is more expensive than conventional alternatives. This was found to be largely because of the cost of buying and maintaining the machine, but also because of differences in the cost of consumables. Shorter operations and reduced lengths of in-patient stay were not found to offset the higher cost of the procedure (Mir et al.2011, Laydner et al. 2013).

There was no evidence about the relationship between hospital volume and clinical outcome and only very limited evidence about the relationship between surgeon experience and clinical outcome (Khalief et al. 2013).

Positive margin rates, requirement for blood transfusion and median length of stay were compared for two arrangements of centres. Firstly in two groups of less than 20 or 20 or more procedures; secondly in three groups of less than 20, 20-39 and 40 or more procedures. There was insufficient evidence of a difference in outcomes by surgical volume when split into three groups. When split into two groups there was a shorter median length of stay in centres which did 20 or more procedures, at 3 days compared to 4 days ($p<0.001$).

Review of BAUS audit data

NHS England also reviewed audit data supplied by BAUS. Targeted interrogation and analysis of this data indicated that the technique may offer patient advantages, such as reduced blood loss and length of stay, and may possibly reduce post-operative complications, where the technique issued to perform partial nephrectomy procedures.

There were 363 RAS partial nephrectomies recorded on the BAUS database for 2012 and 2013, representing approximately 18% of all partial nephrectomies recorded on the database. Of these, 91% required no blood transfusion, with 8% missing data. This compares to 83% in the open group (p-value for open vs robotic < 0.001) with 12% missing data. A sensitivity analysis indicates that if missing data is unbiased then the statistical significance remains ($p<0.001$).

The 30-day mortality rate in all groups was negligible and no comparisons could be made. The median length of stay for the RAS group was 3 days, 4 days for the laparoscopic group and 5 days for the open group (p-value for open vs robotic < 0.001; p-value for laparoscopic vs robotic < 0.001).

It is established that nephron sparing surgical approaches result in better preservation of overall renal function compared with total nephrectomy (MacLennan at al 2012). In the long-term this may result in significantly less chance of chronic renal deterioration, which may ultimately lead to dialysis dependence in some patients. Typically these are patients that are diagnosed and treated for early-stage renal cancer who have a 95% 5 year relative survival rate. Furthermore, studies have shown chronic kidney disease (<60 mL/min/1.73 m(2)) developed more frequently in

Radical Nephrectomy patients than in Nephron Sparing Surgery (NSS) patients (75.6% vs. 41.5%, p<0.001) (Kyung et al KJU 55(7) 2014).

6 Criteria for Commissioning

Robotic assisted partial nephrectomy will be routinely commissioned to treat early-stage kidney cancers that are unsuitable for conventional laparoscopic intervention only in accordance with the following criteria:

- All cases must be discussed in the Specialist Urology Multi-disciplinary Team (MDT); and
- All stage T1a tumours with a Padua complexity score of >6, as determined by the Specialist Urology MDT).

Simple renal masses that are small and mainly exophytic should be considered for laparoscopic partial nephrectomy, determined by the skill-set and expertise within the specialist renal MDT.

7 Patient Pathway

There is no change to the overall patient pathway as a result of this policy proposition. However, the policy will require that all T1a patients suitable for robotic-assisted partial nephrectomy will have procedure delivered within a designated Specialist Urology Centre. Currently some of these patients will receive laparoscopic radical nephrectomies in District General Hospitals with urology Multi-disciplinary Teams (MDTs).

8 Governance Arrangements

Procedures must be delivered in accordance with the requirements of the Kidney, Bladder and Prostate Service Specification. All robotic-assisted partial nephrectomies should be undertaken by a designated Specialist Urology Centre.

9 Mechanism for Funding

Providers will continue to be reimbursed in accordance with the National Tariff Payment System applicable to the year. The intervention attracts both an episodic payment and a pass through payment in relation to the robotic consumable.

Trusts will be required to inform NHS England prior to undertaking robotic assisted partial nephrectomy surgery, through a prior approval system. Trusts will be required to separately identify spend on this intervention.

10 Audit Requirements

Provider organisations are required to participate in the national audit run by the British Association of Urology Surgeons (BAUS), and any other relevant national clinical audit introduced in relation to kidney cancer.

11 Documents which have informed this Policy

None.

12 Date of Review

This document will be reviewed when information is received which indicates that the policy requires revision.

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