ORIGINAL ARTICLE

Transoral laser microsurgery as standard approach to hypopharyngeal cancer. Survival analysis in a hospital based population

Eduardo Breda a,*, Raquel Catarino b, Eurico Monteiro a

a Department of Otolaryngology, Portuguese Institute of Oncology Dr Francisco Gentil, Porto, Portugal
b Molecular Oncology GRP CI, Portuguese Institute of Oncology Dr Francisco Gentil, Porto, Portugal

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KEYWORDS
Transoral laser microsurgery; Hypopharynx; Piriform; Cancer; Carcinoma; Squamous; Survival; Local control; Organ preservation; Laser; Surgery

Abstract
Objective: Cancer of the hypopharynx remains one of the most challenging chapters in head and neck oncology. The objective of this study is to ascertain the relevance of a transoral laser approach as a valid functional option for treatment of cancer of the hypopharynx in Portugal, and additionally, to confirm the reproducibility of survival and functional outcomes described in other reference centers.

Subjects and methods: The outcomes of 37 out of 60 patients presenting hypopharyngeal carcinoma primarily treated by TLM (transoral laser microsurgery) and neck dissection and or adjuvant treatment when needed, with curative intention in tertiary referral center, were retrospectively evaluated and compared with published results.

Results: There were no patients in stage I. Three-year and five-year overall survival (Kaplan–Meier) were 83.5% and 63.5% for stage II (n = 12), 57.1% (only 3-year overall survival evaluable for this stage) for stage III (n = 7), and 53.1% and 39.8% for stage IVa (n = 18), respectively. Five-year local control rates were 90% for stage II and 87.5% for stage IVa, respectively; only three-year local control rates were possible to evaluate for stage III, with a 100% control rate. Five-year total larynx preservation rate was 97.3%.

Conclusions: TLM, alone or with neck dissection and adjuvant therapy, is a valid procedure for treatment of hypopharyngeal cancer in different stages. Furthermore, this kind of approach can be replicated in different oncologic centers with similar oncologic and functional results.

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Microcirugía transoral láser con CO₂ como una opción válida para el tratamiento del cáncer de hipofaringe en un hospital terciario

Resumen

Objetivo: El cáncer de hipofaringe continúa siendo uno de los capítulos más difíciles en la oncología de cabeza y cuello. El objetivo del presente estudio es determinar la relevancia del abordaje con microcirugía transoral láser CO₂ (MTL) como una opción válida para el tratamiento de cáncer de hipofaringe en un hospital terciario. Adicionalmente, se pretende comparar los datos obtenidos con los de otros centros de referencia en relación a la supervivencia y a los resultados funcionales.

Pacientes y Métodos: 37 pacientes de un total de 60 con diagnóstico de carcinoma hipofaríngeo han sido tratados con intención curativa con MTL sola o asociada a disección cervical y terapia adyuvante. Los resultados han sido evaluados retrospectivamente y comparados con los publicados en la literatura.

Resultados: No hubo pacientes en estadio I. La supervivencia global a los 3 y 5 años (Kaplan-Meir) fue de 83.5% y 63.5% en el estadio II (n=12); 57.1% en el estadio III (n=7) (en este estadio sólo pudo ser evaluada la supervivencia global a los 3 años) y 53.1% y 39.8% para el estadio IVa (n=18) respectivamente. El porcentaje de control local a los 5 años fue de 90% en el estadio II y de 87.5% en el estadio IVa, respectivamente; en el estadio III, solamente ha sido posible evaluar el control local a los 3 años, que ha sido de 100%. El porcentaje total de preservación laringea a los 5 años fue de 97.3%.

Conclusiones: La MTL, sola o asociada a la disección cervical y terapia adyuvante, es un procedimiento eficiente para el tratamiento del cáncer hipofaríngeo en diferentes estadios. Esto confirma que este abordaje es una opción válida y reproducible en diferentes centros oncológicos.

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Introduction

Squamous cell carcinoma (SCC) of the hypopharynx accounts for approximately 3–5% of all head and neck SCC, being less prevalent than at most other major sites of the head and neck, such as the oral cavity, larynx and oropharynx.\(^1\) Although occurring less frequently, hypopharyngeal carcinoma has the worst survival rates of all head and neck cancers and is considered a distinct clinical entity.\(^2\) The anatomic proximity of the larynx, advanced stage of disease at presentation and high rates of regional and distant metastasis are characteristics that contribute for a poor prognosis, compared with other head and neck cancer sites.\(^3\)

Additionally, among all head and neck SCC patients, those with hypopharyngeal primary cancer have the highest risk of synchronous second primary malignancy\(^4\) and 22.6% of these individuals are expected to have synchronous or metachronous multiple primary malignancies.\(^5\) All these aspects demand thoughtful reflection when considering treatment options. The last decade’s tendency toward preferential treatment with sequential or concurrent chemoradiation is being questioned\(^6\) and organ-preservation surgery is mentioned as an alternative.\(^7,8\) However, evaluation of the potential survival and/or functional advantages of available management strategies for head and neck cancer is a complicated issue and, although nonrandomized studies may contain several flaws, they often remain the main accessible basis for treatment decision-making.\(^9,10\)

The objective of the present study is to assess the outcomes of TLM as an organ-preserving option in the curative treatment of selected patients with hypopharyngeal cancer in Portugal, by evaluating the oncologic and functional results. To accomplish these goals, a retrospective analysis was performed using data collected from a prospective research, with the main objective of ascertaining the role of TLM in a comprehensive head and neck cancer treatment approach.\(^11\)

Patients and methods

All patients with a primary diagnosis of hypopharyngeal SCC with no distant metastasis and proposed by the Head and Neck Interdisciplinary Group Board (HIGB) for treatment with primary curative intention TLM between 1 January 2006 and 31 December 2011, were enrolled. Selection of patients for TLM approach ordinarily followed the National Comprehensive Cancer Network guidelines for head and neck cancer.\(^11\) Additionally also performed TLM approach selected patients who refused total pharyngolaryngectomy and/or were not suitable for radio(chemo)therapy.

Number of affiliation, age, gender, histopathologic tumor classification according to the WHO International Classification of Diseases for Oncology (ICD-O-3), site of tumor, clinical TNM (cTNM), histopathologic TNM (pTNM) and STAGE assembly in agreement with postoperative TN categories according to TNM Classification of Malignant Tumors (UICC-AJCC) 7th Edition\(^14\) were registered. Type, number and
schedule of performed TLM for each patient, clinical and surgical findings, association or not with neck dissection, type of complementary treatment when done, type, number and schedules of complications if occurred, necessity of TL anytime in the follow-up (FU) and number of months of FU were also considered points to be fulfilled in each patient. Need of gastrostomy later than 3 weeks after surgery and/or of tracheostomy any time in the FU was also considered. In the FU, patients were considered as being alive with and without onologic disease, dead with local, regional or distant disease, and finally dead or lost to FU without disease. The cut-off point for statistical analyses was January 2015, encompassing a minimum follow-up of 36 months.

Subsequent to a broad approach of results considering all patients, further specific analyses were restricted to hypopharyngeal tumors meeting the following exclusion criteria: primary tumor of any location, simultaneous second primary and N3 neck disease. Evaluation of overall survival (OS), disease specific survival (DSS) and local recurrence-free survival (LRFS) estimation of the relative proportion of spared functional larynxes was then accomplished in this final group of patients.

The tumor was resected under general anesthesia in all patients using a CO₂ laser in continuous or superpulse mode. TLM was performed according to Steiner’s technique of cutting through the tumor, step by step, with the tumor being totally resected blockwise, in order to perform a safe excision without unnecessary removal of healthy tissue. Treatment of neck disease was performed according to usual indications for head and neck cancers. Adjuvant (chemo)-radiotherapy was mainly performed in cases of advanced neck disease or when the histopathologic examination revealed extracapsular spread and/or lymphangiosis carcinomatosa (primary/neck).

Statistical analysis was performed using SPSS Statistics, Version 19.0 and Kaplan–Meier curves were selected to estimate survival rate.

**Results**

Sixty (60) patients fulfilled the first mentioned requisites, accounting for a mean of 10 patients treated each year. All of them were male patients, with a mean age of 58.7 years (range 45–81 years; median 58.7 years). Their distribution according to T stage and TNM is listed in Table 1.

**Table 1** Transoral laser microsurgery (TLM) treated cancer patients.

<table>
<thead>
<tr>
<th>Stage</th>
<th>All patients (n=60)</th>
<th>No previous or synchronous tumor and N &lt; 3 (n=37)</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>II</td>
<td>17</td>
<td>12</td>
</tr>
<tr>
<td>III</td>
<td>11</td>
<td>7</td>
</tr>
<tr>
<td>IV</td>
<td>31</td>
<td>18</td>
</tr>
<tr>
<td>pT1</td>
<td>8</td>
<td>4</td>
</tr>
<tr>
<td>pT2</td>
<td>37</td>
<td>25</td>
</tr>
<tr>
<td>pT3</td>
<td>12</td>
<td>6</td>
</tr>
<tr>
<td>pT4</td>
<td>3</td>
<td>2</td>
</tr>
</tbody>
</table>

Subsequent analysis of the present study will only refer to 37 patients with hypopharyngeal tumors satisfying exclusion criteria, and therefore keeping out those patients with previous (n=1) or synchronous (n=9) cancer of any location and N3 neck disease (n=13). Most of them (n=35) were cancers of piriform sinus, one was retrocricoid and another was located at the posterior hypopharyngeal wall.

Stage distribution according to the TNM Classification of Malignant Tumors (UICC/AJCC) 7th Edition was as follows: stage I, 0%; stage II, 32.4% (12 patients); stage III, 18.9% (7 patients); and stage IV, 48.7 (18 patients). pT1, 10.8% (4 patients); pT2, 67.6% (25 patients); pT3, 16.2% (6 patients); and pT4, 5.4% (2 patients) (Table 1).

Four patients were treated exclusively by TLM; 10 by TLM and neck dissection; 5 by TLM and adjuvant radiotherapy; and 18 by TLM, neck dissection, and adjuvant radiotherapy or radio(chemo)therapy.

Median FU was 72 months (mean 69.3, standard deviation 17.4). On January 2015, seventeen out of these 37 patients (45.95%) were alive with no evidence of disease, except one, and 20 (54.05%) died. Twelve patients (32.4%) died because of TNM-related causes (7 with distant metastasis and 5 with local or locoregional disease), 7 (18.9%) died because of second primary cancers and 1 (2.7%) intercurrently. Only one of the 37 patients underwent pharyngolaryngectomy as salvage therapy, accounting for a total larynx preservation rate of 97.3%. Two patients needed permanent gastrostomy, late in the FU. No patients needed tracheostomy anytime in the follow-up. There are four cases of postoperative complications, three with hypopharyngeal bleeding requiring microlaryngoscopy, and one patient with aspiration pneumonia, which was treated conservatively.

These are absolute numbers.

There were no patients in stage I. Three-year and 5-year OS (Kaplan–Meier) were 83.3% and 63.5% for stage II (n=12), 57.1% (only 3-year overall survival evaluable for this stage) for stage III (n=7), and 53.1% and 39.8% for stage IVa (n=18), respectively. Grouping Stage II versus III-IV OS was 63.5% and 39.5%, respectively (P=0.0009). Three-year and 5-year DSS (Fig. 1) were 83.5% and 74.1% for stage II, 85.7% for stage
Table 2  Survival estimation according to stage.

<table>
<thead>
<tr>
<th>N°</th>
<th>Stage</th>
<th>Overall survival 36/60 months %</th>
<th>Disease specific survival 36/60 months %</th>
</tr>
</thead>
<tbody>
<tr>
<td>12</td>
<td>II</td>
<td>83.3/63.5</td>
<td>83.3/74.1</td>
</tr>
<tr>
<td>7</td>
<td>III</td>
<td>57.1/...</td>
<td>85.7/...</td>
</tr>
<tr>
<td>18</td>
<td>IV</td>
<td>53.1/39.8</td>
<td>59/59</td>
</tr>
</tbody>
</table>

Table 3  Local control estimation according to pT classification.

<table>
<thead>
<tr>
<th>N°</th>
<th>pT</th>
<th>Local control 60 months (36 months) %</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>1</td>
<td>100</td>
</tr>
<tr>
<td>25</td>
<td>2</td>
<td>87.4</td>
</tr>
<tr>
<td>6</td>
<td>3</td>
<td>(100)</td>
</tr>
<tr>
<td>2</td>
<td>4</td>
<td>50</td>
</tr>
</tbody>
</table>

III (only 3-year overall survival evaluable for this stage), and 59% for stage IVa, respectively (Table 2). Five-year local control rates were respectively 100% for pT1, 87.4% for pT2 and 50% for pT4; it was possible to evaluate only 3-year local control rates for stage III, with a 100% control rate (Table 3).

Discussion

Cancer of the hypopharynx remains one of the most challenging chapters in head and neck oncology, long associated with a dramatic natural history, poor outcomes and functional disturbing results. Additionally, lesions in this area can grow undetactable to a size larger than most other head and neck sites, and symptomatic disturbance of function is not seen until the disease is advanced. Approximately 70–85% of the patients reported in large series have stage III or IV disease at presentation, and the 5-year OS, independent of the modality of treatment, is reported to be around 15–45%.

Hypopharyngeal cancer treatment is not completely consensual, and different strategic approaches are designed to improve survivals. In our Institution, during the period of the present study, 120 patients were proposed by the Head and Neck Interdisciplinary Group Board (HIGB) for surgical treatment with primary curative intention (60 with TLM and 60 with partial pharyngectomy with total laryngectomy); 27 patients performed salvage pharyngolaryngectomy and 116 performed radiotherapy or (chemo)-radiation either primary or adjuvant (collected data, not published).

Whatever the chosen appropriate therapeutic option, it should be "cost-effective" since treatment duration should be short and associated with minimal morbidity, besides improving the chances of disease-free survival, functional outcomes after treatment must also be considered. Impaired deglutition with dysphagia or aspiration of ingested substances and pneumonia are events frequently associated with hypopharyngeal cancer management, often leading to feeding tube requirement, tracheotomy or even total laryngectomy.

According to Vilaseca et al., there are essentially two ways intending preservation of the function in the treatment of SCC of the hypopharynx: neoadjuvant or concomitant (chemo)-radiotherapy and organ-sparing surgery. Although some authors suggest extension of robotic surgery (TORS) indications to hypopharyngeal cancer, even recently published results are still based mostly on case reports or very small series, and so actually, TLM may be considered the standard transoral approach in this anatomic site, increasing the potentials of organ sparing and progressively replacing partial open surgery. However, few studies have been reported involving significant representative samples of patients. Additionally, the selection of patients most suitable for TLM approach is also a demanding matter. Glanz classified hypopharyngeal tumors depending on their site, growth, and spread into the larynx; accordingly, TLM should be mostly appropriate for limited and exophytic tumors, and also for tumors spreading superficially without deep invasion of the larynx. On the contrary, other management strategies should be considered in tumors growing with ulceration and deep infiltration into the larynx and the neck.

Furthermore, randomized studies comparing results between these functional alternatives (neoadjuvant or concomitant (chemo)-radiotherapy and organ-sparing surgery) are currently not available, and clinical trials for patients with head and neck cancer have been dominated by nonsurgical interventions, ignoring recent advances in head and neck surgery. A recently published study on the 10-year results of the EORTC trial 24891 (comparing total laryngectomy with partial pharyngectomy and neck dissection, followed by irradiation in one arm, and induction chemotherapy for complete responders by irradiation and otherwise by conventional treatment in the other) showed that the 5-year and 10-year OS (33% and 13%, respectively) did not differ between both arms, and that about half of the survivors in the (chemo)-radiation arm could retain a functional larynx.

Meanwhile, nonrandomized data remain an important basis for treatment decision-making, although the match of different studies on neoadjuvant or concomitant (chemo)-radiotherapy and organ-sparing surgery may encompass several bias on patient selection, particularly on T stage evaluation, as pT is clearly more accurate than cT classification.

Mendenhall et al. recently updated previously published data from the University of Florida, in a retrospective study involving 135 patients with T1–T2 pyriform sinus SCC treated with primary RT (adjuvant chemotherapy was employed in 21 patients and 62 patients underwent a planned neck dissection. Median follow-up was 3.5 years). The local control rates at 5 years were 88% for T1 and 84% for T2 and the overall local control rate for T1–T2 was 85%. The 5-year ultimate local control rates, including patients successfully salvaged after local recurrence, were as follows: T1, 92% and T2, 92%. The 5-year OS were as follows: I–II, 62%; III, 48%; and IVa, 35%. Seventeen patients underwent a salvage surgery, including total laryngectomy in 11 patients. Severe postoperative complications occurred in 5 patients, with two of them leading to death. Severe late complications occurred in 16 patients (12%), including temporary tracheostomy (1 patient), permanent tracheostomy...
Table 4  Comparative survival and organ preservation rates.

<table>
<thead>
<tr>
<th>Author</th>
<th>Number of patients</th>
<th>Years of study/mean (number)</th>
<th>T category</th>
<th>Overall survival 5-year [4-year] (3-year)</th>
<th>Disease specific survival 5-year [4-year] (3-year)</th>
<th>Local control 5-year [4-year] (3-year)</th>
<th>Larynx preservation rate 5-year (3-year)</th>
<th>Gastrostomy or tracheostomy rate 5-year [4-year] (3-year)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steiner</td>
<td>129</td>
<td>15/44</td>
<td>T1 (24) T2 (74) T3 (17) T4 (14)</td>
<td>I/II: 71% III/IV: 47%</td>
<td></td>
<td></td>
<td>100% in survivors 0%</td>
<td></td>
</tr>
<tr>
<td>Rudert</td>
<td>29</td>
<td>5/(78)</td>
<td>T1 (8) T2 (19) T3 (1) T4 (1)</td>
<td>I/II: 78% III/IV: 35%</td>
<td></td>
<td></td>
<td>100% in survivors 0%</td>
<td></td>
</tr>
<tr>
<td>Vilaseca</td>
<td>28</td>
<td>3.5/(40.5)</td>
<td>T1 (2) T2 (16) T3 (9) T4 (1)</td>
<td>[43.4] I/II [100%] III/IV [42.5%]</td>
<td>T1: 100% T2: 81.6% T3: 56.2% T4: 100%</td>
<td>100% in survivors 21.5%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Martin</td>
<td>172</td>
<td>17/45</td>
<td>T1 T2 T3 T4</td>
<td>I/II: 68% III: 64% IVa: 41%</td>
<td></td>
<td></td>
<td>9825% 7%</td>
<td></td>
</tr>
<tr>
<td>Leong</td>
<td>11</td>
<td>7/27</td>
<td>T1 (1) T2 (1) T3 (5) T4</td>
<td>(71%)</td>
<td>(99.9%) (10%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Karatzanis</td>
<td>119</td>
<td>25/(71)</td>
<td>T1 (45) T2 (74)</td>
<td>I: 84.4% II: 77.1% III: 68.2%</td>
<td>T1: 90% T2: 83.1%</td>
<td></td>
<td>5%</td>
<td></td>
</tr>
<tr>
<td>López-Alvarez</td>
<td>16</td>
<td>8/(51)</td>
<td>T1 (6) T2 (9) T3 (1)</td>
<td>44%</td>
<td>62%</td>
<td></td>
<td>97.3% 5.2%</td>
<td></td>
</tr>
<tr>
<td>Present study</td>
<td>37</td>
<td>6/72</td>
<td>T1 (4) T2 (25) T3 (6) T4 (2)</td>
<td>II: 63.5% (III: 57.1) IVa: 53.1</td>
<td>II: 74.1% (III: 85.7%) IVa: 59%</td>
<td>T1: 100% T2: 87.4% (T3: 100%) T4: 50%</td>
<td></td>
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</tr>
</tbody>
</table>
and/or permanent gastrostomy (13 patients), and laryngopharyngectomy for necrosis (2 patients), accounting for 20% severe permanent functional damage (27 patients).

Steiner et al. presented in 2001 a retrospective review of 129 previously untreated patients undergoing CO2 laser microsurgery for the treatment of squamous cell carcinomas of the piriform sinus from 1981 to December 1996. The 5-year OS was 71% for stages I and II and 47% for stages III and IV. Rudert et al. presented in 2003 a series of 29 patients resected by TLM with curative intention, reporting 100% organ preservation with 5-year OS of 78% for stage I/II and 35% for stage III/IV. Vilaseca et al. published in 2004 a sample of 28 patients treated with TLM neck dissection. Four-year OS was 43.4% and DSS was 100% for I/II and 42.5% for stage III/IV, with 78.5% function preservation rate.

Martin et al. appended in 2008 previously published results on outcomes of organ preservation by TLM of the pyriform sinus. One-hundred fifty out of 172 patients with hypopharyngeal cancers had piriform sinus carcinoma, and the obtained survival rates were as follows: five-year local control estimates were 84% for pT1, 70% for pT2, 75% for pT3, and 57% for pT4a. The 5-year OS was 72% (combined stages I and II), 61% (stage III), and 43% (stage IVa). The 5-year recurrence-free survival was 79%, 59%, 49%, and 5-year DSS was 100%, 85%, and 57% respectively. Among all 172 treated patients with hypopharyngeal cancer, 13 needed a permanent tracheostomy or a gastrostomy, and 3 patients underwent total laryngectomy for oncologic or functional purposes, accounting for 10.7% of severe permanent functional damage after treatment.

Karatzanis et al. published in 2010 results of a retrospective study involving 119 patients with T1–2 hypopharyngeal carcinoma treated between 1979 and 2004 with CO2 laser microsurgery (mean FU was 71 months). For T1 cases, the DSS was 77.8%, and for T2 cases, it was 70.0%. The DSS was 84.4% for stage I, 77.1% for stage II, and 68.2% for stage III cases. LC was 85.4% overall in this series. For T1 cases, LC was 90%, and for T2 cases, it was 83.1%. Overall incidence of complications was 12.6%, including 3 patients who needed permanent tracheostomy (2.5%) and 3 patients needing permanent gastrostomy (2.5%). The need of total laryngectomy for oncologic or functional purposes is not mentioned for any patient.

According to Hall et al., even tertiary reference centers have limited experience on treatment of these cancers because of its low prevalence and multiple management approaches. This fact is illustrated in a recent literature review demonstrating that most experienced centers needed more than 17 years to achieve more cases than those reported in the present study. Additionally, median time of FU superior to 36 months is also seldom reported (Table 4). Although only 37 patients are considered, a total amount of sixty patients were submitted to TLM in the 6 years of the present study, accounting for a mean of 10 patients treated each year. The minimum FU of 36 months and the median time of FU of 72 months contributed to accomplish enough strength to obtain results in the selected 37 patients.

Survival and laryngeal preservation rates seem to be in line with the related bibliography (Table 4). Unexpected similarities of three-year DSS between stages II and III may be explained by the good local control rate obtained in T3 patients (100%). However, the relevance of these findings may need to be ascertained with larger series, allowing valid log-rank evaluation and longer FU of Stage III patients. Furthermore, according to Hiro et al., surgery remains an indispensable part of treatment in local advanced hypopharyngeal and laryngeal cancer with high survival results and it should be part of a concept that includes adjuvant (chemo)-radiotherapy. The advantages of treatment intensification for resected, high-risk, head and neck SCC cannot be ignored, being an area of active investigation with novel adjuvant regimens still under study.

Additionally, differences between obtained 3-year and 5-year survivals in all patients of this study confirm the need of prolonged FU to understand the real prognosis of this disease. Distant metastasis and second primaries contributed equally (18.9% each) to intensify poor survival rate in presented results, and this significant finding is comparable to the 19% rate of distant metastasis and 26% of second primaries found in Göttingen outcomes.

Evaluation of functional organ-preservation outcomes was also considered in the present study. The need of total laryngectomy (1 patient) or of tracheostomy any time in the FU (no patients) and/or the need of gastrostomy later than 3 weeks after surgery (2 patients), were considered events encompassing functional loss. Accordingly, functional organ preservation was accomplished in 94.6% of patients of the present study. These data are identical to those published by Martin et al. (89.3%) and seem to compare favorably with 80% of Mendenhall.

The present study confirms that TLM combined with neck dissection and with adjuvant therapy when necessary, and achieves good oncologic and functional outcomes in selected hypopharyngeal cancers and should be implemented as a valid strategy in decision arm of patients with this kind of tumors.

Conflict of interest
The authors declare that they have no conflict of interest.

References
Transoral laser microsurgery approach to hypopharyngeal cancer