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Utility of Likert scale (Deauville criteria) in assessment of Chemoradiotherapy response of primary oropharyngeal squamous cell Cancer site☆

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ABSTRACT

Introduction: The aim of this study is to determine whether Likert scale (Deauville criteria) can be used to classify oropharyngeal squamous cell cancer (OPSCC) patients as 'responders' and 'nonresponders' by utilizing FDG-PET/CT for primary tumor site. The second aim is to compare the performance of methods used in interpretation of posttreatment PET/CT scans (Likert scale, SUVmax, ratios of SUVmax primary lesion to mediastinum 'SUVmax P/M' and SUVmax primary lesion to liver 'SUVmax P/L') in predicting treatment response.

Methods: Seventy-seven PET/CT scans were assessed by Deauville criteria, five-point Likert scale. SUVmax of primary lesion, SUVmax primary to mediastinum and SUVmax primary to liver ratios on first follow-up PET/CT were measured and calculated. Pathology results, clinical and imaging follow-up were used as standart reference.

Results: Sensitivity, specificity, positive predictive and negative predictive value of Likert scale were found to be 80%, 89.5%, 53.3% and 96.8% respectively. When Likert scale and PET parameters were compared, no statistically significant difference was found. Receiver operating characteristic (ROC) was used to determine the optimal cut-off points for SUVmax (found as 4) and for ratios (SUVmax P/M = 1.67and SUVmax P/L = 1.7) with the highest specificity and NPV.

Conclusion: Likert scale adequately categorize patients as 'responders' and 'non-responders'. Since its NPV is high and interpretation is relatively easy, it can be utilized to evaluate OPSCC response to treatment in first follow up FDG PET/CT.

1. Introduction

Head and neck cancers account for 3%–5% of all primary malignancies in the United States [1]. Historically, laryngeal and hypopharyngeal carcinomas were most common due to exposure to tobacco and alcohol. The incidence of oropharyngeal carcinoma is increasing due to human papillomavirus exposure, a risk factor for developing oropharyngeal squamous cell cancer (OPSCC) [2]. For locoregionally advanced head and neck squamous cell cancer (HNSCC), concurrent chemoradiotherapy (CRT) has been increasingly preferred as definitive treatment [3]. However, posttreatment-related changes in the neck make evaluation of the neck difficult for both clinicians and radiologists [4]. 18F-Fluoro-D-glucose-positron emission tomography/computed tomography (FDG-PET/CT) is an important imaging modality not only for initial staging, but also for prognosis estimation and treatment monitorization. Semi-quantitative information like standardized uptake value (SUV), maximum, mean and peak can be obtained from FDG-PET/CT. Although these parameters can be used for treatment

Abbreviations: OPSCC, oropharyngeal squamous cell cancer; HNSCC, head and neck squamous cell cancer; FDG-PET/CT, 18F-Fluoro-D-glucose-positron emission tomography/computed tomography; CRT, chemoradiotherapy; SUV, standardized uptake value

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monitoring; they have known limitations in patients with present postradiation inflammatory changes in the neck [5,6]. Qualitative interpretation by visual inspection of the relative differences of the metabolism of the tumor compared to the metabolism of surrounding normal tissues has been suggested and used by some investigators, However, to our knowledge no standardized qualitative criteria for OPSCC has been used in routine daily practice [7].

Likert scale (Deauville criteria) is an accepted method for treatment response evaluation in Hodgkin Lymphoma [7]. In this scale, mediastinal blood pool and liver are taken as background uptake for reference. In HNSCC, there are few studies regarding the qualitative interpretation of FDG metabolism according to Likert scale and they mostly focus on neck node response to therapy but not on the primary tumor site response. Since surgery is not indicated in patients who have a complete response to CRT, differentiation between the 'responders' and 'non-responders' is an important distinction [8–10]. In this study we aimed to determine whether Likert scale (Deauville criteria) can be used to classify patients accurately as 'responders' and 'non-responders' with FDG-PET/CT following CRT, and to compare Likert scale (Deauville criteria) with a number of SUVmax-based parameters in monitoring the treatment response.

2. Material and methods

This is a retrospective study including 77 biopsy-proven OPSCC patients who were treated with CRT between December 2007 and November 2016. Institutional review board approval was obtained before the study and the guidelines of the Health Insurance Portability and Accountability Act were followed. Inclusion criteria for pretreatment FDG PET/CT scans (PET1) is 2 week period prior to the start of CRT and for posttreatment PET/CT scans (PET2) is at least 7 weeks period after completion of CRT. Patients who had initial neck surgery were excluded from the study. Lymph node positivity on PET/CT was not in our inclusion or exclusion criteria but all of our patients had neck lymph node positivity on PET/CT and there was no patient with distant metastasis.

2.1. Patient characteristics

Of 101 biopsy proven OPSCC patient, 77 were eligible for our study as per our inclusion criteria. Twenty four patients were excluded due to unknown primary (4), absent either PET1 or PET2 (12), timewise improperly scheduled PET2 (7) and absence of follow-up (1). The eligible 77 patients consisted of 65 male and 12 female with a median age of 59 years (range 42–81 years). The primary tumor sites were tongue base in 60 (78%), palatine tonsil in 14 (18%) and lingual tonsil in 3 (4%) patients. Regarding HPV status, 55 patients (71%) had HPV and 38 patients (49%) had p16 positivity. Median follow-up time interval between PET1 and October 2017 or until death was 59 months (11–118 months). The median time from completion of CRT to PET2 was 86 days (49–127 days). Patient characteristics are presented in Table 1.

Table 1
Patient characteristics.

Patient characteristics	Value
Age (years) median (range)	59.5 (42–81)
Gender	
Female	12 (16%)
Male	65 (84%)
Primary site (n = 77)	
Tongue base	60 (78%)
Palatine tonsil	14 (18%)
Lingual tonsil	3 (4%)
Stage of primary tumor	
T1	14
T2	33
T3	15
T4	13
Tx	2
N0	7
N1	15
N2	52
N3	3
American Joint Committee on Cancer Stage	
I	0
II	4
III	14
IV	59
HPV positivity (n = 77)	
HPV-positive	55 (71%)
HPV-negative	9 (12%)
Unknown	13 (17%)
p16 positivity (n = 77	
p16-positive	38 (49%)
p16-negative	3 (4%)
Unknown	36 (47%)
Smoking status	
Current	16
Former	35
Never	26
Follow-up (months) median (range)	59 (11–118)
Treatment to PET2 (days) median (range)	86 (49–127)

2.2. Treatment regimens and follow-up

All patients were treated with radiotherapy 70 Gy (simultaneous integrated boost), and most received concurrent chemotherapy. Single-agent cisplatin was the primary choice of chemotherapeutic agent (2–3 cycles of a 100 mg/m^2 dose of cisplatin on days 1, 22, and 43). Some individuals were treated with other regimens.

Based on PET2 results and clinical examination, a decision to either biopsy the primary or to recommend routine follow-up was determined by the multidisciplinary team at the Otolaryngology (ENT) tumor board. Specifically, if PET2 was positive, a biopsy and/or MRI were performed and patients were treated accordingly.

If PET2 was negative, repeat PET/CT scans were obtained at 9 months from end of treatment (PET3) and again at 24 months from end of treatment (PET4). In addition, frequent clinical follow up was performed and every 3 months during the first 2 years, every 4 months in year 3 and every 6 months later on.

2.3. FDG PET/CT imaging technique

Standard clinical FDG PET/CT protocol including CT and subsequent whole-body PET were performed 60 min after intravenous injection of 18F FDG (370–555 MBq). Every patient fasted for at least 6 h before the examination. The serum glucose levels were measured before radiotracer injection administration to exclude those with hyperglycemia (cut-off of 180 mg/dl). Images were acquired from vertex to feet, on a Biograph mCT Flow 64-4R PET/CT system (Siemens Medical Solutions USA, Inc.) using continuous table motion acquisition mode. Table speed was set as 1 mm/s from vertex to upper chest, 1.4 mm/s from upper chest to pelvis and 2.9 mm/s from pelvis to feet. The 3-mm cut thickness triplanar reconstructions of contrast enhanced diagnostic CT which was obtained at the same time with PET/CT, was used for imaging interpretation.

2.4. Image interpretation

All primary tumor sites were evaluated on PET/CT using a 5-point Likert scale (Deauville criteria) (Table 2) by an experienced radiologist (ZC), board certified in Radiology and Nuclear Medicine. The radiologist was blinded to follow-up results. On the basis of 5-point scale, scores 1, 2, and 3 represented 'complete metabolic response', 'likely complete metabolic response', and 'likely postradiation inflammation'

Table 2
Deauville criteria.

Deauville score	FDG uptake	Category
1	No uptake	Complete metabolic response
2	Uptake ≤ mediastinum	Probably complete metabolic response
3	Uptake > mediastinum but ≤ liver	Probably postradiation inflammation
4	Uptake moderately increased compared with the liver at any site	Probably persistent tumor
5	Uptake markedly increased compared with the liver at any site and/or new sites of disease	Persistent tumor

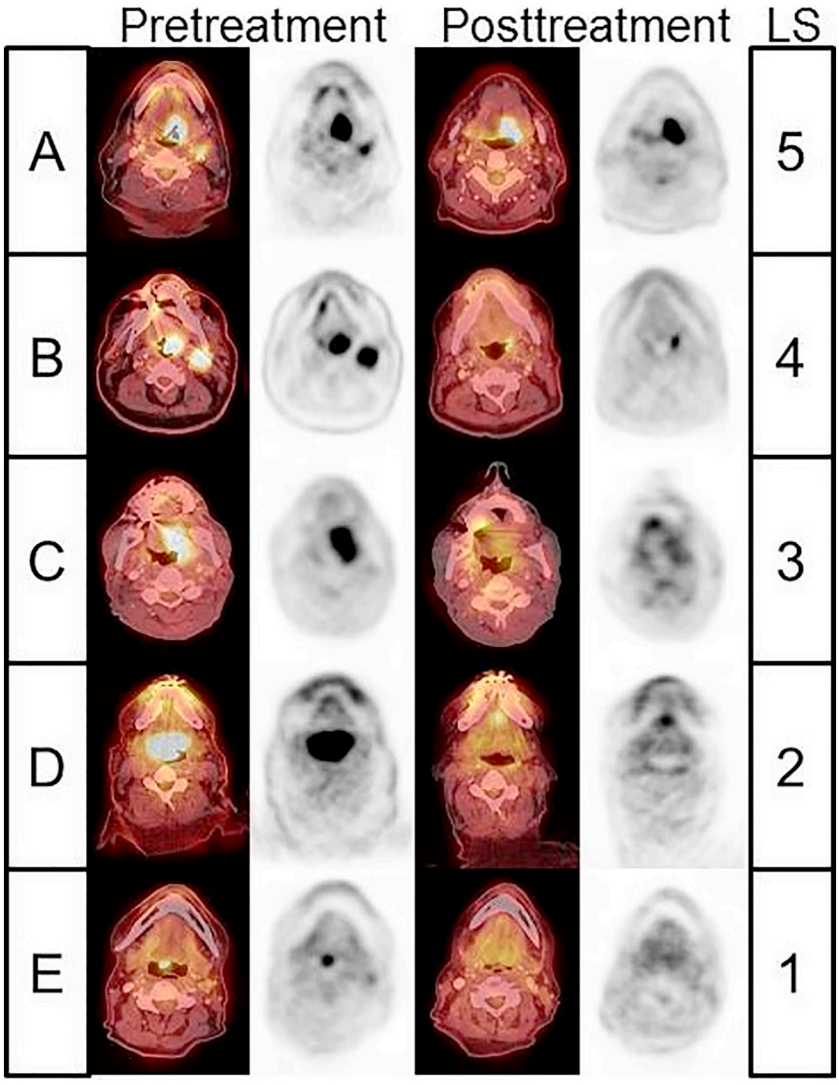

Fig. 1. Five representative cases with pretreatment Likert Scale (LS), posttreatment 5,4,3,2,1 (A,B,C,D,E).

respectively. These were considered as 'responders'. Score of 4 and 5, represented 'likely residual tumor' or 'residual tumor', respectively. These were considered as 'non-responders' (Fig. 1).

Semi-quantitative PET/CT parameters (SUV_{max} of primary site, SUV_{max} of mediastinal blood pool and SUV_{max} of liver) were measured by the same radiologist at another time and blinded to the Likert scale using commercially available software-Syngo.Via® (Siemens Healthcare Forchheim, Germany). The SUV_{max} of the mediastinal blood pool and liver were measured and utilized as reference SUV. The aortic arch and liver segment 8 were taken as reference region for background activity with an average 2.45 cm^3 and 14 cm^3 volume of interest (VOI) respectively. SUV_{max} primary lesion to mediastinum (SUV_{max} P/M) and SUV_{max} primary lesion to liver (SUV_{max} P/L) ratios were calculated. Follow-up results [pathology results, clinical follow-up until October 2017 or until death and imaging (CT, MRI, FDG PET/CT)] were used as standard reference for distinguishing the 'true responders' from false negatives and 'true non-responders' from 'false positives'. Lymph node response was also taken into account in this distinction. Patients who had a negative clinical examination, negative imaging findings on follow up and/or negative biopsy results were categorized as 'true responders'. Patients with positive biopsy results or progression of disease on follow-up imaging were defined as 'true non-responders'.

Patients who had a 'complete response' to CRT at the primary site were defined as 'no residual' or 'no recurrent tumor' following completion of CRT by the last date of follow-up. 'Residual tumor' of primary site was defined as persistent tumor, as per the pathology report and imaging findings during the clinical follow-up. 'Recurrent cancer' was defined as tumor that is found at any stage after a negative PET2 during the follow-up period.

2.5. Statistical analysis

Descriptive statistics included means and standard deviations for continuous variables and counts and percent for categorical variables. The sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) were calculated for dichotomized Likert scale. To compare 'true responders' and 'true non-responders', two-sample *t*-test or Fisher's exact test was performed, as approporiate. Receiver operating characteristic (ROC) curve analysis was performed for PET/CT parameters and Likert scale to compare diagnostic accuracy. Area under the curve (AUC) and 95% CI were reported and also compared pairwisely. Youden's index was used to find the 'optimal' threshold point. The sensitivity, specificity, PPV and NPV were then calculated for PET parameters and 5-point Likert scale. Analyses were performed using SAS system (v9.4; SAS Institute, Cary, North Carolina). Statistical significance was defined at $p < 0.05$.

3. Results

In this study; 'true responders' imply the patients who respond to the treatment and 'true non-responders' imply the patients who didn't respond to the therapy. 'Responders' means; the patients categorized as responders according to Likert scale and 'nonresponders' means; the patients categorized as non-responders according to Likert scale.

There were 67 'true responders' and 10 'true non-responders' (Table 3). Of the 10 'true non-responders', 6 had positive biopsy results. Two had negative biopsy results and 2 patients did not undergo biopsy but all 4 patients showed progression on follow-up.

No significant differences with regard to gender, age, tumor location, HPV and p16 positivity, and follow-up (months) were identified between the 'true responders' (67 patients) and 'true non-responders' (10 patients).

3.1. Diagnostic performance of Likert scale (Qualitative Interpretation)

Sixty-two patients were defined as 'responders' and 15 were defined as 'non-responders' according to the Likert scale. Of these 15 non-responders, 8 were 'true non-responders' and 7 were false positives. In 62 responders as per Likert scale, there were 60 'true responders'and two false negatives (Table 3).

Diagnostic performance including sensitivity, specificity, PPV and NPV of Likert scale (Deauville criteria) in determining the treatment response of OPSCC patients were 80% (CI 44.4–97.5%), 89.5% (CI 79.6–95.7%), 53.3% (CI 34.6–71.1%) and 96.7% (CI 89.6–99%) respectively.

3.2. Diagnostic performance of SUV-based parameters (Semi-quantitative interpretation)

There was a statistically significant difference in quantitative PET parameters between 'true responders' and 'true non-responders'. The median values (range) of SUV_{max}, SUV_{max} P/M and SUV_{max} P/L in 'true responders' were as follows; 3.00 (1.70, 9.40), 1.27 (0.61, 3.44), and 0.92 (0.40, 2.66) respectively.

The median values (range) of SUV_{max}, SUV_{max} P/M and SUV_{max} P/L in 'true non-responders' were as follows; 5.90 (2.90, 11.00), 2.56 (1.16, 5.79), and 1.84 (0.85, 3.44)respectively.

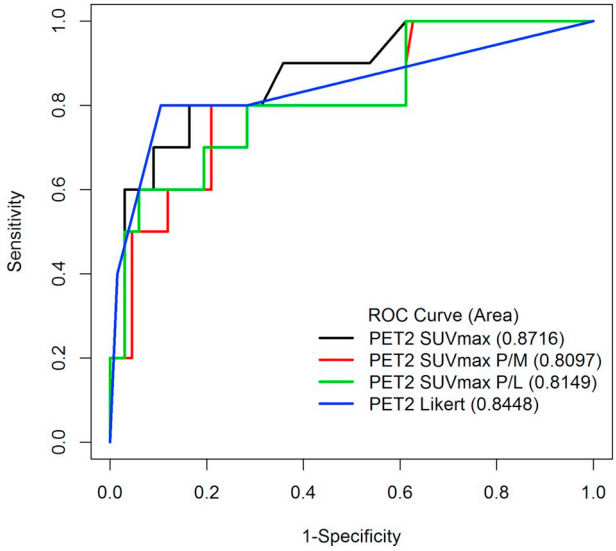

Fig. 2. ROC Curves of Likert Scale and Semi-Quantitative PET Parameters.

3.3. ROC analysis of Likert scale and semi-quantitative PET/CT parameters

No statistically significant difference with regard to AUC of Likert scale, SUV_{max}, SUV_{max} P/M and SUV_{max} P/L was identified ($p < 0.05$).

AUC for PET2 Likert scale, SUV_{max}, SUV_{max} P/M and SUV_{max} P/L were 0.84 (CI 0.68–1), 0.87 (CI 0.75–0.99), 0.81 (CI 0.65–0.96) and 0.82 (CI 0.66–0.97) respectively (Fig. 2).

ROC was used to determine the optimal cut-off points of SUV_{max}, SUV_{max} P/M and SUV_{max} P/L with the highest specificity and NPV in order to evaluate OPSCC patients' treatment response (Table 4).

Cut-off value for PET2 SUV_{max} was 4 with 80% sensitivity, 83.6% specificity, 42.1% PPV and 96.5% NPV; for PET2 SUV_{max} P/M was 1.67 with 70% sensitivity, 79.1% specificity, 33.3% PPV and 94.6% NPV; for PET2 SUV_{max} P/L was 1.7 with 50% sensitivity, 94% specificity, 55.5% PPV and 92.6% NPV.

4. Discussion

FDG PET/CT is a routinely used method in clinical practice for evaluation of treatment response of HNSCC. According to the literature; it has high sensitivity (79.9%) and specificity (87.5%). Its PPV is suboptimal (58.6%) with a high false positivity but its NPV is exceptionally high (95.1%) which is helpful in successfully differentiating 'true responders' from true 'non-responders' [11]. There has no standardized criteria for qualitative assessment of treatment response in HNSCC patients' primary mucosal space tumor sites. Deauville criteria has been an accepted response criteria utilized in Hodgkin Lymphoma patients while interpreting the PET/CT imaging [7]. In our study, we used Likert scale (Deauville criteria) for primary site response assessment in OPSCC following CRT. Sensitivity, specificity, PPV, NPV of Likert scale were 80% (CI 44.4–97.5%), 89.5% (CI 79.6–95.7%), 53.3% (CI 34.6–71.1%) and 96.7% (CI 89.6–99%) respectively. This is similar to the literature. Krabbe et al. assessed 48 OPSCC patients with serial PET/CT scans at 3,

Table 3
Comparison between 'Responders' as per Likert scale and 'True responders'.

	PATH (+) or progression on f/u imaging (TNR)	PATH (−) or no progression on f/u imaging (TR)	
PET2+ (by Likert scale) (NR)	TP (8)	FP (7)	15
PET2− (by Likert scale) (R)	FN (2)	TN (60)	62
	10	67	77

NR: Non responder, R: Responder, TNR: True nonresponder, TR: True responder.
TP: true positive, FP: false positive, FN: false negative, TN: true negative.

Table 4
AUC and cut-off values for PET2 Likert scale and PET parameters.

Variable	AUC	95% CI		Youden's Cutoff	Sensitivity	Specificity	PPV	NPV
		Lower	Upper					
PET2 SUV_{max}	0.8716	0.7486	0.9947	4	0.8	0.8358	0.4211	0.9655
PET2 SUV_{max} P/M	0.8097	0.6551	0.9643	1.667	0.7	0.791	0.3333	0.9464
PET2 SUV_{max} P/L	0.8149	0.6578	0.9721	1.706	0.5	0.9403	0.5556	0.9265
PET2 Likert	0.8448	0.6826	1.0000	4	0.8	0.8955	0.5333	0.9677

Likert scale (Deauville criteria) can be used in qualitative assessment of treatment response in oropharyngeal squamous cell cancer patients.
Likert scale (Deauville criteria) has high NPV in first follow up FDG PET/CT in differentiating responders from non-responders in oropharyngeal squamous cell cancer patients.
Ratios (SUVmax P/M and SUVmax P/L) are as accurate as SUV_{max} and can be promising tools in order to decrease the variability among patients and institutions.

6, 9 and 12 months following treatment. They used results from routine clinical follow-up as the reference. They also used the five point scale similar to Deauville criteria. In that study, the NPV was 100% and PPV was 51% [12]. Marcus et al. studied 214 biopsy-proven HNSCC patients whose posttherapy PET/CT scans were done between 5 and 24 weeks after completion of the treatment. Scans were scored according to qualitative 5-point scale, the Hopkins criteria which is very similar to Deauville criteria. Hopkins criteria use the internal jugular vein and liver as background reference points. Their NPV was 91.1% and PPV was 71.1% for primary tumor site [9]. Porceddu et al. prospectively evaluated posttherapy neck PET/CT imaging and compared focal FDG uptake at the site of nodal disease to the surrounding tissue or liver. NPV was as high as 97.1% [13]. Kendi et al. used Hopkins criteria in posttherapy response assessment of primary site and their NPV was 94.9% and PPV was 30% [8]. Sjövall et al. evaluated neck node response of 105 HNSCC patients by FDG PET/CT 6 weeks after RT. Scans were assessed and compared by using visual inspection, Deauville criteria and SUV_{max}. Sensitivity, specificity, PPV, NPV in predicting neck node response after RT for Likert scale were 47.8%, 93.8%, 68.7%, 86.4% respectively. They attributed this low NPV to PET2 studies' being scheduled too early with median time from completion of treatment to PET2 of 43 days (range 34–87 days), 90% of their patients had their PET2 scan between 37 and 52 days after therapy while our patients were imaged a median of 86 days (range 49–127 days), 90% of our patients had their PET2 scan between 60 and 112 days after therapy. Diagnostic accuracy is significantly affected by the interval between treatment completion and PET2. Accuracy is higher if they are performed at least 7 weeks after treatment completion [10,11,14].

In our study and also in Sjövall et al., PET/CT study results were categorized as false-negative if recurrent cancer was found at any stage after PET2, during the follow-up period, whereas Krabbe and Marcus et al., limited this period to 6 months after PET2. When we evaluated our data retrospectively, the first one had tumor on PET3 which was done 6.5 months following a negative PET2 and was confirmed by pathology. The second patient developed tumor, 4 months following a negative PET2 and was also confirmed by pathology. Since the first one emerged after 6 months, it could be accepted as recurrence. As a result one false negative result on PET2 out of 62 PET2 negative cases ended up decreasing the NPV from 98.4% to 96.8% [9,10,12].

FDG-PET/CT imaging provides a number of semi-quantitative parameters. The most commonly used one is maximum standardized uptake value (SUV_{max}) which is maximum SUV for a voxel in volume of interest. However, it has some limitations due to factors such as inflammation, postradiation and partial volume effect. Also it is variable among people and institutions so it can not be standardized [5,6]. In our study, we analyzed and found a statistically significant difference between 'true responders' and 'true non-responders' in SUV_{max} and ratios calculated from PET2. Cut-off value for SUV_{max} was found as 4 with 80% sensitivity, 83.6% specificity, and 42.1% PPV and 96.5% NPV. According to the literature, Moeller et al. evaluated 98 HNSCC patients and found SUV_{max} cut-off value for primary tumor as 6.5 with 70% sensitivity, 93.7% specificity, 58.3% PPV and 96.1% NPV [15]. Gourin et al. evaluated 32 patients with HNSCC and used threshold SUV_{max} as 3.0 with 40% sensitivity, 91% specificity, 67% PPV and 77% NPV [16]. SUV_{max} is so variable among people and institutions, it can not be standardized. Therefore, we evaluated the ratios of SUV_{max} P/M and SUV_{max} P/L. The ratio calculation would decrease the variability among people and institutions. Cut-off value of SUV_{max} P/M on PET2 was 1.67 with 70% sensitivity, 79.1% specificity, 33.3% PPV and 94.6% NPV and SUV_{max} P/L was 1.7 with 50% sensitivity, 94% specificity, 55.5% PPV and 92.6% NPV. As far as we know, nobody studied these ratios for OPSCC.

When we compared the Likert scale and the three PET/CT parameters; no statistically significant difference with regard to AUC of Likert scale, SUV_{max}, SUV_{max} P/M and SUV_{max} P/L was identified. This is important because this means qualitative evaluation which is easier and reproducible can potentially be used to evaluate response to treatment in OPSCC patients without need for SUV parameter measurements. In daily practice, SUVmax is used to evaluate the treatment response and there is no standardized criteria for qualitative assessment of treatment response in HNSCC patients' primary tumor sites. However, this study shows us; using Deauville criteria as a qualitative assessment is accurate as SUVmax. Since it is easy to practice and standardizable when compared to SUVmax, this criteria should be encouraged to be used. With quantitative evaluation utilizing the SUV parameters, many factors (e.g. biological, physical, technical) are known to affect SUV_{max}, we have shown that the ratios (SUV_{max} P/M and SUV_{max} P/L) are promising tools to decrease the variability among patients and institutions. This can be further investigated with future studies using larger sample sizes.

Retrospective nature is one of the limitations of this study. A second limitation is the low number patients who were found to be non-responders ($n = 10$). A third limitation is the timing of PET2 which has a wide range but the shortest and the longest timing for PET2 is in an acceptable period. The last limitation is the absence of a pathologic evaluation in all non-responder cases. Of the 10 true non-responders, 2 did not have biopsy and 2 had false-negative biopsy results but all 4 patients showed progression on follow-up.

In conclusion, qualitative evaluation using Likert scale is as accurate as the semi-quantitative SUV-based parameters in making the diagnosis of 'response' or 'no response' to CRT on the first follow up PET/CT. Since the NPV of this method is found to be high (96.7%) and qualitative interpretation and scoring is simple, qualitative assessment using Likert scale should be preferred in interpretation of posttreatment PET/CT scans in OPSCC patients.

Conflict of interest

The authors declare that they have no conflict of interest.

Ethical approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/

or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Inform consent

Inform consent was waived due to retrospective nature of the study.

Conflicts of interest/Disclosures

None for any of the authors.

IRB statement

Institutional review board approval was obtained before the study and the guidelines of the Health Insurance Portability and Accountability Act were followed.

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