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NHS England

Clinical Commissioning Policy Proposition:

Robotic assisted surgery for oesophago-gastric cancers

Reference: NHS England B11X02/01

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Plain Language Summary

This policy proposition describes NHS England's commissioning approach to robotic assisted surgery for adults with oesophago-gastric cancers.

Oesophago-gastric cancer refers to cancers of the oesophagus or the stomach.

Oesophageal cancer has become more common in the last 40 years in the UK although the number of females diagnosed with it has decreased since the late-1990s. In contrast, stomach cancer has become less common in the UK in the last 30 years. There are almost twice as many cases of stomach cancer diagnosed in men as in women. Both cancers become more common as people increase in age.

Oesophago-gastric cancer is usually treated with surgery, chemotherapy or radiotherapy and sometimes a combination of all three. The appropriate treatment will depend on the type of cancer, how far it has spread and the general health of the patient. For cancers where surgery is deemed appropriate, the approach to surgery is determined by the position of the tumour. Existing surgical techniques include open and laparoscopic surgery. Robotic assisted surgery is an alternative minimally invasive technique using a sophisticated, computer-enhanced system to guide the surgical tools.

NHS England has concluded that there is not sufficient evidence to support a proposal for the routine commissioning of robotic assisted surgery for adults with oesophago-gastric cancers. More randomised controlled trials and longer term prospective studies within a framework of measured and comparative outcomes against established surgical techniques are needed. Potential future advances in the robotic assisted surgery technology and / or skill sets required to operate such technology could result in a review of the current commissioning position.

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 for patients with oesophago-gastric cancers.

For the purpose of consultation NHS England invites views on the evidence and other information that has been taken into account as described in this policy proposition.

A final decision as to whether robotic assisted surgery for adults with oesophago-gastric cancers will be routinely commissioned is planned to be made by NHS England by June 2016 following a recommendation from the Clinical Priorities Advisory Group.

2. Proposed Intervention and Clinical Indication

Oesophago-gastric cancer is usually treated with surgery (either a gastrectomy or oesophagectomy), chemotherapy or radiotherapy and sometimes a combination of all three. Treatment will depend on the type of cancer, how far it has spread and the general health of the patient. For cancers where surgery is deemed appropriate, the approach to surgery is determined by the position of the tumour not only to ensure radical resection but also safe reconstruction. Robotic assisted surgery is seen by some as a progression on the existing techniques using a sophisticated, computer-enhanced system to guide the surgical tools.

3. Definitions

Oesophago-gastric cancer refers to cancers of the oesophagus and the stomach.

Open surgery can be performed for both oesophageal and gastric cancer. For oesophageal resections, the options are two phase (right thoracic and abdominal), three phase (thoracic, cervical and abdominal), transhiatal and left thoraco-abdominal. For gastric resections, the options are subtotal gastrectomy for distal tumours, total gastrectomy for proximal tumours, and transhiatal extended total gastrectomy or oesophago-gastrectomy for tumours of the cardia.

Minimally invasive surgery, sometimes known as 'keyhole surgery', involves the use of laparoscopic instruments under the guidance of a camera inserted through several small incisions rather than using a large incision characteristic of an open surgical approach. The National Audit data suggests an increasing number of procedures are performed using the minimally invasive technique although there is yet to be consensus about the most appropriate approach for these procedures. This is currently the subject of clinical trials.

Robotic Assisted Surgery is an alternative minimally invasive technique that uses a sophisticated, computer-enhanced system to guide the surgical tools.

4. Aim and Objectives

This policy proposition aims to define NHS England's commissioning position on robotic assisted surgery as part of the treatment pathway for adult patients with oesophago-gastric

cancers.

The objective is to ensure evidence based commissioning with the aim of improving outcomes for adults with oesophago-gastric cancers.

5. Epidemiology and Needs Assessment

Oesophageal cancer has become more common in the last 40 years in the UK although in females the incidence rate has decreased since the late-1990s. It is more common in older people; more than eight out of 10 cases are diagnosed in people aged 60 or over (Cancer Research UK).

Stomach cancer has become less common in the UK in the last 30 years. There are almost twice as many cases of stomach cancer diagnosed in men as in women. As with oesophageal cancer, cancer of the stomach becomes more common with increasing age with 95 out of 100 cases diagnosed in people aged 55 or older (Cancer Research UK).

There are around 13,000 new cases of oesophago-gastric cancers in England per year (Office for National Statistics 2012).

Surgery for oesophageal and gastric cancer is normally undertaken with curative intent although there are indications for palliative surgery for gastric cancer. About 37% of patients present with disease which is appropriate for curative treatments. Surgery is part of treatment, usually in combination with chemotherapy, for about 20-25% of all patients presenting with oesophago-gastric cancer. In England and Wales between April 2011 and March 2013, 3,050 oesophagectomies and 1,848 gastrectomies were performed with curative intent. (National Oesophago-Gastric Cancer Audit, 2014).

6. Evidence Base

NHS England has concluded that there is not sufficient evidence to support a proposal for the routine commissioning of robotic assisted surgery for adults with oesophago-gastric cancers. More randomised controlled trials and longer term prospective studies within a framework of measured and comparative outcomes against established surgical techniques are needed.

The clinical evidence review aimed to address the following research questions:

Question 1: What evidence is available on the clinical effectiveness of robot-assisted surgery for the treatment of oesophago-gastric cancer compared to existing surgical techniques?
Question 2: What evidence is available on the cost effectiveness of robot-assisted surgery for the treatment of oesophago-gastric cancer compared to existing surgical techniques?
Question 3: What is the learning curve for robotic-assisted surgery for oesophago-gastric cancer?

Summary:

The literature search returned 298 abstracts from which 25 studies were considered in detail. Most of the studies were specific to gastric cancer and conducted in South East Asia. There was reference to only two studies which included surgery for oesophageal cancer. In addition, in most of the Asian studies early gastric cancers were treated which is not directly applicable to experience in England. The data is from retrospective observational studies of variable quality. There were no randomised control trials. Many of the systematic reviews and meta analyses include the same group of studies (and thus patients).

Robotic surgery is being used as a minimally invasive modality for surgery because of its assumed technical superiority over conventional laparoscopy. There is, however, limited evidence of superiority in relation to oesophago-gastric cancer. Most of the studies directly comparing laparoscopic to robotically assisted surgery were of poor methodological quality and it is not possible to conclude whether robotic techniques are superior or even non-inferior to standard laparoscopic techniques. There is little to no robust survival data and thus it is equally not possible to state that there is a survival advantage. At best, the short-term operative outcomes are equivalent. There is a blood loss and length of stay advantage, but this is at the expense of longer operating time which is consistently reported in the studies considered.

Much of the literature reports on technical aspects and efficacy as opposed to outcomes. Studies mostly conclude that the robotic technique is feasible and outcomes are acceptable. Few studies reported survival. Some of the studies report short-term oncological outcomes that are equivalent when comparing robotic and laparoscopic surgery, but this cannot be stated as an evidence based conclusion, given the lack of comparative evidence. Similarly, whilst there may be advantages of robotically assisted surgery (compared to laparoscopic) with regards to blood loss and shorter length of stay (LOS), given the lack of comparative evidence it is difficult to state this as an evidence based conclusion. Finally, there are reported advantages to laparoscopic technique with regards to operation time (and thus theatre utilisation) but again there is little comparative data on which to draw this conclusion. There is some (inevitable) duplication in the studies included in the various systematic reviews. No formal cost effectiveness studies were found.

Question 1: What evidence is available on the clinical effectiveness of robot-assisted surgery for the treatment of oesophago-gastric cancer compared to existing surgical techniques?

Chuan (2015) conducted a meta analysis of available RCTs and observational data. It was reported that operation time was significantly longer; that blood loss was less; and length of stay was shorter in the robotic surgery group compared to those receiving laparoscopic surgery. Resection margin and postoperative complications were similar in both groups. These findings by Chuan et al., 2015 typifies most of the literature reviewed with the findings remarkably consistent across studies.

Xiong (2013) concluded in a meta analysis that robotic gastrectomy is a safe technique for treating gastric cancer that compares favourably with laparoscopic gastrectomy in short term outcomes. However, the long term outcomes between the two techniques need to be

further examined.

Xiong (2012) in a meta analysis found less blood loss and shorter length of stay for robotically assisted surgery. No significant differences reported on other outcomes.

Zong (2014) concluded that robotically assisted surgery is technically feasible. In keeping with other studies it has a longer operative time. There are some advantages regarding blood loss, but no significant difference between lymph node harvest, morbidity and mortality. Resection margin is not reported. This was a meta analysis of observational studies.

Coratti (2015) concluded, in a 98 patient case series, that robot-assisted gastrectomy for the treatment of gastric cancer is safe and feasible. It provides long-term outcomes comparable to most open and laparoscopic series.

Okumura (2015) concluded that there was no difference in outcomes comparing robotic gastrectomy in older patients compared to younger patients, and were comparable to the outcomes achieved in laparoscopic surgery in older patients.

Tokunaga (2015) reported that robotic gastrectomy was considered safe in terms of the incidence and severity of post operative outcomes.

Huang (2012) reported a case series of 689 patients undergoing gastrectomy (586 open, 64 laparoscopic and 39 robotic). Robotic gastrectomy was associated with less blood loss, shorter hospital stay, and longer operative time than open and laparoscopic gastrectomy. The retrieved lymph node numbers were similar between the open and robotic groups. Post-operative morbidity rates were similar among the three groups.

Shen (2015) reported on a case series of 423 patients undergoing robotic (n=93) or laparoscopic (n=330) gastrectomy for gastric cancer. The comparative study demonstrates that robotic assisted gastrectomy is as acceptable as laparoscopic gastrectomy in terms of surgical and oncologic outcomes, with lower estimated blood loss, acceptable complications, and radical resection. Robotic assisted gastrectomy is a promising approach for the treatment of gastric cancer although the indication of patients for robotic assisted gastrectomy is critical.

Hyun (2013) concluded that the short-term oncological outcomes of robotically assisted surgery were comparable with those of the other approaches and that laparoscopic gastrectomy was a shorter procedure and less expensive.

Given the state of the literature it is not possible to draw conclusions that robotically assisted oesophago-gastric cancer resection is more effective than the laparoscopic or open procedure technique.

Question 2: What evidence is available on the cost effectiveness of robot-assisted surgery for the treatment of oesophago-gastric cancer compared to existing surgical techniques?

No formal cost effectiveness studies were found.

Given the lack of data on long-term oncologic or survival outcomes, it is not readily possible to draw any conclusions that robotically assisted techniques offer significant advantage. It is also a more expensive approach.

Kim (2015) compared the short-term surgical outcomes including the financial cost of robotic and laparoscopic gastrectomy. This study concluded that whilst the use of robotic systems is assumed to provide a technically superior operative environment for minimally invasive surgery, this analysis of perioperative surgical outcomes indicated that robotic gastrectomy is not superior to laparoscopic gastrectomy, and is significantly more costly. Patients treated with robotic surgery showed significantly longer operative time (robotic = 221 minutes vs. laparoscopic = 178 minutes; $P < 0.001$) and significantly higher total costs (£8,814 vs. laparoscopic = £5,309; $P < 0.001$), compared with those who underwent laparoscopic gastrectomy. N.B. GBP values converted from USD on 18/11/15 at exchange rate of 0.656.

Park JY (2012) concluded in a small observational study that operative time was longer with robotic approaches and there was no difference in outcomes with respect to surgical stress. The cost of robotic surgery was higher than laparoscopic techniques.

Question 3: What is the learning curve for robotic-assisted surgery for oesophago-gastric cancer?

There was some literature reporting on training and learning curve issues, many of these were not considered in the final analysis for comparative effectiveness purposes as the studies were focused on learning curve, not outcome. Most commonly it is reported that the learning curve is shorter than for laparoscopic techniques. It is also commonly reported that skill acquisition is dependent on having prior laparoscopic skills.

Huang (2012) highlighted a significant learning curve effect in the initial 25 cases of robotic surgery with respect to operative time and retrieval of lymph nodes. Park (2013) analysed the learning curve of over 200 cases of robotic assisted gastrectomy. Park (2013) concluded that increased experience (comparing the first 100 with the second 100 cases) with the robotic procedure for gastric cancer was associated with improved outcomes, especially in operating time, lymph node retrieval and shortened hospital stay of complicated patients. Further development of surgical techniques and technology might enhance the role of robotic surgery for gastric cancer.

7. Documents That Have Informed This Policy Proposition

Not applicable

8. Date of Review

This document will lapse upon publication by NHS England of a clinical commissioning policy for the proposed intervention that confirms whether it is routinely or non-routinely commissioned (expected by June 2016).