Clinical and Translational Radiation Oncology 30 (2021) 78–83

Contents lists available at ScienceDirect

Clinical and Translational Radiation Oncology

journal homepage: www.sciencedirect.com/journal/clinical-and-translational-radiation-oncology

Original Research Article

Factors associated with complex oral treatment device usage in patients with head and neck cancer

Stephen Palasi [a], Ning Zhang [b,1], Mikaela Bankston [a], Joy Godby [a], Hannah Burrows [a], Jennifer Lagunas [a], William Perkison [c], Brandon Gunn [a], Mark S. Chambers [d], David I. Rosenthal [a], William Morrison [a], Adam Garden [a], Clifton David Fuller [a], Sharon Giordano [b], Eugene J. Koay [a,*]

[a] Department of Radiation Oncology, Division of Radiation Oncology, MD Anderson Cancer Center, Houston, TX, United States
[b] Health Service Research Department, Division of Cancer Prevention and Population Science, MD Anderson Cancer Center, Houston, TX, United States
[c] Department of Epidemiology, Human Genetics and Environmental Sciences, UTHealth School of Public Health, Houston, TX, United States
[d] Department of Head and Neck Surgery, Division of Surgery, MD Anderson Cancer Center, Houston, TX, United States

ARTICLE INFO

Keywords:
Stent
SEER-Medicare
Oral mucositis
Head and neck cancer
Radiation

ABSTRACT

Purpose: The objective was to identify clinical and epidemiological factors associated with utilization of a complex oral treatment device (COTD), which may decrease toxicity in patients undergoing radiation therapy for head and neck cancer (HNC).

Materials and Methods: We retrospectively reviewed data from 1992 to 2013 in the Surveillance, Epidemiology, and End Results (SEER)-Medicare databases to analyze COTD usage during intensity-modulated radiation therapy (IMRT) for patients diagnosed with cancer of the tongue, floor of mouth, nasopharynx, tonsil, or oropharynx. Patients with a radiation simulation and complex treatment device code within 4 weeks before the first IMRT claim were identified as meeting COTD usage criteria. Demographic, regional, tumor, and treatment data were analyzed.

Results: Out of 4511 patients who met eligibility criteria, 1932 patients (42.8%) did not utilize a COTD while 2579 (57.2%) met usage criteria. COTD utilization increased over time (36.36% usage in 1992 vs. 67.44% usage in 2013, $p < .0001$). Patients less likely to receive a COTD included those aged 86 years or older compared to those aged 66–70 (OR = 0.713, 95% CI: 0.528–0.962), male patients (OR = 0.817, 95% CI: 0.710–0.941), non-Hispanic Black patients compared to non-Hispanic White patients (OR = 0.750, 95% CI: 0.582–0.966), and Louisiana residents (OR = 0.367, 95% CI: 0.279–0.483). Cancer site, grade, stage, or function of IMRT had no significant association with COTD usage.

Conclusions: This study serves as the first known SEER-Medicare review of COTD utilization. Despite an increase in COTD usage over time, our results indicate age, gender, and geographic disparities are associated with utilization. Further research and development into methods that increase availability of COTDs may help increase utilization in specific patient populations.

Introduction

Locally advanced head and neck cancers were historically considered to be difficult to treat due to their aggressive nature. Despite an overall decline in incidence, individuals aged 60 and older have an increased incidence of developing head and neck cancer [1,2]. The emergence of more precise radiotherapy techniques, namely IMRT, have provided benefit to this patient population.

While effective, the use of radiation can lead to debilitating side effects which include radiation-induced oral mucositis (RIOM). Research has shown that the elderly population is at higher risk of developing oral mucositis due to an increased prevalence of xerostomia [3]. RIOM is a

* Corresponding author at: Department of Radiation Oncology, Division of Radiation Oncology, The University of Texas MD Anderson Cancer Center, 1515 Holcombe Blvd Unit 97, Houston, TX 77030, United States.

[1] **Statistical Analyses:** Ning Zhang, FCT9.5080, Health Service Research Department, Division of Cancer Prevention and Population Science, The University of Texas MD Anderson Cancer Center, 1400 Pressler Street, Houston TX 77030.

https://doi.org/10.1016/j.ctro.2021.08.004
Received 4 February 2021; Received in revised form 2 August 2021; Accepted 3 August 2021
Available online 8 August 2021

dose-limiting toxicity which can potentially change the course and efficacy of treatment and negatively affect patient quality of life.

A potential solution to lessening the burden of this radiation-induced toxicity is the tongue displacing intraoral stent. Tongue displacing intraoral stents are complex oral treatment devices that may lessen the risk of developing severe mucositis for head and neck patients [4,5]. Complex oral treatment devices (COTDs) may limit the radiation that affects noncancerous tissue adjacent to the tumor, thereby reducing the potential for toxicities [6]. A variety of devices, such as TruGuard or lateralizing stents, may qualify as a COTD and can differ in both material composition and in configuration (Fig. 1). While standardized stents are available, customized oral stents can reduce the risk of developing RIOM [4]. The production of customized stents is a specialized practice as each stent is unique to the patient's anatomy. This not only requires financial resources, but also relies upon the work of skilled technicians. Currently, it is unknown what factors may influence COTD utilization, which are typically billed as a complex treatment device (CTD), in the head and neck cancer population.

With the SEER-Medicare database, this study characterized the rate of COTD utilization, as measured by usage of CTD and RSC billing codes, in the population of patients with one of five subtypes (tongue, floor of mouth, nasopharynx, tonsil, oropharynx) of HNC that received IMRT.

Methods and materials

Data source

This study is an observational, retrospective analysis of Medicare patients who have received radiation therapy for head and neck cancer. Data for the cohort was obtained from the National Cancer Institute (NCI)-supported SEER-Medicare database [7] SEER is a national registry of incident cancer data that collects clinical, demographic, and cause of death information from tumor registries in the United States. The linkage of SEER-Medicare provides an interface between patients age ≥65 diagnosed with cancer and their associated procedures and treatments received, resulting in a national, population-based database conducive to epidemiological studies.

Cohort selection

The cohort of interest was selected using a multistep exclusion methodology (Fig. 2). Individuals in the cohort were selected based upon the following criteria: individuals aged ≥66 without a previous cancer diagnosis and have received a primary diagnosis with one of five types of head and neck cancer (i.e. tongue, floor of mouth, nasopharynx, tonsil, or oropharynx) between 1992 and 2013. Individuals had to be continuously enrolled in Medicare parts A and B for 12 months prior to diagnosis without Health Maintenance Organization (HMO) coverage and maintain coverage until 12 months after diagnosis or death if the patient died within 12 months of diagnosis. Patients were also required to have a histologically and microscopically confirmed diagnosis. Diagnosis at the time of autopsy was considered an exclusionary criterion. Radiation claims were used to include only patients whose first IMRT radiation claim was within 6 months of the diagnosis, and to exclude any patients with brachytherapy claims within 6 months of diagnosis. A sub-cohort was also created that excluded patients with distant disease, including metastases.

COTD usage selection

In order to predict whether a COTD was used during radiation therapy, billing codes for CTD (complex treatment device code – 77334), RSC (radiation simulation code – 77290), IMRT (intensity-modulated radiation therapy codes – 77414 and G0178 before 2002, 77418 and G0174 after 2000), and IMRT planning codes (77301 for 77418, 77295 for 77414) were used. These codes were used to create an algorithm to predict COTD utilization (See Supplementary Table S1). In order to be classified as receiving a COTD, the following criteria had to be fulfilled:

1) All patients must have had radiotherapy within 6 months after diagnosis based on radiation claims
2) Patients who had brachytherapy claims within 6 months of diagnosis were excluded
3) First IMRT treatment within 6 months of diagnosis date
4) RSC code billed between one day and four weeks prior to the first IMRT treatment date
5) CTD code must be within 4 weeks prior to the first IMRT treatment date

Baseline patient, tumor, and treatment characteristics

Demographic information included age, gender, race/ethnicity, marital status, SEER-registered regions, urban/rural classification, educational level, income level, and poverty level. SEER-registered regions were based on location of residence of the patient. California + Hawaii was used as reference for statistical analysis of SEER-registered regions, chosen based on prior SEER-Medicare studies [8]. Urban/rural classification was based on United States Department of Agriculture 2013 Urban-Rural Continuum Codes [9]. Patients were classified as living within a metro area (Codes 1–3) or not living within a metro area

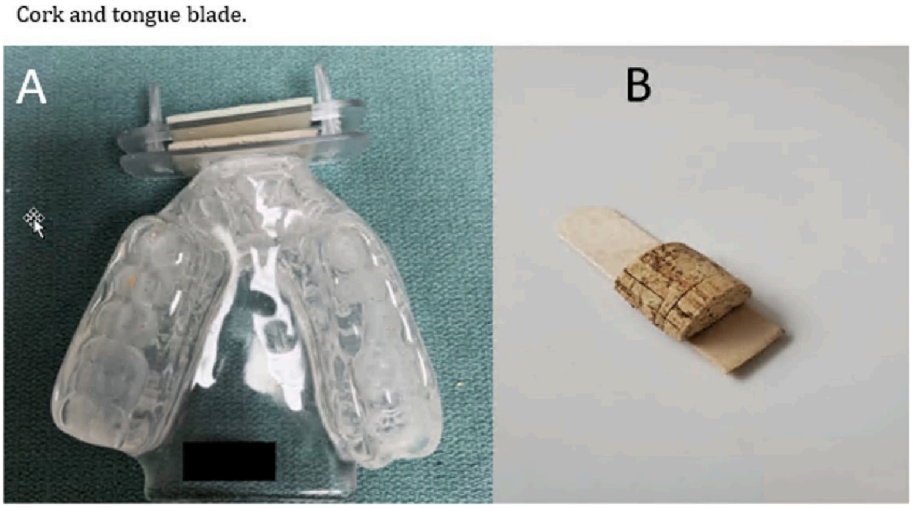

Fig. 1. Types of COTDs. A) Customized mouth opening, tongue-depressing stent. B) Cork and tongue blade.

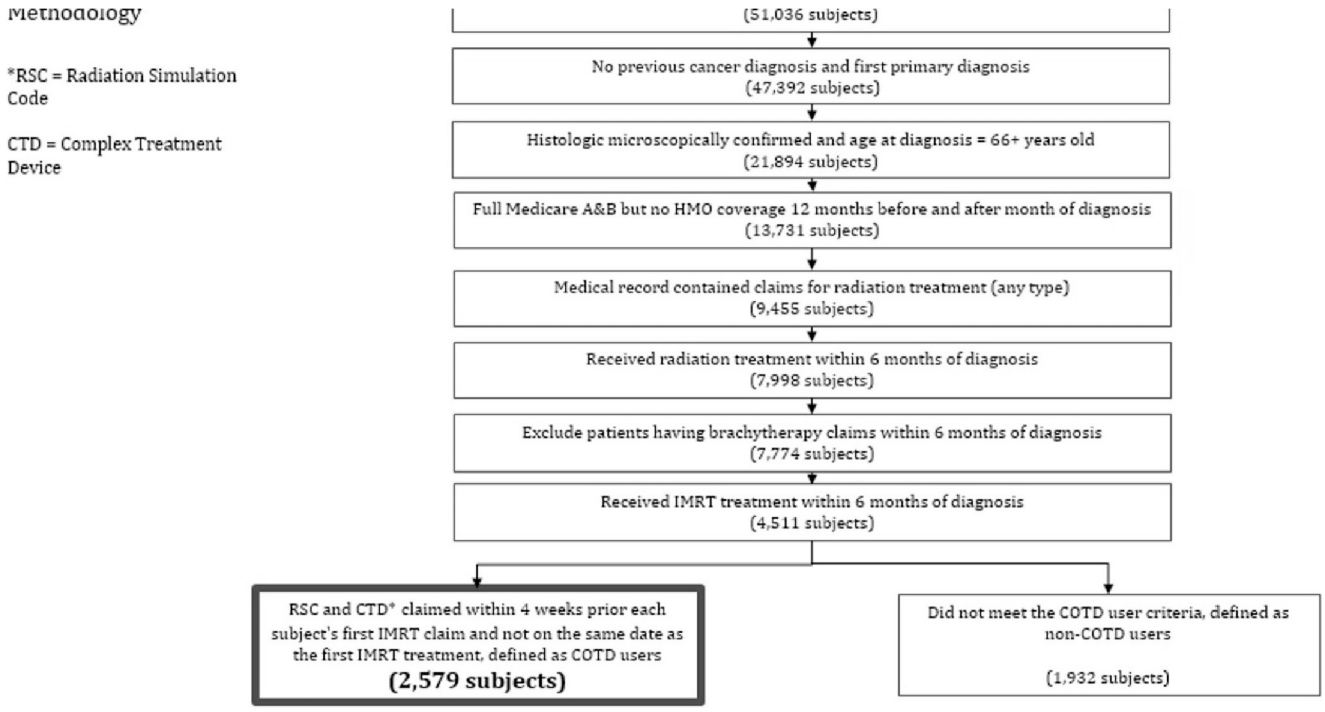

Fig. 2. Cohort selection methodology. *RSC = Radiation simulation Code. CTD = Complex Treatment Device.

(Codes 4–9). Education level was provided by Center for Medicaid and Medicaid Services (CMS) data which categorizes patients into quartiles and rates each quartile based on percentage of those with a high school diploma at age <25 years old. Poverty level was provided by CMS and is classified by the percent of residents within the patient's residential area who were under the poverty income level.

Clinical characteristics included tumor site, stage, grade, and year of diagnosis, IMRT fractions, and Charlson score. IMRT claims were obtained from Medicare and the number fractions was obtained by counting IMRT claims with different claim dates (two fractions claimed on the same date is only counted once). To categorize IMRT treatment intent for each patient, IMRT treatment was required to be initiated within 90 days of cancer diagnosis date. Otherwise, they were categorized into the group "No IMRT initiated 90 days". For each patient who had IMRT treatment initiated within 90 days of cancer diagnosis date, we calculated IMRT fractions as described above, and the time frame we included to count the IMRT treatment fractions started from the first IMRT treatment claim date until 6 months since the patient's cancer diagnosis date. Patients that initiated IMRT treatment within 90 days of diagnosis were classified as follows: 1–14 fractions received within 6 months of diagnosis, 15–24 fractions received within 6 months of diagnosis, or ≥25 fractions received within 6 months of diagnosis.

Comorbidities were recorded as the Charlson comorbidity index, or as individual comorbid illnesses existing within 12 months prior to HNC diagnosis [10]. These include, but are not limited to congestive heart failure, other heart diseases (coronary artery disease, myocardial infarction), diabetes, or pulmonary diseases (chronic obstructive pulmonary disease). Charlson Comorbidity Index values were determined from the 12-month period before initial diagnosis date.

Statistical analysis

Demographic, diagnostic, and time for the SEER-Medicare cohort were obtained (Table 1). Frequencies of demographic data (age, gender, race, and urban/rural classification) were tabulated separately from clinical data (cancer site, grade, stage, IMRT fractions, Charlson score). Frequencies of the date of cancer diagnosis COTD usage by year were calculated.

After applying our COTD usage criteria described above, frequencies of demographic and diagnostic data were obtained between COTD users and non-COTD users. The difference in these frequencies were recorded using chi-square analysis.

Multivariate logistic regression using fixed effects was used to infer correlation between covariates and outcome variables. Covariate variables included in the regression model included year of diagnosis, patient demographics, educational level, poverty level, tumor site, stage of diagnosis, and Charlson Comorbidity Index.

Model diagnostics were performed including the Hosmer and Lemeshow Goodness-of-Fit Test for multivariate logistic regression modeling, a returned p-value of 0.05 or less was considered significant. Statistical analysis was carried out using SAS software program SAS Enterprise Guide 7.1 (SAS Institute, Cary, NC).

Results

From the 1992–2013 SEER-Medicare database, 151,240 patients with head and neck cancer were identified. Of the eligible patients, 51,036 had cancer of the tongue, floor of mouth, nasopharynx, tonsil, or oropharynx. Among these patients, 13,731 had no previous cancer diagnosis, had a first primary diagnosis of oral cancer, were aged ≥66, and had full Medicare A and B but no HMO coverage 12 months before and after month of diagnosis. 4511 of these patients had claims for IMRT treatment and received radiation but no brachytherapy treatment within six months of diagnosis. From this cohort, 2579 (57.2%) out of the 4511 patients in the cohort were classified as receiving a COTD within the first four weeks prior to the first IMRT claim. Using the same cohort, 685 (15.2%) patients were classified as having distant stage HNC, leaving a total of 3826 patients for separate analysis as a sub-cohort for those without distant disease. The analyses of the full cohort and the sub-cohort revealed the same findings for COTD usage (Supplementary Table S2).

Percent frequency of head and neck cancer diagnosis by year within the cohort is summarized in Fig. S1. The figure shows a steady increase in cohort participants diagnosed with head and neck cancer over time

Table 1
Demographic and clinical characteristics of study population.

Demographic Data	Frequency	Percent
Gender		
Female	1376	30.5
Male	3135	69.5
Age		
66–70	1508	33.43
71–75	1358	30.1
76–80	873	19.35
81–85	556	12.33
86+	216	4.79
Race		
Hispanic	209	4.63
Non-Hispanic Black	314	6.96
Non-Hispanic Other	287	6.36
Non-Hispanic White	3701	82.04
Urban Area*		
Metro	3798	84.19
Non-Metro	713	15.81
Education level**		
0–5.88%	990	21.95
5.88–10.73%	984	21.81
10.73–18.67%	990	21.95
18.67%+	983	21.79
Unknown	564	12.5
Percent poverty in area of residence		
0–5%	1025	22.72
5–10%	1077	23.87
10–20%	1171	25.96
20%+	1238	27.44
Clinical Data	**Frequency**	**Percent**
Site		
Floor of Mouth	327	7.25
Nasopharynx	467	10.35
Oropharynx	313	6.94
Tongue	2157	47.82
Tonsil	1247	27.64
Grade		
Moderately differentiated	1500	33.25
Poorly diff/undifferentiated	1742	38.62
Unknown	1000	22.17
Well differentiated	269	5.96
Stage		
Localized	604	13.39
Distant	685	15.19
Regional	2738	60.70
In Situ & Unstaged	484	10.73
IMRT Fractions		
No IMRT initiated first 90 days	1013	22.46
1–14 fractions	652	14.45
15–24 fractions	268	5.94
>=25 fractions	2578	57.15
Charlson Score*		
0	2620	58.08
1	1116	24.74
2+	775	17.18

*Metro = county within metro area based on USDA Rural-Urban Continuum Codes.
Non-Metro = Non-Metro county including those adjacent to metro areas.
** Percent of people who did not finish high school by 25 years old within quartile.
*Co-morbidity within one year prior to initial diagnosis.

(0.49% cohort prevalence in 1992 vs. 10.49% in 2013, $p < .0001$).

Frequency of COTD usage over time is summarized in Fig. S2. COTD utilization has increased with increasing year of diagnosis (36.36% usage in 1992 vs. 67.44% usage in 2013, $p < .0001$). Patients who used COTDs were predominantly male (69.5%), non-Hispanic White (82.0%), and lived in a metro area as defined by USDA Urban-Rural Continuum Codes (84.2%).

Differences in COTD usage based on demographics are outlined in Table 2. COTD usage was significantly associated with age, gender and race. Patients aged 86 years or older were significantly less likely to receive COTDs for treatment of head and neck cancer compared to those aged 66–70. (OR = 0.713, 95% CI: 0.528–0.962). Male patients were significantly less likely to receive COTDs than females (OR = 0.817, 95% CI: 0.710–0.941), with 59.67% females and 56.08% males utilizing a COTD. Non-Hispanic Black patients were significantly less likely to receive COTDs compared to non-Hispanic White patients (OR = 0.750, 95% CI: 0.582–0.966). Urban area classification, education level, and percent poverty in area of residence did not appear to have significant association with COTD usage.

Table 2
Demographic factors and complex treatment device utilization.

Demographic Characteristics	No Stent (%)	Stent (%)	OR	95% CI		*p-value*
Age						
66–70	41.18	58.82	Ref	Ref	Ref	*Ref*
71–75	43.67	56.33	0.910	0.780	1.061	*0.2281*
76–80	43.07	56.93	0.915	0.768	1.091	*0.3216*
81–85	43.35	56.65	0.867	0.705	1.066	*0.1763*
86+*	46.76	53.24	0.713	0.528	0.962	*0.0271*
Gender						
Female	40.33	59.67	Ref	Ref	Ref	*Ref*
Male*	43.92	56.08	0.817	0.710	0.941	*0.005*
Race						
Non-Hispanic White	42.53	57.47	Ref	Ref	Ref	*Ref*
Non-Hispanic Black*	49.04	50.96	0.750	0.582	0.966	*0.0259*
Non-Hispanic Other	43.55	56.45	0.826	0.630	1.082	*0.1642*
Hispanic	37.80	62.20	1.110	0.819	1.503	*0.5008*
Urban Area						
Metro	43.81	56.19	Ref	Ref	Ref	*Ref*
Non-Metro	37.59	62.41	1.163	0.959	1.41	*0.1255*
Education level						
0–5.88%	43.94	56.06	Ref	Ref	Ref	*Ref*
5.88–10.73%	43.09	56.91	0.998	0.827	1.203	*0.9802*
10.73–18.67%	40.20	59.80	1.099	0.899	1.344	*0.3581*
18.67%+	40.28	59.72	1.083	0.866	1.354	*0.4852*
Unknown	49.47	50.53	0.930	0.717	1.206	*0.5850*
Percent poverty in area of residence						
0–5%	47.32	52.68	Ref	Ref	Ref	*Ref*
5–10%	44.01	55.99	1.183	0.967	1.447	*0.4566*
10–20%	40.73	59.27	1.073	0.892	1.291	*0.1026*
20%+	40.06	59.94	1.214	0.966	1.525	*0.0971*

* Statistically significant.

In terms of clinical data, no significant differences were noted for head and neck cancer site, grade, stage, or function of IMRT (Table 3). Those with a Charlson score of 1, indicating presence of one life-threatening co-morbidity, were more likely to receive a COTD compared to a score of 0 (OR = 1.223, 95% CI: 1.055–1.418). However, there was no significant difference in COTD utilization between patients with a Charlson score of 2 or more versus 0. While fractionation did initially show an association with COTD use, this association became non-significant after multivariate logistic regression analysis.

Regional data of patient residence is seen in Table 4. Maps of HNC diagnosis incidence and COTD usage by region are shown in Figs. S3 and S4 respectively. Out of the 11 SEER-registered regions, Connecticut, Louisiana, and New Jersey were locations where patients were significantly less likely to receive a COTD. Louisiana was the least likely location for patients to receive a COTD (OR = 0.367, 95% CI: 0.279–0.483).

Discussion

This study sought to analyze factors that drive utilization of COTDs in order to identify individuals that are less likely to be given this technology for decreasing risk of severe RIOM during head and neck cancer IMRT. Multivariate analysis was conducted using patients from

Table 3
Clinical factors and complex treatment device utilization.

Clinical Characteristics	No Stent (%)	Stent (%)	OR	95% CI		*p-value*
Site						
Tongue	43.07	56.93	Ref	Ref	Ref	*Ref*
Nasopharynx	42.18	57.82	0.997	0.726	1.370	*0.9857*
Oropharynx	42.49	57.51	1.041	0.811	1.336	*0.7528*
Tonsil	42.58	57.42	0.992	0.856	1.151	*0.9196*
Floor of Mouth	43.43	56.57	1.048	0.817	1.343	*0.7128*
Grade						
Well differentiated	43.49	56.51	Ref	Ref	Ref	*Ref*
Moderately differentiated	43.27	56.73	1.039	0.792	1.364	*0.7804*
Poorly diff/ undifferentiated	43.17	56.83	1.065	0.811	1.397	*0.651*
Unknown	41.40	58.60	1.142	0.857	1.522	*0.3651*
Stage						
Localized	42.71	57.29	Ref	Ref	Ref	*Ref*
Distant	41.17	58.83	1.018	0.803	1.289	*0.7921*
Regional	43.79	56.21	0.925	0.767	1.117	*0.4536*
In Situ & Unstaged	39.88	60.12	1.139	0.807	1.609	*0.7717*
IMRT Fractions						
1–14 fractions	46.93	53.07	Ref	Ref	Ref	*Ref*
No IMRT initiated first 90 days	44.03	55.97	0.990	0.797	1.229	*0.9261*
15–24 fractions	46.64	53.36	0.840	0.620	1.139	*0.2625*
>=25 fractions	40.92	59.08	1.107	0.830	1.246	*0.8731*
Charlson Score						
0	44.50	55.50	Ref	Ref	Ref	*Ref*
1*	39.16	60.84	1.223	1.055	1.418	*0.0076*
2+	42.45	57.55	1.053	0.889	1.247	*0.55*

* Statistically significant.

Table 4
SEER regions and complex treatment device utilization.

Region	No Stent (%)	Stent (%)	OR	95% CI		*p-value*
California + Hawaii	40.26	59.74	Ref	Ref	Ref	*Ref*
Connecticut*	52.70	47.30	0.646	0.482	0.866	*0.0034*
Detroit	43.33	56.67	0.984	0.748	1.295	*0.9084*
Greater Georgia	38.12	61.88	1.017	0.822	1.256	*0.8795*
Iowa	34.22	65.78	1.278	0.923	1.769	*0.1403*
Kentucky	38.65	61.35	0.893	0.673	1.184	*0.4317*
Louisiana*	61.79	38.21	0.367	0.279	0.483	*<0.0001*
New Jersey*	48.18	51.82	0.718	0.576	0.896	*0.0034*
New Mexico	33.33	66.67	1.163	0.766	1.767	*0.4781*
Seattle	41.67	58.33	0.977	0.732	1.303	*0.8735*
Utah	47.56	52.44	0.778	0.491	1.234	*0.2864*

* Statistically significant.

SEER-Medicare diagnosed with tongue, floor of mouth, nasopharyngeal, tonsillar, or oropharyngeal cancer who received IMRT. Despite the steady increase in utilization of COTDs from 1992 to 2013, results indicate that usage as of 2013 remains at 67 percent.

Additionally, characteristics that were associated with reduced COTD utilization include age, gender, race, and region of residence. Males, non-Hispanic blacks, and individuals older than 86 showed a significantly decreased likelihood in being given a COTD. These results were found in both the full cohort and the sub-cohort that excluded distant stage HNC patients. The reported odds ratios suggest a statistical but not clinical significance. Perhaps the most surprising finding is that urban area classification, education level, and percent poverty, all of which serve as proxies of socioeconomic status, do not show a relationship with use. These results indicate that specific patient populations may benefit from an increased availability of COTDs and oral oncology support.

SEER-Medicare database research on medical device usage overall is currently limited. There is a current, albeit scarce, body of literature that addresses the relationship between COTDs and reduction of radiotherapy toxicities, namely RIOM [11]. Recently published studies have also shown the dosimetric advantages of oral stents, including decreased mean and/or maximum dose to non-target areas of the oral mucosa [12]. It was also shown that participants with COTDs had lower toxicity-related side-effects such as mucositis and xerostomia [12]. It was also shown that participants with stents had lower toxicity-related side-effects such as mucositis and xerostomia. However, these studies are based upon small, institutional patient populations that lack the representativeness provided by SEER-Medicare. This has led to an increased emphasis in treating head and neck malignancies using IMRT as opposed to 3D Conformal Radiotherapy due to its association with reduction in toxicities and increase in survival outcomes [13,14]. In addition to this, SEER-Medicare has been utilized to analyze the treatment and clinical factors contributing to common head and neck radiation treatment related toxicities such as RIOM [15], dysphagia [16,17], xerostomia [18], and osteoradionecrosis [19]. Furthermore, SEER-Medicare research has shown the differences in outcomes and utilization rates of therapeutic modalities based upon demographic factors such age, region, and socioeconomic status [20,21]. Despite the existing research related to HNC and IMRT, this is the first known study to have used SEER-Medicare to analyze complex oral treatment device utilization. This addresses the current gap in the literature that exists in examining the role of medical devices, specifically COTDs, as they intersect with the current research regarding toxicities, access, and preferred treatment modalities. Future research should aim to identify specific logistic issues with COTD use such as cost, learning curve, and the need for additional verification steps.

To date, no SEER-Medicare database study has been conducted to analyze the relationship between COTD usage and incidence of RIOM and other treatment related toxicities. Utilizing SEER-Medicare for this analysis would allow for research to also identify “at risk” groups who are more likely to experience radiation induced toxicities due to their lack of access to the devices. For instance, billing codes for head and neck cancer patients receiving a gastric feeding tube could be suggestive of severe mucositis, which could be used to assess RIOM in those who received oral complex oral treatment devices versus those who did not. Additional proxies could be used to assess toxicities, including radiation treatment breaks, though establishing a threshold for the number of days that define a scheduled treatment break from a treatment break due to severe toxicity remains a challenge. Further research should focus on COTD usage as a means of lessening toxicity. The current evidence has demonstrated efficacy of oral devices in mitigating the effects of radiation exposure for head and neck cancer patients [13]. By extension, the ability of COTDs to decrease the burden of severe RIOM signals its potential to reduce healthcare costs associated with treatment-related toxicities [20].

A key limitation of the study is that surrogate measurements were used, including billing codes for complex treatment device and radiation simulation. This is due to lack of a direct billing code for a complex oral treatment device, and no standardized method of billing for COTDs. SEER-Medicare nomenclature may vary by clinical site, and a variety of oral devices may qualify as COTDs (Fig. 1). As a result, a major assumption of the study is the accuracy of our current method of delineating COTD use through the current coding guidelines. For instance, treatment with a thermoplastic mask or non-oral customized immobilization device without a customized oral stent could have affected our reported utilization data. Additionally, changes in billing codes over time or methods of billing for COTDs could affect the analyzed data which could explain a sudden increased frequency of COTD usage in 1997 and 2000. The lack of a consistent method of reporting COTD utilization can affect the data either through the over or

underestimation of usage.

Another limitation of the study are the metrics used to determine urban area classifications. SEER urban area classification data was based on United States Department of Agriculture 2013 Urban-Rural Continuum Codes, which stratify counties by population and whether an area is metropolitan. However, there were unclear criteria for each population cut-off between the sub-classifications. As a result, urban area classification within the study was reduced to two categories in order to increase the power of the analysis. Adversely, the guidelines for the 2013 Urban-Rural classifications could further affect our means of categorical reduction. As a result, we cannot guarantee that the urban area classifications reflect the true area demographics of the individuals included in the study. Classification by location was also limited due to demographic data reported on a state level that does not account for variation at the physician or facility level.

To conclude, this study revealed an increase in utilization of COTDs from 1992 to 2013, and found that age, gender, race, and location are associated with differences in COTD utilization. Tumor and treatment characteristics of patients had no association with COTD utilization. This finding suggests that disparities in usage are likely driven by factors other than clinical characteristics which would typically alter treatment techniques. The methodology and results of this study validate the potential of continued usage of the SEER database to further analyze the use of other radiation toxicity reduction devices in other primary sites. This is beneficial for analysis of other medical device technologies that go beyond radiation therapy and has the potential to serve as a means of tracking both efficacy and patterns of access. Additionally, this study could prove useful in advocating for increased funding into research for COTDs and efficient means of producing them [5].

Funding Statement

This research was supported, in part, by CPRIT RP160674, Komen SAC150061 and P30 CA016672. Dr. Fuller received funding and salary support from: the National Institutes of Health (NIH) National Institute of Biomedical Imaging and Bioengineering (NIBIB) Research Education Programs for Residents and Clinical Fellows Grant (R25EB025787-01); the National Institute for Dental and Craniofacial Research Establishing Outcome Measures Award (1R01DE025248/R56DE025248) and Academic Industrial Partnership Grant (R01DE028290); NCI Early Phase Clinical Trials in Imaging and Image-Guided Interventions Program (1R01CA218148); an NIH/NCI Cancer Center Support Grant (CCSG) Pilot Research Program Award from the UT MD Anderson CCSG Radiation Oncology and Cancer Imaging Program (P30CA016672); an NIH/NCI Head and Neck Specialized Programs of Research Excellence (SPORE) Developmental Research Program Award (P50 CA097007); NIH Big Data to Knowledge (BD2K) Program of the National Cancer Institute (NCI) Early Stage Development of Technologies in Biomedical Computing, Informatics, and Big Data Science Award (1R01CA214825), National Science Foundation (NSF), Division of Mathematical Sciences, Joint NIH/NSF Initiative on Quantitative Approaches to Biomedical Big Data (QuBBD) Grant (NSF 1557679); NSF Division of Civil, Mechanical, and Manufacturing Innovation (CMMI) grant (NSF 1933369); the Stiefel Oropharyngeal Research Fund of the University of Texas MD Anderson Cancer; and the MD Anderson Program in Image-guided Cancer Therapy. Dr. Fuller has received direct industry grant support, in-kind hardware, honoraria, and travel funding from Elekta AB. Dr. Koay was supported by funding from the Radiation Oncology Strategic Initiatives (ROSI) at MD Anderson.

Research data are not available at this time.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ctro.2021.08.004.

References

[1] Mourad M, et al. Epidemiological trends of head and neck cancer in the United States: A SEER population study. J. Oral Maxillofac. Surg. 2017;75:2562–72.
[2] Fakhry Carole, et al. Head and neck squamous cell cancers in the United States are rare and the risk is higher among white individuals compared with black individuals. Cancer 2018;124,:2152–3.
[3] A. Gupta, J.B. Epstein, H. Sroussi, Hyposalivation in elderly patients. J. Can. Dental Assoc., 72, 841–846.
[4] Johnson B, et al. Fabrication of customized tongue-discplacing stents: Considerations for use in patients receiving head and neck radiotherapy. J. Am. Dental Assoc. 2013;144:594–600.
[5] Wilke CT, et al. Design and fabrication of a 3D-printed oral stent for head and neck radiotherapy from routine diagnostic imaging. 3D Print. Med. 2017;3.
[6] Rocha BA, et al. Intraoral stents in preventing adverse radiotherapeutic effects in lip cancer patients. Rep. Pract. Oncol. Radiother. 2017;22:450–4.
[7] SEER-Medicare: Brief Description of the SEER-Medicare Database. National Cancer Institute: Division of Cancer Control and Population Sciences. [Online] May 16, 2019. https://healthcaredelivery.cancer.gov/seermedicare/overview/.
[8] I. Vaz-Luis, et al. Duration and toxicity of adjuvant trastuzumab in older patients with early-stage breast cancer: a population-based study. J. Clin. Oncol., 2014, 32, 927-934.
[9] Rural-Urban Continuum Codes. United States Department of Agriculture: Economic Research Service. [Online] October 25, 2019. https://www.ers.usda.gov/data-products/rural-urban-continuum-codes.aspx.
[10] NCI Comorbidity Index Overview. National Cancer Institute: Division of Cancer Control and Population Sciences. [Online] May 23, 2019. https://healthcaredelivery.cancer.gov/seermedicare/considerations/comorbidity.html.
[11] J.R. Verrone, et al., Benefits of intraoral stent in decreasing the irradiation dose to oral healthy tissue: dosimetric and clinical features. Oral Surg. Oral Med. Oral Pathol. Oral Radiol., 2014, 118, 573-578.
[12] S. Stieb, MD Anderson Head and Neck Cancer Symptom Working Group, et al. The impact of tongue-deviating and tongue-depressing oral stents on long-term radiation-associated symptoms in oropharyngeal cancer survivors. Clin. Transl. Radiat. Oncol., 2020, 24, 71–78.
[13] Beadle BM, et al. Improved survival using intensity-modulated radiation therapy in head and neck cancers: A SEER-Medicare analysis. Cancer 2014;120:702–10.
[14] Spiotto MT, Weichselbaum RR. Comparison of 3D conformal radiotherapy and intensity modulated radiotherapy with or without simultaneous integrated boost during concurrent chemoradiation for locally advanced head and neck cancers. PloS One 2014.
[15] Elting LS, et al. Risks, outcomes, and costs of radiation-induced oral mucositis among patients with head-and-neck malignancies. Int. J. Radiat. Oncol. 2007;68:1110–20.
[16] Hutcheson KA, et al. Two-year prevalence of dysphagia and related outcomes in head and neck cancer survivors: An updated SEER-Medicare analysis. Head Neck 2019;41:479–87.
[17] Xu B, et al. Aspiration pneumonia after concurrent chemoradiotherapy for head and neck cancer. Cancer 2014;121:1303–11.
[18] Chambers MS, Rosenthal David I, Weber RS. Radiation-induced xerostomia. Head Neck 2006;29:58–63.
[19] Beadle BM, et al. Evaluating the impact of patient, tumor, and treatment characteristics on the development of jaw complications in patients treated for oral cancers: A SEER-Medficare analysis. Head Neck 2012;35:1599–605.
[20] Guadagnolo B Ashleigh, Liu Chih-Chin, Cormier Janice N, Du Xianglin L. Evaluation of trends in the use of intensity-modulated radiotherapy for head and neck cancer from 2000 through 2005. Cancer 2010;116:3505–12.
[21] Sher David J, Neville Bridget A, Chen Aileen B, Schrag Deborah. Predictors of IMRT and conformal radiotherapy use in head and neck squamous cell carcinoma: A SEER- medicare analysis. Int. J. Radiat. Oncol. Biol. Phys. 2011;81:e197–206.