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ORIGINAL ARTICLE

Evaluating compliance with process-related quality metrics and survival in oral cavity squamous cell carcinoma: Multi-institutional oral cavity collaboration study

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Abstract

Background: Process-related measures have been proposed as quality metrics in head and neck cancer care. A recent single-institution study identified four key metrics associated with increased survival. This study sought to validate the association of these quality metrics with survival in a multi-institutional cohort.

Methods: Multicenter retrospective study of patients with oral cavity squamous cell (1/2005-1/2015). Baseline patient and disease characteristics and compliance with quality metrics was evaluated. Association between compliance with quality metrics with overall survival (OS), disease-free survival (DFS), and disease-specific survival (DSS) was evaluated using Cox proportional hazards models.

Results: Failure to comply with two or more of the quality metrics was associated with worse OS, DFS, and DSS. Adherence to all or all but one of the quality metrics was found to be associated with improved survival.

Conclusions: Process-related quality metrics are associated with increased survival in patients with oral cavity squamous cell carcinoma in a multi-institutional cohort.

KEYWORDS

head and neck cancer survival, multi-institutional study, oral cavity squamous cell carcinoma, process-related metrics, quality metrics

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1 | INTRODUCTION

Evidence-based quality-of-care measures have been emphasized in the current healthcare climate, particularly in oncologic care. Quality of care can be assessed by the extent that it increases likelihood of achieving desired health outcomes.[1] The Donabedian model of determining quality of care evaluates the structure or context of healthcare delivery, the process and clinical components, and ultimately, the patient outcomes.[2] Much of quality improvement research focuses on outcome measures such as morbidity or mortality; however, there is a growing body of evidence suggesting adherence to process-related metric results in improved patient outcomes.[3,4] Process-related quality-of-care measures have been evaluated in the general surgery literature, and robust research has demonstrated variable relationships between compliance with evidence-based performance measures and outcomes.[5] Validated quality metrics for oncologic care have been developed by the National Quality Forum (NQF), American Medical Association—Physician Consortium for Performance Improvement (AMA-PCPI), and the American College of Surgeons (ACS)/National Cancer Database (NCDB)—Commission on Cancer (ACS-CoC) for colorectal, lung, esophagus, breast, and gastric cancer.[3,6] However, there is a lack of validated quality process-related measures in patients with head and neck cancer. Establishing which attributes of care are linked to optimal outcomes becomes of utmost importance, as this empowers physicians to improve care delivery to patients with tangible and actionable interventions to implement.

There has been a movement toward the development of quality-of-care measures for patients with oral cavity squamous cell carcinoma (OCSCC) put forth by the executive council of the American Head and Neck Society (AHNS) in 2007.[7] In the years following, the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) in combination with the AHNS has proposed gathering numerous metrics for patients with head and neck cancer in the RegENT clinical data registry. One of the goals of the RegENT clinical data registry is to facilitate research in quality improvement and patient outcomes.[8] The previously published data for oral cavity cancer assess a variety of care metrics but does not correlate disease survival or patient outcomes with compliance of these quality measures.[9] A recent single-institution study by Graboyes et al evaluated these quality metrics in a population of patients with oral cavity squamous cell carcinoma. In a comprehensive overview of 19 different metrics, the authors identified four quality metrics for which compliance was associated with improved patient survival. This core group of quality metrics was termed a "clinical care signature," analogous to how expression of certain genes in an expression array can carry implications for disease outcome.[10] This "clinical care signature" included neck dissection with lymph node yield of 18 or more, no unplanned surgery within 14 days, no unplanned readmission within 30 days, and referral for adjuvant radiotherapy for stage III or IV disease. In a subsequent study, Appachi et al attempted to reproduce these data at another institution; however, the association between the clinical care signature and survival was not consistently seen in their cohort.[11] One possible explanation for the incongruency could be that the study was limited by single-institution data, from a cohort with overall high level of favorable oncologic outcomes, which could result in a potentially underpowered study.

In this study, we aimed to validate the "clinical care signature" for OCSCC identified by Graboyes et al in a larger multi-institutional patient cohort. The objective of this study was to evaluate if these four key quality metrics of the "clinical care signature" were associated with improved survival in patients with surgically treated OCSCC in a multi-institutional context.

2 | METHODS

A multi-institutional retrospective review was performed of medical records of patients aged 18 and over treated with primary surgical resection for OCSCC at six tertiary care centers between 1 January 2005 and 31 January 2015. Approval was obtained from each respective institutional review board prior to chart review. Inclusion criteria for the study were previously untreated oral cavity squamous cell carcinoma, no prior history of head and neck cancer, and primary definitive surgical-based management. Data collection included demographic data, clinical variables, surgical and adjuvant treatment details, pathologic variables, surveillance, patterns of recurrence, and death. These data were collected with the objective of establishing a large multi-institutional database, and this report represents a subset of institutions in this group able to provide the needed process quality metrics.

Compliance with four predetermined quality metrics comprising the "clinical care signature" was evaluated using this preexisting database. Selection of quality metrics was based on recommendations made by the AHNS and the National Comprehensive Cancer Network (NCCN) and derived from results of the study by Graboyes et al.[10] The data from the respective institutions included in this study were made available in a preexisting database, and the intent was to evaluate the clinical care signature rather than all the 19 process metrics initially evaluated by Graboyes et al. Quality metrics of interest included neck dissection with lymph node yield

TABLE 1 Baseline patient characteristics

	N	Percentage (%)
Age		
Redacted	19	2.46
<40	35	4.53
40-50	100	12.94
51-70	426	55.1
71-80	128	16.56
>80	65	8.41
Gender		
Male	474	61.32
Female	299	38.68
Race		
African	30	3.88
Caucasian	650	84.09
Indian	13	1.68
Other	80	10.35
Tobacco use		
Yes	539	69.73
No	231	29.88
Unknown	3	0.39
Tumor site		
Anterior tongue	25	3.23
Buccal surface	82	10.61
Floor of mouth	146	18.89
Hard palate	18	2.33
Lateral tongue	206	26.65
Mandibular alveolus	68	8.80
Maxillary alveolus	17	2.20
Mucosal lip	8	1.03
Retromolar trigone	58	7.50
Overlapping sites	21	2.72
Tongue unknown location	124	16.04
Surgery type		
Partial glossectomy	294	38.03
Total glossectomy	5	0.65
Wide local excision	161	20.83
Other resection	312	40.36
Unknown	1	0.13
Lymph node dissection		
None	128	16.96
Selective neck dissection	345	44.63
Modified radical neck dissection	220	28.46
Radical neck dissection	16	2.07
Supraomohyoid dissection	52	6.73
Yes, unknown extent	12	1.42
Histological grade		
Well differentiated	95	12.29
Moderately differentiated	486	62.87
Poorly differentiated	179	23.16
Unknown	13	1.68
Margin status		
Positive	94	12.16
Negative	674	87.19
Unknown	5	0.65
Pathology (T)		
T0	7	0.91
T1	239	30.92
T2	246	31.82
T3	50	6.47
T4a	225	29.11
T4b	6	0.78
Pathology (N)		
N0	313	40.49
N1	135	17.46
N2a	8	1.03
N2b	192	24.84
N2c	41	5.30
N3	1	0.13
Unknown	83	10.74
Adjuvant radiation therapy		
Yes	544	70.38
No	229	29.62
Adjuvant chemotherapy		
Yes	194	25.10
No	576	74.51
Unknown	3	0.39
Perineural invasion (PNI)		
None	420	54.33
Present, focal	145	18.76
Present, multifocal	65	8.41
Present, unknown	124	16.04
Unknown	19	2.46
Lymphovascular invasion (LVI)		
Absent	566	73.22
Present	183	23.67

(Continues)

(Continues)

TABLE 1 (Continued)

	N	Percentage (%)
Unknown	24	3.10
Extracapsular extension (ECE)		
Absent	460	59.51
Present, NOS	68	8.80
Present, gross	14	1.81
Present, microscopic	100	12.94
Unknown	3	0.39
N/A	128	16.56

of 18 or more, no unplanned surgery within 14 days, no unplanned 30-day readmission, and referral for adjuvant radiotherapy for stage III or IV disease. As several institutions within the multi-institutional collaboration were unable to provide quality metric data for all patients in the study interval, those institutions were excluded from this analysis to avoid selection bias. Of the six institutions in the database, three were excluded on this basis.

The primary outcome measure assessed was the rate of adherence to quality metrics of interest. Secondary outcome measures assessed were measures of survival (overall, disease-specific, and disease-free). Overall survival (OS) was calculated from the date of surgery to the date of death from any cause. Disease-specific survival (DSS) was calculated from the date of surgery to the date of death from oral cancer or direct treatment effects. Disease-free survival (DFS) was calculated from the date of surgery to the date of either death or first recurrence. Patients lost to follow-up were censored at the date of last contact with the head and neck surgeon.

Statistical analysis was performed to determine the association between compliance with an individual quality metric and survival. Summary statistics of patient characteristics were provided in frequencies and percentages. OS, DFS, and DSS were calculated from surgery date. Kaplan-Meier method was used to estimate survival endpoints comparing patients meeting all, all but one and missing 2 or more metrics in the clinical care signature. Log rank test was used to compare survival between care quality compliance groups. Cox proportional hazard model with backwards elimination procedure was used for multivariate analysis to identify factors significantly associated with survival endpoints. All tests were two-sided and P values of .05 or less were considered statistically significant. Statistical analysis was carried out using SAS 9.4 (SAS Institute, Cary, North Carolina) and R 3.4 (R Foundation, Vienna, Austria).

3 | RESULTS

From the database of 1282 patients from six institutions, 773 patients from three institutions were included in the present study. The percentage of the cohort contributed by each of the three institutions were 44.7%, 35%, and 20.3%. Patient demographics, oncologic characteristics, and treatment data are presented in Table 1. The patient cohort consisted of 474 male patients (61.32%). Five hundred thirty-nine patients (69.72%) were tobacco users. Oral tongue was the most common oncologic site (45.92%). Method of surgical resection included wide local excision (20.83%), partial glossectomy (38.03%), total glossectomy (0.65%), or other composite resection (40.36%). Six hundred forty-four patients (83.31%) underwent some form of cervical lymph node dissection. Four hundred ninety-four patients (63.91%) were found to have advanced pathologic disease (pT3 or pT4 classification), and 242 patients (31.31%) had pathologic N2 or N3 disease. Five hundred forty-four patients (70.38%) received adjuvant radiation therapy and 194 patients (25.1%) also received adjuvant chemotherapy.

Compliance with quality metrics of interest in our cohort showed 507 patients (65.6%) meeting all quality metrics of interest. Two hundred forty patients (31.1%) had adherence to all but one quality metric, and only 26 patients (3.4%) had two or more missing metrics. Compliance with the individual quality metrics included overall was high (Table 2), with 736 patients (95.21%) without an unplanned reoperation within 14 days and 731 patients (94.57%) not requiring readmission within 30 days. In the total patient cohort, 595 patients (76.97%) had a neck dissection with lymph node yield of 18 or greater, and of the 494 patients with stage III or IV disease, 455 (92.1%) received a referral for radiation therapy.

Patient outcomes data are presented with Kaplan Meier estimates of survival in Figure 1. For the cohort of 773 patients with median follow-up of 63.2 months (range: 0.16-178.9 months), there were 327 deaths (42.3%), with 236 patients (30.53%) who developed local or regional disease recurrence. Five-year OS rate of the total patient population was 62% (95% CI: 58-66%), with median survival of 100.1 months (95% CI: 83.1-120.4 months). Five-year DFS rate was 50% (95% CI: 46-52%), with median survival of 59.6 months (95% CI: 44.0-73.6 months). Five-year DSS rate was 78% (95% CI: 74-81%), median survival was not reached.

On Cox regression analysis (Table 3), unplanned surgery within 14 days (HR 1.76, 95% CI: 1.16-2.68) and unplanned readmission within 30 days (HR 1.87, 95% CI: 1.20-2.91) were significantly associated with worse

OS. Unplanned surgery was also significantly associated with worse DSS (HR 2.12, 95% CI: 1.22-3.68). Patients who received a referral for adjuvant radiotherapy for stage III or IV disease had significantly better DFS than patients with stage III or IV disease who did not receive a referral (HR 0.48, 95% CI: 0.33-0.69).

TABLE 2 Rates of compliance with quality metrics of the "clinical care signature"

	Yes (%)	No (%)	N/A (%)
Adjuvant radiation referral for Stage III/IV	455 (92.11)	39 (7.89)	
Neck dissection with 18 or more lymph nodes	595 (76.97)	50 (6.47)	128 (16.56)
Unplanned reoperation within 14 days	42 (5.43)	731 (94.57)	
Unplanned readmission within 30 days	37 (4.79)	736 (95.21)	

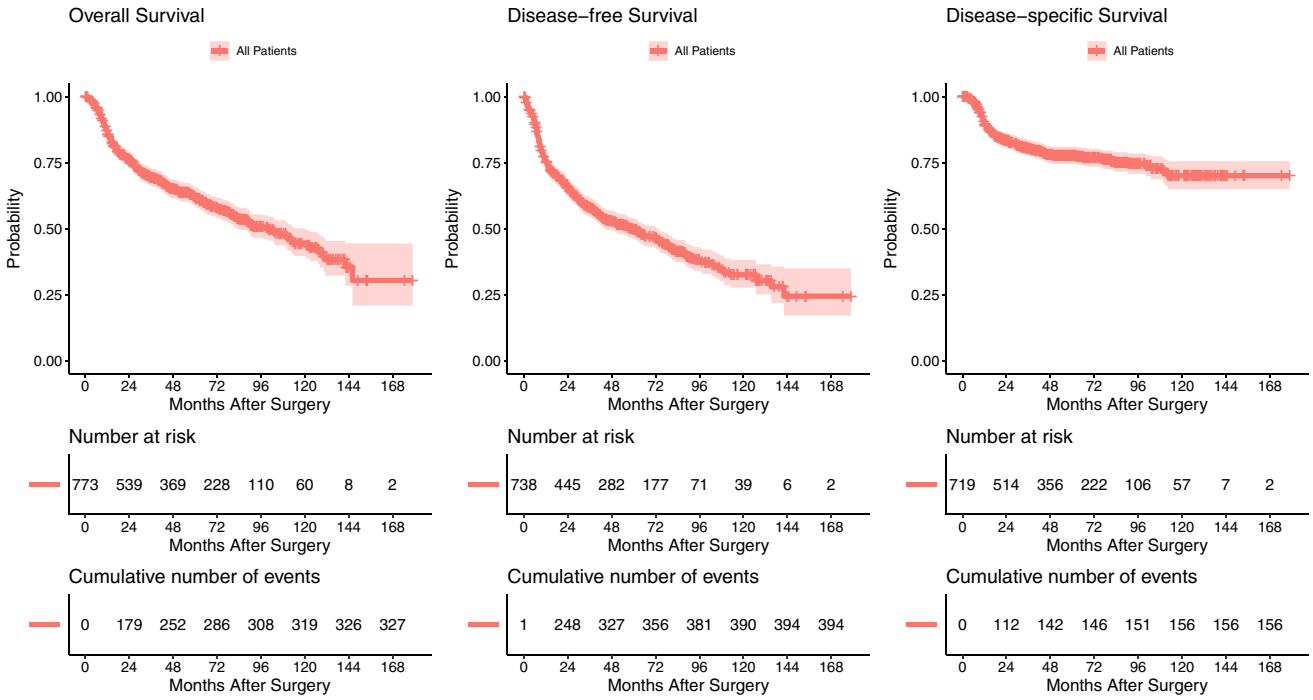

FIGURE 1 Kaplan–Meier estimates of overall survival, disease-free survival, and disease-specific survival [Color figure can be viewed at wileyonlinelibrary.com]

TABLE 3 Compliance with quality metrics and association with overall survival (OS; event = death of any cause), disease-free survival (DFS; event = locoregional recurrence, metastasis, or any death), and disease-specific survival (DSS; event = cancer death)

Endpoint	Quality metric	Hazard ratio	95% confidence interval
Overall survival	Adjuvant RT referred for stage III/IV	0.80	0.52-1.23
	Neck dissection with 18 or more lymph nodes	0.96	0.63-1.44
	Unplanned surgery within 14 days	1.76	1.16–2.68
	Unplanned readmission within 30 days	1.87	1.20–2.91
Disease-free survival	Adjuvant RT referred for stage III/IV	0.48	0.33–0.69
	Neck dissection with 18 or more lymph nodes	0.93	0.65-1.35
	Unplanned surgery within 14 days	1.39	0.93-2.09
	Unplanned readmission within 30 days	1.50	0.99-2.29
Disease specific survival	Adjuvant RT referred for stage III/IV	0.74	0.42-1.31
	Neck dissection with 18 or more lymph nodes	1.21	0.62-2.38
	Unplanned surgery within 14 days	2.12	1.22–3.68
	Unplanned readmission within 30 days	1.63	0.86-3.09

TABLE 4 Summary of multivariate Cox proportional hazard model results for overall survival (OS, event = death of any cause), disease-free survival (DFS, event = locoregional recurrence, distant metastasis, or any death), and disease-specific survival (DSS, event = death due to disease)

		OS		DFS		DSS	
Factor	Comparison	Hazard ratio	95% confidence interval	Hazard ratio	95% confidence interval	Hazard ratio	95% confidence interval
Quality metric compliance	2 or more missed vs 1 or fewer missed	1.77	1.02–3.07	2.18	1.33–3.59	3.15	1.58–6.28
Age	>80 vs <40	4.41	2.05-9.48	2.43	1.28-4.59		
	70-80 vs <40	2.18	1.06-4.49	1.52	0.84-2.73		
	50-70 vs <40	1.56	0.78-3.12	1.10	0.63-1.92		
	40–50 vs <40	1.16	0.54-2.48	0.79	0.42-1.48		
Race	African vs Caucasian	1.73	1.00-2.99			1.65	0.80-3.40
	Indian vs Caucasian	1.75	0.71-4.28			2.33	0.85-6.39
	Other vs Caucasian	0.68	0.42-1.09			0.46	0.21-0.99
Surgery type	Other resection vs wide local excision	0.57	0.42-0.77	0.66	0.50-0.87	0.71	0.47-1.07
	Partial glossectomy vs wide local excision	0.52	0.38-0.71	0.59	0.44-0.79	0.45	0.29-0.72
	Total glossectomy vs wide local excision	2.11	0.64-6.97	1.13	0.35-3.67	2.77	0.83-9.24
Margin	Positive vs negative	1.88	1.39-2.54	1.53	1.15-2.05	2.16	1.43-3.26
Perineural invasion	Present vs absent	1.75	1.36-2.25	1.65	1.32-2.07	2.11	1.46-3.04
Lymphovascular invasion	Present vs absent	1.84	1.41-2.39	1.48	1.16-1.89	2.08	1.45-2.98

Note: Hazard ratio higher than 1 means worse prognosis.

On multivariate analysis adjusting for age, race, surgery type, margin, perineural invasion, and lymphovascular invasion status (Table 4), patients with two or more care quality metrics missing had significantly worse OS (1.77; 95% CI: 1.02-3.07), DFS (2.18; 95% CI: 1.33-3.59), and DSS (3.15; 95% CI: 1.58-6.28) than those with one or no care quality metrics missing (Figure 2).

4 | DISCUSSION

In this study, we sought to validate the relationship between process-related metrics and outcome measures, initially presented by Graboyes et al,[10] in a multi-institutional setting. The authors identified four quality metrics of interest that were proposed to be part of a "clinical care signature" associated with improved outcomes. In this study of a larger patient cohort across multiple tertiary care institutions, our results supported the previously established conclusion that compliance with the clinical care signature was associated with improved outcomes in patients with OCSCC. We found that patients who had adherence to two of fewer metrics of the clinical care signature quality metrics experienced worse OS, DFS, and DSS than those who met compliance of three or more metrics. There was no significant difference in survival outcomes between patients who met three or more metrics and patients with all four, suggesting that 100% achievement of the metrics is not the goal, but rather that high rates of metric compliance may be an indication of high surgical quality, which translates into optimal patient outcomes.

When evaluating individual quality metrics, compliance with all or all but one of the three to four quality metrics (no unplanned surgery within 14 days, no readmission within 30 days, and referral to radiation therapy for stage III or IV disease) was found to be associated with improved survival outcomes. However, neck dissection with lymph node yield of 18 or greater was not significantly associated with OS, DFS, or DSS in this patient population. Recent American Society of Clinical

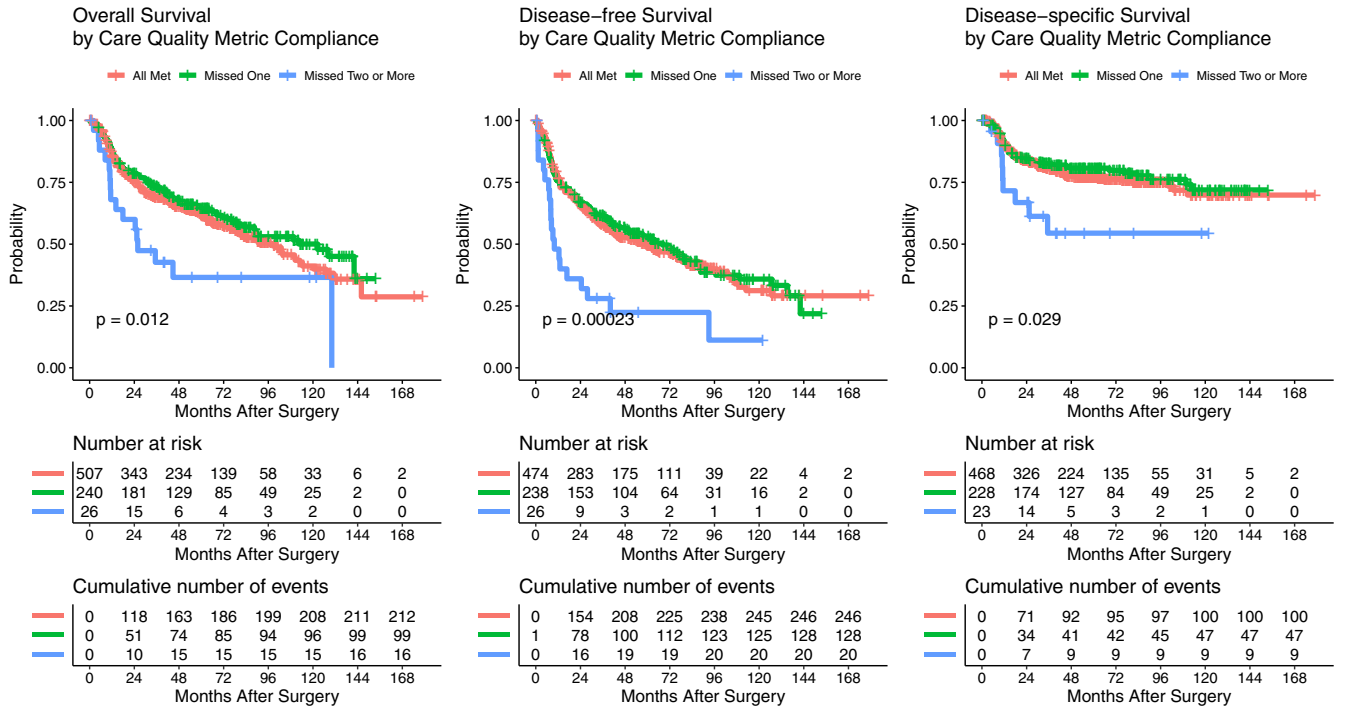

FIGURE 2 Kaplan–Meier estimates of overall survival, disease-free survival, and disease-specific survival. Patients were stratified into three groups: (a) patients who met all four quality metrics of the clinical care signature, (b) patients with three out of four quality metrics, and (c) patients with 2 or less quality metrics [Color figure can be viewed at wileyonlinelibrary.com]

Oncology (ASCO) clinical practice guidelines for oral cavity and oropharyngeal squamous cell carcinoma provided a strong recommendation for ipsilateral elective neck dissection in patients with early stage OCSCC.[12] The role for lymph node dissection has been an ongoing topic of research, not just in head and neck cancer but within other areas of surgical oncology, including colorectal, gastric, and urological cancer.[13-16] Within head and neck cancer research, there is a growing body of literature supporting increased survival outcomes with elective neck dissection in patients with clinically node-negative disease.[17-20] In a recently published meta-analysis, de Kort et al reviewed 15 studies looking at lymph node yield as a prognostic factor for survival in head and neck squamous cell carcinoma.[21] The threshold for lymph node yield was 18 in seven papers, and of these, five concluded that increased survival outcome was associated with neck dissection with lymph node yield of 18. Six other studies had higher cutoffs, and three showed improved survival with additionally lymph node yield. Our study looked at neck dissection with 18 or greater lymph node yield, and this was not shown to be associated with increased survival suggesting perhaps that a higher lymph node yield may confer survival benefit, as suggested in other recent research.[22] Alternatively given the high rates of compliance with the nodal dissection metric, sufficient power to detect a difference in this individual metric may be lacking and overall high rates of this metric may represent quality of surgical dissection and pathologic review which is still benefiting patients for whom the threshold was not met.

Unplanned readmission within 30 days was significantly associated with worse OS. Prior studies have demonstrated that readmission in head and neck surgery patients is often a result of preexisting cardiac or pulmonary comorbidities, surgical site complications, or difficulties with transition in care,[23] calling attention to the importance of preoperative workup and postoperative care transition to mitigate readmissions. Unplanned reoperation in 14 days was also found to be significantly associated with worse OS and DSS. Commonly cited reasons for reoperation in head and neck surgery are re-resection of positive margins or postoperative complications.[10] Postoperative complications tend to occur with higher frequency in patients with underlying comorbid conditions and active tobacco use,[24,25] further emphasizing the importance of preoperative optimization in achieving compliance with this quality metric.

The only quality metric found to be associated with improved DSS was referral for adjuvant radiation therapy for patients with stage III or IV disease. NCCN Clinical Practice Guidelines recommend adjuvant radiation therapy for patients with late stage or advanced OCSCC.[26] Compliance with this process metric reflects alignment

with standard of care. Unlike the other three quality metrics, this particular metric is a simple actionable item and carries clinical implications for improvement. Our data show that statistically significant survival benefits are conferred with referral to radiation therapy for late-stage disease, supporting a recommendation to strive for high compliance rates for this quality metric.

Compliance with key quality metrics across participating institutions of this study showed that 507 patients (65.6%) had 100% compliance with all four metrics, which is comparable to existing data from prior studies of quality metrics in patients with head and neck cancer.[9,10,27] In our study, 747 patients (96.6%) were compliant with three or greater key metrics, and deviation from the clinical care signature with noncompliance with two or greater metrics portended worse survival outcomes. As the cost of healthcare continues to escalate, there is an increasing need to evaluate the process of healthcare delivery and define quality-related metrics in medicine and cancer care in particular. This is the first multi-institutional study to evaluate the correlation of treatment process metrics and survival outcomes in head and neck cancer, and the largest study population to date. The implications of our data suggest that there exist key quality process metrics that should be met in this patient population to optimize survival outcomes. Our results underscore the inherent importance of the metrics and begin to lay out a framework of essential quality metrics necessary in managing OCSCC. Furthermore, while OCSCC is one of the more common cancers of the head and neck, it is not known if these data are applicable to other subsites, therefore future research is needed to identify and validate key quality indicators, as well as determine association with survival for other head and neck cancers. It is worth noting that the aim of this current study was to validate the findings of Graboyes et al, and there may exist other quality metrics that are associated with increased survival that were not detected in the initial study if it was underpowered.

On review of the baseline patient characteristics (Table 1), a few data points warranted further discussion. *N* classification was unknown for 10.74% of patients, which accounts for a limited number of cases where an initial outside surgery was performed and data were not available, or in cases where an elective neck dissection was offered but declined by patient, or not performed. Margin status was found to be positive in 94 patients (12.16%) of our cohort. This is consistent with rates of positive margins seen in the literature for OCSCC.[11,28-30]

Our study has some limitations. Although the data derived from a larger database comprised patients undergoing treatment at six institutions, the data from three of the institutions were excluded and decreased the overall impact of the results. Two institutions were excluded due to the absence of data collected on two of the quality metrics (reoperation and/or readmission rates were not collected). The third institution collected data from date of initial biopsy rather than date of surgery, thus, to maintain consistency in our statistical analysis, these data were excluded. Unfortunately, heterogeneity of data accrual is a function of multi-institutional studies and a distinct limitation. Despite this limitation, however, the analysis still represents the combined result of three high volume institutions across a decade of practice.

It is notable that all participating institutions are of high volume, tertiary care centers and the results seen here may or may not be similar in a community practice setting. The institutions involved in this study include several different national catchment regions as well as one international, suggesting that the metrics are generally applicable. A limitation of the study is that not every geographic region within the United States is represented. It has been shown that geographic variations in cancer survival exist, and such disparities have been attributed to time to diagnosis, access to care, and care preferences. Future directions of study can include the addition of data from other institutions in regions not represented in the current study, as well as the analysis of regional differences in quality metric adherence.

The retrospective nature of the study is subject to the limitations of the accuracy and completeness of the medical documentation and chart review, as well as selection or recall bias. However, given the nature of the subject matter, compliance with quality metrics is not amenable to a prospective randomized trial. Future studies could consider evaluating the impact of parameters such as length of stay and patient comorbidities on adherence to quality metrics and outcomes.

5 | CONCLUSION

In this cohort of patients with OCSCC, adherence with a core group of four process-related quality metrics was found to be significantly associated with disease outcomes and mortality. Patients who underwent unplanned surgery within 14 days or had unplanned readmission within 30 days were found to have worse OS. Disease-free survival was found to be improved in patients who received a referral for adjuvant radiotherapy for stage III or IV disease. Patients with two or more unmet key quality metrics were shown to have worsened survival.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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