# RESEARCH



# Assessment of head and neck-imaging reporting and data system using fluro-deoxy-glucose-positron emission tomography/computerized tomography scan imaging of recurrence of head and neck tumors

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# Abstract

**Background** Worldwide, there are more than 550,000 new instances of head and neck cancer per year, with over 300,000 fatalities. Among the Middle Eastern nations, Egypt had one of the highest overall incidence rates of oral cavity and pharynx cancer (5.5/105). A consistent reporting form for head and neck cancer monitoring provides many crucial functions, including directing patient care with simply explained numerical scores for tumor recurrence suspicion levels. The Neck-Imaging Reporting and Data System (NI-RADS) assigns a numerical grade, from 0 to 4, where 0 represents incomplete, 1 represents no evidence of local recurrence (primary site) or adenopathy (neck), 2 represents low suspicion, 3 represents high suspicion, and 4 represents definite recurrence. Our aim was to improve the management outcome for patients liable to recurrence of head and neck cancers post-treatment with radio or chemotherapy using Neck-imaging Reporting and Data System (NI-RADS) after imaging with Fluro-Deoxy-Glucose-Positron Emission Tomography/Computed Tomography Scan (FDG-PET/CT Scan).

**Materials and methods** The study setting was done at our institution and the type of study was combined prospective and retrospective study for 24 months from June 2020 to June 2022. The study population included 71 scans for 55 patients aged between 18 and 70 years, who had suffered from head and neck cancer and underwent treatment by chemotherapy or radiotherapy to follow up on their cases and determine recurrence or resolution of tumors.

**Results** The results demonstrated the classification of tumor findings according to the degree of malignancy with 16.9% of scans were diagnosed as low pathological grade, 60.6% were diagnosed as intermediate pathological grade and 22.5% were diagnosed as high pathological grade. The initial tumor subsites in our study were as follow: the oral cavity with its different subsites represented the largest group constituting 11 cases (20%) of the total cases, and the larynx and vocal cords came next and constituted 10 cases (18.2%) of the total scans, nasopharynx constituted 9 cases (16.4%) of the cases. According to application of NI-RADS score, cases were classified as 17 cases NI-RADS (1), representing 30.1% of cases, 9 cases NI-RADS (2), representing 16.36% of cases, 18 cases NI-RADS (3), representing 32.7% of cases and 11 cases NI-RADS (4) representing 20% of cases. Percentage of recurrence in NI-RADS (1) was 1/17

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representing 5.9%, in NI-RADS (2) was 2/9 representing 22.2%, in NI-RADS (3) was 12/18 representing 66.66%, in NI-RADS (4) was 10/11 representing 90.9% with total recurrence 25/55 cases representing 45.45%.

Conclusions Neck-Imaging Reporting and Data System using FDG PET/CT Scan imaging for assessment of recurrence of head and neck tumors was a choice of relatively high sensitivity and specificity for improvement of significant results and guiding the clinician to the proper management strategy for the patients as well as organizing a strategy for follow-up of cases according to their score of NI-RADS.

Keywords Deoxy-glucose-positron emission tomography, FDG-PET/CT scan, Head and neck tumors

# Background

The annual incidence of head and neck cancers worldwide is more than 550,000 cases with around 300,000 deaths each year, and Egypt had one of the highest overall incidence rates of cancer of the oral cavity and pharynx (5.5/105) among the Middle East Countries [1].

A standardized reporting template in head and neck cancer surveillance serves many important purposes, such as guiding patient care by easily understandable numerical scores for levels of suspicion of recurrence of tumors, also, data-minable reports are expected to address optimal surveillance imaging algorithms and timing, imaging accuracy, reader performance, interobserver variability and opens avenues for direct patient reporting and highlights the radiologist's added value in patient care [2].

This template is named as neck imaging reporting and data system (NI-RADS), which is a clinically useful and applicable imaging surveillance template. It is created to guide appropriate follow-up and next management steps of the cases suffering from head and neck tumors or lesions. It was developed for the first time for surveillance contrast-enhanced computed tomography (CECT) imaging with or without PET in patients with treated head and neck (H and N) cancer [3].

It assigns a numerical category, ranging from 0 to 4, one related to assessment of the primary tumor site and another one related to assessment of the neck, each indicating the level of suspicion for tumor or recurrence and a linked recommended management [4].

The follow-up of the recurrence of cancers in the head and neck will be assessed according to this new reporting and data system, to assess and classify the results as well as to be more conclusive in diagnosis, to help the clinical doctor. The classification is (0) incomplete, (1) no evidence of local recurrence (primary site) or adenopathy (neck), (2) low suspicion, (3) high suspicion, and (4) definite recurrence [2].

By adopting NI-RADS, radiologists conclude their opinions and commit their findings to one of the previously mentioned categories, and thus convey a specific level of suspicion for residual or recurrent tumors. It is an important and practical way to help decrease the variability in radiology reports and clinical management, so it is expected that outcomes for patients with head and neck cancer ultimately improve [4].

Finally, we are trying to assess the role of using NI-RADS and if it is expected to provide a meaningful framework for discussion of results for patients with a history of head and neck lesions (Figs. 1, 2, 3, 4).

Our primary objectives were to provide critical analysis and to evaluate the performance of proposed RAD system of head and neck lesions. While the secondary objectives were to highlight the constraints of the proposed

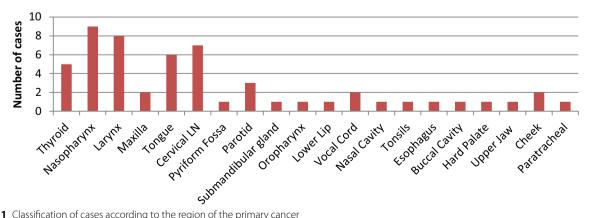


Fig. 1 Classification of cases according to the region of the primary cancer

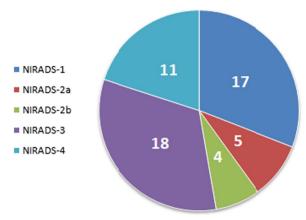


Fig. 2 Classification of cases according to their score of NI-RADS in PET/CT report

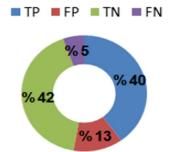


Fig. 3 ROC curve for NO-RADS score to detect tumor recurrence according to Mass FDG. Sensitivity=TP / TP + FN = 22/(22+3)= 88%. Specificity=TN/TN+FP= 23/(23+7) = 76.6%. NPV= TN/TN+FN= 23/26 = 88.5%. PPV=TP/TP+FP= 22/29 = 75.9%. Accuracy=TP+TN/Total cases = 45/55 = 81.8%

NI-RAD System and to assess whether manual review could be enhanced when using the NI-RADS model as a first-pass reader (Figs. 5, 6, 7).

# Methods

This was a combined prospective and retrospective cross-sectional study. It included 71 scans for 55 patients. The duration of the study was 24 months from June 2020 to June 2022.

Individuals aged between 18 and 70 years, who had suffered from head and neck cancer and underwent treatment by chemotherapy or radiotherapy underwent a follow-up imaging study by FDG PET/CT to determine recurrence or resolution of tumors. All cases included in the study were patients under follow-up between 2019 and 2022; cases of 2019 were recorded before the start of our study.

The study was done in our institution, on 55 cases post-treatment (surgical, radio, or chemotherapy) after head and neck cancer, using FDG-PET/CT follow-up imaging and applying the NI-RADS technique to assess the predictive value of treatment success or failure. The study was combined retrospective and prospective, and included males and females patients; their ages ranged from (18 to 70 years).

# Data sources

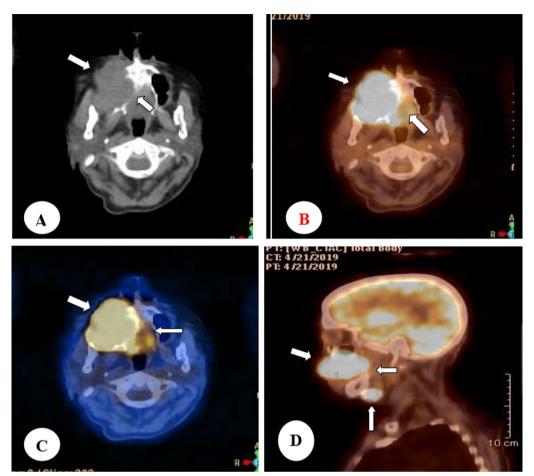
The data used in the present study were obtained from databases and records provided by our institution. Screening records and cancer registry records were used. The criteria for extracting variables from the database are based on the demographic variables and health-related factors related to the incidence of head and neck shown in literature. First, the basic data, history data, and data on health-related behaviors of the subjects were extracted from the cancer screening records. This was followed by the extraction of data such as the date and methods of a confirmed diagnosis of head and neck cancer from the cancer registry records. Data on variables such as sex, age, health status and utilization of preventive health services, and marital status were extracted.

## **Definition of variables**

The variables used in the present study included the following: sex, age, site of the tumor, duration of treatment, types of imaging modality, presence or absence of lymphadenopathy or metastases, and scoring of NI-RADS for each case.

The inclusion criteria of the study were treated cases of pathologically proven primary head and neck lesions, including newly recruited cases and filed cases that meet the NI-RADS template requirements, and available on its picture archiving and communication system (PACS). The newly recruited cases were referred from the oncology department head and neck clinic, and the filed cases also belong to patients treated at the oncology department, patients with age ranged between 18 to 70 years with no sex predilection. Also, patients with normal ranges of glomerular filtration rate (GFR) were selected. While the exclusion criteria were filed cases of head and neck tumors with missing data or scans required for the NI-RADS template, pregnant and lactating women and patients with bad general conditions requiring life support, patients younger than 18 years or over 70 years old, abnormal GFR, diabetic patients and patients with history of tumors in areas other than head and neck.

Simple random sample was used. Informed consent from our institution was obtained explaining the procedure details, risks and complications, and available other imaging modalities alternatives.



**Fig. 4** Female patient, 70 year-old, complaining of a swelling at the right upper jaw and the floor of the right maxillary sinus, **A** Axial CT image, **B** and **C** Axial PET/CT images and **D** Sagittal PET/CT Scan images show mass (about 58 × 38 mm in its dimensions), the mass is ill-defined, involving the floor of the right maxillary sinus, creeping to the buccal cavity and the corresponding superior alveolar margins, eliciting dense tracer fixation with SUV max. of 24.0. A solitary mildly enlarged right submandibular LN (about 17 × 13 mm) is seen eliciting dense tracer fixation with SUV max. of 21.1. Biopsy done on 09/04/2019 showed spindle cell tumor, sarcomatoid carcinoma. According to NI-RADS Template, its score is NI-RADS (IV). Follow-up PET/CT as clinically indicated would be advisable

All patients were subjected to full clinical history and full dedicated clinical examination, PET-CT scans and the ACR NI-RADS reporting template.

Our study included initial baseline scanning of patients who suffered from head and neck tumors, after their treatment with surgery, chemotherapy, or radiotherapy, scans taken at least eight weeks after completion of therapy, some cases have been exposed to second re-scanning three months later if the findings were negative, and others were exposed to the third scan six months after the baseline scan, in the nonsuspicious cases. The included 71 PET/CT scans for 55 patients, as 16 patients repeated the PET/CT scan, The choice of the scan type depended on the site of the tumor, patient's tolerance, clinical condition, referring clinicians' inquiries and questions needed to be answered.

#### Linked management recommendations

After categorizing the scans into the proper NI-RADS category, further action done guided the template recommendations as the following: For NI-RADS 1 cases, the template recommends routine surveillance, in our study, the next surveillance was after three months intervals due to our institution's current protocol. For NI-RADS 2a cases, the template recommends direct clinical inspection, in our study routine visual clinical assessment and endoscopy were done by the oncology and ENT doctors for all patients, and the results correlated with the radiologic findings. For NI-RADS 2b cases, the template recommends further follow-up by PET CT study and/or short interval follow-up after three months, in our study, the choice between both options depends on the referring physician and the patient's tolerance after counseling. In a few cases of 2b category biopsy was done. For

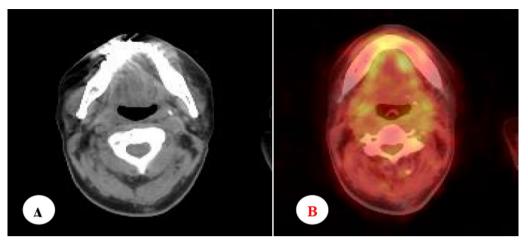


Fig. 5 A male patient 52 year-old, a known case of undifferentiated carcinoma metastatic to the left cervical LNs, diagnosed in April 2012, underwent chemotherapy till March 2013 with disease remission as evidenced by PET/CT done outside our institution on 12/03/2013. In April 2014, he developed a nasopharyngeal soft tissue mass lesion, biopsy showed poorly differentiated keratinizing SCC; accordingly, he was subjected to chemo and radiotherapy. PET/CT done in 2021 showed (**A**) Axial CT image, (**B**) Axial PET/CT image showed no scintigraphic evidence of any foci of increased tracer utilization at the head and neck region, denoting total resolution of the tumor after CRT. According to NI-RADS Template, its score is NI-RADS (I). No biopsy was done (not indicated). Follow-up PET/CT was advisable

NI-RADS 3 cases, a biopsy is the recommendation; in our study, some cases were subjected to biopsy, yet other patients refused biopsy and had a very short interval follow-up instead.

#### Gold standard

The imaging results and NI-RADS categories were compared to the tissue pathological results obtained in some cases specially cases of categories 3 and 4, and compared to the criteria for disease recurrence/residual and the criteria for disease-free detailed previously which depended on three months interval follow-up scan results and clinical assessment. Two consultants of Nuclear Medicine with experience of 20 years and 12 years and one consultant of Radiology with experience of 25 years at our institution have interpreted the images of the cases, some cases were interpreted independently by one of them and some are interpreted as conjoint reading.

# Statistical analysis

After data collection it was entered to the Statistical Package for Social Science (IBM SPSS) version 20. Description of continuous variables: mean + standard deviation or median + range. Description of categorical variables: number and percentage. Then appropriate statistical analyses were applied. *P* value < 0.05 was considered significant.

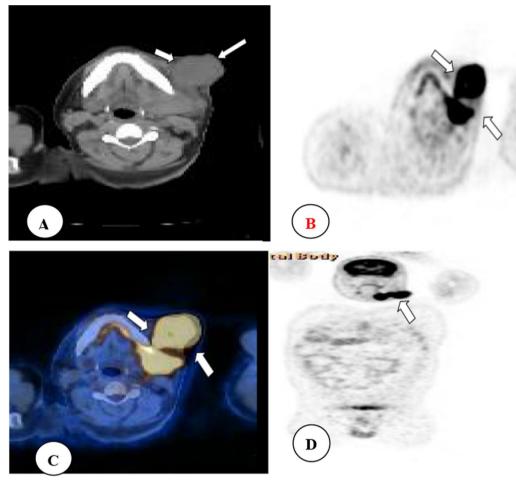
# Results

Population demographics are shown in (Table 1), the range of age of the included patients was (18–70 years) with means 58 years. Out of the 55 patients, the study included 40 male patients and 15 female patients.

Regarding the initial tumor pathological grading: 43 (60.6%) scans correspond to intermediate-grade tumors, 16 (22.5%) scans correspond to high-grade tumors and 12 (16.9%) were low-grade tumors (Table 2).

The initial tumor subsites in our study were as follow: the oral cavity with its different subsites represented the largest group in our study constituting 11/55 (20%) of the total cases, and the larynx and vocal cords comes next and constituted 10/55 (18.2%) of the total cases, nasopharynx constituted 9/55 (16.4%) of the cases, cervical LNs represents 7/55 (12.7%) of the cases, thyroid 5/55 (9.1%) of the cases, parotid 3/55 (5.5%) of the cases, and other subsites constituted 10 (18.2%) of the cases (Tables 3, 4, 5).

According to application of NI-RADS score, cases were classified as 17 cases NI-RADS (1), representing 30.9% of cases, 9 cases NI-RADS (2), representing 16.36% of cases, 18 cases NI-RADS (3), representing 32.7% of cases and 11 cases NI-RADS (4) representing 20% of cases; cases of NI-RADS (2) were sub-classified into NI-RADS (2a) 5 cases and NI-RADS (2b) 4 cases. Percentage of recurrence in NI-RADS (1) was 1/17 representing 5.9%, in NI-RADS (2) was 2/9 representing 22.2%, in NI-RADS (3) was 12/18 representing 66.66%, in NI-RADS (4) was 10/11 representing 90.9% with total recurrence 25/55 cases representing 45.45%.

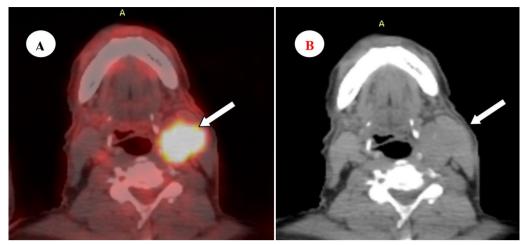


**Fig. 6** Male patient 43 year-old with a known previous history of neuroblastoma, presented with left cheek swelling. MRI was done on 21/02/2020, showed a left cheek mass lesion (35 × 40 mm). **A** Axial CT image, **B** Axial PET image, **C** Axial PET/CT image and **D** Coronal PETScan image, showed a large-sized well-defined left cheek mass lesion, (39X42) mm, eliciting dense tracer fixation with SUV max. up to 19.1. Multiple variable-sized metabolically active LNs are seen at the left submandibular and left upper and lower deep cervical groups, the largest (about 30 × 38 mm) is the former, eliciting SUV max. achieving 20.0. Radiological opinion was highly suspicious of recurrence of neoplasm, according to NI-RADS template, its score is NI-RADS (III). Biopsy was done after reporting and revealed a neuroblastic tumor. Follow-up PET/CT as clinically indicated was advisable

# Discussion

Our work included the correlation between the NI-RADS categories, with the outcome of the patients according to our gold standard for 55 included patients in our institution during the period between 2019 to 2022. Cases have been assessed after completion of their chemo or radio-therapy or both of them. We calculated the positive disease rate for each NI-RADS category.

We founded that there was significant discrimination between different NI-RADS categories, with disease recurrence/persistence rates of 5.9% for NI-RADS 1, 22.2% for NI-RADS 2, 72.3% for NI-RADS 3. A strong association between score and positive disease was found for both the primary site, and the LNs. We compared our study results with the initial study that evaluated the performance of NI-RADS conducted by Krieger et al. [2] which demonstrated significant discrimination between groups, with disease recurrence/ persistence rates of 3.8% for NI-RADS 1, 17.2% for NI-RADS 2, and 59.4% for NI-RADS 3, we found that our study also showed that significant discrimination inbetween different categories, yet we had a high rate of recurrence for NI-RADS 3. We also had a smaller interval between the recurrence rate for NI-RADS 2a and 2b categories, than the difference found by Kreiger et al. [2] and this could be attributed to the relatively low cohort number of scans in our study, and the inhomogeneity inbetween both patients' groups.



**Fig. 7** A male patient, 68 year-old, known to have metastatic undifferentiated epithelial malignancy diagnosed by FNAB from enlarged left cervical LNs in 2011. PET/CT done in 2011 showed metabolically active left cervical and left laryngeal lesions. He received combined CHT&RT with quiescent follow-up till recently when he developed voice change. The figure shows **A** Axial PET/CT image, **B** Axial CT images done for the patient in 2020, Compared to PET/CT done in 2011, the current one showed a glucose avid large amalgamated well defined lesion at the left side of the neck, measuring  $6 \times 5$  cm, picture is impressive of recurrence of tumor and persistence/recurrence of the left cervical lymphadenopathy. According to NI-RADS template, its score is NI-RADS (III). Biopsy was indicated after reporting, the results confirmed the diagnosis. Follow-up PET/CT as clinically indicated would be advisable

### Table 1 Population demographics in the study

Variable	Value	
Age (Yrs)	(Range, 18–70)	
Gender: Male	40 patients (51 scans)	
Female	15 patients (20 scans)	

 Table 2
 Classification
 of
 patients
 according
 to
 treatment

 modality

 <

		Patients	
Treatment modality	RTH and CTH	Count	20
		%	36.4%
	RTH	Count	13
		%	23.6%
	Surgery and CRTH	Count	10
		%	18.2%
	Surgery and RTH	Count	12
		%	21.8%
Total		Count	55
		%	100%

CRTH chemo-radiotherapy, CTH chemotherapy, RTH radiotherapy

For the primary site, the 2a category is used for lowsuspicion superficial mucosal lesions with a linked recommendation of direct inspection. Several benign findings which are considered to be common can induce changes that belong to NI-RADS 2 category such as focal superficial mucosal enhancement in mucositis. These lesions need direct clinical inspection to assess them and differentiate them from residual or recurrent lesions, hence the template classify them for NI-RADS 2a, for more focal enhancing mucosal lesions especially those that develop after initial post-treatment assessment, NI-RADS 3 can be assigned, yet still, assessment is best done directly by the surgeon even in the setting of taking biopsy because of being superficial.

Neck imaging reporting and data system 2b category for the primary site is used for deep, ill-defined, nondiscrete, low-suspicion lesions with only mild FDG uptake. Three months interval follow-up or additional assessment by PET CT is the template recommendation in such cases instead of biopsy. This is more practical in the clinical setting as 2b abnormalities are ill-defined and non-mass and short-term follow-up are more convenient for the patients, and doing PET CT can help in more localization of the abnormality before proceeding to further action.

Biopsy recommendation is reserved for NI-RADS 3 cases for more discrete and enhancing lesions or intense FDG uptake in PET CT studies.

The few available studies describing and evaluating the NI-RADS criteria had not mentioned in detail the diagnostic performance of the individual template criteria regarding the morphologic changes and the enhancement pattern of post-treatment imaging appearance.

We reviewed studies evaluating the performance of the morphologic imaging criteria, yet their diagnostic **Table 3** Classification of tumors according to site of 1rymalignancy and type of pathology

Primary site	Primary diagnosis	Frequency	
Buccal cavity	Differentiated Cancer	1	
Cervical LN	HL	3	
	Metastasis	2	
	NHL	2	
Cheek	Neuroblastoma	2	
Esophagus	Adenocarcinoma	1	
Hard Palate	Differentiated Cancer	1	
Larynx	Differentiated Cancer	2	
	Epithelial Malignancy	1	
	Invasive Cell Cancer	2	
	SCC	3	
Lower Lip	Differentiated Cancer	1	
Maxilla	Differentiated Cancer	1	
Nasal Cavity	NHL	1	
Nasopharynx	NHL	2	
	SCC	5	
	Undifferentiated Cancer	2	
Oropharynx	NHL	1	
Paratracheal	NHL	1	
Parotid	Differentiated Cancer	1	
	HL	1	
	Large Cell Carcinoma	1	
Pyriform fossa	SCC	1	
Submandibular gland	SCC	1	
Thyroid	Papillary Carcinoma	4	
	Undifferentiated Cancer	1	
Tongue	Adenocystic Carcinoma	2	
	Differentiated Cancer	3	
	SCC	1	
Tonsils	NHL	1	
Upper Jaw and Maxilla	Sarcoma	2	
Vocal Cord	SCC	2	
Total		55	

HL Hodgkin Lymphoma, NHL Non Hodgkin Lymphoma, SCC Squamous cell carcinoma

criteria differ from the NI-RADS criteria in some aspects and share some common points.

Despite the limitations of the diagnostic criteria and differences that exist between our work and the available studies; we share common points including expected post-treatment changes, soft-tissue edema, and post-treatment tissue distortion for low-risk cases and mass lesions with a post-contrast enhancement for high-risk cases. For these common diagnostic points, we found agreement between our work and both studies performed by Ailianou et al. [5] and Hermans et al. **Table 4** Classification of cases according to recurrence ofmalignancy in different scores of NI-RADS

			Malignancy/ Recurrence		Total	
			Yes	No		
NIRADS *	Malignancy/R	ecurrence Crosstabu	lation			
NIRADS	NIRADS 1	Count	1	16	17	
		% within NIRADS	5.9%	94.1%	100.0%	
	NIRADS 2a	Count	0	5	5	
		% within NIRADS	0.0%	100.0%	100.0%	
	NIRADS 2b	Count	2	2	4	
		% within NIRADS	50%	50%	100.0%	
	NIRADS 3	Count	12	6	18	
		% within NIRADS	66.6%	33.3%	100.0%	
	NIRADS 4	Count	10	1	11	
		% within NIRADS	90.9%	9.1%	100.0%	
Total		Count	25	30	55	
		% within NIRADS	45.5%	54.5%	100.0%	

[6] in that well-defined criterion for morphologic and enhancement patterns in post-treatment surveillance for head and neck cancers had a high diagnostic performance that could be relied on and could be comparable to the traditional PET/CT reports.

Neck imaging reporting and data system template is evaluating both the primary tumor bed and the neck LNs. For the tumor bed the NI-RADS describes changes in the mucosal surfaces and deep tissues; including their morphology, enhancement pattern, and metabolic activity if F18-FDG PET CT was performed; we focused in our study on the assessment of primary tumor site morphological changes in conventional imaging sequences, post-contrast enhancement pattern and FDG activity in PET CT studies.

Regarding the morphological changes, the NI-RADS template included the following patterns: Expected post-treatment changes as low-density edema and tissues distortion which are categorized as NI-RADS 1 findings, other morphological patterns include mass-like formation which could be ill-defined and hence it is categorized as NI-RADS 2, could be discrete mass which is most suspicious and categorized as NI-RADS 3, and could be proven by biopsy and pathology reports and categorized as NI-RADS 4.

Our study concluded that there is a significant correlation between this range of morphological changes and the outcome at the primary tumor site, with an accuracy of 81.8%, it has higher sensitivity of 88% than its specificity which is 76.6%, it also has high NPV of 88.5%, while its PPV is 75.9%.

		Mass FDG Uptake		Test value	P-value	Sig
		Negative No.=30				
NI-RADS	NI-RADS 1	16 (53.3%)	1 (4%)	55.173*	0.001	HS
	NI-RADS 2a	5 (16.7%)	0 (0.0%)			
	NI-RADS 2b	2 (6.7%)	2 (8%)			
	NI-RADS 3	6 (20%)	12 (48%)			
	NI-RADS 4	1 (3.3%)	10 (40%)			

**Table 5** Tumor recurrence for primary tumor site among NI-RADS categories correlated to the gold standard (old reports and pathology results)

\* Chi-square test

According to Denaro et al. [7], loco regional recurrence occurs in 30% of cases of head and neck cancers. Onethird of them is due to nodal recurrence.

In our study, we had a significant correlation between the patterns of LNs in the NIRADS template and the outcome at the neck LNs, with an accuracy of 91.4%, high specificity of 98%, a high NPV of 94.7%, lesser sensitivity of 77% and PPV of 89.5%.

Kreiger et al. [2] found significant discrimination between LNs categories with NI-RADS 1 lymph node recurrence rate of 4.0%, NI-RADS 2 at 15.0%, and NI-RADS 3 had 70.0%. All nodal categories had a recurrence rate of 6.9%.

Our results showed a recurrence rate for all nodal categories of 19%; lymph node recurrence rate among NI-RADS 1 category of 3.8%, 7.1% for NI-RADS 2, and 55.5% for NI-RADS 3.

We agreed with Kreiger et al. [2] regarding the significant discrimination between the NI-RADS categories for lymph nodes in predicting positive disease residual/ recurrence. We had an almost similar rate of recurrence among the NI-RADS 1 category, and higher recurrence rate for the NI-RADS 2 category, and a less pronounced difference for the NI-RADS 3 category. These differences between the recurrence rate for NI-RADS 2 and 3 categories could be attributed to the higher rate of positive nodal disease in our study which is estimated to be 19% compared to 6.9% in Kreiger et al. [2] study. The high nodal recurrence rate is likely due to differences in tumor characteristics and management plans between both studies and this could be the cause of the higher recurrence rate among NI-RADS 2 and 3 categories in our study.

We compared our results with Kim et al. [8] and Mukundan et al. [9] studies results; taking into consideration that we are working on the NI-RADS templates which are quite different from the usual PET/ CT reporting so the comparison is not so accurate yet needed because the absence of other studies comparing different NI-RADS templates.

In Kim et al. [8] study PET/CT has higher sensitivity than specificity which differs from our results which showed the sensitivity of the PET/CT NI-RADS template for the neck lymph nodes 85.7%, the specificity was 95%, negative predictive value was 91.7%, positive predictive value was 100%, and accuracy was 92.5%. This could be due to the low number of PET/CT cases in our study with no cases underwent PET CT scans diagnosed to have current inflammatory process or osteonecrosis or other conditions that could result in false-positive studies.

From the above-mentioned results, we found that PET/CT template had higher accuracy, higher sensitivity, and specificity than the traditional reporting. The PET/CT template had similar accuracy for both the primary tumor site and lymph-nodes, very high sensitivity and relatively high specificity and PPV, yet the sensitivity and never higher for lymph node assessment compared to the primary tumor site evaluation, this is an agreement with Kim et al. [8] and Mukundan et al. [9] in that PET/CT has the highest sensitivity, specificity, and accuracy.

We had only one case of recurrent tumor in the form of multiple bony osseous deposits with no recurrence or residual detected at the primary tumor site or lymph nodes within the whole follow-up period.

Response assessment according to FDG uptake In a previous study conducted by Allegra et al. [10] to assess the accuracy of PET CT in the detection of the loco regional recurrence in laryngeal cancers, they found overall sensitivity, specificity, and accuracy of PET/ CT at the primary tumor site were 100%, 87.5%, and 91.5%, respectively. This was a retrospective study that included forty-five patients who previously underwent surgical treatment with or without adjuvant radiotherapy for primary laryngeal squamous cell carcinoma. The difference between our study and Allerga et al. [10] is likely to be due to the limited inclusion of laryngeal cancer cases in the Allerga study.

The difference between the FDG uptake and PET CT sensitivity in our study arose because PET CT NI-RADS template categorization depends on other parameters along with the FDG. We had a case of mandible SCC with intense focal uptake at the resection margin yet no corresponding evident discrete enhancing masses and according to the ACR committee recommendation in these cases, we downgraded the NI-RADS category to 2 instead of 3, in the next short-term follow-up we found progressive course regarding the FDG uptake with enhancing mass lesion became more evident; so the downgrading resulted in the false-negative study, yet we have low sample volume for PET CT and one case with this condition is not enough for assessment.

Assessment of the post-treatment surveillance imaging timings: Currently, there are several guidelines for posttreatment head and neck cancers; the National Comprehensive Cancer Network (NCCN) guidelines recommend a baseline imaging exam within 6 months after finishing treatment for T3-4 or N2-3 cancer of the oropharynx, hypopharynx, glottic and supraglottic larynx, and nasopharynx only. The British Association of Head and Neck Oncologists (BAHNO) recommends a baseline imaging study 3 months after completion of treatment. No definite recommendations for surveillance of asymptomatic cases beyond 6 months within both of the previously mentioned guidelines [3].

The ACR surveillance program includes a baseline post-treatment scan 8 weeks after completion of treatment, then three months interval scans for the first year, six months interval scans for the second year then annually thereafter. Assessment of the ACR consensus recommendations regarding the timings for post-treatment imaging for H and N tumors couldn't be done in our study due to the time and sample size limitations. Yet from our study observations regarding the timings of NI-RADS follow-up post-treatment surveillance during the first year we found that the timing intervals are reasonable with the first post-treatment baseline scan 8-12 weeks needed for baseline assessment of the patient's response, then six months interval for the next follow-up in cases of NI-RADS 1 which has a low recurrence rate in our study as well as the initial study conducted by Kreiger et al. [2]. This sounds rationale for six months interval. Three months interval for the next scan for NI-RADS 2 cases is needed as it has a higher recurrence rate compared to NI-RADS 1, so we need to be more cautious and delayed management should be avoided. If the findings are negative the ACR committee recommends follow-up after six months followed by another 12 months interval scan if the findings are still negative this reasonable for us because we had cases with disease recurrence at eight to twelve months post-treatment so we recommend continuing the imaging surveillance for non-suspicious cases for the first two years where most of the cases of disease recurrence occur.

# Limitations of the study

The limited sample volume, the limited period of the study and the lack of inter-observer variability were the main causes of the limitations of the results of our study.

# Conclusions

The performance of the ACR NI-RADS reporting system and its linked management recommendations appears to be of more medical value for the patients and their referring physicians than the traditional radiological reports, with statistically significant discrimination between the different NI-RADS categories for either the primary tumor site and lymph nodes. The use of NI-RADS can help to direct the management plans towards more proper options; avoiding either a delay in the management of query suspicious cases or unnecessary aggressive management or biopsies, hence it helps achieving the remote goal of improving patient care and optimizing the quality of life for patients with H and N cancer. Finally, the applicability of the results of NI-RADS template depends also on the level of training of radiologists to use this template in the field of oncology reports.

### **Recommendations**

Further studies including a larger sample size and a longer duration are needed in the future for upgrading the template and its recommendations for better future results, and to continuously match the evolution in treatment protocols and diagnostic methods.

Abbreviations	
BAHNO	British Association of Head and Neck Oncologists
CECT	Contrast-enhanced computed tomography
CRT	Chemo and radiotherapy
CTH	Chemotherapy
FDG-PET/CTScan	Fluro-Deoxy-Glucose-Positron Emission Tomography/
	Computed Tomography Scan
GFR	Glomerular filtration rate
H and N	Head and neck
NCCN	National Comprehensive Cancer Network
NI-RADS	Neck imaging reporting and data system
PACS	Picture archiving and communication system
RTH	Radiotherapy

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#### Author contributions

M.AS; AA; AG; MH; MA M.AS analyzed and interpreted the patient data regarding PET/CT cases of the patients with previous history of head and neck tumors. AA consultant of nuclear medicine, performed PET/CT reports for the cases. AG supervised the results and contributed in writing the manuscript. MA supervised the results and contributed in writing the manuscript. All authors have read and approved the manuscript, and ensure that is the case.

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#### Availability of data and materials

The data is available upon request of the editorial board.

# Declarations

#### Ethics approval and consent to participate

This study was approved by the Faculty of Medicine Suez Canal University, Research Ethics Committee. The department of nuclear medicine at IMC provided a written informed consent for analysis of anonymized data of the patients.

#### **Consent for publication**

Not applicable.

#### Competing interests

The authors declare that they have no competing interests.

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