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**Is there a role for postoperative radiotherapy following open partial laryngectomy when prognostic factors on the pathological specimen are unfavourable? A survey of head and neck surgical/radiation oncologists**

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**SUMMARY**

Our aim was to survey the opinions of Italian radiation and ENT oncologists regarding the role of postoperative radiotherapy (PRT) and the appropriate dose to be given to patients with remnant larynx (RL) after open partial laryngectomy (OPL). The radio-oncologists (ROs) of the Italian Radiation-Oncologist Association (AIRO) and the ENts of the Head-Neck Oncology Society (AIOT-IHNS) were contacted through a SurveyMonkey online interface questionnaire. There were 148 usable responses. The majority of ROs recommended PRT in the case of positive/close margins (R⁺/R⁺close) or in the case of initial involvement of thyroid cartilage (pT³tci). In the same cases, ENtS prefer a “watch and wait” policy (w&w). Both disciplines recommended w&w in the case of negative margins (R⁻). Finally, the majority of ROs recommended irradiating RL with 62-66 Gy in R⁺, with 56-66 Gy (61.4%) in R⁺close and with 56-60 Gy (34%) in pT³tci. In Conclusion, OPL raises new considerations about PRT.

**KEY WORDS:** Larynx • Postoperative radiotherapy • Conservative laryngectomy • Partial laryngectomy • Head and neck cancer

**RIASSUNTO**

L’introduzione nella pratica clinica della chirurgia conservativa nei carcinomi laringei e della radioterapia ad intensità modulata (IMRT) conformabile ai volumi e ai margini positivi del laringe e provincia una radicale evoluzione. Il principale scopo di questa “Survey” è di raccogliere le opinioni di ORL e radiooncologi italiani relativamente al ruolo della chirurgia conservativa aperta (OPL) e del radioterapia postoperatoria (PRT) e l’entità di dose da assumer al residuo laringeo (RL) dopo chirurgia conservativa aperta (OPL). Un questionario online è stato inviato ai radiooncologi della Associazione Italiana di Radiooncologia (AIRO) e agli ORL della Associazione Italiana di Oncologia cervicofallica (AIOT-IHNS). Le risposte utilizzabili sono state 148. La maggioranza dei Radiooncologi ha raccomandato la PRT in caso di margini positivi o close (R⁺/R⁺close) o nel caso di coinvolgimento iniziale della cartilagine tiroide (pT³tci). Negli stessi casi gli ORL preferivano un atteggiamento di vigilanza attesa (“watch and wait”). In conclusione, OPL eleva nuove considerazioni relative al ruolo della radioterapia postoperatoria per quanto riguarda le indicazioni, le dosi da utilizzare sul residuo laringeo (se giudicato a rischi di recidiva) ed i volumi da radiotrasformare.

**PAROLE CHIAVE:** Laringe • Radioterapia postoperatoria • Laringectomia conservativa • Laringectomia parziale • Tumori testa-collo

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Introduction

The optimal treatment strategy for squamous cell carcinoma (SCC) of the larynx is still a matter of debate. Radiotherapy (RT), with or without chemotherapy (CT), open partial laryngectomy (OPL) and endoscopic resection are established options for functional preservation treatment. Various factors influence the choice of the treatment strategy: primary tumour site, stage and expected results, as well as the expertise of the multidisciplinary team, availability of the service and rehabilitation facilities, along with the patient’s decision. The early clinical stages of supraglottic and glottic cancer that do not require total laryngectomy (most T1-2 N0 cases) are usually considered for either conservative surgery (endoscopic resection, OPL with/without neck dissection) or RT. Single-modality treatment with surgery or RT is generally recommended for early-stage disease (stage I or stage II) in order to preserve the other choice in case of recurrence. Resectable, advanced-stage glottic and supraglottic primaries are usually managed with a combined modality approach. If treated with primary surgery, total laryngectomy is typically required. However, some authors recommend an OPL approach even in selected advanced cancers with or without postoperative radiotherapy (PRT). These selected cases often need to resort to PRT, which could add additional risk of late laryngeal toxicity, jeopardizing the expected functional outcome.

Furthermore, early-stage laryngeal cancers (T1-2 N0) can be clinically under-staged and postoperative adverse pathologic findings might place these cases into a pathologically advanced stage (i.e. early invasion into the thyroid cartilage, metastatic adenopathies (pN+) with or without extra-capsular extension (ECE) or positive residual margins (R+)).

In these situations, the optimal treatment option, whether to transform a conservative approach into immediate total laryngectomy (ITL), or to preserve the organ function by adopting PRT – CT or a close “watch and wait” policy (w&w), is unclear. At present, the most common Head and Neck Cancer (HNC) guideline leaves wide freedom of choice among possible therapeutic options (re-excision, RT, RT-CT), and the recommendations regarding the choice of clinical volumes to be targeted and the respective radiation dose to be released are vague. The aim of this study was to evaluate the opinion of Italian Radiation Oncologists (ROs) and ENTs on PRT ± CT when clinical early-intermediate stage (cT1-T2 or limited T3 conservatively operable with cN0) glottic and supraglottic cancer are pathologically upgraded in consequence of their unfavourable histopathologic prognostic factors (e.g. pT3 or R+).

Analytical overview

Dataset analysis was clusterized into ENTs and ROs for direct comparison.

Statistical analysis

Descriptive statistics, Fisher’s exact tests (Fisher’s P (two-tailed)) or chi-square tests (P (chi-square)) were performed using Winpbi software, where appropriate. When a significant chi-square association was found, adjusted residuals were calculated to indentify those cells that contributed most
Table I. Respondents’ clinical setting and experience.

1. How many years have you been working with Head and Neck Cancer Patients (HNCPs)?

| Answer | RO N (%) | ENT N (%) | Ratio RO%/ENT% | p* 0.001 |
|--------|----------|-----------|----------------|-----------|
| a) Less than 5 years | 16 (16.5%) | 1 (2.5%) | 6.44 | 0.025* |
| b) 6-10 years | 35 (32.1%) | 7 (17.0%) | 1.78 | 0.091 |
| c) 11-20 years | 36 (33.0%) | 12 (30.8%) | 1.073 | 0.796 |
| d) More than 20 years | 20 (18.3%) | 19 (48.7%) | 0.37 | 0.000* |

2. How many HNCPs are taken care of per year in your institution?

| Answer | RO N (%) | ENT N (%) | Ratio RO%/ENT% | p* 0.03 |
|--------|----------|-----------|----------------|---------|
| a) Less than 50 | 39 (35.8%) | 5 (13.6%) | 2.7 | 0.009* |
| b) From 51-100 | 37 (33.9%) | 17 (44.7%) | 0.76 | 0.235† |
| c) From 101-150 | 19 (17.4%) | 7 (18.4%) | 0.95 | 0.890† |
| d) More than 150 | 14 (12.8%) | 9 (23.7%) | 0.54 | 0.113† |

3. How many HNCPs submitted to conservative laryngectomy do you see per year?

| Answer | RO N (%) | ENT N (%) | Ratio RO%/ENT% | p* 0.22 |
|--------|----------|-----------|----------------|---------|
| a) Less than 5 | 25 (22.9%) | 4 (10.2%) | 2.236 | |
| b) 5-10 | 39 (35.8%) | 13 (33.3%) | 1.073 | |
| c) 11-20 | 26 (23.8%) | 11 (28.2%) | 0.846 | |
| d) More than 20 | 19 (17.4%) | 11 (28.1%) | 0.618 | |

4. Do you have a head and neck cancer board (HNCB) in your institution?

| Answer | RO N (%) | ENT N (%) | Ratio RO%/ENT% | p* 0.20 |
|--------|----------|-----------|----------------|---------|
| a) Yes | 93 (85.3%) | 36 (92.3%) | | |
| b) No | 16 (14.7%) | 3 (7.7%) | | |

5. Does your HNCB evaluate:

| Answer | RO N (%) | ENT N (%) | Ratio RO%/ENT% | p* 0.33 |
|--------|----------|-----------|----------------|---------|
| a) Selected patients (inoperable patients selected by ENT)? | 27 (29.03%) | 6 (16.67%) | 1.742 | |
| b) All patients before any specific treatment? | 58 (62.37%) | 26 (72.22%) | 0.864 | |
| c) Other? (please specify) | 8 (8.6%) | 4 (11.11%) | 0.774 | |

*Chi-square tests; † Adjusted residuals (cell-by-cell analyses).

Results

A total of 154 of 262 questionnaires sent (161 to ROs and 101 to ENTs) were filled in (58.8% response rate). Of the 154 respondents, 6 were excluded because they answered only the first three questions, which were concerned only with institutional demographics. Consequently, 148 usable responses (56.4%) were included in the final analysis: 109/161 ROs (respondent RO (%) = 67.7%) and 39/101 ENTs (respondent ENT (%) = 38.6%).

Respondents’ clinical setting and experience (Table I)

Respondents represented a variety of working settings: primarily exploiting activity in non-academic hospitals (58%), academic hospitals (25%), and private institutions (17%). Most respondents (87.2%) had a HNC-board (HNCB) in their institution. Particularly, 65.1% of respondents evaluated all patients before any specific treatment within their HNCB, while 34.9% evaluated only selected patients (inoperable patients selected by ENTs or patients who did not meet institutional guidelines). Among those who answered the questionnaire, 31/39 ENTs (79.5%) vs. 56/109 ROs (51.4%) had more than 10 years’ experience working with HNC patients (Fisher’s P (two tailed) = 0.002) (see details in Table I, Question 1). Conversely, more ROs than ENTs worked in institutions with less than 50 HNCPs per year (see details in Table I; Ques-
Finally, considering the numbers of HNCPs submitted to OPL per year seen for each specialist (Table I, Question 3) there was no statistically difference (F_{\text{Chi-square}} = 0.22) between the two specialist groups.

When does the remnant larynx need further treatment? (Figs. 1-4)

The clinical scenario of T-site prognostic factors (with no consideration of lymph-nodal prognostic factors) is shown in Figs. 1-4. In the case of R(+) after OPL (Fig. 1, Question 6), the majority of specialists recommended RT, with no significant statistically difference between the two specialist groups (p = 0.60). However, ROs more frequently would add CT to RT (RO(%) / ENT(%) = 3.27). In the case of R close (Fig. 2, Question 7), the opinions between the two specialist groups were statistically different (p = 0.000047) since more ROs recommended RT ± CT, while a higher ENT(%) recommended a w&w policy (p = 0.000029). In the case of R(-) disease (Fig. 3, Question 8), the majority of both specialist groups would recommend a w&w policy. Finally, in the case of pT3tci (Fig. 4, Question 9) a higher RO(%) advised RT ± CT (p = 1.3 E-7), while a higher ENT(%) advised a w&w approach (p = 0.000028).

When do neck volumes need to be targeted? (Fig. 5)

Two scenarios in which the RL needed to be irradiated (considering T-site unfavourable prognostic factors) were provided for: first in which the neck was not dissected with clinical negative metastatic lymph-nodes (cNo) and second in which elective neck dissections did not reveal metastatic lymph nodes (pNo). In the former scenario, 64.7% of ROs recommended irradiating both cNo and RL, while in the latter the majority of RO recommended irradiating only the RL. The attitude of ENTs was not statistically different for the two scenarios (p = 0.132) (Fig. 5).
Which doses are more frequently recommended on remnant larynx? (Fig. 6, Table II)

Fig. 6 shows the dosage recommended by 103/109 RO respondents.

Discussion

This study attempted to compare the points of view of ROs and ENTs concerning a relatively new question on the postoperative approach to OPL. To our knowledge, this is the first nationwide survey on this topic. Data from literature are only retrospective and thus come from mono- or bi-institutional studies. The most reported late toxicities are severe oedema condritis (7%), radionecrosis (5.5%), aspiration and pneumonia (29.4%) and toxic death (4%) (Table III). Indeed, the modern approach of OPL has reached prominence in the clinical field only in recent years, and different conservative laryngectomy procedures have been adopted for different extensions of tumour. Recently, a systematic review of retrospective mono-institutional studies in the English language literature has given more credence to the oncologic efficacy and reliable function preservation of these procedures considering the high local control (90%) reported in over 5000 patients and the high larynx preservation rate (91%) in over 3000 patients. However,

Table II. Which radiation dose do you recommend to the laryngeal remnant when radiotherapy is advisable or when the patient refuses immediate total laryngectomy? (Question 12) (see also Fig. 6).

| Answer Options                                      | Not recommended | < 56 Gy | 56-60 Gy | 62-66 Gy | > 66 Gy | Response Count |
|-----------------------------------------------------|-----------------|---------|----------|----------|---------|----------------|
| • R+ (margins < 1 mm)                               | 4               | 1       | 15       | 54       | 29      | 103            |
| • R-close (margins 1-5 mm)                          | 17              | 11      | 30       | 32       | 11      | 101            |
| • Ro (margins > 5 mm)                               | 70              | 6       | 19       | 5        | 1       | 101            |
| • Ro (in patients with cartilage invasion - p T3)   | 27              | 15      | 34       | 20       | 4       | 100            |
| answered question                                   |                 |         |          |          |         | 103            |
| skipped question                                    |                 |         |          |          |         | 6              |
Table III. Tissue tolerance in the case of open neck conservative laryngectomy plus postoperative radiotherapy.

| Author           | Pts   | Surgery                        | RT technique | Remnant larynx average dose | Neck dose | Late toxicity |
|------------------|-------|--------------------------------|--------------|-----------------------------|-----------|---------------|
| Robbins 1988     | 25    | Horizontal supraglottic laryngectomy | 2D-RT        | Not reported                | Not reported | 8/25 (32%)    |
| Spaulding CA     | 23    | Standard supraglottic laryngectomy Extended supraglottic laryngectomy | 2D-RT        | 50-61 Gy                    | 50-61 Gy  |               |
| Lee 1990         | 50 (+10 not irradiated) | Horizontal supraglottic laryngectomy | 2D-RT        | 55 Gy                       | 63 Gy     | NA (mixed to non irradiated patients) |
| Steiniger 1997   | 17 (vs. 12 without postoperative radiotherapy) | Horizontal supraglottic laryngectomy 1 extended to the tongue base HSGL | 2D-RT 4-6 MV LINAC 60Co beam | 59.30 Gy (50.4-66 Gy) | 45.10 Gy (40-50 Gy) |
| Laccourreye 2000 | 90    | Standard supraglottic laryngectomy Supraacricoid partial laryngectomy | 2D RT 60Co beam | 51.2 Gy (25-71) | 50.6 Gy (22-70) | 15/90 (16.6%) |
| Spriano 2000     | 56    | Standard supraglottic laryngectomy Extended supraglottic laryngectomy | 2D RT-60Co beam 2D RT-6MV LINAC | 50 Gy | 46 Gy | 30/56 (54%) |
| Oksuz 2008       | 79    | Horizontal supraglottic laryngectomy Extended supraglottic laryngectomy | 2D RT-60Cobalt beam | 50 Gy | 50 Gy | 22/79 (27.8%) |
| Garibaldi 2009   | 36    | Horizontal supraglottic laryngectomy Extended supraglottic laryngectomy Fronto-lateral laryngectomy Other | 2D RT- 6MV LINAC 3DCRT | 59.5 Gy (45-70.2) | 50.4 Gy (39.6-55.8) | 21/32 (65.6%) |

Thomas reported that approximately 22% of the patients (1151 of 5196) did not have a T-stage available. Thus, blurred stage selections, surgical technique and postoperative care represent challenges that nowadays limit OPL to specific expertise to ensure reproducible results. Specifically, this new scenario generated some concerns among ROs because of the limited amount of data on this subject (Table III), and in particular concerning the radiation tolerance of RL after OPL. Nevertheless, information concerning the risk of toxicity is lacking in tissues (e.g. resected larynx) from high radiation dosages. This opportunity is raising interest for PRT.

At the same time, the possibility to reserve a rescue total (or sometimes partial) laryngectomy without survival detriment can drive physicians’ opinion towards a w&w policy when unpredicted, unfavourable prognostic factors are found in the pathological specimen. Indeed, in our survey a higher ENT(%) advised a w&w policy in case of R_{close} or pT3_{ki} (Figs. 2, 4).

In addition, the recent introduction in radiation oncology practice of modern intensity modulated radiotherapy (IMRT), allowing for conformal RT adaptation to irregular neck shape helps to spare organ function and critical tissues (e.g. resected larynx) from high radiation dosages. This opportunity is raising interest for PRT.

This expectation could explain the higher percentage of ROs’ responses (67.8%) vs. ENTs (38.6%) (RO(%) / ENT(%) = 1.76), tending to testify a higher concern among ROs.

With regards to the Italian-HNC specialists’ attitude towards the T-site prognostic factors, the results describe substantial agreement both in not using PRT in R(-) patients and in using it in R(+). Their opinions diverge in the case of R_{close} and pT3_{ki} (Figs. 2, 4). Indeed, in these cases ROs advise RT more frequently. In contrast, ENTs more frequently suggest a w&w policy in R_{close} and pT3_{ki} cases. However, in the case of R_{close}, the majority of ROs recommended adding CT to RT, while the majority of ENTs did not recommend it (Fig. 1, Question 6). The discussion of
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| Interrupted PRT | Severe complications | Permanent sequel | Toxic death | Dose evaluated as at risk of complication |
|-----------------|----------------------|-----------------|-------------|------------------------------------------|
| Prolonged feeding tube (2/25; 8%) Aspiration with pneumonia (4/25; 16%) | Tracheostomy (2/25; 8%) | Pneumonia (1/25; 4%) | NR | |
| Lymphoedema neck | Laryngectomy (1/23) | None | NR | |
| Prolonged feeding gastrostomies (7/50; -14%) Pneumonia 3% | Laryngectomy (3/50) (6%) Tracheostomy 2% | 3 death | NR | |
| The average time of decannulation 14.3 w (vs. 6.8 w no RT; p = 0.18) To develop adequate oral intake 34.8 w (vs. 7.5 w of no RT) | | | | |
| Acute upper air respiratory in 5 (29.4%) pts (vs. = 0; p < 0.05) Pneumonia in 7 patients (29.4%) vs. 1/12 no RT (8.3%) (P = 0.18) | | | | |
| (5 = 5.5%) (40 Gy) Laryngeal radionecrosis 5/90 (5.5%) Laryngeal stenosis 4/90 (4.4%) Aspiration pneumonia 3/90 (3.3%) Skin necrosis (3.3%) Oesophageal inlet stenosis 2/90 (2.2%) | Gastrostomy 3/90 (3%) Tracheostomy (1/90) (1.1%) | 3 (3.3%) | 60 Gy (univariate p = 0.014) | |
| Severe oedema/chondritis (7%) Laryngeal necrosis (1%) Persistent aspiration (9%) Fistula (2%) | Tracheostomy (1/56) (2%) | None | > 50 Gy (HR = 2.2) | |
| Laryngeal oedema (17/79; 21.5%) Aspiration/dysphagia (6/79; 7.5%) | Definitive laryngectomy (1/79-1.3%) Definitive tracheostomy (3/79 - 3.7%) | None | NA | |
| Temporary feeding tube (3.1%) Temporary tracheostomy (3.1%) Severe neck induration (3.1%) Whispered speech (1%) | Tracheostomy (1/32) (3.2%) | None | 54.9 Gy (estimated) (50.4-55.8) | |

this item brought about an interesting question among the Authors of the present study: does the positive margin of an early-stage tumour in a conservative scenario have the same negative prognostic significance of the positive margin in an advanced-stage tumour in a non-conservative scenario? It is possible that the majority of ENTs did not add CT to RT because they attributed a less negative prognostic meaning to early-stage positive margins. Regarding radiation volumes (Questions 10 and 11), comments were gathered from both specialist groups’ questionnaires (ROs = 9; ENTs = 7) concerning the fact that the questions did not specify the T-stage and/or the T-site (glottis or supra-glottis) contexts. With these limits in mind, the evaluation of responses to two questions permit us to conclude that in the case of cNo both specialist groups would recommend RT both on the undissected neck and the RL whenever the latter needed to be irradiated. This trend is reversed in the case of pNo where only RL irradiation is more often recommended (Fig. 5, Questions 10-11).

Finally, the questionnaire asked ROs to specify the advised radiation dose on the RL. As shown in Fig. 1, a 62-66 Gy dosage was more frequently recommended in R+(+) patients, and 56-60 Gy in the case of pT3ct. The recommendations were substantially equally split between 56-60 Gy (29.7%) and 62-66 Gy (31.7%) in the case of R(−) patients, and 56-60 Gy in the case of pT3ct. The recommendations were substantially equally split between 56-60 Gy (29.7%) and 62-66 Gy (31.7%) in the case of R(−) patients, and 56-60 Gy in the case of pT3ct. However, the trend was to advise doses higher than those usually recommended 23 24. Actually, authors from MDACC, Texas 23 and Ann-Arbor Hospital, Michigan 24 suggest limiting tolerance doses to RL after a horizontal supraglottic laryngectomy up to 55.8 Gy to conserve larynx function. Garden 23 recommend treating the larynx to 60 Gy in the rare cases in which positive margins are encountered, and Laccourreye 12 does not recommend radiation on RL with negative margins as he reported chondroradionecrosis and/or laryngeal stenosis in 6 negative-margin-T3 patients in his retrospective study. Thus, the pros and cons of PRT need to be studied further. To our knowledge, only 3 studies 3 9 12 have provided a relationship between delivered dose to RL and the risk of
radiation-induced complications (Table II); their estimation ranges from 50 Gy to 60 Gy. However, the substantial pitfalls of these studies are that they are retrospective, mono/double-institutional and heterogeneous in evaluation methodology.

Our study has some limitations since it is an opinion-based survey with mainly motivated respondents, and thus it might not reflect actual clinical practice in Italy. In addition, the need to keep the questionnaire short in order to encourage respondents to fill it in limited the clarity of some questions. As mentioned above, it would have been useful to specify: the primary site (glottic or supraglottic), to define margins to be considered disease-free based on the relative anatomical site (either glottis or supraglottic), and to better define the clinical stage in each scenario. Furthermore, the survey was limited to OPL and did not consider trans-oral approaches. Nevertheless, to our knowledge, this study is the first to gather the opinions of ROs and ENTs from two national scientific societies (AIRO and AIOCC-IHNS) concerning RT indications after OPL. Taking into account the modern concepts of function-sparing laryngectomy and latest radiation technology, this topic will probably be increasingly important in institutional HNCB multidisciplinary debates.

Conclusions

This Italian survey of 109 ROs and 39 ENTs shows that:

• both specialist groups would recommend PRT in the case of R0 disease, but most ROs would add chemotherapy. Most ROs (52.4%) recommend 62-66 Gy;

• in the case of R1(+) or pT3(+)c, while ENTs prefer a w&w policy, the majority of ROs prefer RT with a dose of 56-60 Gy (29.7%) – 62-66 Gy (31.7%) in the case of R1 or 56-60 Gy (34%) in the case of pT3c;

• neither specialist groups would recommend PRT in the case of R0 disease, but both would recommend RT for undissected cN0 neck when RT is indicated for the RL.

The issues dealt with in this survey call for renewed attention and prospective studies, considering the introduction of the unique combination of function-sparing laryngectomy concepts in clinical practice and the latest IMRT-techniques allowing for selective target volume irradiation.

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