NHS England

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

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

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Prepared by NHS England Specialised Services Clinical Reference Group for Complex Head and Neck Cancer

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Policy Statement

NHS England will not routinely commission robotic assisted trans-oral surgery for throat and voice box cancers 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 cancer of the oropharynx and larynx

Throat and voice-box cancer is a term used to describe:

- Oropharynx cancers which are found in the middle part of the throat behind the mouth. In 2013 and 2014, there were approximately 2,306 cases of this type of cancer; and

Laryngeal cancers which are found in the voice box. In 2013 and 2014, there were approximately 1,667 cases of this type of cancer.

About current treatments

Cancers of the oropharynx and larynx are usually treated with:

- Surgery – such as Transoral Laser Microsurgery (TLM)
- chemotherapy – cancer medicines
- radiotherapy.

Sometimes more than one of these treatments is used. The right treatment depends on the individual patients.

About the new treatment

Transoral Robotic Surgery (TORS) is a relatively new type of surgery.

- TORS allows the removal of throat and voice box cancers through the mouth.
- TORS allows the surgeon to remove cancers inside the throat without affecting the external muscles.

TORS involves the use of a computer system to help the surgeon to guide the surgical tools.

TLM and TORS both allow surgery through the mouth – although there are some differences in the technique used to remove the cancers.

What we decided

NHS England has carefully reviewed the evidence to treat throat and voice box cancers with Transoral robotic surgery (TORS). 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 trans-oral surgery for throat and voice box cancers.

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.

2 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.

3 Aims and Objectives

This policy 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 in the use of robotic assisted trans-oral surgery for the treatment of adults with cancers of the oropharynx and supraglottis.

4 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.

5 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.

6 Documents which have informed this Policy

NHS England Clinical Commissioning Policy: Robotic-Assisted Surgical Procedures for Prostate Cancer. 2015.

National Institute for Health and Care Excellence. NICE Guideline 36: Cancer of the upper aerodigestive tract: assessment and management in people aged 16 and over (NG36). 2016.

2013 National Head and Neck Cancer Audit data.

7 Date of Review

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

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