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## **Quality Indicators: Measurement and Predictors in Head and Neck Cancer Free Flap Patients**

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From Otolaryngology, February 2018

#### **Abstract**

<u>Objective</u>. To determine the predictors of length of stay (LOS), readmission within 30 days, and unplanned return to the operating room (OR) within 30 days in head and neck free flap patients.

Study Design. Case series with chart review. Setting. Tertiary academic cancer hospital.

<u>Subjects and Methods</u>. All head and neck free flap patients at The Ohio State University (OSU, 2006-2012) were assessed. Multivariable logistic regression to assess the impact of patient factors, flap and wound factors, and intraoperative factors on the aforementioned quality metric outcomes.

Results. In total, 515 patients were identified, of whom 66% had oral cavity cancers, 33% had recurrent tumors, and 28% underwent primary radiotherapy. Of the patients, 31.5% had a LOS greater than 9 days, predicted by longer operative time, oral cavity and pharyngeal tumor sites, blood transfusion, diabetes mellitus, and any complication. A total of 12.6% of patients were readmitted within 30 days predicted by absent OSU preoperative assessment clinic attendance and any complication, and 14.8% of patients had an unplanned OR return predicted by advanced age.

<u>Conclusions</u>. When assessing quality metrics, adjustment for the complexity involved in managing patients with head and neck cancer with a high comorbidity index, clean contaminated wounds, and a high degree of primary radiotherapy is important. Patients seen in a preoperative assessment clinic had a lower risk of readmission postoperatively, and this should be recommended for all head and neck free flap patients. Quality improvement projects should focus on predictors and prevention of complications as this was the number one predictor of both increased length of stay and readmission.



#### **Summary**

The focus in the early years of quality improvement has been on outcome measures, which are the most easily tracked and are considered the "bottom line." Head and neck free flap reconstructive surgery quality metrics have not been thoroughly examined despite having similar mortality and complication rates to other high-risk procedures that have been studied.

In this study, LOS was predicted by OR time, blood transfusion, mucosal tumor site, history of diabetes, and the development of any complication (see Table 3). Readmission was predicted by lack of preoperative assessment consultation and by any major or minor complication. Return to OR within 30 days was only predicted by advanced age.

#### **Strengths**

- The first comprehensive multivariable analysis to assess preoperative, intraoperative, and postoperative predictors of LOS in head and neck reconstructive surge
- This paper provides several actionable items to study using quality improvement methodology to improve outcomes in head and neck patients who undergo free tissue reconstruction. Identifying these factors is critical in implementing pay-for-performance models that allow for appropriate risk adjustment. Furthermore, having baseline metric data is useful moving forward as quality improvement interventions are designed to try to improve these rates.

#### Weaknesses

- smaller N compared to national databases (though these tend to be less granular)
- single institution

Predictor	LOS ≤9 Days (n = 353)	LOS >9 Days (n = 162)	Univariable Odds Ratio (SE)	Univariable P Value	Multivariable Odds Ratio (95% CI)	Multivariable P Value
Age, mean (SD), y	59.6 (12.9)	61.3 (12.7)	0.011 (0.007)	.16		
OR time, mean (SD), min	521.4 (124.5)	594.6 (128.4)	0.0044 (0.0008)	<.01	1.004 (1.002-1.006)	<.01
EBL >500 cc	80 (22.7)	54 (33.3)	0.53 (0.21)	.01		
Crystalloid given intraoperatively, mean (SD)	5267.6 (1654.4)	6031.8 (2430.4)	0.00020 (0.00005)	<.01		
CCI, mean (SD)	4.8 (2.3)	5.3 (2.3)	0.092 (0.041)	.02		
Male sex	228 (64.6)	113 (69.8)	0.23 (0.20)	.25		
Recurrent tumor Tumor T-classification	108 (30.6)	62 (38.3)	0.34 (0.20)	.09		
Other	100 (28.3)	30 (18.5)	Reference			
Mucosal SCC, T1-T2	83 (23.5)	27 (16.7)	0.08 (0.30)	.79		
Mucosal SCC, T3-T4 Tumor N-classification	170 (48.2)	105 (64.8)	0.72 (0.24)	<.01		
N0	211 (59.8)	89 (54.9)	Reference			
NI-N2a	73 (20.7)	34 (21.0)	0.10 (0.24)	.68		
N2b-N3	69 (19.5)	39 (24.1)	0.29 (0.24)	.22		
Tumor site						< 0.01
Other	66 (18.7)	10 (6.2)	Reference		Reference	
Oral cavity and maxilla	227 (64.3)	111 (68.5)	1.17 (0.36)	<.01	4.19 (1.81-9.72)	
Hypo/oropharynx	60 (17.0)	41 (25.3)	1.51 (0.40)	<.01	4.71 (1.89-11.83)	
Type of free flap						
Soft tissue	246 (69.7)	99 (61.1)	-0.38 (0.20)	.06		
Bone containing	107 (30.3)	63 (38.9)	Reference			
Blood transfused	86 (24.6)	74 (45.7)	0.96 (0.20)	<.01	2.31 (1.45-3.70)	<.01
Alcoholism	226 (64.0)	95 (58.6)	-0.23 (0.19)	.24		
Preoperative RT/CCRT	87 (24.6)	58 (35.8)	0.53 (0.21)	<.01		
Preoperative OPAC	310 (93.9)	145 (93.5)	-0.07 (0.40)	.87		
Smoking history						
Never	84 (23.8)	29 (17.9)	Reference			
Yes, current	138 (39.1)	62 (38.3)	0.26 (0.26)	.32		
Yes, quit in past	131 (37.1)	71 (43.8)	0.45 (0.26)	.08		
History of diabetes	48 (13.6)	36 (22.2)	0.60 (0.24)	.01	1.78 (1.01-3.12)	.04
History of heart disease	74 (21.0)	48 (29.6)	0.46 (0.22)	.03		
History of pulmonary disease	166 (47.0)	93 (57.4)	0.42 (0.19)	.03		
History of hypothyroidism	41 (11.6)	28 (17.3)	0.46 (0.27)	.08		
History of malnutrition	62 (17.6)	41 (25.3)	0.46 (0.23)	.04		
Any complication	139 (39.4)	139 (85.8)	2.23 (0.25)	<.01	7.66 (4.59-12.77)	<.01

Abbreviations: CCI, Charlson comorbidity index; CI, confidence interval; EBL, estimated blood loss; LOS, length of stay; OPAC, Ohio State University preoperative assessment clinic; OR, operating room; RT/CCRT, radiotherapy/concurrent chemoradiotherapy; SCC, squamous cell carcinoma; SD, standard deviation; SE, standard error.



## Positron emission tomography/computed tomography after primary transoral robotic surgery for oropharyngeal squamous cell carcinoma

Hobelmann K, Luginbuhl A, Bar-Ad V, Keane W, Curry J, Cognetti D.

From Laryngoscope, September 2017

**Objectives/Hypothesis**: To assess the first post-treatment positron emission tomography/computed tomography (PET/CT) in prediction of disease-free survival after primary transoral robotic surgery (TORS) for oropharyngeal squamous cell carcinoma (OPSCC) with or without adjuvant chemoradiation.

Study Design: Retrospective review.

**Methods**: Ninety-five patients with OPSCC treated with primary TORS from 2010 to 2014 at a single tertiary academic center were evaluated with PET/CT. Imaging was performed between 2 and 7 months after completing all treatment. Radiology findings were categorized as 1) negative, noting either complete resolution of foci without evidence of disease or anatomical changes likely attributed to treatment; 2) equivocal, noting equal likelihood of malignancy versus treatment-related changes; or 3) positive, noting either findings concerning for malignancy or new hyperactivity not attributed to treatment related changes. The median follow-up time was 31 months (range, 23–63 months). Recurrence was defined as biopsy proven invasive malignancy or clinical suspicion sufficient to initiate treatment occurring within 3 years of the completion of all treatment.

**Results**: Of 95 total patients with at least 2 years of follow-up records, 26 had positive post-treatment PET/CT results, with five experiencing actual recurrences. Of 69 patients with negative post-treatment PET/CT results, none experienced recurrences. These results indicate a sensitivity of 100%, specificity of 77%, positive predictive value of 19%, and negative predictive value of 100%.

**Conclusions**: A majority of TORS patients (73%) will have a negative first post-treatment PET/CT. A single negative post-treatment PET/CT is strongly correlated with 2-year disease-free survival in patients treated with primary TORS and may warrant decreased surveillance imaging.

#### **Summary**

- 95 patients with naïve oropharyngeal carcinoma (94% tonsil and base of tongue, 82% HPV +) treated with TORS with/without adjuvant radiation (27%) or chemoradiation (55%) with a PET/CT in the first 2-7 months after finishing the treatment and followed up to 3 years. 90 patients classified as T1-2and 80 N+.
- Evaluation of PET/CT as positive, equivocal or negative with specific criteria and clinical or pathologic assessment of suspicious cases. Imaging was made after a mean time of 14 weeks.
- Recurrence rate at 2 years was 5.3%
- Sensitivity was high (100%) but specificity was low (77%). Positive predictive value was low (19%)

#### Strengths

- Specific criteria for selection and assessment of PET/CT results
- Important number of patients with close follow-up
- Low rate of recurrent which means good selection for TORS
- A negative PET/CT currently discards the diagnosis of recurrence

#### Weaknesses

- There is not information about who made the evaluation of PET/CT, if original assessment was reevaluated with blind observers and the interobserver agreement rate.
- Retrospective assessment of results
- The low number of recurrences makes difficult to accept the high sensitivity
- A low positive predictive value indicates that a positive/equivocal result of PET/CT always have to be confirmed with clinical/pathology evaluation



## The Effect of Frailty on Short-Term Outcomes After Head and Neck Cancer Surgery

Nieman, C.; Pitman, K.; Tufaro, A.; Eisele, D.; Frick, K.; Gourin, C.

From Laryngoscope, January 2018

#### Abstract

**Objective**: To determine the relationship between frailty and comorbidity, in-hospital mortality, postoperative complications, length of hospital stay (LOS), and costs in head and neck cancer (HNCA) surgery.

**Study Design**: Cross-sectional analysis.

**Methods**: Discharge data from the Nationwide Inpatient Sample for 159,301 patients who underwent ablative surgery for a malignant oral cavity, laryngeal, hypopharyngeal, or oropharyngeal neoplasm in 2001 to 2010 was analyzed using crosstabulations and multivariate regression modeling. Frailty was defined based on frailty-defining diagnosis clusters from the Johns Hopkins Adjusted Clinical Groups frailty-defining diagnosis indicator.

**Results**: Frailty was identified in 7.4% of patients and was significantly associated with advanced comorbidity (odds ratio [OR] 5 1.5[1.3–1.8]), Medicaid (OR 5 1.5[1.3–1.8]), major procedures (OR 5 1.6[1.4–1.8]), flap reconstruction (OR 5 1.7[1.3–2.1]), high-volume hospitals (OR 5 0.7[0.5–1.0]), discharge to a short-term facility (OR 5 4.4[2.9–6.7]), or other facility (OR 5 5.4[4.5–6.6]). Frailty was a significant predictor of in-hospital death (OR 5 1.6[1.1–2.4]), postoperative surgical complications (OR 5 2.0[1.7–2.3]), acute medical complications (OR 5 3.9[3.2–4.9]), increased LOS (mean, 4.9 days), and increased mean incremental costs (\$11,839), and was associated with higher odds of surgical complications and increased costs than advanced comorbidity. There was a significant interaction between frailty and comorbidity for acute medical complications and length of hospitalization, with a synergistic effect on the odds of medical complications and LOS in patients with comorbidity who were also frail.

**Conclusion**: Frailty is an independent predictor of postoperative morbidity, mortality, LOS, and costs in HNCA surgery patients, and has a synergistic interaction with comorbidity that is associated with an increased likelihood of medical complications and greater LOS in patients with comorbidity who are also frail.

#### **Summary**

- An evaluation of the Nationwide Inpatient Sample with more than 150.000 registries.
- Head and neck cancer patients who underwent a surgical procedure
- Specific definition of frailty with a method designed for administrative databases
- Outcomes as mortality, complications, length of stay and costs were included.
- The frequency of frailty was 7.4%, higher for larynx/hypopharynx tumors, older people and patients with comorbid conditions. Frail people were more frequently black, from public security and admitted urgently, underwent complex surgical and reconstructive procedures and were discharged to assisted facilities.
- Frailty was independently associated with a higher rate of postoperative complications, in hospital death, longer length of stay and higher care costs. The risk was higher than comorbidity only in postoperative surgical complications. There is interaction between comorbidity and frailty, which increases the risk 2-3 times.



#### **Strengths**

- Big database information from multiple sources that represent adequately the target population
- A multivariate analysis with adjustment for demographic and clinical variables

#### Weaknesses

- Cross sectional analysis of an administrative database which can disregard clinical important variables
- Lack of data about staging of the tumor.
- Impossibility to know if there were an intervention that modified the basal risk established by frailty.
- Individual risk of frailty can be under or overestimated with administrative data

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## <u>Surgical Treatment for Early Stage Glottic Carcinoma with Involvement of</u> the Anterior Commissure

Philipp Wolber, MD, MSc, David Schwarz, MD, Thoralf Stange, MD, Magdalene Ortmann, PhD, Matthias Balk, MD, Andreas Anagiotos, MD, and Antoniu-Oreste Gostian, MD

From Otolaryngology - Head & Neck Surgery, February 2018

#### **Abstract**

<u>Objective</u>. Assessment of the value of transoral laser microsurgery (TLM) compared with open surgery (OS) for early stage squamous cell carcinoma of the glottic larynx with special regard to involvement of the anterior commissure (AC).

Study Design. Case series with chart review. Setting. Tertiary care otolaryngology clinic.

<u>Subjects and Methods</u>. Review of clinicopathological data of all patients with previously untreated T1a, T1b, and T2 glottic squamous cell carcinoma of the larynx who were consecutively enrolled over a 10-year period (January 1, 1992, to December 31, 2002).

Results. Local recurrence rate was 20.4% (10 of 49) for TLM and 10.7% (3 of 28) for OS. Comparison of the TLM and OS groups regarding local recurrence rates revealed a significant difference only for tumors invading the AC (P = .046). Within the TLM group, tumors with involvement of the AC showed a significantly higher recurrence rate (38.1%; 8 of 21) compared with tumors without involvement of the AC (7.1%; 2 of 28; P = .008). In the OS group, involvement of the AC revealed no significant difference (P = .45). The overall survival in both groups was comparable in both groups (TLM, 93.9%; OS, 89.3%; P = .47).

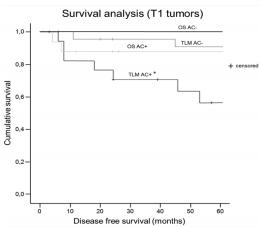
<u>Conclusion</u>. TLM and OS are equally effective surgical treatments for early stage glottic cancer without involvement of the AC, with selection of treatment based on pretreatment endoscopy. However, TLM is associated with less morbidity. In case of invasion of the AC, OS yields lower recurrence rates.

#### **Summary**



This retrospective study from the University of Cologne compared transoral laser microsurgery to open surgery for early stage glottic cancer with focused analysis on anterior commissure involvement (n=77). Primary outcomes include 5-Year Overall Survival, 5-Year Disease-Free Survival, and Local Recurrence Rates.

- The overall 5-year disease-free survival in the TLM group rate was 77.6%
  - AC+ tumors had a significantly poorer 5-year disease-free survival rate compared to AC-tumors (57.1% vs. 92.9%; P < .01).
  - This same significant difference was also seen in the T1a subgrouping
- The overall local recurrence rate in the TLM group was 20.4%.
  - AC+ tumors had a significantly higher local recurrence rate compare with AC- tumors (38.1% vs 7.1%; P < .01).
- The local recurrence rates in the OS group were significantly lower than in the TLM group (38.1% vs 12.5%; P = .04).
- In addition, compared with TLM, recurrence rates of T1a AC+ tumors were also significantly in favor of the OS approach (41.2% vs 7.7%; P = .04).
- TLM and OS both appear to be similarly effective surgical options for treatment of early stage glottic carcinoma without AC involvement



**Figure 4.** Analysis of the disease-free survival of T1 tumors with respect to surgical resection technique and AC involvement. AC+, involvement of anterior commissure; AC-, no involvement of anterior commissure; OS, open surgery; TLM, transoral laser microsurgery. \*P < .05 compared with AC- by TLM.

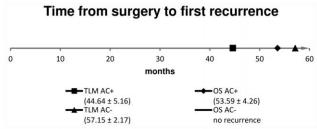


Figure 3. Time from surgery to first recurrence for tumors staged T1. AC+, involvement of anterior commissure; AC-, no involvement of anterior commissure; OS, open surgery; TLM, transoral laser microsurgery.



- 5 year survival data. Excellent length of followup
- This study points out the decisive influence of the invasion of the AC that can be very difficult to determine. The authors indicate that a thorough direct diagnostic laryngoscopy by an experienced surgeon can be considered of outmost importance.

#### Weaknesses

- The presented study is limited due to the selection bias derived from the lack of randomization that is inherent in these types of studies. This particularly refers to the inevitable bias that derives from the selection of the patients based on the criteria applied for the indication toward the respective surgical technique.
- In addition, interpretation of the oncologic results should take into account that statistical power is generally reduced after stratification of subgroups, although the total number of 77 patients in this study is similar to other studies.

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# <u>Insights into the Management of Papillary Microcarcinoma of the Thyroid</u>

Miyauchi A, Ito Y, Oda H.

From Thyroid, January 2018
Abstract

**Background:** Rapid increases in the incidence of thyroid carcinoma with stable mortality rates from thyroid carcinoma have been reported from many countries, and these increases are thought to be due mostly to the increased detection of small papillary thyroid carcinomas (PTCs), including papillary microcarcinomas (PMCs;

i.e., PTCs <10 mm). Some researchers have suggested that small PTCs have been over diagnosed and over treated. In Japan, the active surveillance of patients with low-risk PMCs was initiated by Kuma Hospital (1993) and Tokyo's Cancer Institute Hospital (1995) based on the extremely higher incidences of both latent thyroid carcinomas in autopsy studies and small PTCs detected in mass screening studies using ultrasound examinations compared to the prevalence of clinical thyroid carcinomas.

**Methods:** The above two institutions' data are summarized regarding the active surveillance of low-risk PMCs, and future prospects for their management are discussed.

**Results:** At 10-year observations in the Kuma Hospital series of 1235 patients, only 8% and 3.8% of the PMC patients showed size enlargement by >3mm and the novel appearance of node metastasis, respectively. In contrast to clinical PTC, PMCs are most unlikely to grow in older patients (>60 years). In the Kuma Hospital series, the 974 patients who underwent immediate surgery had significantly higher incidences of unfavorable events than the 1179 patients who chose active surveillance. The total cost of immediate surgery, including the costs for salvage surgery and postoperative care for 10 years, was 4.1 times the total cost of 10-year management by active surveillance. Only 8% of the 51 PMC patients showed tumor enlargement during pregnancy, and the rescue surgeries after delivery were successful. In the Cancer Institute Hospital series of 230 patients with 300 lesions, only 7% and 1% of the patients showed size enlargement and novel node metastasis, respectively, and that institution's analysis also revealed that macroscopic or rim calcification and poor vascularity were correlated with non-progressing disease. In both series, none of the patients who underwent rescue surgery after progression signs were detected showed significant recurrence or died of PTC.



**Conclusion:** Active surveillance of low-risk PMC can be the first-line management. Interestingly, older patients with low-risk PMCs are the best candidates for active surveillance.

#### **Summary:**

 Patients with low risk PMC's who undergo active surveillance have a low risk of primary tumor size progression and the development of novel nodal disease, but this is age dependent, with the lowest rates of progression seen in patients over 60 years of age

#### Clinical high-risk features:

- N1 (may present on imaging studies) or M1 (very rare)
- Signs or symptoms of invasion to the recurrent laryngeal nerve
- or trachea
- High-grade malignancy on cytology (very rare)
- Cases showing progression signs such as size enlargement or a novel appearance of lymph node metastasis during active surveillance

### Features unsuitable for observation, although it is unclear whether they are associated with biological aggressiveness:

- Imaging studies indicate that the tumor may invade the trachea or recurrent laryngeal nerve
- Rescue surgery is done when tumors grow >/= 3mm or when novel nodal disease presents on US f/u (one US at 6 months, then yearly thereafter)
- Rescue surgery in those that progressed was successful with no further signs of progression or death
- Active surveillance and immediate surgery groups had equal oncologic outcomes but immediate surgery resulted in a higher incidence of unfavorable results (surgical complications) and was 4 times more costly

#### **Strengths:**

- Large study, nearly 1500 patients followed carefully since 1995
- Robust analysis

#### Weaknesses:

- No correlation of progression to molecular markers: data wasn't available
- Different thresholds for using FNA of thyroid nodules. The authors used >/= 5mm, the 2015 ATA guidelines recommend for >/= 1.0 cm with high suspicion ultrasonic pattern

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