N2 Disease in Patients With Head and Neck Squamous Cell Cancer Treated With Chemoradiotherapy

Is There a Role for Posttreatment Neck Dissection?

Allis H. Cho, MD; Shivang Shah, MD; Fred Ampil, MD; Sheela Bhartur, MD, PhD; Cherie-Ann O. Nathan, MD

Objectives: To determine whether nodal necrosis and node size of 3 cm or larger are risk factors for recurrent neck disease and whether negative computed tomography–positron emission tomography (CT-PET) results 8 weeks or more after therapy indicate complete response in the neck in patients with N2 disease.

Design: Retrospective study.

Setting: State university hospital.

Patients: Fifty-six patients with head and neck squamous cell cancer and N2 disease treated with chemoradiotherapy were evaluated for persistent or recurrent neck disease. Tumor characteristics analyzed were primary site, T category, nodal size (≥3 cm), nodal necrosis based on hypodensity of one-third or more of the node, and type of N2 disease (N2a, N2b, or N2c). Forty-eight of the 56 patients underwent CT-PET to determine treatment response after chemoradiotherapy. Clinical examination, imaging, and pathologic specimens were used to confirm disease recurrence.

Main Outcome Measures: The number of recurrence events, disease-free interval, and positive posttreatment CT-PET result in the neck.

Results: Most patients had oropharyngeal tumors (n=37; 66%), T2 tumors (n=21; 38%), nodes 3 cm or larger (n=43; 77%), positive necrosis (n=40; 71%), and N2c disease (n=28; 50%). Multivariate analysis determined that no factors were significant predictors of recurrence, except for positive posttreatment PET results (P<.001). Comparison of CT-PET with nodal recurrence demonstrated a sensitivity of 82%, a specificity of 97%, a negative predictive value of 95%, and a positive predictive value of 90%.

Conclusion: Posttreatment neck dissections may not be indicated for patients with N2 disease and a negative CT-PET result, even in patients with nodal necrosis and nodes 3 cm or larger.


CERVICAL NECK NODE METASTASIS in head and neck squamous cell cancer (HNSCC) is a major prognostic factor in disease-specific survival. Nodal metastasis is correlated with increased regional recurrence and a 50% decrease in disease-free survival. Combined modality treatments have been used to improve locoregional control and distant metastases. Organ-preservation concomitant chemoradiotherapy is currently widely used as the primary treatment for advanced stage HNSCC and has yielded high response rates. The introduction of definitive chemoradiotherapy was followed by posttreatment neck dissections for bulky cervical lymphadenopathy because these patients had an unacceptably high rate of recurrence. Controversies have arisen about the timing of and indications for neck dissections. The questions often posed are which patients are at risk for cervical nodal recurrence and which imaging modalities can accurately predict clinical response to nonsurgical treatment?

Many prognostic factors for regional control have been previously identified, with much emphasis on nodal size and necrosis. In some studies, hypoxia had a negative impact on adequate provision of irradiation, and there was a negative correlation between hypodense nodes on computed tomographic (CT) scans and response to treatment. The extent of neck disease also determined regional control, with patients with more extensive neck disease having higher rates of regional failure. Therefore, patients with extremely necrotic nodes and a nodal size of 3 cm or larger have routinely received posttreatment neck dissections. The combination of CT and positron emission tomography (PET) has been in-
creasingly used in the management of HNSCC as a diagnostic tool both before and after treatment. The uptake of radiotracer fluorodeoxyglucose F 18 is greatly increased in cancer cells because of increased glucose metabolism compared with healthy tissues. The sensitivity and specificity of PET in detection of cancer cells are relatively high, and questions have been raised with regard to whether this functional imaging modality can be used to predict clinical response.

Planned neck dissections are certainly indicated in patients with residual or persistent neck disease. However, controversy exists about whether a neck dissection should be performed when there is complete clinical and radiographic response to chemoradiotherapy. Although neck dissections reduce regional recurrence rates, the timing and need for planned neck dissections need clarification because patients who receive them after chemoradiotherapy have higher morbidity. Elimination of the need for neck dissection for bulky cervical disease in patients who achieve complete response after chemoradiotherapy may help avoid unnecessary surgery.

Studies that have attempted to answer this question have focused on a combination of both N2 and N3 diseases, with some studies including even N1 disease. However, the current recommendations for the role of planned neck dissections for N1 and N3 disease are less controversial. There is some consensus that neck dissections are not indicated for N1 disease with complete clinical and radiologic response and that neck dissections are indicated for N3 disease irrespective of the response to treatment. There is no such consensus in N2 neck disease. Hence, we chose to examine patients with N2 disease in our study and aim to answer these controversial questions: Is there a need for a planned neck dissection in patients with complete clinical response and a nodal size of 3 cm or larger and nodal necrosis, and does a negative CT-PET result after chemoradiotherapy outweigh traditional prognostic factors, such as nodal necrosis and size of nodes? The answers to these questions will help clarify the role of neck dissections after chemoradiotherapy in this controversial subset of patients with N2 disease.

METHODS

PATIENT SELECTION

The tumor registry and PET databases between 2002 and 2006 revealed 395 patients with head and neck cancers. However, only 56 with HNSCC met the inclusion criteria of N2 disease treated with primary chemoradiotherapy. Patients with N0, N1, or N3 disease, patients not treated by primary chemoradiotherapy, those treated by other departments (ie, oral maxillofacial surgery), and those with incomplete records or no follow-up were excluded. All patients underwent a pretreatment, contrast-enhanced CT of the neck and received a histologic diagnosis of squamous cell cancer after biopsy.

Specific prognostic factors that were identified included nodal size, nodal necrosis, and type of N2 disease. Nodal metastases were classified by size (<3 cm or ≥3 cm), absence or presence of necrosis, and type of N2 disease (N2a vs N2b vs N2c) based on radiologic test results. Forty-eight of the 56 patients had a minimum of 1 posttreatment CT-PET scan obtained at least 8 weeks after chemoradiotherapy. Most of these patients had additional follow-up CT-PET scans after the first posttreatment CT-PET, ranging from 3 to 54 months (median, 14 months). Disease recurrence in the neck was evaluated by clinical examination, CT-PET or CT scans, fine-needle aspiration biopsy (FNAB), and/or neck dissection. Complete response in the neck was defined as disappearance of all clinically and radiologically detectable disease. Recurrent neck disease was defined as complete response to treatment for at least 6 months then detection of nodal disease, whereas persistent disease was defined as never having a period of complete response. We reviewed treatment outcomes in our patients and correlated these with the listed risk factors.

PATIENT CHARACTERISTICS

Forty-three patients were male (77%), and the median age was 54 years (range, 34-77 years). Primary tumor site distribution was as follows: oral cavity, 1 (2%); oropharynx, 37 (66%); hypopharynx, 3 (5%); supraglottis, 11 (20%); glottis, 1 (2%); nasopharynx, 2 (4%); and unknown primary, 1 (2%). Disease was staged as follows: oral cavity, 1 (2%); oropharynx, 37 (66%); hypopharynx, 3 (5%); supraglottis, 11 (20%); glottis, 1 (2%); nasopharynx, 2 (4%); and unknown primary, 1 (2%). Disease was staged according to the 1997 International Union Against Cancer (UICC) staging system. The patient characteristics are given in Table 1.

TUMOR SIZE AND NODAL DENSITY

The CT scans of the neck were performed with a commercial section scanner (GE LightSpeed VCT 64, General Electric, Wauke-
Posttreatment response was determined by clinical examination, CT with contrast, and/or CT-PET scans. Patients were considered to have persistent neck disease if there was palpable lymphadenopathy on clinical examination, persistent lymph nodes on neck CT and/or CT-PET scans with residual uptake at 8 weeks or more up to 6 months after treatment, and recurrent disease after 6 months. Pathologic evidence of nodal recurrence or persistence was confirmed in 17 patients by FNABs and/or neck dissection specimens.

Patients were evaluated 4 weeks after chemoradiotherapy and then followed up every 3 months for the first 2 years (median, 26 months; range, 4-76 months). Clinical examination was performed at 3-month intervals, and CT and/or CT-PET scans were performed yearly or if clinically indicated. The disease-free interval (DFI) was measured from the last day of treatment to the date that nodal recurrence was confirmed or the most recent date of follow-up.

**STATISTICAL ANALYSIS**

The Kaplan-Meier and the Cox multiple proportional hazards models were used to determine the significant prognostic factors on the DFI. Significant differences between survival curves were calculated by the log-rank test. The following parameters were included in the Cox regression analysis to adjust for prognostic factors: T category, nodal size, node necrosis, and N category. A stratified Cox regression was also performed to see the individual effect of nodal size, necrosis, and T category on the relation between CT-PET scan results and nodal recurrence. The \( \kappa \) statistic was used to determine if posttreatment CT-PET predicts nodal recurrence on follow-up. End points examined were nodal control and DFI rates.

**RESULTS**

Fifty-six patients treated with chemoradiotherapy for N2 disease were evaluated for recurrence in the neck and to assess whether CT-PET scans are a predictor of response to therapy. Thirty-nine patients (70%) had complete response in the neck, and 17 (30%) had nodal recurrence or persistent disease. Among the 39 patients with complete response, most had oropharyngeal cancer (62%), node size of 3 cm or larger (74%), and nodal necrosis (72%). There was an even distribution of T1/T2 disease (51%) and T3/T4 disease (49%), as well as N2b and N2c disease (46% each). Thirty-seven of the 39 patients with complete response underwent posttreatment CT-PET. Thirty-six (97%) had negative CT-PET results. One patient (3%) had positive CT-PET results in the neck and was observed with a follow-up CT-PET in 4 months, the results of which were negative. The patient has been disease free for 22 months.

Among the 17 patients with nodal recurrence or persistence, most had oropharyngeal cancer (76%), T3/T4 disease (65%), node size of 3 cm or greater (82%), nodal necrosis (71%), and N2c disease (59%). Eleven of the 17 patients with nodal recurrence underwent posttreatment CT-PET. Nine (82%) of 11 had positive CT-PET results, and 2 (18%) had negative CT-PET results. The 2 patients with negative CT-PET results had clinically negative neck examination results. However, the results of the follow-up CT-PET scans on the 2 patients at 3 and 9 months, respectively, were positive. The first patient underwent FNAB of the neck, which revealed nodal recurrence; however, this patient did not undergo further surgery and died 14 months from the date of completion of the primary treatment with local and regional recurrence. The second patient underwent a neck dissection for a pathologically proven positive node, which resolved completely at 27 months at the time of the analysis.

The median follow-up for patients in our study was 26 months (range, 4-76 months). The median DFI was 32 months (range, 8-53 months) for patients with T1/T2 disease and 25 months (range, 4-76 months) for pa-

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**TREATMENT**

Treatment consisted of cisplatin and 5-fluorouracil chemotherapy and concurrent external beam radiation. Radiation therapy was administered by a 6-megavolt linear accelerator. Nodal regions were given a total dose of 38 to 72 Gy per 23 to 42 fractions in the upper neck and 50 to 72 Gy per 25 to 28 fractions in the lower neck. Most patients received 2 to 3 cycles of combination of cisplatin (100 mg/m²) followed by a 4- to 5-day continuous intravenous infusion of 5-fluorouracil (1000 mg/m² daily) separated by 21 days for each cycle.

Posttreatment response was determined by clinical examination, CT with contrast, and/or CT-PET scans. Patients were considered to have persistent neck disease if there was palpable lymphadenopathy on clinical examination, persistent lymph nodes on neck CT and/or CT-PET scans with residual uptake at 8 weeks or more up to 6 months after treatment, and recurrent disease after 6 months. Pathologic evidence of nodal recurrence or persistence was confirmed in 17 patients by FNABs and/or neck dissection specimens.

Patients were evaluated 4 weeks after chemoradiotherapy and then followed up every 3 months for the first 2 years (median, 26 months; range, 4-76 months). Clinical examination was performed at 3-month intervals, and CT and/or CT-PET scans were performed yearly or if clinically indicated. The disease-free interval (DFI) was measured from the last day of treatment to the date that nodal recurrence was confirmed or the most recent date of follow-up.
patients with T3/T4 disease. The median DFIs were 24 months (range, 4-53 months) for patients without necrotic nodes, 31 months (range, 4-76 months) for patients with nodal necrosis, 24 months (range, 4-38 months) for patients with node size smaller than 3 cm, and 25 months (range, 4-76 months) for patients with node size of 3 cm or larger. The median DFIs for patients with N2a, N2b, and N2c were 42 months (range, 21-54 months), 32 months (range, 4-61 months), and 21 months (range, 5-76 months), respectively. The Kaplan-Meier curves showed no statistically significant difference in the DFI based on nodal size (P = .74), necrosis (P = .115), T category (P = .56), and the type of N2 disease (P = .76) when nodal recurrence was the end point (Table 2 and Figures 2, 3, 4, and 5). Tumor site could not be statistically evaluated because most patients had oropharyngeal tumors and most patients with other primary tumor sites had either zero or very low recurrence rates. Of the patients who underwent posttreatment CT-PET, the median DFI was 32 months (range, 4-76 months) in patients with negative CT-PET results and 14 months (range, 4-41 months) in patients with positive CT-PET results. Univariate analysis showed that there was a statistically significant difference in DFI in patients who had positive results on posttreatment CT-PET compared with patients with negative CT-PET results (P < .001) (Table 2 and Figure 6).

Among the 56 patients evaluated for the specific risk factors, 48 underwent posttreatment CT-PET. Thirty-eight patients had a negative CT-PET result after completion of treatment, whereas 10 patients had a positive posttreatment CT-PET result. Of 38 patients with negative posttreatment CT-PET results, 36 (95%) tested negative for nodal metastasis (10 based on neck dissections and 28 based on routine clinical examination and follow-up with yearly CT-PET). In 10 patients with posi-

### Table 2. Results of Univariate Analysis

<table>
<thead>
<tr>
<th>Variable</th>
<th>No. of Patients</th>
<th>( \chi^2 )</th>
<th>df</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>T category</td>
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<td></td>
<td></td>
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<tr>
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<tr>
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<td></td>
<td></td>
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<tr>
<td>&lt;3 cm</td>
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<td>0.115</td>
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<td>.74</td>
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<tr>
<td>≥3 cm</td>
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</tr>
<tr>
<td>Necrosis</td>
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<td>.56</td>
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<td>N2 category</td>
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<tr>
<td>a</td>
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<td>1.153</td>
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<td>.76</td>
</tr>
<tr>
<td>b</td>
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<tr>
<td>c</td>
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<tr>
<td>PET results</td>
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<tr>
<td>Positive</td>
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<td>15.414</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Negative</td>
<td>10</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Abbreviation: PET, positron emission tomography.

- Tumor site could not be statistically analyzed for comparison with nodal recurrence because of low recurrence rates in all tumor site groups other than the oropharynx.
- One patient excluded from analysis owing to unknown TX disease.
- Statistically significant difference in disease-free interval of patients with positive posttreatment PET scan results compared with negative PET scan results.
PET results and no nodal disease, and 3 (23%) had positive CT-PET results and nodal disease. One patient had a negative CT-PET result at 8 weeks after treatment, but the results of a follow-up CT-PET scan 9 months later were positive and the neck dissection also revealed nodal disease. This patient has been disease free for 27 months at the time of the analysis. In estimating site-specific recurrence, time was measured from the end of treatment until recurrence in the neck. A patient who experienced disease relapse in the neck but underwent successful salvage surgery was still considered to have received failed treatment at the time of event occurrence.

The multivariate analysis with the Cox multiple proportional hazards model showed that posttreatment CT-PET results (P = .02) were significantly associated with nodal recurrence, whereas association of nodal recurrence with T category (P = .96), node size (P = .55), necrosis (P = .97), and N2 disease status (P = .55) was not statistically significant. It was not possible to compute survival statistics for comparison of nodal recurrence among patients based on the primary tumor site because of low recurrence rates in all tumor sites other than oropharyngeal patients. Most cases in all the comparison groups except oropharynx were censored.

A multivariate analysis was performed by means of stratified Cox regression to determine the confounding effect of nodal size and necrosis on the relation of posttreatment CT-PET scan results and nodal recurrence. When stratified by nodal size, the DFI of patients who had negative posttreatment CT-PET scan results was greater than that of the patients who had positive posttreatment CT-PET scan results (χ²=15.935, P < .001). Similarly, on stratification by necrosis, the patient with negative CT-PET scan results had a higher DFI than the patients with positive CT-PET scan results (χ²=16.276, P < .001). On stratification by T category, the patients with negative CT-PET scan results also had a higher DFI than the patients with positive CT-PET scan results (χ²=3.53, df=2, P = .005).

Table 3 provides data on both CT-PET scan results and nodal recurrence in 48 patients. Significant agreement was found between the CT-PET scan results and node disease, with 45 (94%) of 48 patients having similar results on both CT-PET scan and node status. Among the 38 patients with negative CT-PET scan results, 36 (95%) were free of neck disease, whereas 9 (90%) of 10 patients with positive CT-PET scan results also had nodal recurrence. Hence, there is a highly significant association between PET scan results and nodal recurrence, and we can conclude that posttreatment PET scan results are significant predic-

<table>
<thead>
<tr>
<th>CT-PET Scan Result</th>
<th>No. (%) With Nodal Recurrence</th>
<th>No. (%) With Positive Nodal Recurrence</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative</td>
<td>36 (95)</td>
<td>2 (5)</td>
<td>38</td>
</tr>
<tr>
<td>Positive</td>
<td>1 (10)</td>
<td>9 (90)</td>
<td>10</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>37</strong></td>
<td><strong>11</strong></td>
<td><strong>48</strong></td>
</tr>
</tbody>
</table>

Abbreviation: PET, positron emission tomography.

P = .01 (for H0: k = 0).
Although nodal metastasis in HNSCC is widely accepted as a negative prognostic factor, the prognostic implications of specific nodal characteristics, such as size and necrosis, are far less apparent. This study shows that for patients with N2 disease nodal size, nodal necrosis, and N2 subclassification are not significant predictors of nodal recurrence. Specifically, nodal size of 3 cm or larger and necrosis did not influence recurrent disease in the neck after chemoradiotherapy. This may be attributable to the addition of chemotherapy to radiation, which has been shown to increase the response of necrotic nodes to radiotherapy. \(^{14}\) Negative CT-PET scan results for prediction of response to treatment were observed to be a significant predictor of negative nodal recurrence (negative predictive value [NPV], 94.7%). Therefore, from our study, posttreatment neck dissections may not be indicated in patients who have had a complete clinical response.

This study revealed 3 patients with posttreatment CT-PET scans that did not correlate with nodal status as described earlier in the “Results” section. Even though the first posttreatment CT-PET scan did not correlate with nodal status in these 3 patients, follow-up CT-PET scans correlated with nodal status before any clinical evidence of disease was noted. Survival of all 3 patients was not affected by the posttreatment CT-PET scan results because the patients did not die of neck disease or are alive without disease.

Several studies\(^ {8-10,14-18}\) have shown a correlation between nodal size or density and regional control. Most of these studies show nodes 3 cm or larger and necrosis to be poor prognostic factors in control of nodes in the neck. Tumor hypoxia may induce dihydrofolate reductase gene amplification, which plays a significant role in the development of drug resistance to methotrexate.\(^ {19}\) Thus, it is believed that node necrosis could affect treatment outcome. However, Chua et al\(^ {17}\) demonstrated that nodal necrosis in nasopharyngeal carcinoma did not affect nodal response and control with radiotherapy with or without chemotherapy. There are some explanations for the differences in results from our study. First, most of these reports included all subtypes of nodal disease, such as N1 and N3 disease.\(^ {8,10,14-18}\) Our study specifically addressed only those patients with N2 disease. As stated previously, the role of posttreatment neck dissections in N1 and N3 disease is less controversial. There is more of a consensus for planned neck dissection for N3 disease with chemoradiotherapy, and posttreatment or pretreatment neck dissection is recommended based on individual clinical considerations. On the other hand, patients with N1 disease have high regional control rates with radiotherapy with or without chemotherapy; therefore, observation is the recommended option after a complete clinical response. Second, many of the studies that evaluated prognostic factors were conducted before the year 2000. The CT-PET scans were not readily used for management before this date because it was first developed and available in the United States in 2000.\(^ {20}\) The guidelines for posttreatment neck dissections on bulky neck disease may have been a result of difficult clinical evaluation from fibrotic radiation changes in the neck. However, the addition of chemotherapy to radiotherapy has significantly improved regional control.\(^ {10}\) Positron emission tomographic scans may be able to guide physicians in the treatment of patients with severe cervical fibrosis from high radiation doses. Our study shows that CT-PET scans performed at least 8 weeks (28 of 48 patients) and preferably more than 12 weeks (20 of 48 patients) after radiation were a predictive factor of response to chemoradiotherapy.

Given that clinical examination after therapy may not reveal any lymphadenopathy, multiple imaging techniques have been used to evaluate the neck for persistent or recurrent disease. Both CT and magnetic resonance imaging are not highly consistent in the prediction of residual neck disease.\(^ {21}\) However, posttreatment CT-PET imaging may be helpful to differentiate patients who will benefit from a neck dissection after chemoradiotherapy. Our CT-PET results for sensitivity (81.8%), specificity (97.3%), positive predictive value (PPV) (90.0%), and NPV (94.7%) validate the power of this imaging modality in the detection of treatment response and are comparable with other studies, although these investigators included all N1 through N3 disease in their studies. Porceddu et al\(^ {22}\) reported on 39 patients with residual neck masses (28 with N2 neck disease) after complete response at the primary site with chemoradiotherapy. Thirty-two patients had negative posttreatment PET results obtained at a median of 12 weeks. Of these patients, 5 underwent neck dissections with pathologically negative specimens, and 27 were observed for a median of 34 months, with only 1 patient having recurrence in the neck and 4 patients with distant metastases. An NPV of 97% and a PPV of 71% led investigators to recommend that patients with residual neck abnormalities but a negative PET result at 12 weeks did not require a neck dissection. Ware et al\(^ {23}\) identified 53 patients with residual neck abnormalities on standard radiologic examination (CT and/or magnetic resonance imaging) after surgery, radiation, and/or chemotherapy and had a median follow-up of 55 months. The NPV and PPV were 83% and 95%, respectively, whereas the PPV for standard imaging was 53%, which demonstrated that PET had significantly better diagnostic accuracy. Wong et al\(^ {24}\) studied 143 patients with previously treated HNSCC. PET scans revealed a sensitivity of 96%, a specificity of 72%, a PPV of 69%, and an NPV of 96%. The results of these studies concluded that patients with complete response on PET could be observed safely.

Residual disease in the neck after chemoradiotherapy is the basis of posttreatment neck dissection in bulky N2 through N3 disease. Numerous investigations\(^ {24-28}\) have been performed to investigate whether a neck dissection is needed after complete response is attained. Some authors argue that posttreatment neck dissections are not indicated in patients with complete response because studies\(^ {29-31}\) show that most patients have high regional control rates. Others report that planned neck dissections are justified based on high histopathologic evidence of disease, ranging from 25% to 56%.\(^ {32-34}\) These studies also did not incorporate the use of PET scans.
in the management decisions of the patients. The decision to pursue a posttreatment neck dissection must also be carefully weighed because it is well established that there is an increased postoperative complication rate in necks that have received radiation therapy. Lavertu et al reported an overall complication rate of 46% in the organ preservation group, whereas the rate of complications reported was 61% in a study by Sessler et al. In conclusion, this study addresses some controversial questions with regard to predictive factors for nodal recurrence or persistence in advanced-stage HNSCC specifically with N2 disease, the use of CT-PET scans in treating patients who have received chemoradiation therapy, and the need for planned neck dissections. On the basis of our results, we believe nodal size and necrosis are not significant predictors for nodal recurrence, CT-PET scans are significant predictors (both negative and positive) for nodal metastases, and patients with complete response and negative CT-PET scan results can be safely observed with sequential CT-PET imaging.

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Correspondence: Cherie-Ann O. Nathan, MD, Department of Otolaryngology—Head and Neck Surgery, Louisiana State University Health Sciences Center, Head and Neck Surgical Oncology, Feist-Weiller Cancer Center, 1501 Kings Hwy, Shreveport, LA 71130-3932 (chatha@lsuhsc.edu).

Author Contributions: Drs Cho and Nathan had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. Study concept and design: Cho and Nathan. Acquisition of data: Cho, Ampil, and Bhurtar. Analysis and interpretation of data: Cho, Shah, and Nathan. Drafting of the manuscript: Cho, Shah, Ampil, and Bhurtar. Critical revision of the manuscript for important intellectual content: Cho and Nathan. Study supervision: Nathan.

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REFERENCES


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