Clinical Commissioning Policy: Robotic assisted lung resection for primary lung cancer

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Clinical Commissioning Policy: Robotic assisted lung resection for primary lung cancer

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Contents

Policy Statement

NHS England will not routinely commission robotic assisted lung resection for primary lung 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 lung cancer

Lung cancer is one of the most common types of cancer and every year in the United Kingdom (UK) over 41,000 people are diagnosed with lung cancer. Lung cancer is:

- Rare in people younger than 40, however after the age of 40 the number of people diagnosed with lung cancer rises sharply
- Most commonly diagnosed in people aged over 70

Primary lung cancer, which means that the cancer first appeared in the lungs, can be grouped into two main types: (i) non small cell; and (ii) small cell.

Smoking is the main cause of lung cancer cases, accounting for over 90% of cases. However, a small proportion of lung cancer cases are diagnosed in people who have never smoked.

About the current treatment

The right treatment for lung cancer depends on:

- The type of cancer ('small cell cancer' or 'non-small cell cancer')
- How far it has spread
- The patient's general health

For some patients, surgery is a possible treatment. The main types of, or 'conventional', surgery techniques include:

- Open thoracotomy (open surgery)
- Video assisted thoracoscopic surgery (VATS) - which allows surgeons to see inside the chest and lungs. This is a 'minimally invasive technique' - which means that the body does not have to be cut open as much.

About the new treatment

Robotic assisted thoracic surgery (RATS) may be seen as an evolution of existing minimally invasive techniques. The surgery uses a computer system to help the surgeon to guide the surgical tools.

What we decided

NHS England has carefully reviewed the evidence to treat primary lung cancer with robotic assisted lung resection. 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 lung resection for primary lung cancer.

The appropriate treatment for lung cancer depends on the type of cancer, how far it has spread and how good one's general health is. The treatment of lung cancer is a rapidly developing field. Existing surgical techniques include Video Assisted Thoracoscopic Surgery (VATS) and open thoracotomy. VATS is an evolving minimally invasive technique that is increasingly applied in situations where traditional open thoracotomy has long been used for lung resections. VATS may have a number of benefits over open thoracotomy including smaller incisions, less blood loss, fewer complications and faster recovery times. However, VATS has not been widely adopted by the surgical community. In 2013/14 30% of resections for primary lung cancer were performed by VATS (SCTS Return 2013/14) in part due to the steep learning curve. Thus the majority of patients currently receive open thoracotomy.

Robotic Assisted Thoracoscopic Surgery (RATS) is an alternative minimally invasive operation platform with a number of potential benefits including three-dimensional, high-definition (3DHD) vision affording 360 degree vision of the whole of the inside of the chest, a fully articulated arm which allows more complex operations in tight spaces and greater ease of use for the surgeon due to the better ergonomics.

2 Definitions

Robotic Assisted Thoracoscopic Surgery (RATS) uses 3DHD vision and articulated arms that move inside the patient, but are pivoted gently through small holes made in the rib spaces. The arms are controlled by the operating surgeon working at a console nearby with a second surgeon scrubbed at the table for positioning of instruments.

Video Assisted Thoracoscopic Surgery (VATS) is an evolving minimally invasive technique that is increasingly applied in situations where traditional open thoracotomy has long been used for lung resections.

An open thoracotomy is a form of open surgery that can be used to resect part or all of the lung.

3 Aims and Objectives

This policy proposition aims to define NHS England's commissioning approach to robotic assisted lung resection for primary lung cancer.

The objective is to ensure evidence based commissioning in the use of robotic assisted lung resection for adults with primary lung cancer.

4 Epidemiology and Needs Assessment

Lung cancer is one of the most common and serious types of cancer. Over 41,000 people are diagnosed with the condition every year in the UK. Lung cancer mainly affects older people. It is rare in people younger than 40, but the rates of lung cancer rise sharply with age. Lung cancer is most commonly diagnosed in people aged 70-74 years. Although people who have never smoked can develop lung cancer, smoking is the main cause (about 90% of cases). This is because smoking involves regularly inhaling a number of different toxic substances.

Robotic Assisted Thoracoscopic Surgery (RATS) would predominately be used for early stage lung cancer although potentially more advanced lung cancer (N2) could also be treated through the use of RATS.

5 Evidence Base

NHS England has concluded that there is not sufficient evidence to support a proposal for the routine commissioning of robotic assisted lung resection for primary lung cancer.

Overall the quality of evidence to address the clinical effectiveness questions around the use of RATS in treatment of lung cancer is limited as the predominant sources of evidence are single-centre case series reports. There are no large cohorts or randomised control trials (RCTs) comparing RATS and alternative thoracic surgery techniques. Systematic reviews and meta-analysis identified in the literature are limited by the quality and type of studies available.

In summary, robotic lobectomy is a feasible, safe, technically reproducible and oncologically sound surgical treatment for early-stage lung cancer. There may be advantages in cancer upstaging, reduced length of stay, complications, blood loss and earlier recovery. Disadvantages include capital costs, the learning curve for the team, and the lack of tactile feedback. Early experiences suggest that the learning curve is approximately 20 cases for experienced surgeons. There was no evidence relating outcome to volume of cases per surgeon or centre.

Learning curve:

The literature has suggested that it takes surgeons 18-20 cases (Brooks et al, 2015) and approximately one year learning time to go from maximally invasive techniques to minimally invasive robotic techniques which is primarily related to the positioning of trocars in the chest wall, accessibility of the appropriate surgical tools, ability to determine the use of correct robotic arms, and understanding the patient positioning (Brooks et al, 2015). Additional learning aspects of robotic-assisted thoracic lobectomy were cited as the loss of tactile senses, the increased time of the procedure, and the need for a surgical assistant to fire the stapler. A stapler that the surgeon can use has been developed and is expected to be introduced soon.

Safety and peri-operative outcomes:

Safety and perioperative outcomes in relation to this evidence review are defined as operation times, length of stay, conversion to open procedures, estimated blood loss, rates of morbidity and mortality.

A systematic review of twelve observational studies including one multi-institutional retrospective review of 325 consecutive patients that looked at long term outcomes concludes that RATS is a safe surgical option for lobectomy, thymectomy and

mediastinal node resection in early stage lung cancers (Brooks et al, 2015). A recent meta-analysis of perioperative morbidity data from eight observation studies did not find any significant difference in perioperative morbidity rates (RR, 1.02; 95% CI, 0.94-1.10; P=0.605) between RATS and VATS for lung cancer. There was no significant difference in overall perioperative mortality rates (RR, 0.28; 95% CI 0.06-1.25; P=0.095) based on meta-analysis of data from four of the eight studies (Ye et al, 2015).

The operative complications for RATS were identified as

- Atelectasis (1-22%)
- Atrial Fibrillation (3-19%)
- Air Leak (3-13%)
- Acute Respiratory Disease Syndrome (1-13%)
- Pneumonia (1-5%)

Commonest complications were arrhythmias and air leaks.

Velez-Cubian et al, 2015 combined data taken from 23 studies identified in a literature search with a retrospective case series (n=208) from their own institution. Data taken from the literature was divided into two groups based on year of publication and the authors' own data was divided into an early series and a late series of procedures. In a solely descriptive analysis without statistical tests of comparisons, the authors described how mortality and morbidity rates were comparable in the first two groups.

Published Studies	**2005-2010**	**2011-2014**
Operative Time (mins)	150- 240	90-242 ns
Conversion Rates	0-19%	0-11% - *more difficult cases, larger tumours, advanced stages, patients with pre induction chemo
Mortality Rates	0-5%	0-2%
Morbidity Rates	11-39%	11-44%
Own Centre Data		
LOS (days)	3-11	2-6
Morbidity rates	43%	38%
Mortality rates	0.5%	0.2%
Operative Time	179	172
Conversion rates	9.6%	13% (*and also hybrid procedures)

Quality of Life outcomes:

There was limited evidence for impact on quality of life. Balduyck et al, 2011 reports that patients who underwent RATS returned to pre surgery levels of physical, role and social functioning sooner than those who underwent open sternotomy. Significant limitations in the study design prevent extrapolation of these findings beyond the study population.

Oncological outcomes:

Nodal upstaging is a surrogate measure of the quality of the surgery. Higher rates of nodal upstaging are preferred and the ability to assess more nodes provides a strong prognostic tool.

Several studies have reported that the open thoracotomy approach has higher mean total number of N2 lymph nodes retrieved than the VATS approach (Velez-Cubian et al, 2015). The rate of nodal upstaging for RATS (10.9%) appeared to be superior than for VATS and similar to thoracotomy data by clinical tumour stage. Velez-Cubian's own cohort had an overall 30% upstaging rate and a 19% nodal upstaging rate. Wilson et al, 2014 demonstrated upstaging in 33 out of 302 patients, however, 2 year disease free survival and overall survival at 70.2% and 88% remained similar to VATS and Thoracotomy. Similar rates of lymph node upstaging and lack of an impact on 2 year disease free and overall survival was also shown by Lee et al, 2015. The inference is that RATS permits meticulous and detailed dissection and lymph node dissection that can improve early detection of metastatic disease. This more accurate staging will allow further appropriate adjuvant chemotherapy. A multi-centre study (Park et al, 2012) has also shown that RATS resulted in an overall 5-year survival for the group of 80%. By cancer stage there was 5 year survival of stage 1A cancers of 91%, 1B of 88% and 49% for all patients with stage II.

In Velez-Cubian et al, 2015 the oncological outcome was measured in terms of mediastinal nodal station dissection and upstaging rates. The oncological outcomes were not reported in the same comparative groups (literature review 2005-10; 2011-14) but instead a comparison was undertaken with the National Comprehensive Cancer Network (NCCN) database and one study identified by the authors. Mediastinal lymph node (LN) dissection and detection of occult mediastinal LN

metastases were improved during robotic-assisted lobectomy for non-small-cell lung cancer, as demonstrated by an overall 30% upstaging rate, including a 19% nodal upstaging rate, in the cohort.

Published Studies	RATS (own centre data)	VATS (NCCN/NSLC database)	Open surgery (NCCN/NSLC) database
Assessment of mediastinal nodal stations			
Mean number of N2 LN stations dissected	3.7 +0.1	3.1 / 2.5	2.9 / 3.7
>3N2 LN dissected	98%	66%	58%
Individual N2 LNs retrieved	7.2 ± 0.3	2.5*	3.7*
Nodal upstaging rate			
cN0-to-pN2	8.2%	2.1-4.9%	1.9-5%
cN0-to-pN1	18.4%	8.8-15.9%	14.3-14.5%

*Damico TA et al, 2011

Cost effectiveness:

Data from US studies indicates open thoracotomy remains the most costly out of the three options with longer hospitalisation, intensive care and respiratory therapy use. The cost of RATS increases the minimal invasive surgery (VATS) cost by 3000 to 4500 USD per case. The key cost drivers of RATS were the capital costs, followed by cost of specific consumables (Swanson et al 2014, Deen et al 2014). Park et al, 2008 report further additional costs due to additional procedures undertaken for RATS cases. Current evidence is largely cost–comparisons of direct peri-operative costs. More studies are needed for evaluating the cost effectiveness and long term clinical benefit to the patients.

6 Documents which have informed this Policy

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

7 Date of Review

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

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