ACR Neck Imaging Reporting and Data Systems (NI-RADS): A White Paper of the ACR NI-RADS Committee

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Abstract

Imaging surveillance after treatment for head and neck cancer is challenging because of complicated resection and reconstruction surgery, in addition to posttreatment changes from radiation and chemotherapy. The posttreatment neck is often a source of anxiety for diagnostic radiologists, leading to suboptimal reporting and no standardized guidance for next management steps. Nevertheless, imaging is critical for detecting submucosal recurrences in a timely manner, so that patients remain candidates for salvage surgery. In 2016, the ACR convened the Neck Imaging Reporting and Data Systems (NI-RADS) Committee with the goals to (1) provide recommendations for surveillance imaging; (2) produce a lexicon to distinguish between benign posttreatment change and residual or recurrent tumor in the posttreatment neck; and (3) propose a NI-RADS template for reporting on the basis of this lexicon with defined levels of suspicion and management recommendations. In this article, the authors present the ACR NI-RADS Committee's recommendations, which provide guidance regarding the management of patients after treatment for head and neck cancer.

Key Words: NI-RADS, Neck Imaging Reporting and Data Systems, head and neck cancer, surveillance, structured reporting, templates

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INTRODUCTION

The anatomy of the neck is complex, containing critical neurovascular structures and almost half of the lymph nodes in the body, posing a diagnostic challenge for radiologists. Head and neck (HN) cancer is an important cause of morbidity with the majority due to squamous cell carcinoma (SCCA), though additional cancers include salivary gland malignancies, adenocarcinomas, sarcomas, thyroid and sinonasal malignancies. Treatment options are wide, from surgical resection and reconstruction with composite flaps to minimally invasive endoscopic resections or radiation therapy, and can make the posttreatment neck difficult to evaluate by clinical and imaging examinations. Otolaryngologists (ear, nose, and throat surgeons) and medical and radiation oncologists can inspect for mucosal recurrences. The radiologist plays a critical role in evaluating for deep recurrences early, when a patient may still be a candidate for salvage surgery or additional chemoradiotherapy (CRT). The complex appearance of the posttreatment neck is often a source of anxiety for diagnostic radiologists, leading to suboptimal reporting and poor or incomplete

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interpretation with little to no standardized guidance for next steps in management. The purpose of this white paper is to present a lexicon and a proposed system for risk stratification of neck imaging after treatment for HN cancer.

PROJECT RATIONALE AND CONSENSUS PROCESS

The current National Comprehensive Cancer Network guidelines recommend imaging a patient after treatment within the first 6 months, but beyond 6 months there is no official recommendation for surveillance imaging in an asymptomatic patient. The guidelines do state that "routine annual imaging may be indicated for areas difficult to visualize on exam" [1,2]. Imaging with a PET/CT at minimum 12 weeks after the completion of treatment is generally agreed to be the best first posttreatment baseline imaging, though some studies suggest posttreatment imaging be performed as early as 8 weeks after completion of treatment [3-7]. Most cancer centers have surveillance imaging schedules extending far beyond 6 months, especially because submucosal local recurrences and regional nodal recurrence cannot be "visualized on exam." However, there is no current consensus on extended imaging surveillance regimens and no data on the impact of surveillance imaging on survival.

Recognizing the importance of standardization of imaging surveillance and reporting to improve patient care and collect data, the ACR formed the Neck Imaging Reporting and Data Systems (NI-RADS) Committee in August 2016 with the charge to provide a risk stratification system to guide the management of patients with treated HN cancer. The risk stratification system would be based on a standard lexicon, be associated with specific imaging recommendations, and be reported with validated imaging reporting templates. The proposals presented in this white paper were developed via conference calls, in person meetings, and through e-mails and represent the consensus opinion of the ACR NI-RADS Committee. They are based on the literature, current best practices, and available evidence, multidisciplinary consensus, ultrasound- and CT-guided biopsy experience of the NI-RADS authors, and expert opinion [8].

Our recommendations are intended to serve as guidance for practitioners who interpret posttreatment imaging for HN cancer. They should not be construed as standards. Interpreting and referring physicians are legally and ethically responsible for applying their professional judgment to every case, regardless of the ACR NI-RADS recommendations. The management decision should also account for the referring physician's preference, patient's comorbidities and life expectancy, and other relevant considerations.

NI-RADS was originally developed for surveillance contrast-enhanced CT (CECT) imaging with or without PET in patients with treated HN cancer [8]. The template is easily adaptable to other modalities, including MRI. The ACR committee sought to standardize the nomenclature to facilitate uniform reporting across institutions, simplify communication, and allow radiologists to make unequivocal recommendations regarding patient management. An additional goal was to facilitate radiologic-pathologic correlation to continually refine and improve thresholds for desired sensitivity, specificity, and accuracy of interpretation. The following were primary goals for creating a NI-RADS template in HN cancer surveillance:

- To reduce ambiguity and variability of narrative interpretation by the use of numerical categories to convey levels of suspicion of recurrence
- To link categories of suspicion to consensus management recommendations, which reflect a multidisciplinary and standardized approach to patient care
- To improve direct patient communication by radiologists and to emphasize the radiologists' added value in patient care by simplifying language and including concrete or actionable next steps in each report
- To build a multi-institutional large database to more accurately assess the probability of disease and to facilitate outcomes research

OVERVIEW OF ACR NI-RADS

On a posttreatment imaging study, the status of disease at the primary site and regional nodes can be simplified into four categories that drive management: negative, low suspicion, high suspicion, and definite recurrence. If prior imaging is lacking to place the patient in one of these categories, then the study is designated as "incomplete."

Both the primary tumor site and neck (and in the case of whole-body imaging, distant disease) are assessed for recurrence and assigned a category 0 to 4 based upon imaging suspicion.

- Category 0: Incomplete. The management recommendation is acquisition of appropriate comparison examinations that are currently unavailable.
- Category 1: No evidence of recurrence. The management recommendation is routine surveillance.
- Category 2: Low suspicion, defined as ill-defined non-mass-like areas(s) of soft tissue with only mild differential enhancement or mild fluorine-18-2-fluoro-2-deoxy-D-glucose (FDG) uptake. The management recommendation is direct inspection for mucosal abnormalities or short-interval follow-up with CECT or an additional PET for deep abnormalities.
- Category 3: High suspicion, defined as a discrete, new, or enlarging lesion with marked enhancement or intense focal FDG uptake. The management recommendation is biopsy.
- Category 4: Definite recurrence, defined as pathologically proven or definite radiologic or clinical progression. The management recommendation is treatment of disease with or without biopsy.

A recent publication demonstrated a good baseline performance of NI-RADS in a mixed cohort of both CECT and PET/CECT surveillance for HN SCCA at different times [9]. There was significant discrimination between the groups, with NI-RADS 1 recurrence rate of 3.5%, NI-RADS 2 recurrence rate of 17%, and NI-RADS 3 recurrence rate of 59.4%. At the time of this publication, NI-RADS 4 was more narrowly defined as only biopsy proven disease so that the recurrence rate was 100% by definition. Most NI-RADS 4 patients were on a trial or undergoing palliative chemotherapy. NI-RADS categories will likely have a larger range of positive disease rates, when future studies look at the predictive value across different modalities and different time points.

ACR NI-RADS CATEGORIES AND LEXICON

In this section, the four ACR NI-RADS categories (Table 1) are defined in detail with a suggested lexicon for reporting (Table 2). ACR NI-RADS structured reporting template with separate legends for two different scenarios are showed on the online appendix: cross-sectional imaging without PET (originally designed for CECT but can easily be used for MRI) and cross-sectional imaging combined with PET (originally for PET/CECT, but could be easily modified for PET-MRI). Flowcharts for interpretation and linked management suggestions are included for the primary site and the neck (Fig. 1 and Fig. 2). Imaging examples for assigning the NI-RADS category will be included in online figures, and a more detailed pictorial review of the practical application has been published previously [10].

Table 1. NI-RADS category descriptors, imaging findings, and management

Category	Category	Imaging Findings	Management
Incomplete	0	▪ New baseline study without any prior imaging available *and* knowledge that prior imaging exists and will become available as comparison*	Assign score in addendum after prior imaging examinations become available
No evidence of recurrence	1	▪ Expected posttreatment changes ▪ Non-mass-like distortion of soft tissues ▪ Low-density "mucoid" mucosal edema ▪ No abnormal FDG uptake ▪ Diffuse linear mucosal enhancement after radiation	Routine surveillance
Low suspicion	2a	▪ Focal mucosal enhancement, but not mass-like ▪ Focal mild to moderate mucosal FDG uptake	Direct visual inspection
	2b	▪ Deep, ill-defined soft tissue, not discrete ▪ Little to no differential enhancement ▪ Mild or moderate FDG uptake	Short-interval follow-up (3 months), repeat PET
High suspicion	3	▪ New or enlarging primary mass or lymph node ▪ Discrete nodule or mass with differential enhancement ▪ Intense focal FDG uptake	Image guided or clinical biopsy
Definitive recurrence	4	▪ Pathologically proven or definite radiologic and clinical progression	Clinical management

FDG = fluorine-18-2-fluoro-2-deoxy-D-glucose; NI-RADS = Neck Imaging Reporting and Data Systems.
*Morphologically abnormal features that are definitive = new necrosis or gross extra nodal extension as evidenced by invasion of adjacent structures.

Table 2. NI-RADS Lexicon

Masses
▪ Morphology: ill defined (2) vs discrete (3)
▪ Enhancement: mild (2) vs intense (3)
▪ FDG avidity: none (1) vs mild (2) vs intense (3)
Non-mass-like soft tissue (1)
▪ Soft tissue distortion without a discrete mass (1)
Mucosal abnormality
▪ Low-density submucosal edema (postradiation edema) (1)
▪ Diffuse curvilinear enhancement of FDG (benign radiation mucositis) (1)
▪ Focal mucosal enhancement (2a)
▪ Focal mucosal FDG uptake (2a)
Lymph nodes
▪ Residual nodal tissue + no FDG (1)
▪ Residual nodal + mild FDG (2)
▪ Residual nodal + intense FDG (3)
▪ Growing lymph node without definite morphologically abnormal features* along expected nodal drainage (2)
▪ Growing lymph node with morphologically abnormal features (3)
▪ Growing lymph node + intense FDG (3)

FDG = fluorine-18-2-fluoro-2-deoxy-D-glucose; NI-RADS = Neck Imaging Reporting and Data Systems.
*Morphologically abnormal features that are definitive = new necrosis or gross extranodal extension.

The committee recommends that interpreting radiologists review prior clinical history and endoscopic notes, a practice that is increasingly possible with the use of electronic medical records. Comparison with baseline imaging, including pretreatment FDG avidity, is also critical. The subjective interpretation of the PET/CECT should include an evaluation of disease on fused PET, CECT, and a dedicated PET workstation. Because previous studies have established that the standard uptake value data do not improve diagnostic accuracy for disease after treatment for HN cancer, a strict threshold for standard uptake value was not used. Instead, NI-RADS is based upon a subjective analysis of FDG uptake, placing avidity into one of three categories: no FDG uptake, mild FDG uptake, and intense FDG uptake. The recently published Hopkins criteria is another qualitative posttherapy assessment scoring system for HN PET, with FDG uptake less than internal jugular vein (IJV) considered a complete response [11].

NI-RADS 0

This category reflects a new baseline study without any prior imaging available *and* knowledge that prior imaging exists and will become available as comparison. In other words, a patient has been treated or followed at another institution, so the best decisions regarding the next step in management will be made after review of prior imaging (Fig. 3). However, a radiologist must know that prior imaging will be available or uploaded to categorize as a "0" and this category should be rarely used. The final NI-RADS score should be assigned in an addendum after prior imaging examinations become available. If the prior imaging will not

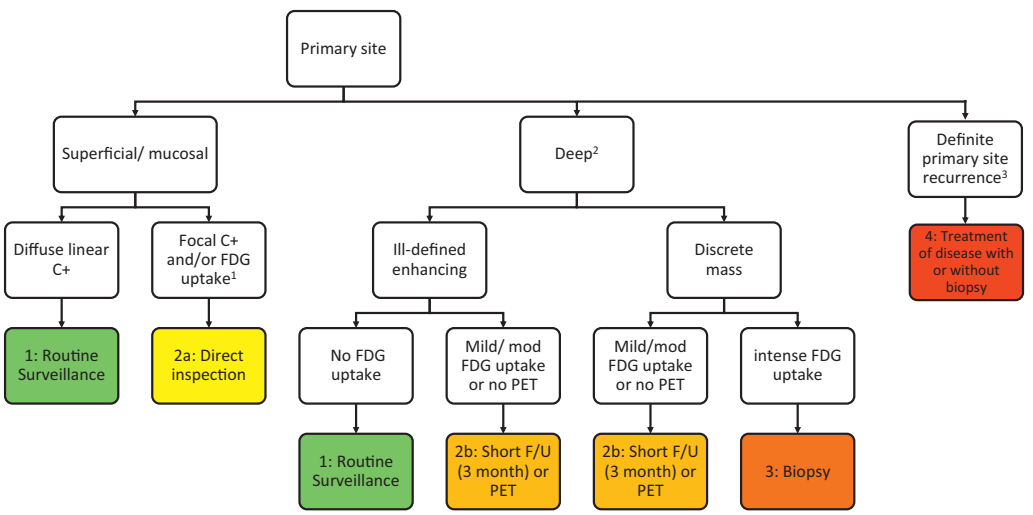

Fig 1. Flow chart depicting primary site category and management. Flowchart showing four categories on the basis of the ACR NI-RADS lexicon and categories to direct follow-up or biopsy. Explanatory notes appear at the bottom. FDG = fluorine-18-2-fluoro-2-deoxy-D-glucose; F/U = follow-up; NI-RADS = Neck Imaging Reporting and Data Systems.

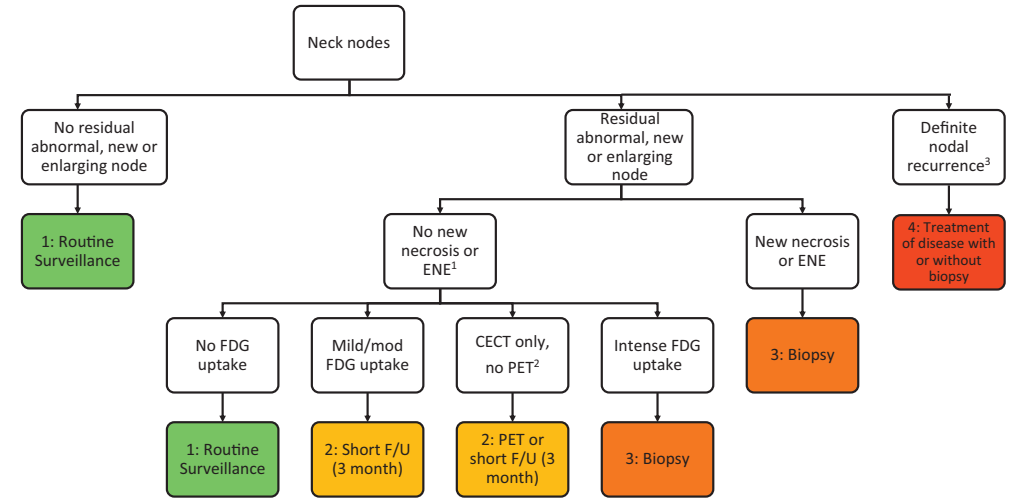

Fig 2. Flowchart depicting NI-RADS neck nodes category and management. Flowchart showing four categories on the basis of the ACR NI-RADS lexicon and categories to direct follow-up or biopsy. Explanatory notes appear at the bottom. FDG = fluorine-18-2-fluoro-2-deoxy-D-glucose; F/U = follow-up; NI-RADS = Neck Imaging Reporting and Data Systems.

necessarily be available, then the NI-RADS score and next best step in management will need to be assigned based on available information.

NI-RADS 1

This category reflects no imaging evidence of recurrence and the linked management is routine surveillance. NI-RADS category 1 has 3.5% rate of positive disease [9].

Lexicon and Imaging Appearance.

- Expected posttreatment changes with non-mass-like distortion of soft tissues
- Low-density submucosal edema (postradiation edema)
- No abnormal FDG uptake
- Diffuse curvilinear mucosal enhancement or FDG uptake (benign radiation mucositis)
- Residual nodal tissue with no FDG uptake

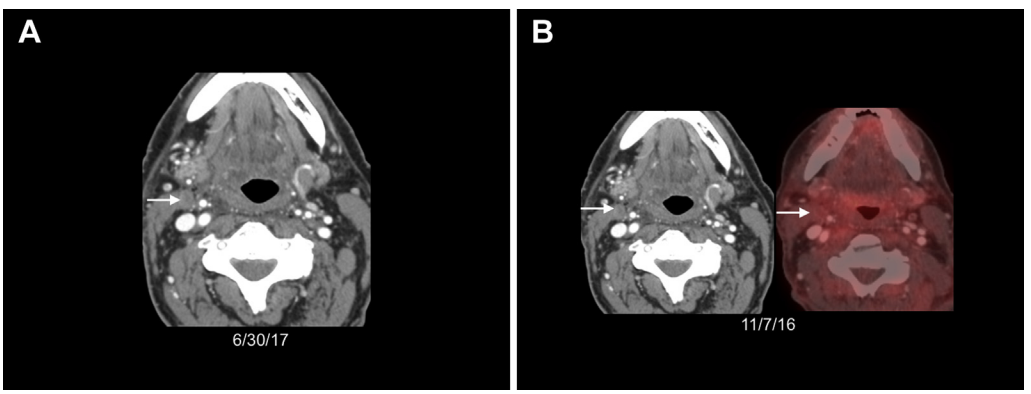

Fig 3. NI-RADS neck 0: oropharyngeal SCCA completed CRT at outside hospital. (A) Patient transferred care and had this CECT nearly 10 months after treatment. At time of dictation, no prior examinations were available. CECT shows 1 cm of residual nodal tissue on right at level II (arrow). This finding should be interpreted with prior images and especially baseline posttreatment PET-CECT. Therefore, this is assigned NI-RADS 0, with an addendum and updated NI-RADS score when priors are available. (B) Initial posttreatment PET-CECT, now available, showed no FDG uptake in this residual nodal tissue (arrows), confirming that it is a treated node. Data have shown salvage neck dissection is *not* needed in these cases, and this can be added in as a NI-RADS 1. CECT = contrast-enhanced CT; CRT = chemoradiotherapy; FDG = fluorine-18-2-fluoro-2-deoxy-D glucose; NI-RADS = Neck Imaging Reporting and Data Systems; SCCA = squamous cell carcinoma.

Primary. NI-RADS primary category 1 should have no residual FDG uptake or abnormally enhancing soft tissue at the primary site (Fig. 4). After complicated surgical resection and flap reconstruction, especially for oral cavity SCCA, PET false-positives are more likely. Radiologists' knowledge and familiarity with common flap reconstructions can help to avoid this pitfall. Tongue fasciculations after partial glossectomy and flap reconstruction resulting in increased FDG uptake are a common PET pitfall. Diffuse mucosal enhancement without deep extension is more likely mucositis and should fall under NI-RADS 1. More focal mucosal enhancement may be either tumor or posttreatment change and should be categorized as NI-RADS 2. Primary category "X" can be used for unknown primary.

Neck. NI-RADS nodal category 1 should have no residual FDG uptake on the posttreatment 12-week baseline study. In this setting after CRT, radiologist input is critical because providers are often deciding whether a salvage neck dissection is needed. If there is no FDG uptake, a NI-RADS 1 category can be assigned even if residual nodal tissue is present (Fig. 3) [12]. Previous prospective studies have shown that HN SCCA patients with residual CT nodal abnormalities after definitive CRT could be spared a salvage neck dissection if PET was negative [11,13,14]. A recent publication by Mehanna et al showed similar survival for patients with advanced HN cancer treated with CRT, who underwent planned neck dissection versus PET-CT surveillance. PET-CT surveillance resulted in fewer operations and was more cost-effective [15]. For subsequent surveillance studies, stable nodal soft tissue and little to no FDG avidity can be categorized as a NI-RADS 1. It is important to recognize posttreatment CECT and PET pitfalls that show enhancement or FDG uptake that represent posttreatment change and not tumor persistence or recurrence [16,17].

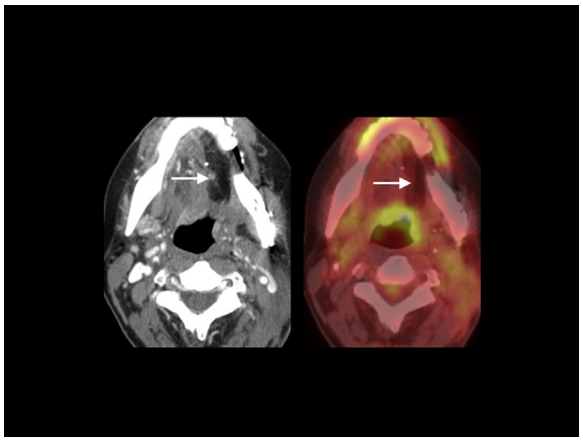

Fig 4. NI-RADS primary 1: oral cavity SCCA treated with glossectomy, mandibulectomy, free fibular flap reconstruction, and selective neck dissection. Twelve-week status postresection and CRT, baseline surveillance PET/CECT shows complicated postsurgical appearance with minimal FDG uptake in remaining oral tongue and base of tongue. This is an expected posttreatment appearance. Review of surgical pathology results revealed that margins were negative and careful examination of the bone and soft tissue components of the flap revealed no nodularity. CECT = contrast-enhanced CT; CRT = chemoradiotherapy; FDG = fluorine-18-2-fluoro-2-deoxy-D glucose; NI-RADS = Neck Imaging Reporting and Data Systems; SCCA = squamous cell carcinoma.

NI-RADS 2

The primary site NI-RADS category 2 is divided into subcategories based upon management differences for mucosal (2a) versus deep (2b) abnormalities. This category reflects low suspicion for recurrence and the linked management options are direct mucosal inspection (2a), short-term follow-up in 3 months, or addition of PET imaging. Ultimately, this category includes ill-defined non-mass-like abnormalities, *which are not good biopsy targets.* Therefore, additional data (short-term follow-up to assess incremental change or PET to assess FDG avidity) is needed to determine whether biopsy is indicated or even feasible. NI-RADS category 2 lesions only have a 17% rate of positive disease [9].

Lexicon and Imaging Appearance.

- Focal mucosal enhancement or FDG uptake without a discrete nodule or mass (2a)
- Ill-defined non-mass-like deep tissue with only mild contrast enhancement or FDG uptake; no discrete nodule or mass (2b)
- Residual nodal tissue with mild FDG uptake
- Growing lymph node without morphologically abnormal features (such as necrosis or extra nodal extension); although an increase in size after treatment is worrisome, normal reactive nodes may show mild increase in size secondary to inflammation so that shorter follow-up or PET is needed for more data rather than a biopsy.
- When there is a mismatch between CECT and PET (eg, focal FDG uptake but no discrete nodule or correlative findings on CECT)

Primary. NI-RADS category 2 is subdivided at the primary site to align with practical management recommendations. NI-RADS category 2a is a special category for superficial mucosal abnormalities with the linked management recommendation of direct clinical inspection with biopsy at the discretion of the surgeon (Fig. 5). Traditionally, radiologists have not considered themselves "mucosal doctors," but it is not uncommon for PET or CECT to show more focal FDG uptake or enhancement along the mucosal surfaces. It is most efficient to communicate the area to our surgical or oncology colleagues who can visually assess or palpate that specific location and biopsy if there are worrisome findings. Focal mucosal enhancement or enhancement deep to an ulceration is more concerning than diffuse mucosal enhancement. This is assigned a NI-RADS 2a category and should prompt direct clinical inspection, accessible to the referring clinician, as the first management step. Some mucosal surfaces, like the postradiated larynx, are particularly challenging, and PET/CECT often helps to direct the clinical examination and biopsy in the posttreatment setting. CECT also shows postradiation edema rather than a focal enhancing mass in this category. In our experience, 17% of NI-RADS 2 will be tumor persistence or recurrence, with the greatest likelihood in the category 2a. Mucosal lesions in the larynx are often harder for our referring clinicians to assess accurately, so PET is very helpful in the postradiated larynx to direct clinical inspection and biopsy.

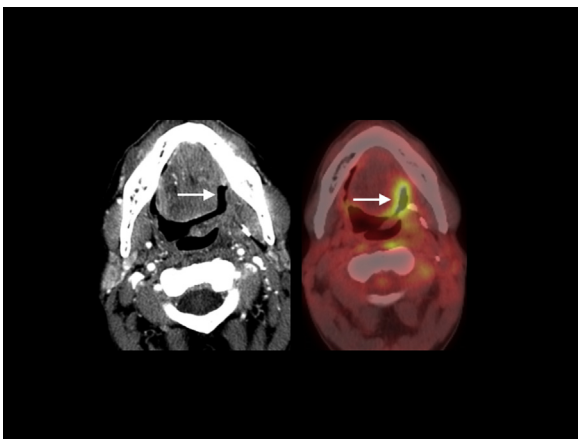

Fig 5. NI-RADS primary 2a: oropharyngeal SCCA treated with CRT. Twelve weeks post-CRT, baseline surveillance PET/CECT shows an ulceration along left glossotonsillar sulcus (arrow) without deep enhancement or other concerning features on CECT. However, PET shows intense focal uptake in this region (arrow). Although anatomic appearance on CECT is reassuring, study is assigned a NI-RADS category 2a so that surgeons look specifically at this area. On direct inspection, this seemed consistent with radiation injury and follow-up PET was negative. CECT = contrast-enhanced CT; CRT = chemoradiotherapy; FDG = fluorine-18-2-fluoro-2-deoxy-D glucose; NI-RADS = Neck Imaging Reporting and Data Systems; SCCA = squamous cell carcinoma.

A deep ill-defined soft tissue abnormality without a discrete mass but differential enhancement or mild FDG uptake falls into the NI-RADS category 2b, with the linked management recommendation for shorter-interval follow-up (3 months) or immediate PET if the examination being scored is a CECT only. The majority of deep ill-defined abnormalities with mild enhancement and mild FDG uptake (NI-RADS 2b) will be posttreatment change (83%), and therefore biopsy should be avoided in most circumstances. In many cases, especially if this ill-defined abnormality is not adjacent to critical structures, waiting for 3 months would not change the options for salvage surgery even if it is proven to represent recurrence. The only exception to this rule is if osteoradionecrosis or soft tissue necrosis is the alternate consideration because hyperbaric oxygen therapy may be provided for patients with radionecrosis, but it is contraindicated in the setting of viable tumor. Therefore, there may be rare requests to biopsy NI-RADS 2 lesions or an even shorter imaging follow-up (such as 6 weeks) because a more immediate pathologic diagnosis is needed that will impact the treatment regimen.

Outside of the posttreatment baseline study, surveillance may be done with a CECT or MRI without a combined PET. In this scenario, recommendation for PET may be part of the NI-RADS 2 linked management to obtain more data. For example, deep, ill-defined, nonbulky, mildly enhancing soft tissue may be scored NI-RADS 2b on CECT or MRI alone (low suspicion). Referring clinicians can decide between short-term follow-up (3 months) or PET. If PET is performed and the interpretation finds no FDG uptake, the finding can be downgraded to NI-RADS 1, or if there is focal intense uptake on PET, then it will be upgraded to a NI-RADS 3.

Because NI-RADS 2 lesions should be ill-defined and non-mass-like, they are difficult biopsy targets. It is helpful to consider this next step in management when deciding whether to assign a particular abnormality as a NI-RADS 2 versus NI-RADS 3. If an immediate biopsy is appropriate, NI-RADS 3 should be the correct category. If it would be prudent to wait 3 months and

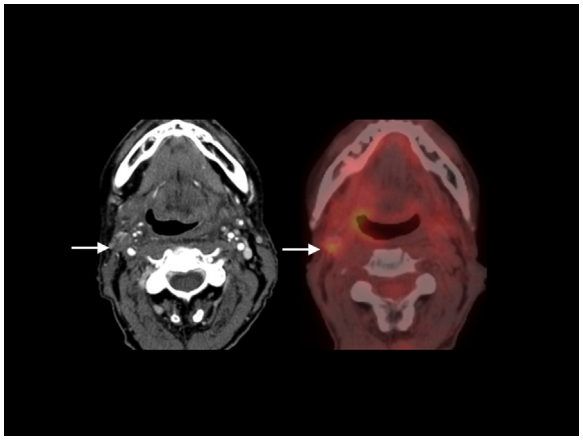

Fig 6. NI-RADS neck 2: oropharyngeal SCCA treated with CRT. Twelve weeks post-CRT, baseline surveillance PET/CECT shows interval decreased size and FDG avidity of right IIA node (compared with pretreatment), but there is persistent 1.2 cm heterogeneous nodal tissue with mild FDG uptake (arrow). This was assigned NI-RADS category 2 because FDG uptake was very mild. In our experience, many cases with only mild residual FDG uptake were negative at salvage neck dissection. It would be a reasonable approach to offer patient short-term follow-up imaging, preferably PET/CECT at 3 months. CECT = contrast-enhanced CT; CRT = chemoradiotherapy; FDG = fluorine-18-2-fluoro-2-deoxy-D glucose; NI-RADS = Neck Imaging Reporting and Data Systems; SCCA = squamous cell carcinoma.

reimage or add a PET scan (if done as a CECT only), then the lesion should be assigned a NI-RADS 2.

Neck. Lymph nodes that would be considered NI-RADS 2 include mild residual FDG uptake in nodes after definitive CRT (Fig. 6) or mildly enlarging lymph node without specific morphologically abnormal features such as new necrosis or extracapsular spread. It is important to note that posttreatment pathologic nodes often have central low-density, rim enhancement necrosis, which is an expected posttreatment change and can still be scored NI-RADS 1 if there is no FDG uptake or NI-RADS 2 if there is mild FDG uptake. It is always important to compare with baseline imaging and pretreatment imaging. This is different from a newly enlarging node that *develops* new low density or irregularity after the first posttreatment baseline scan, which would be upgraded to a NI-RADS 3. A newly enlarging node on a CECT alone, without definite morphologically abnormal features, could be given a NI-RADS 2 with a recommendation for PET. Then PET would downgrade or upgrade depending on the FDG uptake (Fig. 7).

NI-RADS 3

This category reflects high suspicion for recurrence and the linked management is biopsy. NI-RADS category 3 cases have a 59% rate of positive disease [9]. Tumefactive

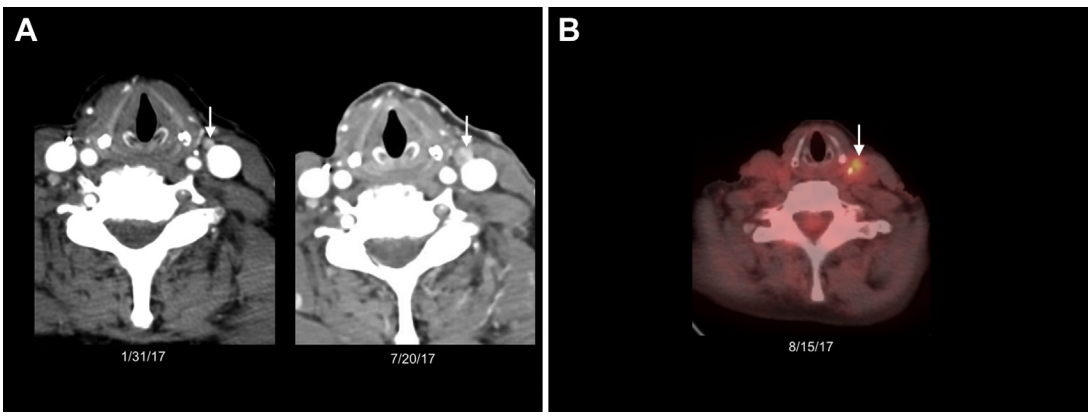

Fig 7. NI-RADS neck 2 upgraded to NI-RADS 3 with PET: oropharyngeal SCCA treated with CRT. (A) CECT neck alone 9 months after treatment showed increased size of left level III node with questionable heterogeneous enhancement (arrows). Because there was no definitive new necrosis or extra nodal extension, the interpreting radiologist gave this a NI-RADS 2 with the suggestion that PET may be helpful before biopsy. (B) Subsequent PET showed focal FDG uptake (arrow) in this node and was therefore assigned a NI-RADS 3. The patient did have contralateral ORN, so an inflammatory node was considered. However, after discussion with the surgeon and patient, an ultrasound-guided FNA confirmed a reactive node. This is an example of a false-positive NI-RADS 3. CECT = contrast-enhanced CT; CRT = chemoradiotherapy; FDG = fluorine-18-2-fluoro-2-deoxy-D glucose; FNA = fine needle aspiration; NI-RADS = Neck Imaging Reporting and Data Systems; ORN = osteoradionecrosis; SCCA = squamous cell carcinoma.

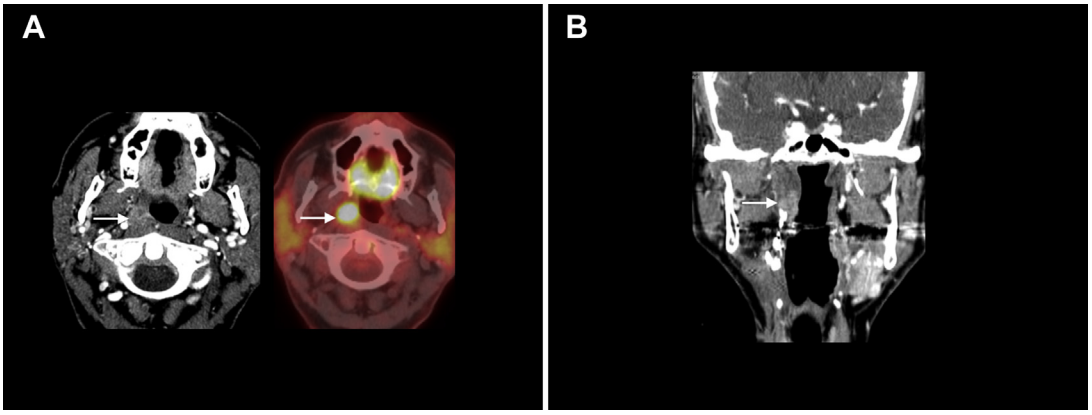

Fig 8. NI-RADS primary 3: oropharyngeal T2N1 SCCA treated with TORS and neck dissection. (A) Twelve weeks post-CRT, a baseline surveillance PET/CECT shows fullness and asymmetric enhancement in right nasopharynx with corresponding intense FDG. (B) Coronal reformatted images show the enhancement to be along the superior margin of the TORS resection (arrow). Surgeon reported that the mucosa in this location was intact without ulceration, but reported the superior margins had been difficult. The patient was reluctant to undergo radiation because the margins were officially negative and there was no extranodal extension. After the radiologist and surgeon discussed the abnormality with the patient, and high level of suspicion was conveyed, he agreed to a biopsy, and diagnostic laryngoscopy with deeper biopsy if the clinic biopsy was negative. Indeed, the clinic biopsy was negative but deeper biopsy in the operating room confirmed recurrence. This case underscores the importance of our level of suspicion in guiding management to ensure radiologic-pathologic concordance. CECT = contrast-enhanced CT; CRT = chemoradiotherapy; FDG = fluorine-18-2-fluoro-2-deoxy-D glucose; FNA = fine needle aspiration; NI-RADS = Neck Imaging Reporting and Data Systems; SCCA = squamous cell carcinoma; TORS = Trans-oral robotic surgery.

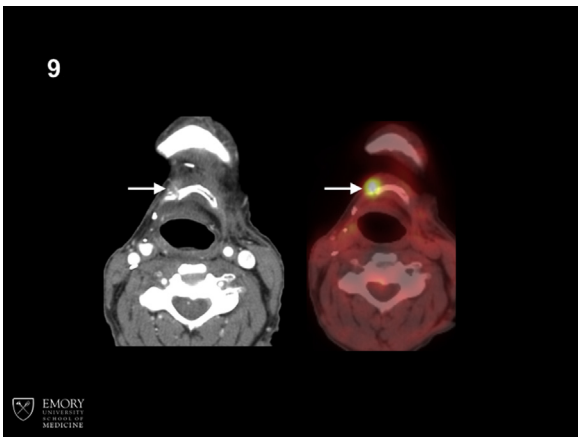

Fig 9. NI-RADS neck 3: patient had undergone salvage marginal mandibulectomy and modified radical neck dissection for recurrent nodal disease in right level IB node (adherent to mandible and extending to hyoid bone) after CRT for "oropharyngeal SCCA" (unknown human papillomavirus status and pretreatment imaging not available) treated at outside hospital with CRT. Twelve-week post-CRT baseline surveillance PET/CECT shows a focal nodule of enhancement at anterior right hyoid margin (arrow), with focal intense FDG uptake (arrow). This is a high-risk area for residual disease so the recommendation should be for biopsy. CECT = contrast-enhanced CT; CRT = chemoradiotherapy; FDG = fluorine-18-2-fluoro-2-deoxy-D glucose; FNA = fine needle aspiration; NI-RADS = Neck Imaging Reporting and Data Systems; SCCA = squamous cell carcinoma.

radiation injury represents the largest portion of false-positives in this category.

Lexicon and Imaging Appearance.

- New or enlarging discrete nodule or mass with intense enhancement or FDG uptake
- Enlarging lymph node with intense FDG uptake
- CECT and PET concordant for high suspicion

Primary. NI-RADS category 3 should be assigned to lesions that are of high suspicion and warrant biopsy (Fig. 8 and Fig. 9). Primary site recurrences are either mucosal or submucosal or deep. Most mucosal abnormalities are assigned a NI-RADS 2a category because the surgeons can best assess the mucosal surfaces. However, more discrete mucosal or very superficial submucosal abnormalities can be upgraded to a NI-RADS 3 especially if they develop after the posttreatment baseline study. The ultimate recommendation and management, however, is often the same because the surgeons or oncologists will directly inspect and decide on biopsy based on their clinical examination. In contrast, the decision to biopsy deep abnormalities is primarily based upon the imaging appearance, so that the designation of NI-RADS 3 should generally be reserved for lesions that the radiologist is willing to biopsy by ultrasound or CT guidance. Occasionally, NI-RADS 3 lesions will not be amenable to

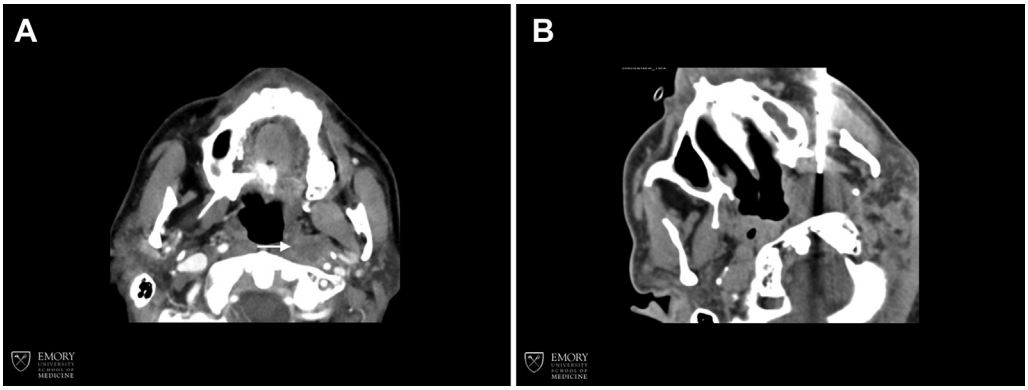

Fig 10. NI-RADS neck 3: left nasal rhabdomyosarcoma. (A) Surveillance CECT alone at 12 months shows a new necrotic left retropharyngeal lymph node (arrow). Because this new node has definite abnormal morphologic features (ie, necrosis or extra nodal extension), a NI-RADS 3 can be assigned based on CECT alone. (B) A CT-guided biopsy confirmed recurrence (arrow). CECT = contrast-enhanced CT; CRT = chemoradiotherapy; FDG = fluorine-18-2-fluoro-2-deoxy-D glucose; FNA = fine needle aspiration; NI-RADS = Neck Imaging Reporting and Data Systems; SCCA = squamous cell carcinoma.

image-guided biopsy, and further management should be discussed among the treatment team. NI-RADS 3 is not based upon size but rather morphologic, especially mass-like, appearance and FDG avidity. A subcentimeter discrete lesion with focal intense FDG uptake is a NI-RADS 3. Often deep recurrences at the primary site occur along the margins of the flap or resection bed (Fig. 8). The most common cause of a false-positive in this category is radiation injury to the soft tissue or bone, which can have a tumefactive appearance on anatomic images and PET with marked FDG uptake from inflammation [10].

Neck. NI-RADS category 3 in the neck should be assigned for a new or enlarging lymph node with either focal intense FDG uptake or new morphologically abnormal features (Fig. 10). Although NI-RADS 3 is the high-suspicion category, false-positives do occur and are more commonly seen with PET/CECT than CECT alone [9].

NI-RADS 4

This category reflects definitive known recurrence, and, therefore, there is usually no need for biopsy. However, occasionally biopsies, for specific biomarkers, will be needed for NI-RADS 4 lesions so that patients can enroll in a trial or otherwise continue with treatment.

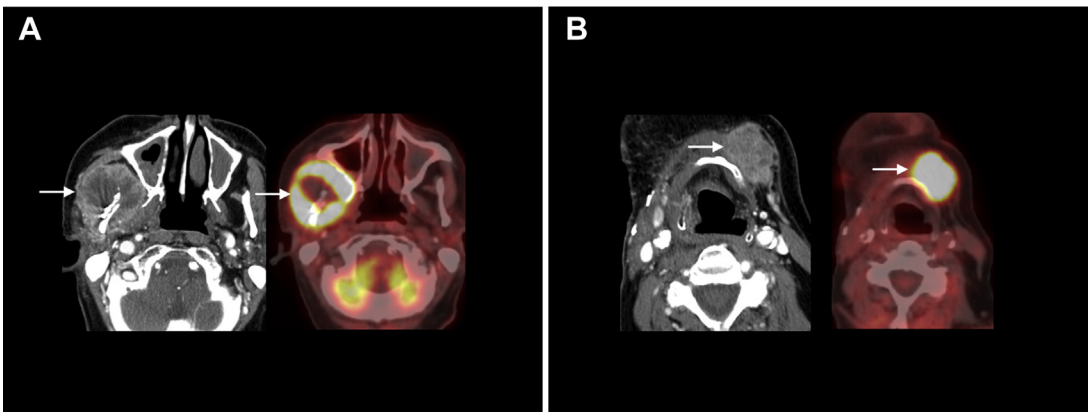

Fig 11. Neck Imaging Reporting and Data Systems (NI-RADS) primary and neck 4: T4a retromolar trigone SCCA s/p resection and flap reconstruction at outside hospital. (A) Twelve-week posttreatment baseline surveillance PET/CECT shows a huge heterogeneous mass at superior margin of the flap in the masticator space (arrow), with corresponding intense FDG uptake (arrow). (B) Inferiorly, there was an additional heterogeneous mass with intense FDG uptake anterior to the hyoid (arrows). These findings were compatible with multifocal recurrence. CECT = contrast-enhanced CT; CRT = chemoradiotherapy; FDG = fluorine-18-2-fluoro-2-deoxy-D glucose; FNA = fine needle aspiration; NI-RADS = Neck Imaging Reporting and Data Systems; SCCA = squamous cell carcinoma; s/p = status post.

Lexicon and Imaging Appearance.

- Pathologic confirmation
- Definite radiographic progression

Primary and Neck. Initially, the NI-RADS 4 category was described as biopsy-proven residual or recurrent disease, often in patients on palliation or undergoing routine imaging as part of a clinical trial. The category has expanded to include cases with definite clinical or imaging progression or single time point unequivocal tumor in the neck (Fig. 11). If a lesion is borderline between a NI-RADS 3 and 4, one approach would be to talk to referring clinicians to determine if they require a biopsy to prove recurrence before the next stage of treatment. If it is considered definitive by imaging and clinical examination, then it can be assigned a NI-RADS 4.

SURVEILLANCE IMAGING ALGORITHM FOR ASYMPTOMATIC PATIENTS

To most effectively use NI-RADS and its linked management recommendations, it is important to have an institutional surveillance imaging policy in place to direct the timing and frequency of posttreatment scans. The current National Comprehensive Cancer Network guidelines recommend imaging a patient after treatment within the first 6 months, but there is no official recommendation for surveillance imaging in an asymptomatic patient after 6 months. The guidelines do state that "routine annual imaging may be indicated for areas difficult to visualize on exam" [1]. The ACR NI-RADS committee sought to develop a consensus on best practice for standard imaging surveillance after treatment for HN SCCA. Although NI-RADS categories can be applied to most all HN neoplasms, the following discussion of surveillance focuses on HN SCCA. Combined FDG-PET/CECT has been adopted as the imaging choice after treatment in the majority of HN SCCA patients because it provides metabolic information as well as high-resolution anatomic detail. PET/CECT is more accurate than either PET or CECT alone and has a high negative predictive value in HN SCCA surveillance [3,18,19]. Timing of the PET/CECT is considered optimal at 12 weeks after treatment, but recent data suggest that it can be as early as 8 weeks posttreatment [7]. Ninety-five percent of asymptomatic recurrences are detected within the first 24 months after treatment, so that routine PET/CT surveillance after this time may be of limited value [20]. If two consecutive PET/CECT studies are scored NI-RADS 1, then no further surveillance is needed based on a study by McDermott et al [4]. MRI is reserved for patients with tumors near or involving the skull base, where evaluation for perineural, intracranial, or intraorbital tumor extension is needed. Therefore, the following algorithm can often be modified to include MRI with or without PET at similar time points and frequency for surveillance of non-SCCA and skull base neoplasms.

The following standard surveillance imaging algorithm reflects the available data (described previously) but also the consensus of the committee members and their multidisciplinary institutional approaches.

- PET/CECT at 8 to 12 weeks after completion of definitive therapy as a baseline
- If this is negative, then a CECT or PET/CECT 6 months later
- If CECT is negative, a CECT neck alone 6 months later (if two consecutive PET/CECTs are negative, then stop surveillance imaging)
- If second CECT is negative, CECT neck and chest 12 months later

FUTURE DIRECTIONS

Interobserver variabilities need to be tested to determine the robustness of NI-RADS for surveillance imaging interpretation and recommendation for patients with HN cancer. In addition, a multicenter collection of imaging data with clinical outcome is essential to improve diagnostic accuracy and precision of NI-RADS categorization for detection of recurrence.

TAKE-HOME POINTS

- NI-RADS is a simple, practical imaging surveillance template used to guide appropriate imaging interpretation, follow-up, and next clinical management steps.
- The standardization of linked management recommendations and correlation with patient outcomes has the potential to validate performance and highlight radiologists' added value in patient care.

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ADDITIONAL RESOURCES

Additional resources can be found online at: https://doi.org/10.1016/j.jacr.2018.05.006.

REFERENCES

1. Pfister DG, Spencer S, Brizel DM, et al. Head and neck cancers, Version 2.2014. Clinical practice guidelines in oncology. J Natl Compr Canc Netw 2014;12:1454-87.
2. Wierzbicka M, Napierala J. Updated National Comprehensive Cancer Network guidelines for treatment of head and neck cancers 2010-2017. Otolaryngol Pol 2017;71:1-6.
3. Koshkareva Y, Branstetter BF, Gaughan JP, Ferris RL. Predictive accuracy of first post-treatment PET/CT in HPV-related oropharyngeal squamous cell carcinoma. Laryngoscope 2014;124:1843-7.
4. McDermott M, Hughes M, Rath T, et al. Negative predictive value of surveillance PET/CT in head and neck squamous cell cancer. AJNR Am J Neuroradiol 2013;34:1632-6.
5. Ong SC, Schoder H, Lee NY, et al. Clinical utility of 18F-FDG PET/CT in assessing the neck after concurrent chemoradiotherapy for Locoregional advanced head and neck cancer. J Nucl Med 2008;49:532-40.
6. Gilbert MR, Branstetter BF, Kim S. Utility of positron-emission tomography/computed tomography imaging in the management of the neck in recurrent laryngeal cancer. Laryngoscope 2012;122:821-5.
7. Leung AS, Rath TJ, Hughes MA, Kim S, Branstetter BF. Optimal timing of first posttreatment FDG PET/CT in head and neck squamous cell carcinoma. Head Neck 2016;38(Suppl 1):E853-8.
8. Aiken AH, Farley A, Baugnon KL, et al. Implementation of a novel surveillance template for head and neck cancer: Neck Imaging Reporting and Data System (NI-RADS). J Am Coll Radiol 2016;13:743-746 e741.
9. Krieger DA, Hudgins PA, Nayak GK, et al. Initial performance of NI-RADS to predict residual or recurrent head and neck squamous cell carcinoma. AJNR Am J Neuroradiol 2017;38:1193-9.
10. Aiken AH, Hudgins PA. Neck Imaging Reporting and Data System. Magn Reson Imaging Clin N Am 2018;26:51-62.
11. Marcus C, Ciarallo A, Tahari AK, et al. Head and neck PET/CT: therapy response interpretation criteria (Hopkins criteria)-interreader reliability, accuracy, and survival outcomes. J Nucl Med 2014;55:1411-6.
12. Wray R, Sheikhbahaei S, Marcus C, et al. Therapy response assessment and patient outcomes in head and neck squamous cell carcinoma: FDG PET Hopkins criteria versus residual neck node size and morphologic features. AJR Am J Roentgenol 2016;207:641-7.
13. Porceddu SV, Pryor DI, Burmeister E, et al. Results of a prospective study of positron emission tomography-directed management of residual nodal abnormalities in node-positive head and neck cancer after definitive radiotherapy with or without systemic therapy. Head Neck 2011;33:1675-82.
14. Sherriff JM, Ogunremi B, Colley S, Sanghera P, Hartley A. The role of positron emission tomography/CT imaging in head and neck cancer patients after radical chemoradiotherapy. Br J Radiol 2012;85:e1120-6.
15. Mehanna H, Wong WL, McConkey CC, et al. PET-CT Surveillance versus neck dissection in advanced head and neck cancer. N Engl J Med 2016;374:1444-54.
16. Aiken AH. Pitfalls in the staging of cancer of oral cavity cancer. Neuroimaging Clin N Am 2013;23:27-45.
17. Plaxton NA, Brandon DC, Corey AS, et al. Characteristics and limitations of FDG PET/CT for imaging of squamous cell carcinoma of the head and neck: a comprehensive review of anatomy, metastatic pathways, and image findings. AJR Am J Roentgenol 2015;205:W519-31.
18. Branstetter BF, Blodgett TM, Zimmer LA, et al. Head and neck malignancy: is PET/CT more accurate than PET or CT alone? Radiology 2005;235:580-6.
19. Nayak JV, Walvekar RR, Andrade RS, et al. Deferring planned neck dissection following chemoradiation for stage IV head and neck cancer: the utility of PET-CT. Laryngoscope 2007;117:2129-34.
20. Beswick DM, Gooding WE, Johnson JT, Branstetter BF. Temporal patterns of head and neck squamous cell carcinoma recurrence with positron-emission tomography/computed tomography monitoring. Laryngoscope 2012;122:1512-7.