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Outcomes and Predictive Value of Post-adjuvant Therapy PET/CT for Locally Advanced Oral Squamous Cell Carcinoma

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Objectives/Hypothesis: For locally advanced oral squamous cell carcinoma (OSCC) treated by surgery and adjuvant therapy, consensus has yet to be reached on whether the optimal time to initiate surveillance positron emission tomography/computed tomography (PET/CT) scan is before or after adjuvant therapy. In this study, we characterize the utility of PET/CT scans obtained 3 months after adjuvant therapy.

Study Design: PET/CT scans were obtained for 220 patients with stage III, IVA, or IVB OSCC who underwent resection followed by adjuvant radiotherapy or chemoradiotherapy.

Methods: Using the Neck Imaging Reporting and Data System, PET/CT scans were dichotomized as suspicious (primary or neck category ≥3, or distant lesion present) versus nonsuspicious. We then computed differences in locoregional progression, distant progression, and overall survival; positive predictive value (PPV), negative predictive value (NPV), sensitivity, and specificity; and success rate of salvage.

Results: Sixty-seven patients (30%) had suspicious PET/CT scans, which were significantly associated with local failure (hazard ratio [HR] 14.0, 95% confidence interval [CI] 7.3–26.6), distant failure (HR 18.4, 95% CI 9.6–35.3), and poorer overall survival (HR 9.5, 95% CI 5.0–17.9). Overall PPV, locoregional PPV, NPV, sensitivity, and specificity were 85%, 79%, 73%, 58%, and 92%, respectively. Among those with biopsy-confirmed progression, 37 patients (65%) underwent salvage therapy; four (11%) were without evidence of disease at last follow-up.

Conclusions: For locally advanced OSCC, PET/CT scan 3 months after adjuvant therapy is strongly predictive of disease recurrence and survival, demonstrating improved performance over postoperative imaging in previous studies. Following a suspicious post-adjuvant therapy PET/CT scan, cure of locoregional recurrence is possible but unlikely.

Key Words: Oral squamous cell carcinoma, PET/CT scan, surveillance imaging, adjuvant radiotherapy.

Level of Evidence: 4

INTRODUCTION

In 2019, there will be approximately 35 thousand new oral cavity cancers in the United States, and 7 thousand Americans will die as a result of oral cavity cancer.1 Positron emission tomography/computed tomography (PET/CT) has become an essential tool for evaluating, planning treatment for, and tracking treatment response in patients with oral cavity cancer. PET/CT is considered a first-line imaging modality to stage patients;2 detect metastatic disease;3,4 and identify second primary cancers, which tend to be 10 to 30 times more common among head and neck cancer patients than the general population.4,5 By integrating anatomic and biologic tumor information, PET/CT also allows more accurate tailoring of intensity-modulated radiotherapy (IMRT) volumes and dosage to disease sites compared to anatomic imaging alone.6,7 Furthermore, PET/CT has been shown to be more effective than CT and magnetic resonance imaging at monitoring treatment response as well as disease recurrence.8,9

Standard of care for locally advanced oral squamous cell carcinoma (OSCC) is surgery followed by adjuvant radiotherapy (aRT) or adjuvant chemoradiotherapy (aCRT).10 Recurrence is estimated to be 50% to 60% among patients with resectable disease and is a major cause of mortality.11,12 However, due to difficulties distinguishing posttreatment inflammatory changes from hypermetabolic tumor cells on PET/CT,13 consensus has yet to be reached on whether the first surveillance PET/CT scan should be scheduled between surgery and adjuvant therapy or after adjuvant therapy. A separate issue is when to obtain the post-adjuvant therapy
PET/CT scan. Disease recurrence should be detected as early as possible to prevent significant progression and delay salvage treatment opportunities. On the other hand, several weeks are needed for aRT and adjuvant chemoradiotherapy (aCRT) to display their full effect as well as for treatment-related inflammation to recede on PET/CT imaging. For example, waiting at least 12 weeks to perform surveillance PET/CT has been shown to absolve the need for diagnostic neck dissection in the setting of a negative neck scan result.14

National Comprehensive Cancer Network guidelines recommend that PET/CT scan is performed within 6 months after adjuvant therapy.15,16 Recent studies sought to demonstrate the utility of postoperative scans in altering management prior to adjuvant therapy.17–19 In the Mayo Clinic experience,17 positive predictive value of postoperative PET/CT scan for identifying locoregional disease was only 27% (3 of 11 patients) among a variety of head and neck cancers. The Memorial Sloan Kettering series19 reported 38% (5 of 13 patients) with OSCCs had biopsy-proven locoregional disease following a concerning postoperative PET/CT scan. The Taiwan study18 mentioned that all seven of seven patients with recurrence of OSCC before adjuvant therapy were detected by PET/CT scan; however, the study did not specify the total number of positive scans. Most of the studies’ ensuing management changes also had the potential to be guided by surgical pathology results and interval clinical findings without additional imaging. Moreover, the reported differences in locoregional failure, distant failure, and overall survival between patients with positive versus negative postoperative PET/CT scans were either not statistically significant or were small in magnitude.

In this study, we report the predictive value and prognostic stratification of PET/CT scan scheduled for 3 months after aRT with or without chemotherapy. To our knowledge, this is the largest study of surveillance PET/CT for locally advanced OSCC and the first to apply standardized scan classification criteria, the American College of Radiology’s (ACR) Head and Neck Imaging Reporting and Data System (NI-RADS),20 to exclusively locally advanced OSCC. Previous studies usually denoted “positive” or “negative” reads without further elaboration,17–19 or they pooled analysis across all disease stages.21,22 Outcomes after initial PET/CT scan were also followed to characterize the cure rate of confirmed recurrence and the role of subsequent surveillance imaging under various scenarios.

**MATERIALS AND METHODS**

**Patient Population**

The medical records of 805 patients with pathologically confirmed OSCC consecutively resected between January 1, 2010, and December 31, 2017, at Winship Cancer Institute of Emory University (Atlanta, GA) were retrieved for review. Ethical approval was granted by our institution’s internal review board (IRB000108094).

One hundred thirty-two patients were excluded for having received previous treatment outside of Winship Cancer Institute prior to January 1, 2010, or for another head and neck cancer with invasion into the oral cavity. Two hundred eighty-three patients were excluded for not having presented with locally advanced disease, defined as stage III, IVA, or IVB according to the American Joint Committee on Cancer (AJCC) Staging Manual 7th edition.23 Of the remaining 390 patients, 220 underwent surgery followed by aRT or aCRT with curative intent as recommended by a multidisciplinary tumor board. All 220 patients received surveillance PET/CT scan after adjuvant therapy.

**Treatment Approach**

Primary treatment was surgical, with adjuvant IMRT usually provided for primary OSCCs of the oral tongue larger than 1 cm, and other OSCCs with ≥T2 disease, ≥N1 disease, perineural invasion, or lymphovascular invasion. aCRT was recommended for patients with extranodal spread or surgical margins of ≥5 mm. All patients were scheduled to return for follow-up and PET/CT scan around 3 months after end of adjuvant therapy and then for CT scans of the neck and chest every 6 months for 2 years. Subsequent CT scans of the neck and chest were scheduled once a year for up to 5 years after end of treatment. Concerning findings on interval clinical exam or CT scans were worked up with PET/CT scan and biopsy as necessary. Locoregional and distant recurrences after 5 years are expected to be unlikely.24

**Imaging Studies and Interpretation**

All imaging was performed on GE Healthcare (GE Healthcare, Chicago, IL) PET/CT scanners. Patients fasted for at least 6 hours prior to scan, and serum glucose concentration was measured immediately before 18F-fluorodeoxyglucose (FDG) administration. The examination was deferred if serum glucose concentration was above 200 mg/dL. One hour after intravenous administration of 10 to 14 mCi FDG, combined PET/CT scan from the skull vertex through the midthigh was obtained, along with a dedicated CT scan of the neck and including IV contrast whenever possible. For each patient, 110 mL of intravenous iopamidol contrast (Isovue-370, Bristol-Myers Squibb, Princeton, NJ) was used; 55 mL was first injected at a rate of 2.5 mL per second, followed by a 40 second delay and another 55 mL at the same rate. Total scan delay was 90 seconds, including a pre- and postcontrast saline bolus. Contiguous axial images from the frontal sinuses through the mediastinum were acquired with the following settings: 1.25 mm slice thickness, pitch 0.984:1, 0.7 second gantry rotation time, 25 cm field of view, 120 kVP, and Smart mA with a noise index of 13.78. Reformatted images at 2.5 mm slice thickness in the axial planes, as well as 3 mm sagittal and coronal reformations, were then stored.

All scans were reviewed by both a neuroradiologist and a nuclear medicine physician. The primary tumor site and the neck were each assigned NI-RADS category 1 through 4. Prior clinical history and endoscopic notes were carefully reviewed. Comparison to baseline imaging, including pretreatment FDG avidity when available, was also made for all patients. The subjective interpretation of the PET/CT scan included evaluation of disease on both the fused PET images and the CT. As defined by ACR NI-RADS,20 factors incorporated into the assessment of lesions include borders, FDG avidity, morphology, and enhancement pattern. Scans interpreted as NI-RADS category ≥3 at the primary tumor site or neck or found to have increased FDG avidity at any distant site (below level of the clavicle) were deemed highly suspicious, warranting further follow-up and biopsy. All other scan results were dichotomized as negative in this study.

Laryngoscope 130: December 2020 Qian et al.: Surveillance PET/CT Scan for Locally Advanced OSCC
**Statistical Analysis**

Data were analyzed from January through March 2019. Associations between patient characteristics and PET/CT scan result were computed using t test for continuous variables and χ² test for categorical variables. Sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) were computed across all patients as well as across subsets of patients whose times to scan fell within sliding 4-week windows. Differences in locoregional progression-free survival (PFS), distant PFS, and overall survival (OS) were computed for patients with suspicious versus nonsuspicious PET/CT scans using Cox proportional hazards regression. Progression events were recorded at the first instance of an abnormal finding on physical exam or scan, which then led to a confirmatory biopsy or death. Overall survival events were recorded at time of last known follow-up. All analyses were performed in R version 3.4.2 (https://www.r-project.org/).

**RESULTS**

**Patient Characteristics**

A total of 220 patients met study inclusion criteria (Table I). The most common tumor sites were oral tongue, floor of mouth, and gingiva. Sixty-seven patients received a suspicious PET/CT scan result after adjuvant therapy, whereas 153 patients did not. Most of the patients in this study (76%) had stage IVA disease, consistent with an expected frequency of about 70% among locally advanced OSCC at diagnosis. Not surprisingly, more advanced nodal stage and extracapsular extension were associated with having a suspicious PET/CT scan because these features confer higher risk of recurrence in general. Sex, age, primary tumor size, AJCC stage 7th edition, oral cavity location, perineural invasion (PNI), lymphovascular invasion (LVI), and margins were not associated with scan result. Patients with nonsuspicious scans had much longer follow-up because they survived for a greater period of time.

**Disease Progression and Overall Survival**

As shown in Figure 1, a suspicious PET/CT scan result was associated with significantly worse PFS (hazard ratio [HR] 11.9, 95% confidence interval [CI] 7.7–18.5, \( P = 1.67 \times 10^{-23} \)) and OS (HR 9.5, 95% CI 5.0–17.9, \( P = 3.94 \times 10^{-12} \)). These differences persist even on stratified analysis of stage III, stage IVA, and stage IVB patients (see Supporting Information Figure S1), ensuring the stage IVA majority of patients did not skew findings. The difference in PFS can also be partitioned into significant differences in both locoregional PFS (HR 14.0, 95% CI 7.3–26.6, \( P = 9.11 \times 10^{-16} \)) and distant PFS (HR 18.4, 95% CI 9.6–35.3, \( P = 1.40 \times 10^{-18} \)). Among patients with suspicious PET/CT scans, observed events mostly occurred within the first 2 years of completing adjuvant therapy. For patients with NI-RADS category ≥2 scans, events were more evenly distributed over time. In line with previous studies, the most common sites of disease recurrence were locoregional and intrapulmonary.

Redefining suspicious as NI-RADS category ≥2 did not yield differences in PFS and OS between patients with suspicious versus nonsuspicious PET/CT scans in every
disease stage (see Supporting Information Table S1); thus, this cutoff was not further explored.

**PET/CT Accuracy**

Due to right-censoring, sensitivity (58%), specificity (92%), PPV (85%), and NPV (73%) are bounded estimates rather than precise derivations. PPV is 79% for locoregional recurrence and 91% for distant recurrence (Table II). Absence of disease is confirmed only for as long as a patient is followed; thus, sensitivity and NPV should be considered overestimates. Presence of disease can be missed after loss to follow-up; therefore, specificity and PPV should be considered underestimates.

As expected, not every patient set to receive their first surveillance PET/CT scan at 3 months after adjuvant therapy underwent the scan as scheduled. Figure 2 plots PPV, NPV, sensitivity, and specificity as functions of time subsequent to the end of adjuvant therapy over 4-week moving windows. NPV was optimized between 10 and 16 weeks,
whereas PPV and specificity were optimized at the tails. Eighty-two percent of patients received scans between 2 and 4 months after adjuvant therapy. The remaining patients who were rescheduled for scans far before or after 3 months each had reasons that sway detection pretest probability. Patients who were scanned significantly sooner than planned either had a sufficiently worrisome physical exam finding in clinic to prompt an earlier scan or required hospitalization and underwent PET/CT scan as part of an inpatient workup. Patients scanned much later were delayed by treatment for other issues unrelated to cancer, difficulties with insurance approval, challenges with travel to appointments, or personal indecision with end-of-life goals.

### Outcomes after PET/CT Scan

Subsequent outcomes following suspicious and nonsuspicious results of the initial surveillance PET/CT scan are depicted in Figure 3 in both aggregate and stratified by OSCC site. Rates of positive biopsy following suspicious PET/CT were similar across sites. Overall, 57 of the 67 patients (85%) with suspicious PET/CT scans had biopsy-confirmed disease recurrence; 37 patients (65%) were then re-treated with curative intent (i.e., excludes hospice, palliative chemotherapy, palliative radiotherapy). Of these, four patients (11%) were found be without evidence of disease at most recent follow-up. Three of these potentially salvaged patients (75%) had no clinical sign of recurrence prior to surveillance imaging, whereas one had a concerning physical exam. More broadly, 46 of the 57 patients (81%) with biopsy-confirmed disease

<table>
<thead>
<tr>
<th>Suspicious Scan</th>
<th>Locoregional Site</th>
<th>Distant Site</th>
<th>Nonsuspicious Scan</th>
<th>Subtotals</th>
</tr>
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<tr>
<td>Biopsy-proven recurrence</td>
<td>26</td>
<td>31</td>
<td>41</td>
<td>98</td>
</tr>
<tr>
<td>No evidence of disease</td>
<td>7</td>
<td>3</td>
<td>112</td>
<td>122</td>
</tr>
<tr>
<td>Subtotals</td>
<td>33</td>
<td>34</td>
<td>153</td>
<td>220</td>
</tr>
</tbody>
</table>

**TABLE II. PET/CT Scan Results and Disease Status.**

PET/CT = positron emission tomography/computed tomography. Scans with suspicious findings at only locoregional site(s) were counted toward locoregional. Scans with any suspicious distant lesion, including those with suspicious locoregional lesions, were counted toward distant.

**Fig. 2.** PET/CT scan prediction metrics as a function of time since adjuvant therapy. PPV, NPV, sensitivity, and specificity were calculated over sliding 4-week windows (at each point in time ± 2 weeks). PET/CT = positron emission tomography/computed tomography; NPV = negative predictive value; PPV = positive predictive value.

**Fig. 3.** Outcomes following suspicious and nonsuspicious PET/CT scans. Patient status and management after PET/CT scan result, in aggregate and stratified by primary tumor site. PET/CT = positron emission tomography/computed tomography.
recurrence had no clinical suspicion of recurrence prior to initial surveillance imaging.

Among the 153 patients with scans rated as NI-RADS category ≤2, 41 patients (27%) were eventually diagnosed with disease recurrence at a later time. There was no statistically significant association between NI-RADS category 1 versus 2 and later recurrence ($\chi^2$ P value > .05 for both primary site and neck).

**DISCUSSION**

For locally advanced OSCC treated by surgery and aRT or aCRT, the optimal time to undergo surveillance PET/CT scan has yet to be established. Despite concern of false positive reads arising from posttreatment inflammatory changes, some studies have advocated scheduling PET/CT scan soon after surgery because it can lead to management changes prior to adjuvant therapy in 24% to 32% of patients. However, the majority of described management changes had the potential to be guided by interval physical exam and pathology of surgical specimens: leveraging margin status, extracapsular extension status, PNI status, LVI status, and difference between clinical stage and pathologic stage. In up to 36% to 42% of these patients, suspicious findings on postoperative PET/CT scan were biopsy-proven to be false positives.

The evidence to suggest that postoperative PET/CT scanning contributes to OSCC cure is thin. In the Mayo Clinic experience, 91 patients were prospectively studied, including 14 with OSCC. Four of these patients had locoregional recurrence inferred from PET/CT scans and underwent adjuvant radiation with increased dose; however, it is unclear if any patient was cured. The Taiwan experience featured 29 OSCC patients with extracapsular disease. Of the seven patients discovered to have disease recurrence, three with distant recurrence were transitioned to palliative care, whereas four with locoregional recurrence received increased doses of aRT. Two of these four patients were without evidence of disease at 7 and 23 months of follow-up, although it may be premature to deem cure at 7 months. The Memorial Sloan Kettering experience described 44 patients with locally advanced OSCC who had undergone surgical resection and postoperative PET/CT scan. However, only 27 patients had preoperative PET/CT scans, and thus many patients were likely understaged. Despite alterations in management, including more surgery, intensified radiation, and addition of chemotherapy, locoregional control and overall survival were not improved over 3 years of follow-up.

We found that PET/CT scan scheduled for 3 months after the conclusion of adjuvant therapy offered more prognostic value. PET/CT scans with NI-RADS category ≥3 at the primary tumor site or neck, or with any distant FDG-avid lesions, portend significantly worse locoregional PFS, distant PFS, and OS (Fig. 1). Most events occurred within 2 years, as reproduced in several other studies. In contrast, median survival for PFS and OS were not even reached over 8 years of follow-up among patients with non-suspicious PET/CT scans. Deferring initial surveillance PET/CT scan until after adjuvant therapy may be the more meaningful and cost-effective choice.

Regarding scan time, Figure 2 should not be misinterpreted to suggest that undergoing PET/CT scan earlier than 10 weeks or later than 16 weeks after adjuvant therapy improves PPV and specificity. Rather, the subset of patients with changes in health or other life circumstances that required significant adjustment to the initially set 3-month scan time were predisposed to have a revealing PET/CT scan result. If patients are deliberately scheduled for PET/CT scan sooner than 10 weeks after radiotherapy or chemoradiotherapy, meta-analysis has already shown that sensitivity suffers, whereas specificity remains unchanged. Reassuringly for NPV, it was found to be optimized between 10 and 16 weeks at 76% to 78%. A recent study that also used NI-RADS category ≤2 as recurrence rule-out 2 to 3 months after treatment reported a slightly higher NPV of 85%, although follow-up was for only 2 years. Biopsy-confirmed PPV of NI-RADS category ≥3 was previously reported to be 69%, which is lower than the 85% of this study but reflected all head and neck SCCs across disease stages. Biopsy-confirmed PPV of PET/CT scan for OSCC performed between surgery and adjuvant therapy was only 38%. Other attempts to systematize the PET/CT scan review process include examining PET parameters, such as standardized uptake value (SUV), metabolic tumor volume (MTV), and total lesion glycolysis (TLG). However, SUV was found to have no correlation with PFS or OS after correcting for stage. There are also conflicting reports on the prognostic value of MTV and TLG. The Hopkins criteria provides a scoring system for surveillance PET/CT in which FDG uptake at hypermetabolic areas are compared to uptake in the internal jugular vein and liver. This method boasts sensitivity, specificity, PPV, and NPV of 68%, 92%, 71%, and 91%, respectively, for head and neck cancers. Our results appear to trade off greater PPV and specificity for lower NPV and sensitivity relative to the Hopkins criteria. A wholly superior method of assessing surveillance imaging based entirely on observer-independent metrics likely does not exist at this time.

After receiving a suspicious PET/CT scan result, patients in the current study had an 85% chance of biopsy-proven disease recurrence. Among the 37 patients who further underwent salvage therapy, only four patients (11%) had no evidence of disease (NED) at most recent follow-up. Their observed durations of NED since salvage were 10 months, 1 year, 1 year 3 months, and 3 years 2 months. The patient with 10 months of NED presented with an enlarged submandibular lymph node prior to surveillance PET/CT. The other three patients (75%) did not have concerning symptoms or physical exam findings prior to imaging. Forty-six of the 57 total patients with biopsy-confirmed disease recurrence following suspicious imaging were without clinical evidence of disease between the end of adjuvant therapy and surveillance PET/CT scan. Each of the remaining 11 patients had locoregional symptoms or exam findings that foreshadowed recurrence, whereas three of them were then incidentally found to have distant disease on imaging. Distant progression appears to be more elusive without imaging. There was no obvious trend for sites of false
positive biopsies or clinically evident recurrence. Overall, a 15% false positive rate is heavily outweighed by not catching 81% of disease recurrence with omission of PET/CT scan and no worrisome clinical findings. The benefit of post-adjuvant therapy PET/CT scan clearly overcompensates for its risk.

All four of the potentially salvaged patients were candidates for surgery. As similarly demonstrated in other studies,28 nonsurgical candidates treated with salvage radiotherapy or chemoradiotherapy had a cure rate of 0%. With surgical intervention, salvage cure rate across stages of OSCC is estimated to be 20%.29 Overall, the prognosis associated with a suspicious first surveillance PET/CT scan is bleak, especially the identification of distant progression. We emphasize PET/CT's superior locoregional-specific PPV (78%) after adjuvant therapy compared to that of postoperative scans (below 27%–38%) because locoregional recurrence and surgical candidacy offer hope of cure, albeit guarded. For distant metastases, recent promising gains have been made by systemic therapies, especially immunotherapy.30 On the other hand, the sensitivity of initial surveillance PET/CT to allude disease recurrence at any future time is only 58%. Therefore, patients with a nonsuspicious first surveillance PET/CT scan should undergo regular surveillance imaging.

Limitations of this study include its single institution experience and generalizability beyond locally advanced OSCC treated with surgery and adjuvant therapy. Winship Cancer Institute is part of a large academic hospital system, with possible selection bias for challenging OSCC referrals. The cure rate following salvage treatment of confirmed disease recurrence may be higher for patients in other settings. Comparison of post-adjuvant therapy versus postoperative PET/CT scan utility following adjuvant therapy and following surgery was compared across several studies. Although the observed differences have been striking, prospective head-to-head comparison within a single dataset would be more ideal. Our findings also may not pertain to patients with OSCC treated by definitive chemoradiation.

CONCLUSION

To our knowledge, this is the largest study of surveillance PET/CT for locally advanced OSCC treated by surgery and radiotherapy and the first to apply standardized scan classification criteria to exclusively locally advanced OSCC. PET/CT scan scheduled for 3 months after adjuvant therapy with NI-RADS category ≥3 at the primary tumor site or neck, or with increased distant FDG avidity, is associated with significantly worse locoregional PFS, distant PFS, and OS. In addition to offering better prognosis stratification, it features a much lower false positive rate than that of PET/CT imaging between surgery and adjuvant therapy reported in previous studies. Patients with a suspicious initial scan should be informed of the high likelihood of disease progression and the low likelihood of cure, even with salvage therapy. Patients should also be encouraged to enroll in clinical trials after biopsy confirmation. Otherwise, subsequent surveillance scans carry low value. Recurrence can often develop after the first scan; thus, patients with a nonsuspicious initial PET/CT scan should continue to receive interval imaging.

BIBLIOGRAPHY


