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Outcome of transoral robotic surgery for stage I–II oropharyngeal cancer

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Abstract Traditionally T1-2N0 oropharyngeal carcinoma is treated with a single treatment modality, being either radiotherapy or surgery. Currently, minimally invasive surgery, such as transoral robotic surgery (TORS), is gaining popularity. The aim of this study is to assess whether T1-2N0 oropharyngeal cancer can be safely and effectively resected with TORS, and to determine the oncologic and functional outcomes. In addition, the long-term quality-of-life outcomes are reported. Between 2007 and 2012, 18 patients with early stage oropharyngeal cancers underwent transoral resection with the da Vinci robot system in the Netherlands Cancer Institute. All surviving patients filled out the self-report assessments of quality-of-life questionnaires. Median robot-assisted operating time was 115 min (range 43–186 min), while median estimated blood loss was 5 ml (range 0–125 ml). In three cases the exposure was insufficient to obtain clear tumor margins because of tumor extension and local anatomy. Fourteen patients had clear surgical margins. Four patients received adjuvant radiotherapy. Nine patients underwent an elective unilateral neck dissection. The oropharyngeal cancer recurred in two

patients. Regarding the quality of life, patients who needed postoperative radiotherapy had a worse outcome and patients treated with transoral resection only did quite well. TORS seems to be an oncologically safe surgical treatment for early stage T1-2N0 oropharyngeal cancer based on this relatively small group of patients. Selecting patients in whom sufficient surgical exposure can be obtained, should be performed with the greatest care to avoid the need for adjuvant radiotherapy. Comparing radiotherapy and TORS or CO₂ laser should be the next step in finding the optimal treatment for patients with T1-2N0 oropharyngeal carcinoma.

Keywords Robotic surgery · Oropharynx carcinoma · Minimally invasive · Morbidity

Introduction

Treatment by means of minimally invasive surgery is gaining popularity in early stages of head and neck cancer, including oropharyngeal cancer. The 2004 DHNS (Dutch Head Neck Society) guidelines state that stage I and II oropharyngeal cancers should preferentially be treated with a single modality [1]. With smaller oropharyngeal carcinomas (T1 and T2), surgery and radiotherapy (external therapy or brachytherapy) are equally useful [2]. When choosing the treatment modality, functional outcome and morbidity are the main parameters to guide this choice.

Primary surgery has the advantage that it can be repeated for recurrences or second primaries. However, treating oropharyngeal cancer often requires composite resections leading to significant morbidity and prolonged hospital stays. Using surgery, 5-year local control rates are in the range of 83–96 % [3, 4]. Like surgery, radiotherapy is effective

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in obtaining locoregional tumor control in early stage oropharyngeal carcinoma. Local control can be achieved in 83–93 % of the cases [5–9]. The disadvantages are the prolonged treatment time, high costs, acute and late toxicity and its ‘one-time-only’ character.

The robot-assisted transoral surgery potentially allows a more meticulous endoscopic resection under direct vision, obviating the need for a composite resection for tumors in the oropharynx and supraglottic larynx. As surrounding structures are not damaged, transoral robotic surgery (TORS) might be more function preserving than other modalities, such as composite resection or radiotherapy. A recent review of literature by Dowthwaite et al. [10] about the role of TORS in the management of oropharyngeal cancer states that “TORS offers impressive functional and oncologic outcomes, specifically for patients with early T-classification and low-volume regional metastatic disease”. One published article showed that when using TORS as a single-modality treatment for these tumors, high local control rates can be achieved and that it is associated with low surgical morbidity [11].

However, there are other techniques to resect a tumor transorally, such as using the cautery under direct vision or using a CO₂ laser in combination with the operating microscope. The advantage of TORS over transoral resection using knife and cautery is that the optics allow for significant magnification and the instruments are optimized to work “around a corner”. In many countries, as in our institute, there is significant experience in using the CO₂ laser with the operating microscope. Several studies have described its use in oropharyngeal cancer [12–14]. A disadvantage is the fact that base-of-tongue tumors are sometimes difficult to expose because the laser cannot be angled.

Studies evaluating HRQOL profiles for patients who underwent TORS show promising results [15, 16]. However, so far, no comparative studies between radiotherapy and TORS have been performed.

In 2006, a study was set up in the Antoni van Leeuwenhoek hospital to assess whether stage I and II oropharyngeal tumors can be safely and effectively resected transorally using the da Vinci robot system. Also, the long-term quality-of-life outcomes for these patients were assessed.

Materials and methods

This prospective clinical trial obtained approval from the *protocol review board* of the NKI-AvL and all patients signed informed consent. Between August 2007 and July 2012, 18 patients were eligible for this TORS protocol. Inclusion criteria were as follows: (1) biopsy-proven T1-2 oropharyngeal squamous cell carcinoma; (2) sufficient exposure for transoral resection without the need for local

reconstruction; (3) sufficient condition to be treated surgically. All patients had to give informed consent prior to treatment. Criteria to exclude patients were limited mouth opening or trismus and previous treatments for head and neck cancer. Excluded patients underwent primary radiotherapy. Criteria to abort the protocol were also laid down: firstly, if the da Vinci robot could not be positioned in such a way that safe local excision was possible, the procedure was to be terminated and the patient treated alternatively with either more extensive surgery, CO₂ laser or radiotherapy. Secondly, if the histopathology showed an incomplete resection, either a re-excision or radiotherapy was indicated.

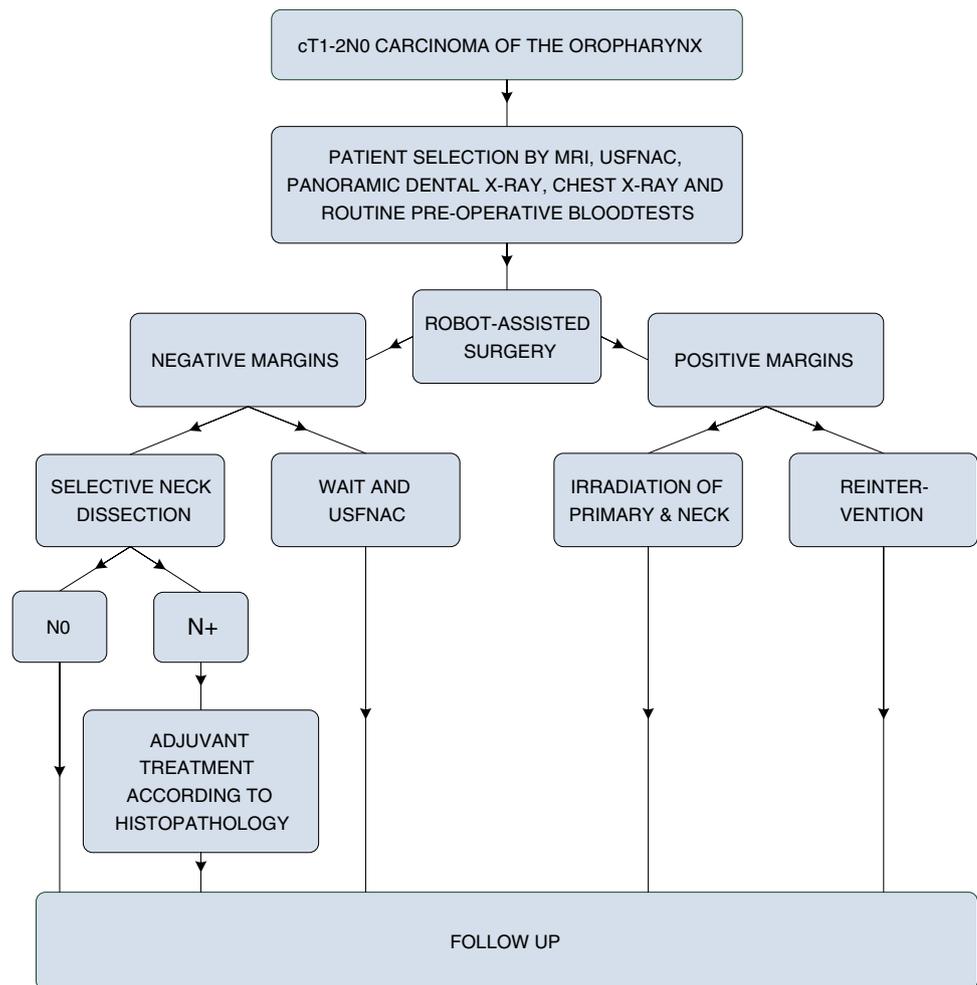
The preoperative diagnostic workup consisted of clinical examination, MRI, ultrasound-guided fine needle aspiration cytology (USFNAC) of the neck, panoramic dental X-ray, chest X-ray and routine preoperative blood tests. These studies were carried out not longer than 4 weeks prior to the planned surgery. Examination under general anesthesia was not routinely applied. To assess the exposure, the dental status, mouth opening and neck extension were evaluated in the outpatient clinic, as we were used to in laser surgery. At the start of robot surgery, a routine triple endoscopy was carried out to assess operability. Four to eight weeks after robot-assisted resection of the primary, nine patients underwent an elective selective neck dissection of levels I, IIa and b, III and IV and five patients were subjected to a strict follow-up protocol for the neck nodes using regular USFNAC. In four patients, the neck was electively radiated because these patients had radiotherapy for tumor-positive resection margins. Figure 1 shows the flow chart for treatment policy after a patient has been selected for TORS.

Seventeen patients met the criteria and underwent robot-assisted transoral surgery. One patient did not meet all the criteria, but nonetheless underwent TORS. These patients had a second primary in the tonsillar region after a transoral resection of a T1N0 palatal carcinoma several years before (case 5). One patient who did meet the criteria was treated for a T1N0 carcinoma in the base of tongue simultaneously with CO₂ laser treatment for a T1a glottic carcinoma (case 1).

The Feyh–Kastenbauer retractor set was used in all patients as described in <http://www.uphs.upenn.edu/pennorl/education/documents/daVinciTORSProcedureGuide.pdf>.

Within a total of 18 patients, males and females were equally represented. The mean age was 62.6 years with a range of 54–77 years. HPV status was tested using p53 and p16 immunohistochemistry [17]. Two patients tested HPV positive and 15 patients were tested negative.

To assess feasibility, surgical technical issues and patient outcome, we collected data during treatment and follow-up. We used two different perspectives for outcome measures: a treatment perspective and a patient perspective. For the treatment perspective, the primary outcome measure was successful local excision. Secondary outcome measures

Fig. 1 Flow chart for treatment policy

were blood loss, duration of surgery, status of resection margins, duration of hospitalization and potential complications. For the patient perspective, the primary outcome measures were the 2-year overall survival rate and the 2-year recurrence-free survival rate. The secondary outcome measure was quality of life.

To assess the quality of life, we used a questionnaire that was set up and used in studies in the NKI-AvL and has proved to be effective for this purpose [18]. This questionnaire is based on the validated EORTC-C30 with a four-point scale and the EORTC-H&N35 [19, 20]. Studies done earlier in the NKI-AvL have substantiated its validity and have shown that it is similar to the EORTC-C30 and EORTC-H&N35 [18, 21, 22]. The questionnaire we used consisted of questions related to patients' socio-demographics and health-related problems associated with specific tumor localization and treatment. The questions were combined to obtain an inventory of the quality of life in several categories: functional aspects (mastication, swallowing, oral transport), psychosocial aspects (speech, social contacts, social anxiety), smoking, drinking, and pre- and

post-operative information (counseling) [18]. Because this questionnaire was structured and developed for a more specific patient group, it was expected to be capable of producing the essential information for assessing the quality of life, especially if the interest lies in identifying intervention-related changes over time [22]. In addition, the SWAL-QOL was included in this study because of the major role the oropharynx plays in the patient's swallowing function. This questionnaire has been found to be validated and valuable to detect problems with swallowing in the daily life of patients who have been treated for an oropharyngeal carcinoma [23]. The questionnaire was analyzed with Likert scales (Cronbach's α) to calculate the internal consistency of the items and to give a representation of the reliability of the test scores.

Results

The median follow-up time was 36.0 months with a range of 6–68 months. One patient passed away during follow-up

as a consequence of a pancreatic carcinoma. All other patients are alive without evidence of disease.

Treatment perspective

Table 1 shows the clinical data and results. Median hospital stay was 1.5 nights, with a range of 0–17 nights. For all patients the Feyh–Kastenbauer retractor was used.

In 12 cases easy exposure for resection of the lesion was achieved. In six cases the exposure was more difficult, because of the location and extension of the tumor. This was mainly because the retractor deformed the base of tongue or compressed the posterior floor of mouth making it more difficult to remove the tumor especially because the robot arms and tongue depressors occupy quite some place in smaller mouths. However, in only three of these six, this limited exposure was the cause of incomplete resection.

Thirteen patients had tumor-free resection margins, two close margins and four patients had positive resection margins (cases 2, 6, 9 and 13). In the cases with close margins, in one a wait-and-see policy was followed, whereas the other had a re-excision. The extra resection margins were free of tumor cells and no adjuvant therapy was given (case 18).

In four cases the resections margins were tumor positive. In one case, the base-of-tongue tumor extended submucosally to the floor of mouth was underestimated during endoscopy prior to surgery and at the MRI. In that case the tumor could not be removed completely (case 2). In another case (case 6) exposure was too limited and a conversion to an open procedure was carried out, followed by radiotherapy. In case number 9 the exposure was adequate, but still there was a positive resection margin for which radiotherapy was administered. The last case (case 13) had a re-excision with the CO₂ laser as the surgeon felt more comfortable in this difficult case with that instrument. He was also irradiated afterward. Two of these four patients who were radiated developed osteoradionecrosis of the mandible on the side of the tumor. The first patient was treated with hyperbaric oxygen and underwent a sequestrectomy (case 6). The second patient needed a segmental mandibular resection with fibula reconstruction (case 2). This patient had several severe complications and is a total oral cripple now.

Nine patients underwent an elective unilateral neck dissection and nine patients had no neck dissection. Five of these nine had a wait-and-USFNAC policy of the neck because they had small superficial tumors (cases 10, 14, 17 and 18) or because they refused neck dissection (case 14). Four had elective postoperative radiotherapy for tumor-positive resection margins. In the elective neck dissection group eventually two patients had lymph node metastases and in the wait-and-USFNAC group one patient developed

neck node metastases (cases 11, 12 and 15). In the patient with tumor-positive node in the elective neck dissection specimen, a small intra-capsular metastasis was present and no adjuvant radiotherapy was given (case 12). One patient had a neck recurrence low in level 4 after an elective neck dissection that was pathologically tumor-negative 28 months after the TORS. This patient was treated with (chemo)radiation as there was carotid encasement (case 11). The patient who had a wait-and-USFNAC policy and developed a neck node metastasis was 10 months after the TORS. She underwent a neck dissection and postoperative radiotherapy. She developed laryngeal edema and is dependent on a tracheostomy since 6 months (case 15).

The median time between robot-assisted surgery and neck dissection was 4.0 weeks with a range of 2–8 weeks. The first six patients had a neck dissection within 2–3 weeks after robot-assisted surgery. However, patients experienced this interval to be too short. With two patients, an open communication between the oral cavity/pharynx and neck occurred during the neck dissection (cases 5 and 18). This defect was closed using local tissues and healed uneventful in both patients. The protocol was changed to wait at least 4 weeks to do the neck dissection.

The median robot-assisted operating time for primary tumor removal was 115 min with a minimum of 43 min and a maximum of 186 min (Table 2). Hemostasis was optimal in all cases. The median estimated blood loss was 5 ml with a range of 0–125 ml. Two patients suffered complications as a result of TORS. The first patient had an acute arterial hemorrhage 1 week postoperative, which caused the patient to have a threatened airway. The patient underwent a tracheotomy and the bleeding was stopped. The second patient had an infection of the wound in the oral cavity, which was successfully treated with antibiotics.

Patient perspective

The mean follow-up time for this study was 33.7 months. Results of Kaplan–Meier survival analysis showed a 2-year recurrence-free survival rate of 86 % (SD 9.1 %) and overall survival of 100 % (SD 0.0 %). One patient passed away as a result of pancreatic cancer 32 months after treatment without evidence of locoregional disease.

Quality of life

All surviving patients filled out the questionnaires. Because these are quite comprehensive questionnaires, we primarily focused on those aspects most relevant for this analysis. In the questions we used Likert-type scales. Cronbach's α was calculated wherever possible to give a representation of the reliability of the test scores, with a recommended reliability standard of 0.70.

Table 1 Cases, resection margins and adjuvant treatment

Case	Tumor site	cTNM	ROT (min)	Surgical margins	pTNM	Period until ND (weeks)	Hospital stay (nights)	Adjuvant therapy/surveillance	Complications/recurrence/management	Outcome
1	Base of tongue	cT1N0	129	Negative	pT1N0	2	4	Surveillance	None	NED
2	Base of tongue	cT2N0	186	Tumor positive	pT2Nx	No ND	8	RT	ORN; mandibulectomy + fibula	NED
3	Tonsillar region	cT2N0	128	Negative	pT1N0	6	1	Surveillance	None	NED
4	Tonsillar region	cT2N0	109	Negative	pT1N0	2	3	Surveillance	None	NED
5	Soft palate	cT1N0	160	Negative	pT1N0	2	1	Surveillance	None	NED
6	Tonsillar region	cT2N0	163	Tumor positive	pT2Nx	No ND	1	Conversion to open surgery, RT	ORN; HBO + sequesterotomy	NED
7	Base of tongue	cT1N0	80	Negative	pT1N0	4	0	Surveillance	None	NED
8	Tonsillar region	cT2N0	110	Negative	pT2N0	4	1	Surveillance	None	Died of pancreatic carcinoma
9	Tonsillar region	cT2N0	140	Tumor positive	pT1Nx	No ND	5	RT	None	NED
10	Tonsillar region	cT1N0	80	Negative	pTxNx (fibrosis)	No ND	0	Surveillance and USFNAC	None	NED
11	Tonsillar region	cT2N0	51	Close	pT2N0	3	1	Surveillance	Neck recurrence: (chemo) radiation	NED
12	Base of tongue	cT2N0	121	Negative	pT1N1	4	9	Surveillance	None	NED
13	Base of tongue	cT2N0	124	Tumor positive	pT2Nx	No ND	17	Postoperative bleeding, re-excision using CO ₂ -laser followed by RT	Severe dysphagia for which laryngectomy	NED
14	Lateral pharyngeal wall	cT1N0	68	Negative	pT1Nx	No ND	1	Surveillance and USFNAC	None	NED
15	Vallecula	cT2N0	148	Negative	pT2Nx	No ND	11	Surveillance and USFNAC	Nodal metastasis: ND and RT, tracheostomy and tube feeding dependent	NED
16	Tonsillar region	cT1N0	43	Negative	pT1N0	8	2	Surveillance	None	NED
17	Tonsillar region	cT1N0	47	Negative	pT1Nx	No ND	0	Surveillance and USFNAC	None	NED
18	Soft palate	cT1N0	99	Close	pT1Nx	No ND	11	Re-excision, Surveillance and USFNAC	Palatal defect, closure	NED

Patients are numbered chronologically. Negative margins are defined as margins 5 mm or more in infiltrative carcinomas or 3 mm or more in tumors with pushing borders. Close margins are margins without tumor but with less margin than the tumor-free category. Tumor-positive margins are margins with tumor cell in the margin

ROT robotic operating time, ND neck dissection, NED no evidence of disease, ORN osteoradionecrosis

Table 2 Per- and post-operative course and variables

Variables	All TORS patients (<i>N</i> = 18)
Surgical robotic time (min)	115 (43–186)
Estimated blood loss (ml)	5 (0–250)
Time to discharge (nights)	1.5 (0–17)
Time between TORS and neck dissection (weeks)	4.0 (2–8)
Follow-up time (months)	36.0 (3–65)

Values are median (range)

The first set of questions was related to functional aspects, with three oral transport and three swallowing items combined with one item on mastication. Cronbach's α of these combined items was 0.93. Two patients were receiving tube feeding, so these questions did not apply to them. Fourteen patients did answer these questions and six of them reported having oral transport dysfunction. Four patients were having trouble with swallowing foods and four patients had problems with mastication. Six patients were experiencing trismus and two of these patients reported difficulties in speech or eating because of this.

The second set of questions was related to psychosocial aspects, consisting of five questions about speech and three questions about social contacts and social anxiety. Seven patients reported that their intelligibility has decreased for various reasons. Six of these seven patients found the volume of their voice to have been lowered as well. Five of these patients reported a lower pitch perception and rate of speech. Telephone intelligibility is found to be inadequate by six patients. Three patients felt a little inhibited to get in contact with other people, only one patient reported to avoid getting in contact with new people.

Four questions were added to assess if patients had experienced pain during the last week before filling out the questionnaire. Nine patients reported to have had no pain, three patients had experienced a little pain, four patients had experienced moderate pain and one patient severe pain. Six patients used pain medication during this week.

The SWAL-QOL was included in this study because of the major role the oropharynx plays in the patient's swallowing function. This questionnaire assessed the degree of dysphagia and impact of dysphagia on quality of life in different categories, such as general burden and eating duration. The SWAL-QOL questionnaire was not filled out by one patient due to absence of swallowing dysfunction. In the SWAL-QOL questionnaire we found reliability coefficients (Cronbach's α) ranging 0.884–0.997, therefore good internal consistency of the items was achieved. The SWAL-QOL consisted of 44 items, grouped into 11 subscales, as shown in Table 3. Scores were calculated for each subscale

Table 3 Reliability estimates and mean scores of SWAL-QOL

SWAL-QOL	No. of items	Internal consistency (Cronbach's α)	Mean score \pm SD
General burden	2	0.949	76.25 \pm 5.30
Eating duration	2	0.971	75.00 \pm 13.13
Eating desire	3	0.884	85.71 \pm 5.15
Food selection	2	0.997	91.43 \pm 2.01
Communication	2	0.991	75.63 \pm 4.42
Fear of eating	4	0.981	82.81 \pm 8.86
Social functioning	5	0.994	85.75 \pm 4.01
Mental health	5	0.995	85.50 \pm 3.91
Sleep	2	0.952	68.75 \pm 3.54
Fatigue	3	0.895	76.89 \pm 5.94
Symptoms	14	0.958	80.81 \pm 6.03

Sample size is *N* = 16

on a range of 0–100, with a score of 100 representing the most favorable state. Table 3 shows mean scores and reliability estimates of the subscales.

Two patients were getting their food strictly through a feeding tube (cases 2 and 13) and four patients were eating soft solids instead of solid food (cases 6, 9, 15 and 18). All other patients had a normal diet. Despite the presence of dysphagia and the impact it has on the different aspects of quality of life, only three patients rated their own health to be poor to average (cases 2, 13 and 15). The other patients found themselves to be in good to excellent health. Three patients had TORS and a wait-and-observe policy of the neck without any adjuvant treatments. These patients are currently without evidence of disease and have no functional disabilities.

Discussion

The aim of this study was to assess whether early stage oropharyngeal tumors can be safely and effectively resected transorally using the da Vinci robot system, working with a specific group of patients. Only patients with early stage oropharyngeal tumors without any sign of cervical or metastatic disease (T1–2N0) were included. This is the first time research concerning TORS is carried out with this specific group of patients. Other than most research published on TORS, this study was a prospective trial.

Multiple studies have shown promising results regarding technical feasibility and safety of TORS [24–27]. Most of these studies use the operating robot to resect larger oropharyngeal tumors before definitive (chemo) radiation. As we very much doubt whether this policy renders better oncological and functional outcome as compared to (chemo) radiation alone, we did not opt for this policy and

still do not. Factors taken into consideration when analyzing safety and effectiveness are surgical robotic time, estimated blood loss, length of hospital stay and postoperative complication rates. In accordance with other studies the estimated blood loss in our patient series was found to be very low with a median of 5 ml and a maximum estimated blood loss of 250 ml. With a median hospital stay of 1.5 nights, in a range of 1–17 nights, no real difference with other studies was observed [10]. In their review, Dowthwaite et al. [10] find that the average surgical robotic time across all studies reporting these data was just under 75 min. In this study, the average robotic operating time was 110 min (range 43–186 min) with the early procedures taking more time. The mean reason is probably the limited number of cases included in this study and the fact that there is a learning curve influencing surgical setup and operating time.

TORS offers considerable challenges in some patients, such as control over bleeding, careful manipulation of tissue and complete removal of the tumor preserving all other structures. Depending on the patient's anatomy and tumor site this sometimes leads to conflicts between these robotic arms, pressure against teeth or deformation of the base of tongue making it more difficult to obtain optimal exposure. In three patients in this study this exposure problem led to incomplete tumor excision. The development of improved mouth gags, such as the one developed by Remarkle and Lawson [28] and optimized instruments for transoral surgery might facilitate tumor exposure in the future. Furthermore, an examination under general anesthesia to assess the exposure on beforehand can reduce problems with exposure during the procedure. Despite our limited experience using the da Vinci robot, in 14 cases (78 %) resection margins were free of tumor and the other four had adjuvant radiotherapy. No local recurrence occurred. As radiotherapy is equally effective in achieving local and locoregional tumor control (83–93 % LR control rates) in T1-2N0 oropharyngeal carcinomas, the choice between transoral resection and radiotherapy should mainly depend on estimated side effects and morbidity [5, 6, 8, 9].

The recent popularity of the transoral robot excision resembles the enthusiasm for transoral laser surgery some decade ago. Possibly the da Vinci robot has the advantage that the arms can work around an angle when there is enough room to maneuver. However, an experienced laser surgeon can certainly obtain similar results at much lower costs. No comparative trial has yet been done and the preference is mainly a personal choice.

Quality of life and functional outcomes

Dowthwaite et al. conclude that they see a potential for de-intensification of treatment, particularly for patients

who are HPV positive. A recent systematic review and meta-analysis of literature showed that the proportion of oropharyngeal cancer caused by HPV has increased significantly worldwide from around 40 to 70 % of patients under study before 2000 and after 2005, respectively [29]. HPV-positive patients are typically younger and have lower rates of medical comorbidities [17]. Long-term quality of life and complications are especially relevant when considering the different treatment options for these patients. In this study only two patients were HPV positive, which is lower than expected. However, this might be caused by the fact that only selected N0 cases were eligible for this study and most HPV tumors are N+.

In this study, the self-report questionnaire regarding quality of life was filled out only at one point in time. The time between operation and assessment was different for every patient. Consequently, there are no pretreatment or baseline measurements. Few studies have addressed patient perception of quality of life after treatment of an oropharyngeal carcinoma with TORS. Especially when considering the major role the oropharynx plays in patients' swallowing function, it is valuable to ask for patient perception on his/her swallowing ability and any possible changes in this ability after resection. A study performed by Sinclair et al. [30] showed that, after TORS, approximately one-third of patients will experience long-term swallowing dysfunction. That same study points out that the degree of dysphagia will decrease over time, even after 12 months. Several studies also found that most of the health-related problems, associated with their head and neck tumor localization and treatment, return to pretreatment levels at 12 months. In the study performed by Hurtuk et al. [15, 16] an exception was seen for eating function and attitude, which remained deteriorated for a longer period of time. The reason could be the high number of oropharyngeal lesions resected with TORS in that study. Because we have no baseline measurements, it was not possible to analyze if the health-related problems returned to pretreatment levels at 12 months. In our study patients who had exclusively TORS without postoperative radiotherapy had almost no complaints related to their tumor resection. Patients who needed additional surgery or postoperative radiotherapy had more long-term complaints. Three of the five patients who also had (chemo) radiations reported that they were not satisfied with counseling about possible morbidities.

Conclusion

TORS is a safe and effective surgical approach of early stage T1-2N0 oropharyngeal cancer based on this relatively small group of patients. Patient selection should be done with the greatest care to avoid the need for adjuvant

radiotherapy as the toxicity of both modalities together is high. So far, no comparative studies between radiotherapy and TORS or CO₂ laser have been performed. Such studies would be interesting and could lead to conclusive arguments in favor of either of the modalities, based on their functional and oncologic outcomes.

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