Clinical Commissioning Policy: Robotic Assisted Surgery for Bladder Cancer

Reference: NHS England: 16033/P

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Finance		

Publications Gateway Reference:	**05527s**
Document Purpose	Policy
Document Name	Clinical Commissioning Policy 16033/P
Author	Specialised Commissioning Team
Publication Date	13 July 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, NHS Trust CEs
Additional Circulation List	
Description	Not Routinely Commissioned - NHS England will not 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Superseded Docs (if applicable)	N/A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 Bladder Cancer

First published: July 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 not routinely commission robotic assisted surgery for bladder cancer 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 bladder cancer

Bladder cancer is where a growth of abnormal tissue, known as a 'tumour', develops in the bladder lining. In some cases, the tumour spreads into the muscle wall of the bladder.

Most cases of bladder cancer appear to be caused by exposure to harmful substances, which lead to abnormal changes in the bladder's cells over many years. Tobacco smoke is a common cause and it's estimated that half of all cases of bladder cancer are caused by smoking.

About the current treatment

Bladder cancer can be treated with surgery by removing the bladder (called a 'cystectomy procedure'). There are three types of cystectomy:

- simple (removal of just the bladder)
- radical (removal of the bladder 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 very similar to the laparoscopic procedure, however it involves the use of a computer system to help the surgeon to guide the surgical tools).

What we have decided

NHS England has carefully reviewed the evidence to treat bladder cancer with robotic assisted surgery. We have concluded that there is not 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 not routinely commission robotic assisted surgery (RAS) for the treatment of bladder cancer.

Bladder cancer is the seventh most common cancer in the United Kingdom, affecting many more men than women.

Bladder cancer can either be muscle invasive or non-muscle invasive. In cases of non-muscle-invasive bladder cancer, it's usually possible to remove the cancerous cells while leaving the rest of the bladder intact. This is done using a surgical technique called transurethral resection of a bladder tumour (TURBT). This is followed by a dose of chemotherapy medication directly into the bladder, to reduce the risk of the cancer returning.

Muscle invasive bladder cancer can be surgically treated using cystectomy procedures which involve the removal of the bladder and diversion of the urine via an ileal conduit (stoma) or a neobladder (bladder reconstruction). It is also treated by radiotherapy and is some cases, with neoadjuvant chemotherapy.

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 use of RAS techniques essentially replaces other forms of surgery in the treatment pathway.

2 Definitions

There are three types of cystectomy:

- Simple cystectomy is defined as the removal of the bladder only, without removal of adjacent structures or organs. It is seldom performed nowadays.
- Radical cystectomy is the removal of the bladder, prostate and seminal vesicles in men and of the bladder, uterus, ovaries and fallopian tubes in

women. The operation also includes the removal of the perivesical tissues and pelvic lymph nodes. It is usually carried out for cancer.

- Partial cystectomy is the removal of part of the bladder. It is used to treat cancer that has invaded the bladder wall in a small area far enough from the openings where urine enters or leaves the bladder. We do not cover partial cystectomy in this evidence review, in line with its agreed scope.

Cystectomy can be carried out in three different ways:

- Open cystectomy is where the bladder is removed through a large incision in the front of the abdomen. Open radical cystectomy is a major operation, associated with significant perioperative complications even when performed by an experienced urologist. This is because of the long incision, prolonged abdominal wall retraction, lengthy exposure of the peritoneal surface with major fluid shifts and poor visibility, particularly in the depth of the pelvis and in the retrovesical area.

- Laparoscopic cystectomy is where the surgeon inserts a laparoscope and other surgical instruments through small incisions in the abdominal wall. The operation is otherwise similar to an open cystectomy. A conventional laparoscopic radical cystectomy is technically demanding, especially the intracorporeal suturing and the extensive pelvic lymph node dissection which contributes to survival. Urinary diversion or the formation of a neo-bladder can be carried out laparoscopically or, more commonly, by an open procedure.

Robot-assisted laparoscopic cystectomy is a variant on the laparoscopic approach. Once the instruments are inserted, the surgeon sits apart from the patient, viewing the operative field in three dimensions through the laparoscope and manipulating the instruments remotely. The equipment provides three-dimensional vision and robot-assisted control of the instruments, allowing for scaling of movement, increased precision and tremor damping. It differs from conventional laparoscopic cystectomy, which only has two-dimensional vision and offers fewer degrees of freedom for instrument movement. Differences in perspective mean that robot-assisted procedures require different skills from the operator, and there is a learning curve while these are acquired.

3 Aims and Objectives

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

The objectives were to establish whether RAS should be routinely commissioned to treat bladder cancer, and if so, to identify any appropriate commissioning criteria.

4 Epidemiology and Needs Assessment

Urinary bladder cancer is the second most frequently occurring malignancy of the urinary tract, after prostate cancer. It is the seventh commonest cancer in the U.K with 10,341 new cases diagnosed in 2013 (CRUK, 2016). Bladder cancer is the fourth commonest cancer in men and the thirteenth in women, with 5,369 deaths attributable to bladder cancer in 2014 (CRUK 2016).

Bladder cancer is rare under the age of 50, with the peak age standardised rate (ASR) occurring in men aged 75-79 and in women over the age of 85 in the U.K.

In the U.K. there has been a progressive decline in bladder cancer incidence rates since a peak in the early 1990's, with overall ASR falling from 18.4 per 100 000 in 1993 to 11.5 in 2008, although this decline is far more pronounced in men than women. This trend in the U.K. corresponds to declining incidence and mortality rates in the European Union (EU) since the early 1990's and in USA since the 1970's (Bosetti 2011, Ferlay 2008, Zhang 2012).

Bladder cancer (BC) can be non-muscle invasive (NMBC (stage cis, Ta-1)) or muscle invasive (MIBC (stage T2-4)). MIBC accounts for approximately 25% of cases, equating to approximately 2000 cases per annum, of which approximately half are treated with cystectomy. The 3-5 year survival for treated MIBC varies between 50-80%.

Cystectomy is also used as treatment for other cancers, including some recurrent colorectal and gynaecological cancers, some pelvic sarcomas and as salvage treatment for failed radiotherapy for bladder cancer.

In the UK Cystectomy continues to be undertaken mainly using an open technique. A handful of centres in England have developed laparoscopic and robotic assisted surgery (RAS) techniques. RAS continues to develop in other specialties but in all clinical specialties this has been generally uncoordinated and with no NHS Policy. NHS England have recently published a RAS for Prostatectomy Policy which will be taken into consideration within this Policy where needs arise.

5 Evidence Base

NHS England has concluded that there is insufficient evidence to support a proposal for the routine commissioning of this treatment for the indication.

The evidence review (August, 2014) and subsequent evidence search and synthesis (November, 2015) concluded that there is insufficient compelling evidence that robot-assisted approaches are associated with lower mortality or recurrence risk, longer survival or any durable patient advantage from the use of robotic procedures when compared to laparoscopic or open approaches.

Some limited evidence was identified to suggest that robot assisted cystectomy compared favourably to open radical cystectomy in that patients had less blood loss and a lower risk of receiving a transfusion. The yield of lymph nodes was higher though there were no differences in the rate of positive surgical margins. Furthermore complications were less common and though procedures took longer to perform, patients left hospital earlier. However, there was substantial confounding and heterogeneity in this evidence, limiting its reliability (Tang et al. 2014).

The Ishii et study (2014), which used a meta-analysis to compare robotic approaches to open approaches, reported statistically significant differences in favour of robotic approaches in relation to transfusion rates and high grade complication rates. No differences were reported in terms of surgical margins. Operating times were reported as longer using the robotic approach. The authors also conclude the need for further research addressing methodological flaws of some of the studies included, but conclude robotic approaches to be a safe and feasible alternative to approaches.

The Fonseka et al study (2015) compared open, laparoscopic and robotic methods for cystectomy incorporating 24 studies and 2,104 cases using a meta-analysis.

Compared to laparoscopic approaches no significant differences were found in relation to length of stay, blood loss, lymph node yield or surgical margins. The authors therefore concluded that robotic assisted cystectomy is comparable to laparoscopic approaches. Significant differences compared with open approaches were reported.

There was some limited evidence to suggest that robotic assisted cystectomy has lower rates of some complications compared to open radical cystectomy. However, an absence of studies which compare robot assisted cystectomy with conventional laparoscopic cystectomy prevents any reliable conclusions about the comparative safety of these procedures (Kader et al. 2013).

Bochner et al (2015) randomised 118 patients. The study reported no significant results when comparing robotic and open approaches over a range of clinical measures including 90-d complication rates, hospital stay, pathologic outcomes, and 3- and 6-mo QOL outcomes concluding that trial failed to identify a large advantage for robot-assisted techniques over standard open surgery.

In relation to Health Related Quality of Life measures when comparing robotic to laparoscopic and open approaches, Messer et al (2014) concluded that there were no statistically significant differences across a range of HRQOL measures at 3 months post-surgery.

There was some evidence to suggest that robotic procedures are more expensive than traditional alternatives (Lee et al.2011, Yu et al.2012). Other studies reported cost benefits (Martin et al.2011). All of these studies were US based and differences in the reporting and analysis of cost hinder accurate comparisons.

There was no evidence about the relationship between hospital volume and clinical outcome. However there was some evidence that increasing surgeon experience reduces operation time and improves lymph node yield (Hellenthal et al. 2011). There is no evidence of an effect of volume on complications, positive surgical margins, blood loss, recurrence or survival (Hayn et al. 2011).

Laparoscopic cystectomy is supported by NICE Interventional Procedure Guidance (IPG) 287, it is noted that the IPG states that this procedure ‘may be performed with computer (robotic) assistance’.

6 Documents which have informed this Policy

National Institute for Health and Care Excellence Interventional Procedure Guidance 287. Laparoscopic Cystectomy. 2009.

7 Date of Review

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

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