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# The role of ultrasound-guided transcutaneous tru-cut biopsy in diagnosing untreated and recurrent laryngo-hypopharyngeal masses

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#### ABSTRACT

*Objective:* To evaluate the diagnostic performance of Ultrasound-guided Transcutaneous Tru-Cut biopsy (USGTCB) of laryngo-hypopharyngeal masses suspicious for malignancy. Furthermore we investigated whether USGTCB is accurate for both untreated masses and suspected recurrences.

Materials and methods: From August 2004 to July 2014 we prospectively enrolled 66 patients for a total of 68 USGTCBs: 38 USGTCB were performed for a suspicious untreated mass and in 30 for a suspected recurrence. We calculated the sensitivity, specificity, positive predictive value and negative predictive value for all procedures and separately for untreated masses and suspected recurrences.

*Results*: USGTCB diagnosed 57 malignancies (51 squamous cell carcinomas, 6 other tumors) and 11 benign lesions. There were no false positives reported, whereas five false negatives were observed: two in patients with an untreated mass, three in patients with a suspected recurrence. Overall, the sensitivity of the technique was 91.9% (95% confidence interval [CI]: 82.2–97.3%); the specificity was 100% (95% CI: 54.1–100%); positive and negative predictive values were 100% (95% CI: 93.7–100%) and 54.5% (95% CI: 23.5–83.1%) respectively, with similar performances in untreated masses and suspected recurrences of SCC.

*Conclusion:* USGTCB is an effective procedure for the histological diagnosis of laryngo-hypopharyngeal masses suspicious for malignancy in patients showing contraindications to biopsy via microlaryngoscopy under general, with similar performances for untreated masses and suspected recurrences.

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#### 1. Introduction

Biopsy via microlaryngoscopy under general anesthesia is the standard diagnostic procedure in patients with laryngohypopharyngeal masses suspicious for malignancy. However the need for general anesthesia and subsequent intubation in these

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http://dx.doi.org/10.1016/j.ejrad.2015.10.015 0720-048X/© 2015 Elsevier Ireland Ltd. All rights reserved. patients has several limitations. Patients with bulky masses are often difficult to intubate with an associated high risk of bleeding and may sometimes require protective tracheotomy. Deep suspicious lesions are often not detectable at microlaryngoscopy, especially after radiotherapy or chemo-radiotherapy. Patients may also have absolute or relative contraindications to general anesthesia due to other medical co-morbidities.

The assessment of recurrent laryngo-hypopharyngeal masses previously treated with chemo-radiotherapy poses greater diagnostic challenges than new untreated masses [1]. In many of these recurrent masses endoscopy and imaging studies are often inconclusive [2–5]. Fine needle aspiration cytology (FNAC) is unable to differentiate between tumor recurrence and radiotherapy-induced inflammatory changes [6,7]. Therefore biopsy via microlaryngoscopy under general anesthesia is the most reliable technique to obtain a histological diagnosis in these patients [1]. However





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Abbreviations: USGTCB, Ultrasound-Guided Transcutaneous Tru-Cut biopsy; FNAC, fine needle aspiration cytology; SCC, squamous cell carcinoma.

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if there are serious contraindications to the procedure or technical problems in obtaining adequate samples from deeply seated lesions, diagnosis is often delayed and only made at follow-up imaging, thus delaying treatment and increasing the risk of disease progression.

Previous studies in small cohorts of patients have demonstrated that Ultrasound-Guided Transcutaneous Tru-Cut Biopsy (USGTCB) of laryngo-hypopharyngeal masses is feasible, allowing histological diagnosis without major complications for patients who have contraindications to biopsy via microlaryngoscopy under general anesthesia [8,9]. This minimally invasive approach can be applied in an outpatient setting, thus avoiding the need for general anesthesia and protective tracheotomy.

The purpose of our study was to evaluate the diagnostic performance of USGTCB of laryngo-hypopharyngeal masses suspicious for malignancy in larger cohort of patients showing contraindications to biopsy via microlaryngoscopy under general anesthesia, and to investigate whether USGTCB is accurate for both untreated masses and suspected recurrence of squamous cell carcinoma (SCC).

#### 2. Materials and methods

#### 2.1. Patients

After an initial pilot study demonstrating the feasibility and safety of the procedure, which has been already published elsewhere [8], USTGCB was implemented as a standard of care at our Institute. Nonetheless our ethical committee still issued a formal letter of approval for our study.

From August 2004 to July 2014 we enrolled patients with an untreated bulky laryngo-hypopharyngeal mass suspicious for malignancy, or for a suspected recurrence of a previously treated SCC (endoscopic laser surgery, radiotherapy alone or combined with endoscopic laser surgery orchemotherapy). We enrolled patients who met the following criteria: (1) stress dyspnea due to airway stenosis, which would have required a protective tracheotomy for a microlaryngoscopy under general anesthesia; (2) signs indicating difficult intubation or (3) relative contraindication to general anesthesia. To be considered eligible for USGTCB, patients underwent a loco-regional work-up including: (1) examination by fiber-optic laryngoscopy; (2) CT and/or MRI examination of the head and neck: (3) preliminary ultrasound exam in order to be sure that the mass was detectable and a safe path for the needle to approach the lesion could be identified. After the loco-regional work-up the following exclusion criteria were applied: patients with cT1 disease or superficial glottic lesions, cT2 masses not detectable by ultrasound, patients with massively ossified thyroid cartilage, abnormal coagulation profiles (assessed by prothrombin

activity, partial thromboplastin timeand international normalized ratio).

All patients signed a written informed ad-hoc consent form, which clearly outlined the procedure along with its implications for patient care.

Forty of the 78 patients have been previously reported [9]. The prior article dealt with development of 36 procedures whereas in this manuscript we report 68 procedures. Data analysis is implemented with the assessment of performance separately for procedures in untreated masses and in suspected recurrences of SCC, and in the subgroup of suspected recurrences of SCC separately for patients who underwent previous radiotherapy (alone or combined with other treatments) and patients who underwent endoscopic laser surgery (see Section 2.3).

#### 2.2. Biopsy technique

All biopsies were performed with a free-hand technique by a single radiologist with 10 years' experience in free-hand US-guided biopsies. US exams were performed on one of two machines: Sequoia 512 USG using a multifrequency linear 15L9W probe (Siemens, Erlangen, Germany) and on a LogicQ9 machine using a multifrequency linear 15L6W (General Electrics systems, Milwaukee, USA). The procedure was performed with the patient supine on a bed reclined at 35° and with the head hyperextended.

At the preliminary US assessment the operator identified the path for the needle and vessels adjacent to the mass by color-Doppler interrogation. Generally the masses were approached as follows: (1) through the free edge of the thyroid cartilage or through the thyrohyoid membrane for hypopharyngeal lesions (Fig. 1) through the thyrohyoid membrane for masses located supraglottically or in the region of the aryepiglottic and pharyn-goepiglottic folds (Fig. 2); (3) through the cricothyroid membrane or through non-calcified thyroid cartilage for glottic masses (Fig. 3); (4) through the cricothyroid membrane for subglottic masses (Fig. 4). If the mass infiltrated the thyroid cartilage biopsy was performed through it (Fig. 5).

After the preliminary US assessment, the skin was disinfected with antiseptic and covered with a sterile drape. An 18-gauge cannula was placed in the antecubital vein. The local anesthesia (10 ml of 2% carbocaine) was performed in the tissues along the hypothesized path of the needle as well as in the subcutaneous tissues, using a 22-gauge spinal needle (Terumo Medical Corporation, Tokyo, Japan). USGTCB were performed with 16- or 18-gauge springloaded biopsy needle (Biopsy-bell, Mirandola, Italy) inserted in line with the long axis of the ultrasound probe. Tissue cores were placed in 10% phosphate-buffered formalin for 12 h, paraffin embedded and sectioned at  $4 \,\mu$ m, followed by standard stain with hematoxylin and eosin (H & E); when required, an immunohistochemical

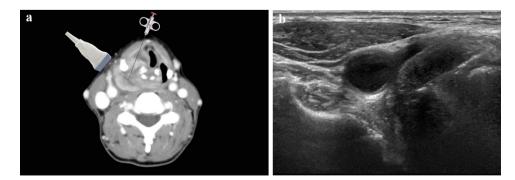


Fig. 1. A 44 years-old woman with an untreated SCC in the hypopharyngeal region.

(a) Axial contrast-enhanced CT shows a mass in the right piriform sinus. (b) USGTCB is performed introducing the needle through the free edge of the thyroid cartilage. *Note*: the probe and the needle are superimposed.

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