NHS England

Clinical Commissioning Policy: Robotic-Assisted Surgical Procedures for Prostate Cancer

Reference: NHS England xxx/x/x

Clinical Commissioning Policy: Robotic-Assisted Surgical Procedures for Prostate Cancer

First published: Month Year

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

Published by NHS England, in electronic format only.

Contents

Policy Statement

NHS England will commission robotic assisted surgical techniques for the treatment of prostate cancer (i.e., for radical prostatectomies for prostate 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

Throughout the production of this document, due regard has been given 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 in under the Equality Act 2010) and those who do not share it.

Plain Language Summary

Prostate cancer is the most common cancer in men, with around 35,000 men being diagnosed in England. Prostate cancer can progress slowly and as a result the range of management options is wide, ranging from 'watchful waiting' and active surveillance to hormone therapy and surgical/radiotherapy procedures.

This policy proposes a change to the range of surgical options available to clinical teams to treat early, or localised, prostate cancer. This is where the cancer is only in the prostate gland and has not spread into the surrounding tissues or to other parts of the body. It is also called localised prostate cancer.

Just over half of men who choose surgical treatment currently receive either open or laparoscopic surgical procedures. This policy recommends that all men with early/localised prostate cancer can also be offered robotic assisted laparoscopic surgery within a networked approach.

1. Introduction

Prostate cancer, which is a cancer of the urological system, is the most common male cancer in England. In 2011, 35,567 men were diagnosed with prostate cancer in England, with a corresponding Age Standardised Rate (ASR) of 106.7 per 100,000 population (95% Confidence Interval 105.6-107.8) (ONS, 2013).

In January 2014, the National Institute for Clinical Effectiveness (NICE) published revised clinical guidelines for the treatment and management of prostate cancer (NICE, 2014). This guideline confirmed that commissioners should consider whether to offer robotic assisted surgical techniques in the management of localised prostate cancer. It further stated that commissioners should ensure that, where the technique was to be offered that those centres should be performing at least 150 robot assisted laparoscopic radical prostatectomies per year.

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. This commissioning policy relates to the treatment of prostate cancer, rather than the wider field of urological cancers which also includes: kidney, bladder, testicular and penile.

RAS carries a large capital cost and greater revenue costs as compared to either laparoscopic or open surgery. Currently providers are reimbursed for RAS procedures both through Payments by Results and via pass through payments for the cost of the robotic consumables. Therefore, both open and laparoscopic procedures cost commissioners less to perform.

This commissioning policy has been developed because:

- Over the last ten years the NHS has seen a significant increase in the use of RAS. This increase has not been subject to any national strategy both in location of provider or in the clinical application where it should be supported; and
- Though NICE has recently included the use of RAS as a treatment option for the management of localised prostate cancer (specifically robot assisted radical laparoscopic prostatectomy), NHS England had not reviewed the clinical and cost effectiveness evidence relating to RAS.

2. Definitions

Localised prostate cancer: is where the cancer is only in the prostate and has not spread into the surrounding tissues or to other parts of the body. It is also called

localised prostate cancer.

Prostatectomy: is the removal of the prostate gland, usually performed to treat cancer. There are two types of prostatectomy:

- Trans-urethral prostatectomy, which is used to treat BPH and sometimes to provide symptomatic relief in prostate cancer. Only part of the gland is removed in this case; and
- Radical prostatectomy, which is used to treat localised prostate cancer and involves the removal of the whole prostate gland and the attached seminal vesicles.

Radical prostatectomies can be carried out in three ways:

- Open retropubic radical prostatectomy, which is where a surgeon uses an incision in the lower abdomen to reach and remove the prostate and lymph nodes;
- Laparoscopic prostatectomy, which is where the surgeon inserts a laparoscope through small incisions in the abdominal wall to remove the prostate and nodes; and
- Robot-assisted laparoscopic radical prostatectomy, which is a variant of the laparoscopic procedure.

Payments by Results (PbR): is the name of the current funding flows mechanism employed in the UK NHS. It was introduced in the last decade to reimburse providers on an output basis rather than pay against provider inputs. The principle underpinning PbR is that providers are paid the same tariff nationally, therefore providers will become more efficient in patient throughput. This encourages patient choice and works towards the principle of short waiting times.

Market Forces Factor (MFF): is an adjustment to the PbR tariff that reflects the different costs of healthcare provision in different parts of the country. It was developed to adjust the unavoidable variations in input costs, for example, staff costs, regional weighting, land, buildings and equipment in health care delivery.

Pass through payment: is a mechanism to reimburse provider organisations for specifically identified high-cost exclusions from the PbR tariff price. These are paid in addition to any appropriate PbR tariff (or locally agreed) price.

Non PbR: Services outside of the scope of PbR, deemed more complex to put into a tariff on the basis of the range in service costs from providers.

3. Aim and objectives

This policy aims to ensure that patients with localised prostate cancer are routinely offered RAS procedures, alongside other management options, to treat their disease.

The objectives are to:

- support the cost-effective use of NHS resources; and
- ensure the equitable access to RAS as an appropriate treatment option in the management of prostate cancer.

4. Epidemiology and needs assessment

Prostate cancer epidemiology

Prostate cancer is the most common cancer in men and makes up 26% of all male cancer diagnoses in England. In 2011, 35,567 men were diagnosed with prostate cancer, with a corresponding Age Standardised Rate (ASR) of 106.7 per 100,000 population (95% Confidence Interval 105.6-107.8). There were 9,123 deaths from prostate cancer in 2011 in England, translating to a mortality rate of 23.8 per 100,000 population (95% Confidence Interval 23.3-24.4) (ONS, 2014).

Prostate cancer is predominantly a disease of older men (aged 65–79 years) but around 25% of cases occur in men below the age of 65. Increased incidence and mortality is observed in men of black African or Caribbean family origin compared with white Caucasian men (NICE, 2014).

Treatment by prostatectomy

Prostatectomy is one of a range of treatments available which are dependent on the stage and severity of the disease. Other options include active surveillance, external beam radiotherapy and brachytherapy, the latter two with/without neoadjuvant hormone therapy (androgen deprivation).

Epidemiological data obtained from Public Health England (2014) shows that the rate of prostatectomies peaked in 2005 following a rise in the preceding years associated with the rapid increase in detection of cancers due to increased Prostate Specific Antigen (PSA) testing. Since 2005, the percentage of diagnosed patients who undergo a prostatectomy has remained relatively stable at approximately 13% (PHE, 2014). However, it should be noted that procedure trends remain sensitive to changes in incidence, and the impact of PSA testing rates.

The British Association of Urological Surgeons Analysis of prostatectomy data for the UK, published in June 2013, showed that in 2013 the number of procedures performed was 3,695, by 130 surgeons in 62 Centers. This represents an increase from the 2,093 performed in 2012, where 110 surgeons performed these across 57 Centres. This increase could be due to a number of factors, including changes in reporting processes to BAUS. These are also UK figures, and therefore a number of cases relate to practice undertaken outside of England.

The most common indication for prostatectomy is the primary treatment of prostate cancer, with 77% of procedures performed for this purpose (BAUS, 2014). Previous active surveillance (13.2%), where patients progress to surgical intervention following an increase in Prostate Specific Antigen (PSA) level, is the second most common reason for prostatectomy, with salvage therapy accounting for 0.7% of operations. For 8.7% of operations, the reason for surgery was not recorded (BAUS, 2014).

The largest proportion of prostatectomies for cancer were performed on men aged between 60-69 (57%), with 24% performed on men aged between 50-59, and 15.1% performed on men aged between 70-79 years of age.

Robot Assisted Prostatectomy

The BAUS data shows that of the 3,695 procedures performed in 2013, 1,824

(49.7%) were performed using robotic assisted approaches.
HES data* suggests that approximately 5,271 prostatectomies will have been undertaken to treat cancer during 2013/14 (NHS England, 2014). This data set also demonstrates that the proportion of robotic (48%) to non- robotic (52%) to be relatively even and comparable to the proportions demonstrated within the BAUS data set.
The differences in the absolute number of prostatectomies undertaken reported in BAUS and HES datasets relates to a number of factors, chiefly that: (i) BAUS reports for the United Kingdom as a whole, whereas HES data relates to England only; and (ii) BAUS reports are based on self-reported data, covering approximately 70% of surgeons.

*** 2013/14 HES data search scope**

Diagnosis Code	Procedure Code
C61- Malignant neoplasm of prostate	M611 - Total excision of prostate and capsule of prostate M612 - Retropubic prostatectomy M613 - Transvesical prostatectomy M614 - Perineal prostatectomy M618 - Other specified open excision of prostate M619 - Unspecified open excision of prostate

5. Evidence base

Efficacy summary

An in-depth evidence review was commissioned from Solutions for Public Health. Findings are summarised below (Solutions for Public Health, 2014). Overall, the review concluded;

- There was no compelling evidence that robot-assisted approaches impact on long term oncological outcomes when compared with laparoscopic and standard approaches.
- There is some evidence of clinical advantages from robot-assisted prostatectomy when compared with both laparoscopic and open radical procedures. These include lower risk of incontinence or sexual dysfunction, and reduced blood loss and lengths of stay, when compared to open prostatectomy.
- There was no clear evidence of particular sub-groups which might benefit from robotic approach compared to open or laparoscopic approaches. Such groups require further targeted research.

- Higher volume hospitals for robot-assisted prostatectomy are associated with better outcomes and productivity. There is no clear threshold to achieve better outcomes, but particularly small numbers of procedures appear to be especially adverse. It remains unclear how much experience is needed before a high and stable level of skill is attained. Outcomes continue to improve even for surgeons with substantial experience.

A summary of the key findings of the evidence review are included below.

Robot-assisted radical prostatectomy compared to conventional laparoscopic radical prostatectomy.

The review identified two randomised controlled trials of robot-assisted radical prostatectomy versus conventional laparoscopic radical prostatectomy (Asimakopoulos et al. 2011, Porpiglia et al. 2013). In both of these randomised trials, no significant differences between robot-assisted and laparoscopic approaches were reported between the two surgical techniques in any perioperative or early postoperative outcome measure. Both trials reported a greater urinary continence rate at one year in men who had undergone robot-assisted surgery, but this difference was only statistically significant in one trial. In both trials, recovery of sexual function at one year was more frequent after robot-assisted surgery. In both of these studies, there were no significant differences observed in the percentage of positive surgical margins or biochemical relapse-free survival at one year.

A systematic review which included un-randomised studies reported no evidence of differences in operative time, but patients having a robot-assisted procedure had shorter length of admissions (Healthcare Improvement Scotland, 2013).

The results on positive surgical margins were contradictory. Some meta-analyses reported lower rates with robot-assisted prostatectomy; however, a meta-analysis which only included studies at lowest risk of bias reported no significant differences, in common with the two randomised trials (Healthcare Improvement Scotland, 2013).

A similar pattern was seen with urinary continence, with different results from different analyses; again, the most reliable meta-analysis showed no significant differences (Healthcare Improvement Scotland, 2013).

None of the meta-analyses showed higher rates of sexual function after robot-assisted prostatectomy compared with the laparoscopic procedure (Healthcare Improvement Scotland, 2013).

There was widespread and substantial heterogeneity in the meta-analyses reported in the Health Technology Assessment, casting doubt on the reliability of the comparisons reported.

Robot-assisted radical prostatectomy versus open radical prostatectomy

There were no randomised comparisons of robot-assisted radical prostatectomy versus open radical prostatectomy (Healthcare Improvement Scotland, 2013).

Observational studies included in the Scottish review reported similar operative durations for open retropubic and robot-assisted radical prostatectomy, though

hospital stays were shorter after the latter procedure. Rates of positive surgical margins and biochemical recurrence-free survival were similar.

Blood loss was less and fewer patients needed transfusions after robot-assisted surgery (Trinh et al. 2012, Gandaglia et al. 2014). Results for overall rates of complications varied between analyses.

Rates of urinary continence and sexual function at one year were higher after robot-assisted prostatectomy (Healthcare Improvement Scotland, 2013). There were no studies reporting on health-related quality of life.

A large controlled but un-randomised study comparing open and robot-assisted radical prostatectomy reported similar results of the two procedures for most outcomes. Men who had robot-assisted surgery were more likely to have complications. They had shorter lengths of stay and fewer blood transfusions, but despite this, had higher costs (Gandaglia et al. 2014).

Conversely, a second similar study reported that patients undergoing robot-assisted radical prostatectomy were less likely to experience an intraoperative or postoperative complication. Other results were consistent with the first study, in that patients undergoing robot-assisted radical prostatectomy were less likely to receive a blood transfusion, and to experience a prolonged length of stay (Trinh et al. 2012).

NICE Guidance

In issuing their guidance on robotic assisted prostatectomy (NICE, 2014), NICE also acknowledged the potential for reduced transfusions and shorter length of stay compared to other surgical approaches. NICE considered the Health Technology Assessment conducted by Close et al (2013), particularly in relation to positive surgical margin outcomes. Close et al (2013) found significantly less positive surgical margins with robot-assisted prostatectomy compared to laparoscopic prostatectomy. Whilst studies published since this HTA, and analysed in the evidence review (Solutions for Public Health, 2014), have found no significant difference in positive margin rates between robot-assisted prostatectomy compared to laparoscopic prostatectomy. The NICE Committee noted differences in the methodologies used within these studies,, compared to the HTA, for ascertainment of positive margin rates. The NICE Committee therefore noted in the final guidance that “more weight” had been placed on the HTA result in informing their decision to approve RAS as a treatment option for prostatectomy.

Safety

Estimated blood loss is less with robot-assisted prostatectomy than with either alternative procedure. No other differences relating to safety was consistently reported in the studies analysed as part of the review.

Impact on quality of life

There is evidence that robotic approaches can improve quality of life measures through demonstrating reduced length of stay, and improved urinary continence and sexual function.

Cost effectiveness

A health economic analysis concluded that robot-assisted prostatectomy was more expensive than laparoscopic prostatectomy, but produced better outcomes, and was more cost-effective (Close et al, 2013).

The result depended on the difference in positive surgical margin rates between the two interventions and an assumption that the number of robot-assisted procedures would be at least a hundred per year. If either of these assumptions are not met – and evidence calls into question the first one – then the analysis' results are not reliable.

Activity and cost

The total number of prostatectomies carried out to treat cancer during 2013/14 is estimated to be 5,271, of which 48% was carried out robotically and 52% non-robotically (NHS England, 2014). The current cost of this activity, using an appropriate tariff price and the average cost of consumables for robotic surgery, is estimated to be £26 million.

Should all procedures be carried out robotically, the total cost pressure associated with robotic surgery for prostate cancer will be £31 million.

The total cost of implementing this policy, based on the assumption that all radical prostatectomies would be undertaken robotically and that HES is an accurate gauge of both the absolute activity undertaken and the proportion of robotic to non-robotic activity currently performed in England, is approximately £5 million.

6. Rationale behind the policy statement

There is reasonable evidence for the clinical effectiveness of RAS procedures in the management of localised prostate cancer, specifically relating to:

- Reducing the risk of incontinence
- Preventing sexual dysfunction
- Minimising blood-loss in theatre
- Reducing margin positive rates

The evidence review concluded that at the present time there is no evidence that using this procedure conveys any additional survival gain for those patients undergoing the procedure as compared with open or laparoscopic techniques.

To conclude, the procedure offers reasonable and discrete quality of life-gains for patients undergoing RAS as compared with open and laparoscopic techniques, together with some efficiency savings for the healthcare system as a whole (through reduced blood-loss). Furthermore, NHS England currently commissions a significant proportion of robotic assisted prostatectomy activity, for which provider organisations have already invested substantial capital in purchasing the equipment required to deliver this.

7. Criteria for commissioning

RAS procedures will be offered as a choice alongside existing commissioned procedures (open and laparoscopic) to all patients with localised prostate cancer,

where deemed suitable by Specialist Multi-Disciplinary Teams (MDTs).
RAS procedures will be commissioned from networked centres performing high volumes of RAS procedures in line with the evidence relating to volume and outcome. Criteria for 'high volume' centres will be agreed through the Specialised Urology Clinical Reference Group.

8. Patient pathway

The policy does not impact on the clinical pathway. RAS is a different way of carrying out a radical prostatectomy, if used the procedure would be delivered at the same point in the clinical pathway and necessitate the same outpatient follow-up arrangements.
However, the policy may entail some provider organisations to enter into expanded clinical network arrangements to ensure that all patients can be offered all three surgical options by the Specialist Multi-disciplinary Team (SMDT).
It may be the case that, following the wider-availability of RAS procedures, some patients that currently select radiotherapy as a treatment option may instead select RAS. Currently there is no published literature available to enable this to be modelled or quantified.

9. Governance arrangements

RAS procedures shall only be undertaken in centres that:

- Undertake a minimum annual volume of 150 radical prostatectomies.
- Have a recognised training programme to support the safe and effective delivery of RAS techniques.
- Undertake local audits to support continued professional learning and development.

Participate in all national audits, such as that supported by BAUS and/or RCS (NPCA).

10. Mechanism for funding

Due to indifferent classifications on the application of the Identification Rules across the country, the commissioner paying for robotic surgery remains a mix of both CCGs and NHS England. Furthermore this may well be the case for non-robotic surgery, so any shift in how the procedure is carried out may also mean a shift of commissioner paying for this treatment.
If this shift in commissioner is significant enough, this may require a baseline transfer between commissioners in order to alleviate the funding impact of one commissioner offset by the benefit of the shift to another.
Providers will continue to be reimbursed as per PbR rules applicable to the year.

11. Audit requirements

Provider organisations are expected to continue to report through BAUS Audits and/or National Prostate Cancer Audit mechanisms.

12. Documents which have informed this policy

In addition to those stated within the references section, this policy has been informed by the independent rapid evidence review (Solutions for Public Health, 2014) which assessed the evidence for using RAS to treat prostate cancer.

13. Links to other policies

This policy follows the principles set out in the ethical framework that govern the commissioning of NHS healthcare and those policies dealing with the approach to experimental treatments and processes for the management of individual funding requests (IFR).

14. Date of review

This policy will be reviewed in April 2017 unless information is received which indicates that the proposed review date should be brought forward or delayed.

References

Asimakopoulos AD, Pereira Fraga CT, Annino F, et al. Randomized comparison between laparoscopic and robot-assisted nerve-sparing radical prostatectomy. J Sexual Med 2011; 8: 1503-1512.

British Association of Urological Surgeons (BAUS). Analyses of Prostatectomy Dataset January 1st-31st December 2013. Published June 2013. Available at: http://www.baus.org.uk/Resources/BAUS/Documents/PDF%20Documents/Data%20and%20Audit/Prostatectomies2013FinalAnalyses.pdf

Close A, Robertson C, Rushton S, et al. Comparative cost-effectiveness of robot-assisted and standard laparoscopic prostatectomy as alternatives to open radical prostatectomy for treatment of men with localised prostate cancer: A health technology assessment from the perspective of the UK National Health Service. Euro Urol 2013; 64: 361-369.

Cooperberg MR, Ramakrishna NR, Duff SB, et al. Primary treatments for clinically localised prostate cancer: a comprehensive lifetime cost-utility analysis. BJU Int 2013; 111: 437-450.

Gandaglia G, Sammon JD, Chang SL, et al. Comparative effectiveness of robot-assisted and open radical prostatectomy in the postdissemination era. J Clin Oncol 2014; 32: 1419-1426.

Healthcare Improvement Scotland. Open, laparoscopic and robot-assisted laparoscopic radical prostatectomy for localised prostate cancer. Edinburgh: Healthcare Improvement Scotland, 2013.

National Institute for Health and Care Excellence (NICE). Prostate Cancer: Diagnosis and Treatment. Cg175. 2014. Available at : http://www.nice.org.uk/Guidance/CG175

NHS England. Hospital Episode Statistics (HES) analysis for RAS Working Group. August 2014.

Public Health England. National Cancer Intelligence Network. Personal Communication to RAS Working Group. 9th September 2014.

Porpiglia F, Morra I, Lucci Chiarissi M, et al. Randomised controlled trial comparing laparoscopic and robot-assisted radical prostatectomy. Euro Urol 2013; 63: 606-614.

Sandoval Salinas C, Gonzalez Rangel AL, Catano Catano JG, at al Efficacy of robotic-assisted prostatectomy in localized prostate cancer: a systematic review of clinical trials. Advances in Urology 2013; http://dx.doi.org/10.1155/2013/105651.

Trinh QD, Sammon J, Sun M, et al. Perioperative outcomes of robot-assisted radical prostatectomy compared with open radical prostatectomy: results from the nationwide inpatient sample. Euro Urol 2012; 61: 679-685.