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Carotid Artery Stenosis in Head and Neck Cancer Patients Treated with Radiotherapy

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Abstract

Introduction Radiotherapy (RT) is a crucial treatment modality for 80% of head and neck cancer (HNC) patients, often combined with surgery or chemotherapy, leading to a significant reduction in cancer-related mortality. However, as cancer survival rates increase, therapy-related complications also increase, impacting both mortality and morbidity. One such late complication is radiation-induced carotid artery stenosis (CAS), a condition associated with an increased risk of cerebrovascular events. Radiation-induced CAS is rarely studied, especially in the Indian population. Despite its potential severity, there is no standardized screening or management protocol for radiation-induced CAS in HNC patients.

Objectives This study aims to assess the prevalence, risk factors, complications, management, and outcomes of CAS in HNC patients who received RT, with or without chemotherapy and surgery at our institution.

Materials and Methods This is a retrospective observational study of newly diagnosed primary HNC patients who received RT between January 2012 and December 2021. Patients with metastatic HNC and those treated elsewhere were excluded. Data on demographics, tumor characteristics, treatment, and imaging for vascular stenosis were collected. Statistical analysis was performed using R version 4.4.1, with categorical variables analyzed using the chi-square or Fisher's exact test and continuous variables using the Mann–Whitney's *U* test. Significance was set at *p*-value $</=0.05$.

Results Of 949 patients, 34 (3.6%) developed CAS. Preradiation vascular stenosis was rare (0.1%). Among the 34 patients categorized by time since treatment, CAS developed in 47.1% of patients after 5 years, 32.4% within 2 to 5 years, and 5.9% within 1 year. CAS severity included near-total occlusion in 23.5%, $\geq$70% stenosis in 20.6%, and neurological deficits in 8.8%. The median age was 62 years, and the majority were male (85.3%). Common risk factors were hypertension (29.4%), diabetes (20.6%), tobacco use (82.4%), and alcohol consumption (41.2%). Tumors of oral cavity and hypopharynx were more common. Most CAS patients (76.5%) received radical chemoradiation. Only 23.3% of CAS patients received anticoagulation therapy, with 14.3% undergoing mechanical thrombectomy.

Keywords
- carotid artery stenosis
- head and neck cancer
- radiotherapy
- cerebrovascular events

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Conclusion This study highlights the prevalence of radiation-induced CAS in HNC patients, especially in the Indian population, and identifies associated risk factors. Hence, standardized screening and management protocols for CAS are crucial for improving long-term outcomes in HNC survivors.

Introduction

Radiotherapy (RT) is an essential therapeutic modality in the treatment of 80% of head and neck cancer (HNC) patients, often combined with surgery or chemotherapy. With the improvement in integrity of treatment, cancer-related mortality has been markedly reduced.[1] Since the number of cancer survivors has increased, therapy-related complications also increased, which impacted both mortality and morbidity.[2]

Among these complications, one of the underidentified and undertreated late complications is radiation-induced carotid artery stenosis (CAS), which is associated with a higher risk of cerebrovascular events.[3] Prevention and treatment of radiation-induced CAS is important for improving the long-term prognosis of the survivors.

Currently, there is no definitive algorithm for screening and subsequent management of CAS in HNC patients who have received radiation.[4] This study aims to analyze the prevalence, risk factors, and complications due to CAS in HNC patients treated with radiation, as well as its management and outcomes in our institution.

Materials and Methods

Study Design

This is a retrospective observational study.

Sample Size

Assuming an actuarial risk of 29% for CAS at 8 years, as reported by Carpenter et al, the study required a minimum sample size of 317 participants. This sample size was calculated to estimate the expected proportion with an absolute precision of 5% and a 95% confidence interval. The calculation was performed using the Statulator's online sample size calculator.

All newly diagnosed primary patients with HNC who underwent RT $\pm$ chemotherapy and surgery from January 2012 to December 2021 were included in the study. Those patients with metastatic HNC, patients who defaulted treatment with radiation and patients with other synchronous malignancies and who had treatment elsewhere were excluded from the study. The demographic details of the study population, tumor characteristics, and treatment received were collected from the hospital-based registry medical records. The imaging modality used for diagnosis of vascular stenosis, the degree of stenosis, details of further evaluation, and management were reviewed in the study.

Primary Outcome: To analyze the incidence of CAS in HNC patients treated with radiation in our institution.

Secondary Outcome: To analyze the risk factors and complications due to CAS in HNC patients treated with radiation, as well as its management and outcomes.

Inclusion Criteria

1. Patients with HNC.
2. Biopsy-proven malignancies.
3. Patients who received treatment with radiation either alone or in combination with surgery or chemotherapy.
4. Patients above 18 years of age.

Exclusion Criteria

1. Patients with metastatic HNC.
2. Patients with other synchronous malignancies.

Statistical Analysis

Descriptive analysis was performed by mean, standard deviation, median, and interquartile range for continuous variables, and frequency and percentage for categorical variables. The significance of differences in the distribution of categorical variables among patients who developed vascular stenosis and who did not, such as diagnosis, subsites, and stages, was analyzed using the ci-square test and Fisher's exact test. The difference in the distribution of continuous variables was compared using the Mann–Whitney's *U* test for skewed distribution. Two-tailed significance at <0.05 was taken as statistically significant. Overall survival was defined as the time from the date of RT initiation to the last follow-up (i.e., censor date). The cumulative incidence in the presence of competing risks was constructed using the Kaplan–Meier's method.

Ethical Approval

All the procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional or regional) and with the Declaration of Helsinki of 1975, as revised in 2013. This study was approved by the institutional ethics committee (G. Kuppuswamy Naidu Memorial Hospital), and patient informed consent for this study was waived as this is a retrospective study (ECR number 2023/IEC/059 dated December 21, 2023).

Results

Out of 949 patients, 34 of them had developed CAS. In the diagnostic evaluation of CAS among the subset of 34 patients, computed tomography (CT) imaging was the exclusive modality utilized. The analysis of preradiation vascular stenosis among the study cohort highlights a low prevalence (0.1%) of preexisting stenosis. Among the 34 patients categorized by

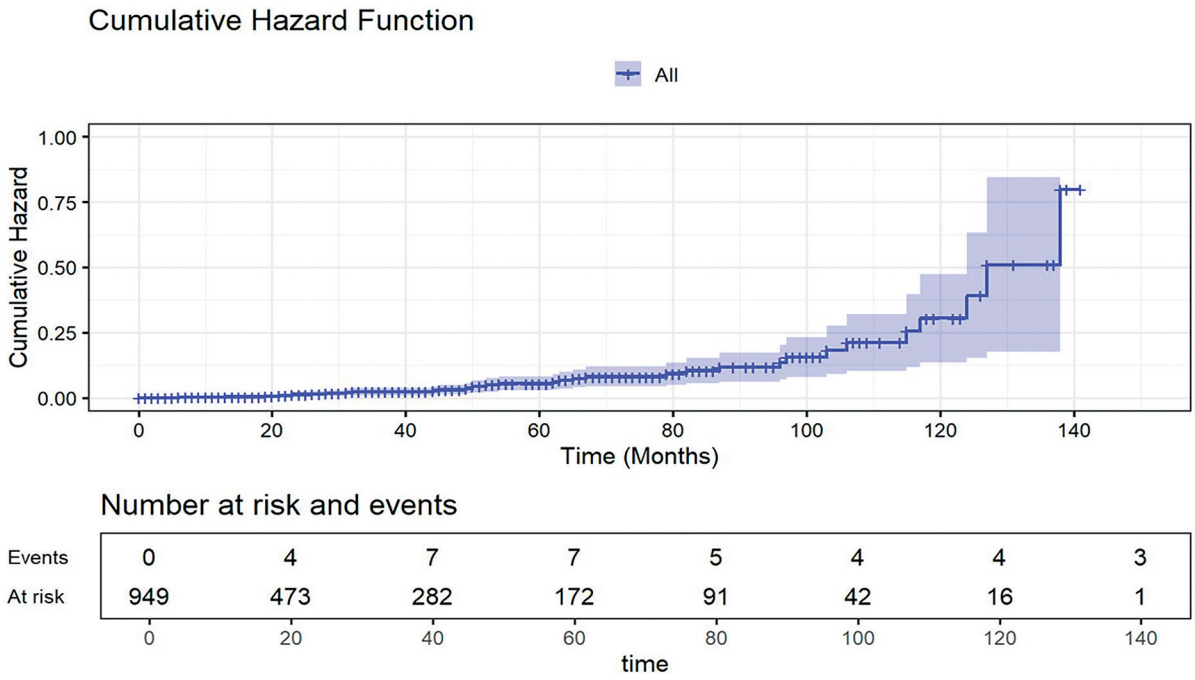

Fig. 1 Showing the number of events (carotid artery stenosis) over a period of time.

time since treatment, 47.1% developed CAS after 5 years of radiation, while 32.4% within 2 to 5 years, 14.7% within 1 to 2 years, and 5.9% within 1 year postradiation (►**Fig. 1**). The cumulative hazard rate at 5 years (60 months) is 0.0546 (confidence interval: 0.0333–0.0898) as compared with 10 years (120 months) of 0.3013 (confidence interval: 0.1736–0.5233). This signifies the cumulative hazard rate increases manyfold with time. Among 34 patients diagnosed with post-RT CAS, 23.5% had near-total occlusion, 20.6% had >/=70% stenosis, 17.6 had 40 to 50% stenosis, and 8.8% experienced neurological deficits (disorientation, giddiness, and paraplegia) attributed to the stenosis.

The median age for those who developed stenosis was 62 (range 57–67.5). Among the 34 patients who developed CAS, 85.3% were males and 14.7% were females. Notably, individuals with stenosis demonstrated higher prevalence rates of hypertension (29.4%) and diabetes mellitus (20.6%). Coronary artery disease (CAD) was present in 5.9% of patients, along with dyslipidemia (2.9%) and a history of cerebrovascular accident (CVA) (2.9%), compared with the general patient population. Other risk factors for atherosclerosis also need to be monitored. In patients with CAS, there was a higher prevalence of tobacco use (82.4%) and alcohol consumption (41.2%) compared with the total patient cohort. Conversely, a smaller proportion of those with stenosis reported no habits (17.6%).

Among 34 patients who developed CAS, the distribution of primary tumor was 29.4% in the oral cavity, 29.4% in the hypopharynx, 26.5% in the oropharynx, 11.8% in the larynx, and 2.9% in the nasopharynx.

Among patients who developed CAS, 44.1% of them were in stage IV, 41.2% in stage III, 11.8% in stage II, and only 2.9% in stage I (►**Table 1**).

A total of 76.5% of patients who had developed CAS received radical chemoradiation, 17.6% received radical RT alone, and 5.9% received adjuvant chemoradiation. Intensity-modulated radiotherapy was the common technique used in our institution, which accounted for 78.7% of total HNC patients; 88.23% of patients received a total dose of 66 Gy and 5.8% received 60 Gy. Out of 34 patients with CAS, 4 were already on anticoagulants—3 due to CAD and 1 due to a history of CVA. Among the remaining 30 patients who were not on anticoagulants, only 7 (23.3%) received treatment, of which 6 (85.7%) were managed with oral anticoagulants alone, while 1 (14.3%) underwent mechanical thrombectomy followed by oral anticoagulant therapy.

Survival analysis shows an overall median time to onset of carotid stenosis was 138 months. However, in the presence of comorbidities, the median time to onset of carotid stenosis was 117 months. The overall risk of carotid stenosis among patients with comorbidities is 2.89 (1.41–5.91, $p = 0.004$) times higher than those without comorbidities. The probability of onset of carotid stenosis (i.e., the hazard rate) at 60 months was 0.08 in the presence of comorbidities, and at 96 months, the same was 0.3 (►**Fig. 2**).

Using a multivariate hazard regression model, which includes sex, cancer stage, overall RT dose delivered, and presence of comorbidities, we found higher hazard rates for the male gender, presence of comorbidities, and stages III and IV of disease (►**Table 2**).

Discussion

RT plays a crucial role in the management of HNC, both as a primary treatment modality and in combination with surgery and/or chemotherapy. As the survival increases, the

Table 1 Showing baseline characteristics

Characteristics ($N = 949$)		*N* (%)	Post-RT vascular stenosis		*p*-Value[a]
			Yes (%)	*N* (%)	
		949	34 (3.6%)	915 (96.4%)	
Age (y)	Median (Q1, Q3)	60 (51, 68)	62 (57.2, 67.8)	60 (50, 68)	0.12[b]
Sex	Male	746 (78.6%)	29 (85.3%)	717 (78.4%)	
	Female	203 (21.4%)	5 (14.7%)	198 (21.6%)	0.45[c]
Comorbidities	HTN	117 (12.3%)	10 (29.4%)	107 (11.7%)	0.005
	DM	122 (12.9%)	7 (20.6%)	115 (12.6%)	0.187
	CAD	34 (3.6%)	2 (5.9%)	32 (3.5%)	0.346
	DLP	6 (0.6%)	1 (2.9%)	5 (0.5%)	0.197
	CVA	6 (0.6%)	1 (2.9%)	5 (0.5%)	0.197
	None	748 (78.8%)	21 (61.8%)	727 (79.5%)	0.023[c]
Habits	Tobacco	644 (67.9%)	28 (82.4%)	616 (67.3%)	0.098[c]
	Alcohol	249 (26.2%)	14 (41.2%)	235 (25.7%)	0.069[c]
	None	292 (30.8%)	6 (17.6%)	286 (31.3%)	0.134[c]
Diagnosis	Ca oral cavity	331 (34.9%)	10 (29.4%)	321 (35.1%)	0.618[c]
	Ca hypopharynx	222 (23.4%)	10 (29.4%)	212 (23.2%)	0.523[c]
	Ca oropharynx	209 (22%)	9 (26.5%)	200 (21.9%)	0.67[c]
	Ca larynx	120 (12.6%)	4 (11.8%)	116 (12.7%)	1
	Ca nasopharynx	22 (2.3%)	1 (2.9%)	21 (2.3%)	0.556
	Others	45 (4.7%)	0	45 (4.9%)	0.401
Stage	I	74 (7.8%)	1 (2.9%)	73 (8%)	
	II	275 (29%)	4 (11.8%)	271 (29.6%)	
	III	276 (29.1%)	14 (41.2%)	262 (28.6%)	
	IV	319 (33.6%)	15 (44.1%)	304 (33.2%)	
Preradiation vascular stenosis	Yes	1 (0.1%)	0	1 (0.1%)	
	No	948 (99.9%)	34 (100%)	914 (99.9%)	1

Abbreviations: CAD, coronary artery disease; CVA, cerebrovascular accident; DLP, dyslipidemia; DM, diabetes mellitus; HTN, hypertension; RT, radiotherapy.
[a]Fisher's exact test.
[b]Mann–Whitney's *U* test.
[c]Chi-square test.

incidence of long-term complications, including CAS is less addressed.[5,6] Radiation-induced CAS is rarely studied, especially in the Indian population. This institutional study was performed to study the prevalence of CAS in HNC patients treated with radiation, along with its associated risk factors and complications.

In the general population, the prevalence of asymptomatic moderate (>50%) CAS is 4.2% and severe (>70%) CAS is 1.7%.[7] A meta-analysis of 22 studies conducted by Lin et al in 2022 reported that the prevalence of CAS >50% was 26% in HNC patients treated with RT.[3] The present study demonstrated a pooled prevalence of 3.68% CAS in Indian patients who have undergone radiation.

Digital subtraction angiography is the gold standard for diagnosis of vascular stenosis.[8] Since the procedure is invasive and time-consuming, noninvasive imaging modalities, such as CT angiography and magnetic resonance angiography, have replaced digital subtraction angiography.[9] In our study, the diagnosis of post-RT CAS was exclusively performed using CT imaging. Studies have revealed that severe stenosis and vascular changes gradually develop over several years post-RT.[10,11] In our study, the interval from radiation to diagnosis was that 14.7% were diagnosed within 1 year to 32.4% after 5 years. The degree of stenosis also varied widely: 25.7% had near occlusion, 17.1% had 40 to 50% stenosis, and 20% had >/= 70% stenosis.

Most cases were diagnosed beyond 5 years (16 patients) and between 2 and 5 years (11 patients) postradiation showing a trend in developing CAS progressively over several years, with a notable increase in severity of stenosis and occlusions.

The identified typical manifestations of extracranial carotid stenosis are amaurosis fugax, paresis, sensory disturbances, aphasia, and dysarthria.[12] In the current study, only

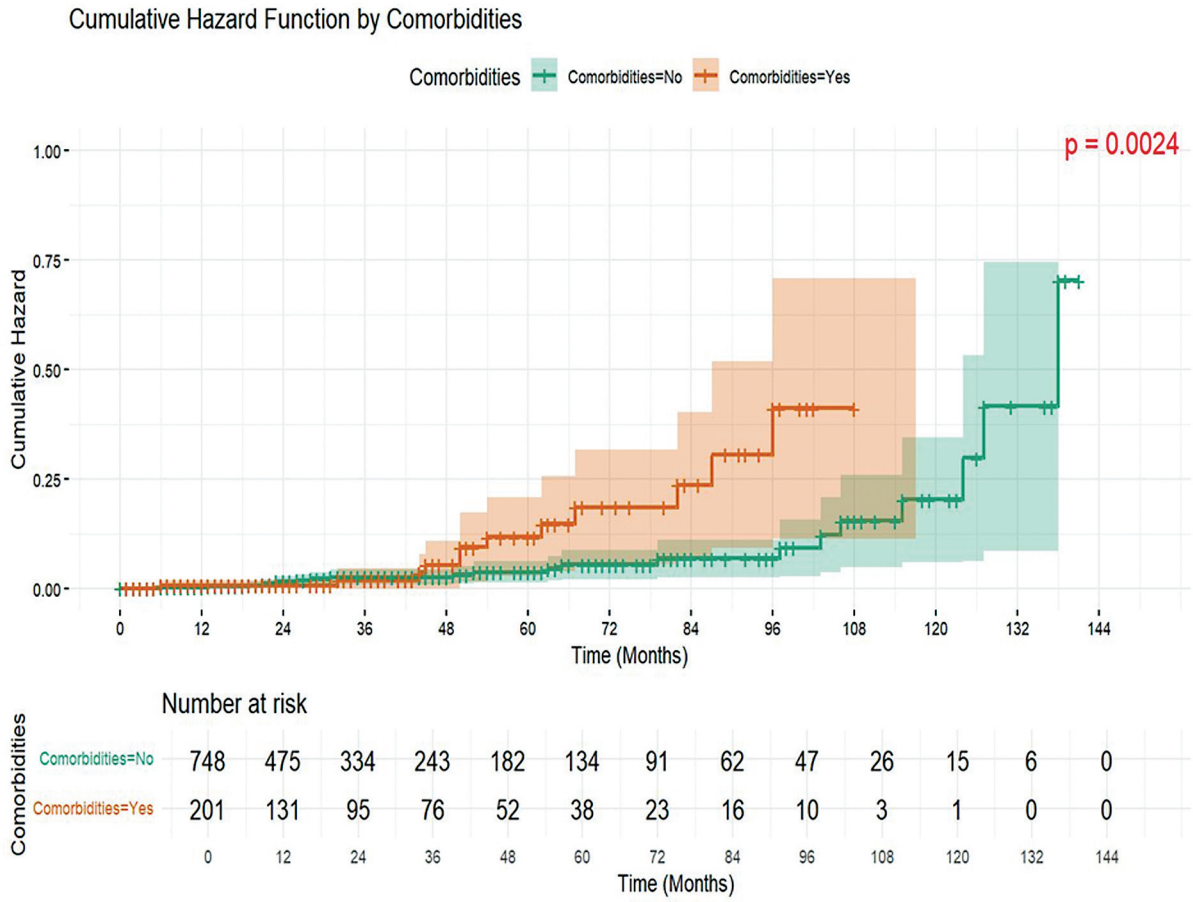

Fig. 2 Probability of onset of carotid artery stenosis in the presence of comorbidities.

Table 2 Multivariate hazard regression model showing higher hazard rates for male gender, presence of comorbidities, and stages III and IV of disease

Characteristics		*N* (%)	Univariable			Multivariable		
			Hazard rate	95% CI	*p*-Value	Hazard rate	95% CI	*p*-Value
Sex	Female	203 (21.4)						
	Male	746 (78.6)	2.03	0.76–5.41	0.157	2.38	0.81–6.99	0.116
Comorbidities	No	748 (78.8)						
	Yes	201 (21.2)	2.89	1.41–5.91	0.004	2.70	1.28–5.70	0.009
Dose delivered	61–65 Gy	9 (0.9)						
	66–70 Gy	740 (78.0)	0.24	0.03–1.82	0.169	0.23	0.03–1.79	0.158
	</= 60 Gy	200 (21.1)	0.09	0.01–0.88	0.039	0.08	0.01–0.88	0.038
Stage	I	74 (7.8)						
	II	275 (29.0)	1.05	0.12–9.42	0.967	1.32	0.14–12.21	0.805
	III	276 (29.1)	4.46	0.58–34.08	0.150	6.28	0.80–49.38	0.081
	IV	319 (33.6)	6.21	0.82–47.25	0.078	7.07	0.91–54.78	0.061
	Recurrence	5 (0.5)	0.00	0.00–infinity	0.998	0.00	0.00–infinity	0.998

Abbreviation: CI, confidence interval.

8.6% experienced neurological deficits primarily presented with disorientation, giddiness, limb weakness, or dysarthria.

The study by Chang et al demonstrated no significant association of age and sex with the development of CAS after RT.[13] This result is similar to our current study. However, in the study by Lam et al, a significant relationship was found between age and irradiation as key factors in the development of CAS.[14] Diabetes mellitus played an important role in increasing the risk of CAS, as studied by Carpenter et al. Our study also demonstrated the same results but with no statistical significance.[10] Cheng et al and Dorth et al highlighted the association of hypertension in the rapid progression of postradiation CAS. Our results also corroborate with these findings, indicating a significant prevalence of hypertension in those patients, signifying its potential in the development of CAS.[15,16]

The overall risk of carotid stenosis among patients with comorbidities is 2.89 (1.41–5.91, $p = 0.004$) times higher than those without comorbidities. The probability of onset of carotid stenosis (i.e., the hazard rate) at 60 months was 0.08 in the presence of comorbidities, and at 96 months, the same was 0.3.

In the study by Chiyoko et al, which favors a higher prevalence of DLP, CAD, and CVA in patients who developed CAS post-RT, our study also reported the same results, although the differences were not statistically significant.[17]

Cheng et al addressed the significance of smoking in developing CAS.[11] In our study population, 67.9% of the total patients used tobacco, with a higher proportion among those who developed post-RT vascular stenosis (82.4%). The *p*-value of 0.09 suggests a trend toward significance, indicating that tobacco use might be associated with an increased risk of CAS. Alcohol consumption was reported by 41.2% of patients who developed CAS, yielding a *p*-value of 0.06. This suggests a potential association between alcohol use and the development of post-RT CAS. Although the result is not statistically significant, the higher prevalence among those who developed CAS is toward a possible correlation.

Alcohol and its combined use with tobacco have been reported to have a synergistic effect, exacerbating the risk of atherosclerosis and related complications. Addressing these modifiable risk factors could potentially reduce the risk of developing CAS and improve overall patient outcomes.

Patients who underwent radiation for nasopharyngeal carcinoma, laryngocarcinoma, and hypopharyngeal carcinoma had a six times higher risk of developing carotid stenosis than others.[18] In our study, the most common cancer sites with a higher prevalence of CAS are found to be the oral cavity (29.4%), hypopharynx (29.4%), and oropharynx (26.5%), though these differences were not statistically significant, with *p*-values of 0.61, 0.52, and 0.67, respectively. These findings suggest that the site of cancer alone does not significantly predict the likelihood of developing CAS postradiation.

A higher incidence of developing CAS post-RT was noted in patients with stages III and IV HNC compared with those in earlier stages, which is also comparable with the literature.[16]

Halak et al suggested yearly duplex scans starting 3 years post-RT.[19] In contrast, Cheng et al recommended regular screening for patients beyond 5 years of RT since the relative risk of developing CAS is high (15 times).[11] In the current study, 45.7% of patients diagnosed with CAS had follow-up imaging, which was exclusively CT.

Studies have shown that antiplatelet drugs, such as aspirin and clopidogrel, and statins reduce the risk of stroke and also reduce the need for carotid endarterectomy.[20] In our study, among 34 patients diagnosed with CAS, 4 (11.4%) were already on anticoagulants, and 7 (22.6%) received treatment. Six were treated primarily with oral anticoagulants, and one patient underwent mechanical thrombectomy followed by oral anticoagulants.

Limitations

Digital subtraction angiography is the gold standard for diagnosis of vascular stenosis.[8] However, in this study, CT imaging was the exclusive modality used. The prevalence rate might be higher if we had used the angiography.

Conclusion

Patients treated with RT for HNC are at significantly increased risk of developing CAS and cerebrovascular disease. The present study demonstrated a pooled prevalence of 3.68% CAS in Indian patients who have undergone radiation. The cumulative hazard rate at 5 years (60 months) is 0.0546 (confidence interval: 0.0333–0.0898) as compared with 10 years (120 months) of 0.3013 (confidence interval: 0.1736–0.5233). This signifies the cumulative hazard rate increases manyfold with time. Timely diagnosis and prevention are necessary. Close monitoring should be considered among head and neck survivors with comorbidities following RT to prevent cerebrovascular disease.

Patient Consent

The patient consent was waived by the Institutional Ethics Committee.

Authors' Contribution

M.N. conceptualized the study and he is the guarantor. R.B. designed the study, defined the intellectual content, and edited the manuscript. R.B. and D.S. performed the literature search and prepared the manuscript. D.S. helped in data acquisition. J.M. performed the data analysis and statistical analysis. R.B. and M.N. reviewed the manuscript.

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None.

Conflict of Interest

None declared.

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