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TRANSORAL ROBOTIC SURGERY (TORS)

Soham D Pathare[1], Hasmukh S Shah[1*], Dr. Vanita Kanase[2], Dr. Pramila Yadav[3]

Oriental College of Pharmacy[1], Sector 2, Behind Sanpada Railway Station, Sanpada West, Navi Mumbai, Maharashtra 400705

HOD Pharmacology[2], Oriental College of Pharmacy, Sector 2, Behind Sanpada Railway Station, Sanpada West, Navi Mumbai, Maharashtra 400705

Professor in Pharmacology[3], Dr. D. Y. Patil Medical College, Belapur, Navi Mumbai,Maharashtra 400614

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***Correspondence**
For Author
Hasmukh S Shah
Oriental College of Pharmacy, Sector 2, Behind Sanpada Railway Station, Sanpada West, Navi Mumbai, Maharashtra 400705.

ABSTRACT

About transoral robotic surgery

During transoral robotic surgery, your surgeon sits at a remote control console a short distance from you and the operating table and precisely controls the motion of the surgical instruments using two hand-and-finger control devices. The console displays a magnified, 3-D view of the surgical area that enables the surgeon to visualize the procedure in much greater detail than in traditional laparoscopic surgery.

Transoral robotic surgery may be used to treat:

- Mouth cancer
- Throat cancer
- Tongue cancer
- Tonsil cancer

Compared with other operations, transoral robotic surgery typically offers excellent cure rates, shorter hospital stays and fewer complications.

KEY WORDS: Robotic surgery, Minimal Invasive, Transoral, Oropharyngeal cancer.

INTRODUCTION

Transoral robotic surgery is a procedure to remove oral cancers in which a surgeon uses a sophisticated, computer-enhanced system to guide the surgical tools.

Transoral robotic surgery gives the surgeon an enhanced view of the cancer and surrounding tissue. Using a robotic system to guide the surgical tools allows for more precise movements in tiny spaces and the capability to work around corners.

When compared with more-traditional procedures, transoral robotic surgery for oral cancer tends to result in a quicker recovery and fewer complications.

PROCEDURE

da Vinci Transoral Robotic Surgery (TORS) allows your surgeon to operate through your mouth – avoiding a large incision through the jaw and throat. The*da Vinci* System features a magnified 3D high-definition vision system and special wristed instruments that bend and rotate far greater than the human wrist. As a result, *da Vinci* enables your surgeon to operate with enhanced vision, precision, dexterity and control.

State-of-the-art *da Vinci* uses the latest in surgical and robotics technologies and is beneficial for performing complex surgery. Your surgeon is 100% in control of the *da Vinci* System, which translates his or her hand movements into smaller, more precise movements of tiny instruments inside your body.*da Vinci* – taking surgery beyond the limits of the human hand.

Patient characteristics

Data were collected from a group of consecutive patients who underwent TORS for tumours of the base of the tongue at the Department of Otolaryngology, Head Neck Surgery of the Regina Elena National Cancer Institute in Rome, Italy. The study was a prospective, single-centre cohort trial. The local ethics committee approval was obtained to perform a clinical trial using the da Vinci Robot (Intuitive Surgical Inc., Sunnyvale, CA) for the resection of head and neck tumours.

Inclusion criteria was the presence of a T1-T2 (≤ 3 cm) oropharyngeal tumour of the base of the tongue, histologically- proven, that was amenable to transoral radical "en bloc" resection. Decision making to treat or not these patients by TORS was made in a tumour board counseling upon clinical evaluation and magnetic resonance imaging (MRI) or computed tomography scan, in case of impossibility to obtain MRI, that was used for detecting tumour extension. Patients with a tumour of the tongue base with superficial extension or infiltration into intrinsic muscles ≤ 3 cm were included in the study, while infiltration of the extrinsic muscle by the tumour (cT4a) represented a contraindication to this surgery. Patients with a

mouth opening < 2.5 cm and/or distant metastasis were excluded from the study. Presence of nodal metastasis or previous treatment for head neck malignancy did not influence the procedure on the primary tumour. Neck dissection (ND) was always indicated for patients with squamous cell carcinoma staged as T1 and T2, while ND was not indicated for patients with mucoepidermoid carcinoma (low grade), in accordance with NCCN guidelines [19]. Informed consent form was obtained by all patients after attending a counselling session on the alternatives to surgery. Patients were followed up every 2 months for the first year, every 3 months for the second and third year and every 6 months thereafter. At each visit, history and clinical examination were performed, including flexible endoscopy. PET-CT scan and MRI of the tongue base were performed every 6 months for the first two years and every year thereafter.

INDICATION

The *da Vinci* System is indicated for transoral otolaryngologic surgical procedures (i.e., use in removing tumors from the mouth, tonsils, tongue and throat through the mouth), but restricted to cancerous and non-cancerous tumors classified as T1 and T2 (i.e., early and mid stage cancers only). The*da Vinci*® System is not indicated for pediatric transoral otolaryngology surgical procedures. The safety and effectiveness of the *da Vinci* Surgical System has not been established in patients with poor mouth openings (< 1.5 cm), advanced tumors (e.g., invading the mandible, abutting the carotid artery, requiring bone resection, etc.). The *da Vinci*® System is not recommended for use in dental surgery (i.e. tooth extraction).

Serious complications may occur in any surgery, including *da Vinci*® Surgery, up to and including death. Examples of serious or life-threatening complications, which may require prolonged and/or unexpected hospitalization and/or reoperation, include but are not limited to, one or more of the following: injury to tissues/organs, bleeding, infection and internal scarring that can cause long-lasting dysfunction/pain. Risks of surgery also include the potential for equipment failure and/or human error. Individual surgical results may vary.

Risks specific to minimally invasive surgery, including *da Vinci* Surgery, include but are not limited to, one or more of the following: temporary pain/nerve injury associated with positioning; temporary pain/discomfort from the use of air or gas in the procedure; a longer operation and time under anesthesia and conversion to another surgical technique. If your

doctor needs to convert the surgery to another surgical technique, this could result in a longer operative time, additional time under anesthesia, additional or larger incisions and/or increased complications.

Patients who are not candidates for non-robotic minimally invasive surgery are also not candidates for *da Vinci*® Surgery. Patients should talk to their doctor to decide if *da Vinci* Surgery is right for them. Patients and doctors should review all available information on non-surgical and surgical options in order to make an informed decision. For Important Safety Information, including surgical risks, indications, and considerations and contraindications for use, please also refer to www.davincisurgery.com/safety andwww.intuitivesurgical.com/safety. Unless otherwise noted, all people depicted are models.

ADVANTAGES

- Precise removal of cancerous tissue.[1, 2, 3]
- Low rate of complications.[2, 3]
- Low blood loss.[3, 4]
- Minimal need for tracheotomy (breathing tube).[4]
- Minimal need for chemoradiation therapy.[1, 2]
- Ability to swallow following surgery.[1, 2, 3, 4]
- Short hospital stay.[4]
- No visible scarring or disfigurement.[5]

DISADVANTAGES

- Vocal cord damage
- Speech and swallowing dysfunction
- Need for a tracheostoma (hole in neck) to breathe

There are potential risks related to minimally invasive surgery, including *da Vinci* TORS, such as post-operative hemorrhage and bleeding at the surgical site.[6]

CONCLUSION

TORS represents a good tool for staging and treating neoplasms of the base of the tongue. The procedure is safe and can radically remove limited oropharyngeal tumours of the tongue base with good functional outcomes. Costs may be high but are related to the number of

procedures carried out per year, although the advantages for patients seem to justify performing the procedure. TORS can represent the definitive treatment in selected T1-T2 cases of oropharyngeal tumours of the base of the tongue without adverse features and allow the possibility to deintensify adjuvant treatments.

DISCUSSION

The use of TORS started in animal models in 2003. It was first applied in humans in 2005 for vallecula cyst,[9] In 2006, O'Malley and colleagues published the first three cases of tumour of the base of the tongue excised by TORS.[10] They demonstrated that the Da Vinci Robot provided excellent visualization and enabled transoral removal of the tumour while preserving key structures and nerves. In addition, they showed that it further allowed a complete resection with negative surgical margins and without complications. Recently, many authors published reports using TORS for head and neck cancer. Weinstein and colleagues described the use of TORS in supraglottic laryngectomy,[11] and radical tonsillectomy.[17] in patients with squamous cell carcinoma. Desai et al. reported results in 7 cases with oropaharyngeal and laryngeal tumours using the robotic system combined with flexible carbon dioxide laser.[18]

We analyzed the use of the Da Vinci system for radical treatment of oropharyngeal tumours, localized in the base of the tongue in order to gain an homogeneous group of patients with similar sites and sizes of tumours, whose excision would have previously required trans-mandibular or trans-pharyngeal approach. All the cases consisted of T1 and T2 smaller than 3 cm because we aimed to: (1) verify the feasibility of TORS as primary treatment in case of malignancy, (2) allow "en bloc" resection with free margins, (3) avoid reconstruction and (4) increase the learning curve before approaching more challenging cases. A longer follow-up time is required to confirm the data about the local control published by Weinstein et al.[16] The routine use of tracheostomy and NGFT was the surgeon's first choice before opting for this new surgical approach. It was decided to begin the procedure in the safest way guaranteeing respiration and nutritional status in order to avoid complications such as extubation, haemorrhage and weight loss. Temporary tracheostomy was used in all cases. However, it was not required in patients who already had a total laryngectomy. In the Weinstein study on radical tonsillectomy, 20/27 patients were extubated at the end of the TORS,[11] Genden did not perform any tracheostomies in 20 cases treated with TORS.[5] The use of tracheostomy in the literature is less frequent than that observed in our study, even

though the published papers focused on tonsil tumours and the authors preferred to extubate patients 24-48 hours after surgery. A great advantage in performing a temporary tracheostomy before TORS consisted in obtaining better exposure of the oropharynx. This may not justify routine use of the tracheostomy, but it can be taken into consideration for candidates opting to undergo TORS without good oropharyngeal exposure. We maintained the NGFT in the 77% of cases for a mean time of 7.5 days to avoid that the swallowing movement could facilitate bleeding. All patients started swallowing saliva on the first postoperative (p.o.) day and water on the second p.o. day. No patient complained about swallowing and all were discharged without NGFT. Other authors described discharging patients earlier from hospital and the use of percutaneous gastrostomy for a longer period than the NGFT reported in our study.[15, 8, 13, 14]

TORS for tongue base neoplasms contributed to improving all these aspects offering a substantial advantage for the patient. Future studies should validate the procedure in terms of oncologic outcomes.

One of the main criticisms against using robotic surgery is related to the cost of the procedure. At our hospital the cost per procedure is about €2500, considering that 400 "Da Vinci" procedures a year are carried out in 4 departments (urologic, gynaecologic, abdominal and otolaryngology). When considering this cost alone versus traditional surgical techniques (endoscopic or open), the amount seems excessive, but the true comparison should be done between using a surgical transcervical or transmandibular approach to using non-surgical options like radiation or chemoradiation. Saving hospitalization time itself could be enough to balance the costs of using the robotic system, but the advantages related to the less invasive procedure, the best recovery and the functional outcomes justify the expense. The advantages of TORS compared to the external approach are already well known. Future studies should confirm whether robotic surgery represents the main field for tongue base cancers because the alternatives (external approach or non-surgical options) seem to be related to a high incidence of complications and sequelae,[2, 19-21]

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