NHS England

Clinical Commissioning Policy Proposition:

Robotic assisted trans-oral surgery for throat and voice box cancers

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Clinical Commissioning Policy Proposition: Robotic assisted trans-oral surgery for throat and voice box cancers

Reference: NHS England B16X01/01

First published: January 2016

Prepared by NHS England Specialised Commissioning Team

Published by NHS England, in electronic format only.

Classification: OFFICIAL

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Plain Language Summary

The policy proposition aims to confirm NHS England's commissioning approach to robotic assisted trans-oral surgery for throat and voice box cancers.

In 2013/14 there were approximately 2,306 malignant tumours of the oropharynx and 1,667 malignant tumours of the larynx.

It is recognised that there is a role for both surgery and (chemo)radiation therapies for the treatment of these cancers, dependent on the circumstances of individual patients. Transoral Robotic Surgery (TORS) is a relatively new surgical technique that permits removal of throat and voice box cancers through the mouth. TORS enables the surgeon to resect squamous and non-squamous cancers without disrupting the external muscles of the throat. While Transoral Laser Microsurgery (TLM) has been widely used for Head and Neck Cancer treatment, TORS is seen by some as a progression on the existing techniques using a sophisticated, computer-enhanced system to guide the surgical tools, giving better access to tumours in otherwise hard to reach areas in this region. TLM and TORS are both procedures that permit natural orifice surgery with some differences in the technique used to remove the cancers.

TORS requires expensive equipment, which represents a capital cost as well as the cost of consumables. Currently providers are reimbursed for the TORS procedure through national prices, with separate additional payment for the cost of the robotic consumables.

NHS England has concluded that there is not sufficient evidence to support a proposal for the routine commissioning of robotic assisted trans-oral surgery for throat and voice box cancers.

1. Introduction

This document describes the evidence that has been considered by NHS England in formulating a proposal to not routinely commission robotic assisted trans-oral surgery for throat and voice box 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 trans-oral surgery for throat and voice box 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. The proposed intervention and clinical indication

Transoral Robotic Surgery (TORS) is a relatively new surgical technique that permits removal of throat and voice box cancers through the mouth. TORS enables the surgeon to resect squamous and non-squamous cancers without disrupting the external muscles of the throat. While Transoral Laser Microsurgery (TLM) has been widely used for Head and Neck Cancer treatment, TORS is seen by some as a progression on the existing techniques using a sophisticated, computer-enhanced system to guide the surgical tools, giving better access to tumours in otherwise hard to reach areas in this region. TLM and TORS are both procedures that permit natural orifice surgery with some differences in the technique used to remove the cancers.

TORS requires expensive equipment, which represents a capital cost as well as the cost of consumables. Currently providers are reimbursed for the TORS procedure through national tariff, with separate additional payment for the cost of the robotic consumables, which is a specific tariff exclusion.

3. Definitions

Transoral Robotic Surgery (TORS) is a procedure to remove cancers of the oropharynx and supraglottis in which a surgeon uses a sophisticated, computer-enhanced system to guide the surgical tools.

Transoral Laser Microsurgery (TLM) is a minimally invasive procedure to remove oropharynx and supraglottis cancers through the mouth.

Transoral resections not using TLM or TORS require major open neck surgery.

4. Aim and objectives

This policy proposition aims to define NHS England's commissioning approach to Transoral Robotic Surgery for cancers of the oropharynx and supraglottis.

The objective is to ensure evidence based commissioning with the aim of improving outcomes for adults with cancers of the oropharynx and supraglottis.

5. Epidemiology and needs assessment

The overall crude incidence rate for head and neck cancers is approximately 18.1 per 100,000 population. This includes cancers of the oral cavity (2,250, 4.4 per 100,000 population), larynx (1,800, 3.5 per 100,000 population), oropharynx (1,500 cases, 3.0 per 100,000 population), nasopharynx (200 cases, 0.4 per 100,000 population) hypopharynx (400, 0.8 per 100,000 population) and thyroid (2,000 cases, 3.9 per 100,00 population). There are a wide range of other cancer sites and rarer pathologies of the head and neck. Oral cancer has the highest incidence of the head and neck cancers and is increasing in incidence. The incidence of cancers of the oropharynx is estimated to grow at c.9% per year and incidence of cancer of the larynx is growing at a slower rate of c.1% per year. There is evidence that the proportion of oropharyngeal cancer cases that are HPV positive has increased over time with 73% of oropharyngeal cancer cases in Europe HPV-positive (Mehanna et al., 2013).

In 2013/14 there were approximately 2,306 malignant tumours of the oropharynx and 1,667 malignant tumours of the larynx (2013 National Head and Neck Cancer Audit data). Of these, clinicians estimate that up to 20% would be suitable for TORS.

6. Evidence base

NHS England has concluded that there is not sufficient evidence to support a proposal for the routine commissioning of robotic assisted trans-oral surgery for throat and voice box cancers.

The research questions to inform the evidence review sought to determine whether there is sufficient evidence of clinical and cost effectiveness for Transoral Robotic Surgery (TORS) as a surgical option for patients with head and neck cancers compared to existing surgical techniques. Comparator interventions included open surgery, chemotherapy and radiotherapy and Transoral Laser Microsurgery (TLM).

Clinical effectiveness is assessed in terms of oncological outcome (survival and disease-free survival), functional outcomes, quality of life and adverse effects. Secondary outcomes are those associated with perioperative outcomes e.g. length of stay, complications etc.

The overall grade of evidence for this clinical evidence review is Grade D, reflecting the reliance on case series in the systematic reviews and the complete absence of randomisation in any of the studies, therefore introducing a high risk of bias. There was one recently published study on cost effectiveness of TORS. All studies were on adult patients. None of the studies were specifically designed to analyse outcome of TORS by disease stage. In the studies where tumour staging was specified, the majority of patients included had early oropharyngeal carcinoma (listed as early stage or T1/2, with N0/1 staging specified only in Choby et al 2015). Some studies included patients across all tumour stages (Hutcheson et al 2015, Weinstein et al 2012, Richmon JD et al 2014). Genden et al 2011 included 73% patients in Stage III-IV patients in the thirty patient case series.

Overall the literature review identified 5 systematic reviews all graded as having a high risk of bias (1-) due to the reliance on non-randomised case series studies as the primary source of data. The literature review identified 3 cohort studies directly comparing 2 or more interventions and one cohort study looked at survival outcome for TORS cases. Nine case series studies (excluding those reported in the systematic reviews) were identified and excluded as lower grade evidence sources and no further action was taken with them in the review.

Oncological outcomes:

Three systematic review papers (Yeh et al 2015, Kelly et al 2014 and de Almeida 2014) were identified that described oncological outcomes in terms of survival and disease-free survival of cancers of the oropharynx. All three papers describe the findings from primary research papers with limited follow up (less than 2 years). Two of the reviews (Yeh et al 2015 and de Almeida et al 2014) are comparisons to Intensity Modulated Radiotherapy and concluded that there was no advantage in terms of survival. The final paper (Kelly et al 2014) did not include comparisons to other interventions.With regards to locoregional control the review authors conclude that TORS is equivalent to comparator interventions (IMRT or chemoradiation) in control of disease.

A cohort study of 410 patients treated across 11 centres treated with TORS with or without chemotherapy or radiotherapy (de Almeida 2015) found that the 2- year locoregional control rate was 91.8% (95%CI, 87.6%-94.7%), disease-specific survival was 94.5% (95%CI, 90.6%-96.8%), and overall survival was 91%(95%CI, 86.5-94.0%).

Functional outcomes and Quality of Life (QoL) measures:

The consensus across the systematic review literature (Yeh et al 2015, Hutcheson et al 2015) is that TORS has improved functional outcomes, with lower rates of feeding tube usage, and better quality of life outcomes around swallowing and oral feeding than in comparators. When comparing between TORS and radical open surgery (Park et al 2013) and CRT (Genden et al 2011), the authors found in unmatched case cohort studies more favourable outcomes for TORS in terms of functional and QoL measures.
Adverse events:

Comparison of adverse events is problematic for a large part of the literature where comparators treatments are not both surgical, and there is some cross over with reporting of functional outcomes.

Perioperative outcomes:

One systematic review (Chan et al 2015) summarised perioperative outcomes for TORS but without comparison to another therapeutic modality. A single study of 9601 patients undergoing treatment for head and neck cancers (Richmon et al 2014) found that TORS (n=116) was associated with significantly shorter lengths of stay in hospital.

Safety and learning curve:

The clinical evidence review was asked to address the question of the impact of the surgeon or centre volume on outcomes. Largely the literature is weighted towards a small number of centres or surgeons who have been pioneering the use of TORS, and therefore impact of the surgeon or centre volume is difficult to assess. The evidence review identified 5 case series (evidence level 3) that described experiences of the authors in the first cases of use of TORS. Findings were comparable between the papers, identifying good clinical perioperative and post functional outcomes across the time series. Two reports found no evidence of a learning curve measureable in terms of shortening operative times (Richmon et al 2011 and Vergez et al 2012), and this was explained by either the preparatory programme of work prior to the first surgery, or the inclusion of senior experienced surgeons as a part of the surgical team. Across the 3 remaining reports (Lawson et al 2011, Hans et al 2012, and White et al 2013) reductions in operative and total surgical times were observed. In the first two reports, a significant reduction was observed between the first half of the case series and the second (split at the 10-12 case). The latter report described a 4 year time series during which there was constant improvement in operative times, total surgical times and hospitalisation time. Even within this longer time series, rapid improvements in time metrics were observed in the first 10-20 cases. In all cases, the patients were not randomised in whether they received TORS but were subject to rigorous selection processes.

Cost effectiveness:

Comparative cost effectiveness modelling of TORS based on systematic review (De Almeida JR et al, 2014) found that over a 10-year time horizon, without taking capital cost into account, the cost of TORS compared to the cost of (chemo) radiotherapy is expected to result in a cost savings to the society of $1366 USD [£871 based on the exchange rate reported on XE.com on 26/10/15] per patient treated and incremental effectiveness of 0.25 QALY/ patient. The cost effectiveness reduces progressively as adjunct therapy is added to the treatment plan. The costing data is based on a US single centre clinical costs and US societal value estimates, limiting the direct application of the study in UK context.

7. Documents which have informed this policy

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

8. Date of review

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