Oncological and survival outcomes following transoral robotic surgery versus transoral laser microsurgery for the treatment of oropharyngeal squamous cell carcinoma: a systematic review protocol

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Objective/review questions: The objective of this systematic review is to synthesize the best available evidence regarding the oncological and survival outcomes (as measured by disease control, disease-free survival, disease-specific survival and overall survival) of transoral robotic surgery (TORS) versus transoral laser microsurgery (TLM) in the treatment of oropharyngeal squamous cell carcinoma in adults (aged 18 years or older). Specifically the review questions are:

1. Is there a difference in oncological outcomes between a traditional “Halstedian” en bloc tumor resection technique used in TORS versus a modern segmental tumor dissection technique used in TLM?
2. Does one surgical approach confer better oncological outcomes with respect to a particular patient subgroup, such as patients with a positive human papilloma virus status or patient’s with different tumor T-stages?

Keywords: Carcinoma; head; neck; oropharynx; robotic surgical procedures; minimally invasive surgical procedures

Background

Head and neck squamous cell carcinoma (HNSCC) is the sixth most common cancer worldwide.1 Oropharyngeal squamous cell carcinoma (OPSCC) accounts for about 10% of this burden.1 The oropharynx is the only site in the head and neck where there is a rising incidence of disease, and in the last decade this has been linked with the human papilloma virus (HPV) epidemic.2 Improved public health measures to reduce tobacco and alcohol use, coupled with a rise in the prevalence of HPV, have seen an increasing proportion of patients with HPV-positive OPSCC.3 These patients tend to be younger and have a better prognosis.4 This has provided the stimulus for advancements in management to reduce morbidity. These include organ preservation intensity modulated radiotherapy and minimally invasive transoral endoscopic surgery (TES). Currently, there are two principal
tonsils. These are large ovoid collections of lymphoid tissue housed in the tonsillar fossa between the palatoglossal and palatopharyngeal arches. The posterior extent of the oropharynx is the posterior pharyngeal wall. This is composed of the superior constrictor muscle and the buccopharyngeal and pharyngobasilar fascia covered by the pharyngeal mucosa. The oropharyngeal contents therefore include the soft palate, base of tongue, palatine tonsils and posterior pharyngeal wall (from the hard/soft palate junction superiorly to the tip of the epiglottis inferiorly).

The risk factors for OPSCC have traditionally been tobacco and alcohol use. The risk of OPSCC is nearly seven times higher in active smokers compared with non-smokers and 2.5 times higher in regular drinkers compared with non- or occasional drinkers. Case-control studies have shown a super-multiplicative effect in patients with use of both substances. In the last decade, HPV infection, transmitted by orogenital sex, has become a well recognized risk factor for OPSCC and has been attributed to its progressing epidemic. From 2000 to 2005, the proportion of OPSCC caused by HPV increased from 40.5 to 72.2%.

The etiology of OPSCC is of significance in management decisions because the population of patients that it affects and their prognosis is different. Traditional OPSCC, with smoking and alcohol as its risk factors, affects people over the age of 60 years. It has p16 inactivation and tends not to have bulky cervical lymph nodes. Patients with this disease have a guarded prognosis, with a five-year survival estimated to be between 40% and 60%.

Patients with HPV-associated OPSCC tend to be younger, typically within the age range of 40–60 years. They do not usually have a history of smoking or alcohol addiction, and epidemiological studies propose a correlation with multiple sexual partners, sex from an early age and transmission of the virus via orogenital sex. These tumors overexpress p16, and patients are found to have a small primary tumor at presentation with bulky and cystic cervical nodes. Unlike the traditional group of OPSCC patients, HPV-positive OPSCC patients have a good prognosis with a five-year survival quoted at 80–90% and infrequent local recurrence.

Diagnosis and assessment of OPSCC require a clinical evaluation, imaging and tissue sampling. Patients with OPSCC can present with a neck lump, dysphagia (difficulty swallowing), odynophagia (pain on swallowing), a sore throat, a sensation of a mass in the throat or referred otalgia (ear pain). Examination involves a close inspection and palpation of the oropharyngeal site as well as examination of the other subsites of the head and neck to exclude a simultaneous primary. The neck is palpated for cervical lymphadenopathy (enlarged neck nodes) to determine if there has been lymphatic spread of cancerous cells from the oropharynx to the neck. Spread from the oropharynx is usually to the level IIa lymph nodes at the upper aspect of the internal jugular vein (jugulodigastric or tonsillar node). The diagnosis of squamous cell carcinoma (SCC) is confirmed with a tissue sample from the tumor, which can be taken from the primary site under local or general anesthesia. The tissue undergoes histopathological assessment, and p16 status is determined as a surrogate marker of HPV tumors. A Computerised Tomography (CT) scan of the head and neck helps to plan treatment, and a staging CT scan of the chest and upper abdomen helps evaluate the presence of distant metastases. Examination under anesthesia and performance of rigid endoscopy are used to determine the extent of the disease and its suitability for transoral resection, as well as to evaluate the remainder of the upper aerodigestive tract for simultaneous primaries.

Ororopharyngeal cancer is staged using the American Joint Committee on Cancer Staging system Edition 7. This categorization of head and neck tumors assists with assessing disease status, prognosis and management. The T category indicates tumor size, depth and spread to adjacent structures. The N category indicates the degree of spread to regional cervical lymph nodes. The M category simply identifies whether or not there is a distant metastasis. A table is used to give a numerical status of the disease from I to IV based on the Tumour, Node, Metastasis classification. Stages I and II are considered early disease, and stages III and IV are considered advanced. Early-stage disease can be treated with single modality treatment, whereas late disease usually requires multimodality treatment if the intent to treat is curative.

Oropharyngeal squamous cell carcinoma has primarily been treated with radiotherapy or surgery. Over the years, the preference between the two treatment modalities has shifted back and forth as technology evolves and understanding of the disease
progresses. At the start of the 20th century, early methods of radiation were used. The use of this rudimentary technology resulted in large necrotic wounds requiring carotid artery ligation to prevent life-threatening bleeds and tracheostomy to allow for breathing below the edematous post-radiated upper aerodigestive tract. In the 1940s, surgical resection of OPSCC became favored, as there were advances in perioperative medical care that made postoperative management of these patients feasible.\textsuperscript{19} Open surgery was again not without significant morbidity. The lip and mandible (jawbone) needed to be split and separated in order for the surgeon to access the tumor for resection. The trauma to the tissue and musculature around the mouth disrupted the patient’s ability to swallow and speak, and often left them with temporomandibular joint pain and cosmetic deformity. These patients often required tissue transfer for reconstruction, a percutaneous enteric gastrostomy tube for feeding and a tracheostomy for breathing.\textsuperscript{19}

In the second half of the 20th century, radiotherapy made a resurgence with improvements in technology allowing for more targeted radiation fields with the ability to deliver higher dosage radiation to specific areas while limiting damage to sensitive surrounding healthy tissue.\textsuperscript{20} In 1991, the landmark Veterans’ Administration study demonstrated that chemoradiation had equal survival outcomes to surgery, and also allowed for preservation of the larynx in patients with advanced laryngeal SCC.\textsuperscript{21} These results were extrapolated to the oropharynx and again chemoradiation swung back into favor, as head and neck clinicians adopted a non-surgical “organ-preservation” mentality.

In the current epidemic of oropharyngeal SCC related to HPV, where patients are being diagnosed younger and are surviving longer, treatment choice is now focused on providing cure with the least long-term complications. The oncological outcomes from surgical and radiotherapy protocols are deemed to be comparable.\textsuperscript{7,22-24} Radiation-based treatment has come under scrutiny for its delayed toxicity resulting in adverse effects such as mucositis (painful ulceration of the mucous membranes in the mouth), xerostomia (dry mouth), fibrosis, dysphagia (difficulty swallowing), trismus (inability to open the mouth fully) and osteoradionecrosis (bone death) of the jaw which can occur many years after the initial treatment.\textsuperscript{25} This has lead to the development of transoral surgical protocols, designed to correctly stage the tumors with minimal morbidity and allow the potential in selected cases that are pathologically favorable to deintensify the toxic adjuvant therapy.\textsuperscript{26-28} The ability to remove these tumors transorally has led to significant improvements in patient morbidities compared with open surgical techniques.\textsuperscript{29}

Transoral laser microsurgery was developed in Europe in the 1960s and 1970s and was the first transoral endoscopic surgical approach used by head and neck surgeons. Transoral laser microsurgery uses a laser delivery device (usually a carbon dioxide [CO\textsubscript{2}] laser) and a binocular-operating microscope to direct a laser beam through the mouth at the area of tissue to be resected. The CO\textsubscript{2} laser beam is absorbed by water at the tissue-laser interface and is transformed into thermal energy, which results in a tissue-cutting capability. Initially, TLM was developed for early-stage laryngeal cancer and was found to have good functional and oncological outcomes.\textsuperscript{2,5,6} Because of this, its use expanded to the pharynx and oral cavity where it has also been shown to have good survival results.\textsuperscript{30} A prospectively assembled database of 204 patients treated with TLM collected between 1996 and 2006 at three centers showed a three-year overall survival (OS), disease-specific survival (DSS) and disease-free survival (DFS) results of 86, 88 and 82\%, respectively.\textsuperscript{30} Transoral laser microsurgery has since become a well established technique in the treatment of OPSCC.

The use of TLM for OPSCC resection is an extremely unique form of surgical oncological resection. The microscope provides a limited field of view and has diminished illumination deep in the oropharynx. Because the laser is projected in a linear fashion there are line-of-site restraints that prohibit the laser from being deployed around curved surfaces. This has meant that resection of the tumor often requires a segmental, sometimes labeled “piece-meal”, approach to dissection as described by Steiner et al.\textsuperscript{31} Each piece of tumor removed, enabling access visually for removal of subsequent segments. This approach was initially thought to go against traditional Halstedian surgical oncological principles of removing a tumor en bloc, as it posed a theoretical risk of leaking tumor and disseminating cancerous cells. Several case series of patients with head and neck SCC at various subsites treated with TLM have shown good oncological results and have
since been used to establish oncological safety of this approach.\textsuperscript{32-34}

There are noticeable limitations of this surgical technique. The TLM technique requires the surgeon to use one hand to hold an instrument, while the other manipulates the laser and this has resulted in a steep learning curve for this technique. The laser is not an ideal tool for hemostasis, so the TLM procedure requires alternations between the laser and a cautery instrument or surgical clips to achieve hemostasis, adding further complexity to the procedure. The technique also relies on uniplanar instruments being used through the laryngoscope, which act as a fulcrum, leading to accentuation of tremor at the distal tip, as well as counter intuitive movements (moving the hand holding the instrument to the right moves the instrument in the resection field to the left).

Transoral robotic surgery, the second transoral endoscopic approach to be developed, has “intuitive” surgery as its greatest appeal. The surgical robot was initially designed with the goals of performing telesurgery and eliminating human tremor, but it became better recognized for its effectiveness in minimally invasive surgical approaches in the abdomen and pelvis. Hockstein \textit{et al.}\textsuperscript{35,36} demonstrated on a mannequin that the robot could be used through the natural orifice of the mouth to gain access to the larynx and pharynx. Weinstein \textit{et al.}\textsuperscript{37-39} refined the use of oral retractors and instrumentation in canine and cadaveric models and thereby paved the way for FDA approval in 2009 for transoral otolaryngological use of the robot in humans. It has since gained significant momentum with studies showing good oncological and functional outcomes.\textsuperscript{7} A prospective single institution case series of 66 TORS patients showed three-year local control and regional control of 97 and 94\%, respectively, and two-year DSS and recurrence-free survival were 95.1 and 92.4\%, respectively.\textsuperscript{7}

The da Vinci Surgical System (intuitive Surgical Inc., Sunnyvale, CA, USA) is a device used for robotic surgery. This system comprises a surgeon console and a patient side cart consisting of a 30-degree maneuverable binocular scope, a vision system and two arms for attachment of endowrist instruments.\textsuperscript{39} The surgeon sits away from the robot at the surgeon console, which provides a three-dimensional high-definition image of the operating area and a wide field of vision. Here, the surgeon manipulates the movement of the robotic arms and camera in a “master-slave” fashion with controls that de-escalate movement and filter tremor. The two robotic arms allow for bimanual handling of tissue and give greater range of motion of the robotic instruments. These features of the robotic system eliminate line-of-sight issues and one-handed surgery that make TLMS so challenging. Because of this, Haldstedian principals of en bloc tumor resection can more easily be upheld in TORS. The major drawbacks of TORS relate to the high expense of robot setup and ongoing use, which limits its uptake to hospitals and departments that can afford it.\textsuperscript{40,41} Furthermore, training and credentialing requirements restrict which surgeons can use this operating system. The robot is often shared between various other surgical subspecialties impeding its day-to-day availability.

Transoral laser microsurgery and TORS are both well established transoral endoscopic surgical approaches for management of OPSCC with individually proven acceptable oncological and functional outcomes as already outlined. There are, however, no studies comparing these two approaches. Given the ethical and practical difficulties of randomizing surgical patients into different arms, there are no randomized control trials (RCTs) or quasi-experimental studies comparing TORS with TLM. Almost all of the studies looking at clinical outcomes following TORS and TLM are retrospective or prospective case series.

A preliminary search of the JBI Database of Systematic Reviews and Implementation Reports, the Cochrane Library, MEDLINE, Embase and CINAHL found several literature reviews on TES for OPSCC.\textsuperscript{42-46} These reviews were performed by experts in the field and describe some of the oncological and functional results of both TORS and TLM; however, there are no systematic reviews comparing the oncological outcomes of TORS with TLM. The significant differences between TLM and TORS with respect to tumor resection principals (segmental versus en bloc), tissue cutting instruments (laser versus cautery), learning curve and accessibility have already been outlined. The purpose of this systematic review therefore is to take these differences into account and to compare TORS and TLM with respect to their oncological and survival outcomes as defined by disease control (DC), DFS, DSS and OS.
Inclusion criteria

Types of participants
The patient population that will be studied are male and female adults (aged 18 years or older) who have undergone TES for the treatment of primary squamous cell carcinoma arising from the oropharyngeal mucosa (confirmed pathologically). The tumor can be of any T-stage and HPV status. Surgical treatment must be aimed at curative intent rather than for palliation.

The exclusion criteria are:
- Pediatric populations/animal studies
- Non-English studies
- Patients with non-SCC lesions
- Patients with lesions of the oral cavity, hypopharynx, nasopharynx and larynx
- Patients treated with other forms of treatment, for example, primary chemoradiotherapy or neoadjuvant chemoradiotherapy
- Patients treated with novel surgical approaches such as curved lasers or combining laser instruments with robotic technology
- Salvage surgery (i.e. surgery performed after failed primary treatment with other modalities such as chemotherapy and/or radiotherapy).

Types of interventions
The current review will consider the following interventions: Primary TORS with or without adjuvant radiotherapy or adjuvant chemoradiotherapy.

The comparator intervention is primary TLM with or without adjuvant radiotherapy or adjuvant chemoradiotherapy.

As this review is looking at primary TES treatment of OPSCC only, re-intervention will not be considered. The interventions will be included regardless of the experience level of the person delivering them. The intensity and dosage of the adjuvant therapy will not be able to be controlled for and will be dependent upon the treatment protocols used at any individual institution. Subgroup analysis may be attempted for group results with similar adjuvant therapy protocols.

Outcomes
The current review will consider studies that include the following oncological and survival outcomes at 1-10 years:
- Disease control — local, regional and distant — defined as the time from surgery to the date of recurrence of the disease. Recurrence can be classified as occurring locally (at the site of resection), regionally (elsewhere in the head and neck) and distantly (elsewhere in the body)
- Disease-free survival — defined as the time from surgery to the date of death from the disease or recurrence of the disease
- Disease-specific survival — defined as the time from surgery to the date of death from disease or the direct effects of treatment of the disease
- Overall survival — defined as the time from surgery to the date of death resulting from any cause.

The type of data that will be extracted is the percentages of patients (with confidence intervals) from individual case series that have achieved DC/DFS/DSS/OS at time intervals between one and 10 years. This time period will be variable depending on length of follow-up practised at different institutions and included in their case series. Subgroup analyses may be undertaken to group similar time intervals.

Types of studies
The current review will consider both experimental and epidemiological study designs including RCTs, non-RCTs, quasi-experimental trials, before and after studies, prospective and retrospective cohort studies, case-control studies and analytical cross-sectional studies. Due to the nature of this topic, there are currently no published RCTs due to ethical concerns. Thus, in the absence of RCTs and quasi-experimental studies, other studies will be considered for review. It is likely that the majority of studies included will be case series.

Search strategy
A three-step search strategy will be utilized in this review to find both published and unpublished studies. An initial limited search of MEDLINE will be undertaken followed by an analysis of the text words contained in the title and abstract, and of the index terms used to describe the article. A second search using all identified keywords and index terms will then be undertaken across all included databases. Finally, the reference list of all identified reports and articles will be searched for additional studies. Databases will be searched from 1960 (the decade in which TLM was first used) for studies published in English. Non-English studies will be excluded.
The databases to be searched include
- MEDLINE (PubMed)
- CINAHL
- Embase
- Web of Knowledge
- Scopus.

Gray Literature will be searched through the Cochrane Register of Controlled Trials, Scirus, MedNar and ProQuest.

**Assessment of methodological quality**

Papers selected for retrieval will be assessed by two independent reviewers for methodological validity prior to inclusion in the review using standardized critical appraisal instruments from the Joanna Briggs Institute Meta Analysis of Statistics Assessments and Review Instrument (JBI-MAStARI) (Appendix I). Any disagreements that arise between the reviewers will be resolved through discussion or with a third reviewer.

**Data extraction**

Quantitative data of percentages of patients from case series’ (with confidence intervals) who have achieved DC/DFS/DSS/OS at time intervals between one and 10 years will be extracted from papers included in the review using the standardized data extraction tool from JBI-MAStARI (Appendix II). The data extracted will include specific details about the interventions, populations, study methods and outcomes of significance to the review question and specific objectives. The authors of the included studies will be contacted if important data that are relevant to the review are missing from the published papers. There will be one data extractor.

**Data synthesis**

Quantitative papers, where possible, will be pooled in statistical meta-analysis using the JBI-MAStARI software. All results will be subjected to double data entry to minimize the risk of error during the data entry. Where appropriate, relative risks and odds ratio and their associated 95% confidence intervals will be calculated for analysis of categorical data. For continuous data that is collected using different scales, the standardized mean differences will be calculated. A random effects model will be used, and heterogeneity will be assessed statistically using the standard Chi square test and if found will be investigated prior to any further analysis. Where appropriate, meta-analysis will be conducted using JBI-MAStARI. Where statistical pooling is not possible, the findings will be presented in narrative form including tables and figures to aid in data presentation. Where possible, a subgroup analysis will be performed. Data will be split into subgroups such as tumor site in the oropharynx, HPV-status, tumor T-stage and type and intensity of adjuvant therapy received.

**Acknowledgments**

The authors acknowledge University of Adelaide Librarian Maureen Bell for her input and feedback regarding search strategy.

The current review will be conducted as part of a Masters of Clinical Science degree at the Joanna Briggs Institute, the University of Adelaide, Adelaide, Australia.

**References**

S.G.S. Krishnan et al.


## JBI Critical Appraisal Checklist for Randomised Control / Pseudo-randomised Trial

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Overall appraisal: Include □ Exclude □ Seek further info. □

Comments (Including reason for exclusion)

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### JBI Critical Appraisal Checklist for Comparable Cohort/ Case Control

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Comments (Including reason for exclusion)

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# JBI Critical Appraisal Checklist for Descriptive / Case Series

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**Date**

**Author**  
**Year**  
**Record Number**

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Appendix II: Data extraction instruments

**MASTARI data extraction instrument**

**JBI Data Extraction Form for Experimental / Observational Studies**

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**Study Method**

- RCT
- Quasi-RCT
- Longitudinal
- Retrospective
- Observational
- Other

**Participants**

- Setting

**Sample size**

- Group A
- Group B

**Interventions**

- Intervention A
- Intervention B

**Authors Conclusions:**

- 
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**Reviewers Conclusions:**

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**Study results**

**Dichotomous data**

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