



Original Article

Treatment package time in oral cavity cancer patients in regional cancer centre in South Tamil Nadu-A prospective cross-sectional study

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ABSTRACT

Background: Oral cavity squamous cell carcinoma (OCSCC) is a major health concern in India, with over 75% of patients presenting with locally advanced disease. Combined modality treatment with surgery followed by adjuvant radiotherapy improves survival outcomes. Timely initiation of radiotherapy, ideally within six weeks of surgery, and a Treatment Package Time (TPT) the total interval from the date of surgery to the completion of radiotherapy under 100 days are considered critical for optimal outcomes.

Methods: A prospective cohort study was conducted at Madurai Medical College, Regional Cancer Centre during November 2023 to November 2024 in fifty patients with histologically confirmed OCSCC who underwent surgical resection followed by planned adjuvant radiotherapy. Four patients who did not complete radiotherapy were excluded. Demographic data, tumor characteristics, Surgical type and radiotherapy timing, and TPT were compared and analysed.

Results: Among the 46 patients, 65.2% were male, and 91.4% had a history of tobacco use. The most common tumor sites were buccal mucosa (37.0%) and tongue (30.4%). Advanced-stage tumors (T₃-T_{4a}) were observed in 71.7% of patients, with nodal involvement in 67.4%. Only 30.4% initiated radiotherapy within six weeks of surgery. TPT was ≤100 days in 52.2% of patients, while 47.8% exceeded this duration. Flap reconstruction was performed in 74.0% of patients; although more patients in this group completed treatment within 100 days, the association was not statistically significant ($p = 0.129$).

Conclusion: A substantial proportion of OCSCC patients experienced delays in adjuvant radiotherapy and prolonged TPT. Efforts to streamline postoperative care and reduce delays are essential to improve treatment outcomes.

Keywords: Oral cavity cancer, treatment package time, radiotherapy delay, surgical oncology, squamous cell carcinoma, adjuvant therapy, head and neck cancer, India

Introduction

Oral cavity cancer constitutes major health burden in the world with incidence of 3 lakh new cases per year and 1.5 lakh people succumbing to the disease ^[1]. In India, it is estimated that annually there are approximately 77,000 incident cases and 52,000 deaths due to oral cancer, accounting for about one-fourth of global incidences ^[2]. This shows there is trend towards increase in the incidence, whereas the mortality remains the stable. Indian data shows about 75% of patients present in locally advanced and advanced stage and requiring the need for combined modality treatment. The rising incidence of oral cancer poses a critical concern for community health, given its prevalence as one of the most common types of cancer in the country. The five-year relative survival rate for oral cancer stands at 68.0% in developed countries ^[3]. In contrast, in India, it is approximately 50% following treatment with surgery and radiotherapy, significantly lower than in many developed nations ^[4]. Survival of early-stage oral cavity cancer is around 70-85%, when stage advances, survival drops to less than 50%. When combined modality treatment is added, survival is around 50-60% for locally advanced oral cavity cancer ^[5]. The development of OSCC is a multistep process which starts from some changes in the normal mucosa and continues until the development of invasive cancer and metastasis. During this progress, the accumulation of multiple

genetic and chromosomal alterations occurs. Oral cancer is a multifactorial disease and the risk factors include tobacco and alcohol, chronic inflammation, ultra violet (UV) radiation (for lip cancer), human papilloma virus (HPV) or Candida infections, immunosuppression, genetic predisposition, and diet. [6]. Among them, tobacco use and alcohol consumption are considered as the main risk factors for development oral cavity Cancer and both have the synergistic effect. Recent evidence shows in patients undergoing surgery followed by adjuvant radiotherapy, the detrimental impact of prolonging the treatment duration has been reported. Well-defined Treatment duration parameters include interval from surgery to radiotherapy commencement, overall radiation duration (first to last day of radiation course) and Treatment Package Time (TPT) which encompasses the timeframe from the day of surgical resection till the last radiation fraction. The National Comprehensive Cancer Network (NCCN) endorsed the recommendation to start adjuvant Radiation within six weeks from surgery [7]. Optimal Treatment package time (TPT) cut-off varied between different studies with range of around 100 days in classic studies. Any delay in TPT would not add benefits of adjuvant radiotherapy, would result in high recurrence and low survival rates with additional morbidity of radiotherapy [8]. Our study aims to study Treatment of Package Time of oral cavity squamous carcinoma Patients in Regional Cancer Centre in South Tamil Nadu and factors contributing to the delay.

Methodology

A cohort of 50 patients diagnosed with oral cavity squamous cell carcinoma (OSCC) who underwent surgery followed by adjuvant radiotherapy at our institute between November 2023 to November 2024 were included in the study. Patient who had any preoperative treatment, recurrent or second primary were excluded from the study. Sample size of 50 was calculated by sampling method of convenience. Data collected includes demographic details, involved oral cavity subsite, type of surgery performed, postoperative complications, the interval between surgery and initiation of radiotherapy, overall treatment package time, and any delays along with their reasons. Data entry was performed using Microsoft Excel, and statistical analysis was carried out using the Statistical Package for Social Sciences (SPSS) software, version 20. Qualitative variables were expressed as frequencies and percentages. Normally distributed continuous variables were presented as mean $\pm$ standard deviation (SD), while non-normally distributed variables were expressed as medians. Categorical variables were analysed using the Chi-square test or Fisher's exact test, as appropriate and statistical significance was determined accordingly.

Results

Patient demographics data, risk factors, clinical characteristics, pathological data, treatment details, radiotherapy initiation period, Treatment Package Time (TPT) are summarized in Table 1. As shown, study comprise of 50 patients in whom 4 patients did not complete the adjuvant radiotherapy were not included. The majority of the cohort were male (65.2%), with females comprising 34.8%. A significant proportion of patients had a history of tobacco use, either in form of smoking (45.7%) or chewing tobacco (45.7%). In our study, the most commonly affected subsite was the buccal mucosa, accounting for 37.0% of cases, followed by the tongue (30.4%). Other less frequent subsites include floor of mouth (10.9%), lip (8.7%), alveolus (6.5%), hard palate (4.3%), and retromolar trigone (2.2%).

In terms of tumor staging, a considerable number of patients presented with advanced primary tumors. T_{4a} stage was noted in 39.1% of cases, followed by T₃ in 32.6% and T₂ in 28.3% in our study. Nodal involvement was present in the majority of patients. While 32.6% had no nodal disease (N0), the remainder showed varying degrees of nodal metastasis: N1 in 26.1%, N2b in 26.1%, N2c in 6.5%, N2a in 2.2%, and N3b in 6.5%.

With regard to adjuvant treatment timelines, only 30.4% of patients were able to initiate radiotherapy within the recommended 6 weeks following surgery. The treatment package time (TPT), defined as the interval from the date of surgery to the completion of radiotherapy, was less than 100 days in 52.2% of patients, while the remaining 47.8% experienced a delay beyond 100 days. Flap reconstruction was performed in 37 patients (74.0%), while 13 patients (26.0%) underwent surgery without flap coverage. Among patients with flap reconstruction, 58.8% completed treatment within 100 days compared to 33.3% in the non-flap group (Table 2, 3). However, this difference was not statistically significant ($p = 0.129$).

Table 1: Patient demographic and clinical parameters

		Number of Cases	Percentage
Sex	Female	16	34.8%
	Male	30	65.2%
Smoking	No	25	54.3%
	Yes	21	45.7%
tobacco chew	No	25	54.3%
	Yes	21	45.7%
Site	Alveolus	3	6.5%
	Buccal mucosa	17	37.0%
	Floor of mouth	5	10.9%
	Hard palate	2	4.3%
	Lip	4	8.7%
	Retromolar trigone	1	2.2%
	Tongue	14	30.4%

T_Stage	T ₂	13	28.3%
	T ₃	15	32.6%
	T _{4a}	18	39.1%
N_Stage	0	15	32.6%
	1	12	26.1%
	2	1	2.2%
	2b	12	26.1%
	2c	3	6.5%
	3b	3	6.5%
RT Iniation less than 6 weeks	No	32	69.6%
	Yes	14	30.4%
TPT	<100	24	52.2%
	>100	22	47.8%

Table 2: Co-relation between Flap surgery and TPT

		TPT				P value
		<100		>101		
		Count	Row N%	Count	Row N%	
Flap	No	4	33.3%	8	66.7%	0.129
	Yes	20	58.8%	14	41.2%	

Table 3: Co-relation between clinico-pathological factors and TPT

		TPT				P value
		<100		>100		
		Count	Row N%	Count	Row N%	
Sex	Female	7	43.8%	9	56.3%	0.404
	Male	17	56.7%	13	43.3%	
Smoking	No	12	48.0%	13	52.0%	0.536
	Yes	12	57.1%	9	42.9%	
tobacco chew	No	14	56.0%	11	44.0%	0.571
	Yes	10	47.6%	11	52.4%	
Site	Alveolus	0	0.0%	3	100.0%	0.011
	Buccal mucosa	8	47.1%	9	52.9%	
	Floor of mouth	0	0.0%	5	100.0%	
	Hard palate	2	100.0%	0	0.0%	
	Lip	3	75.0%	1	25.0%	
	Retromolar trigone	0	0.0%	1	100.0%	
	Tongue	11	78.6%	3	21.4%	
T_Stage	T ₂	10	76.9%	3	23.1%	0.02
	T ₃	9	60.0%	6	40.0%	
	T _{4a}	5	27.8%	13	72.2%	
N_Stage	0	9	60.0%	6	40.0%	0.042
	1	10	83.3%	2	16.7%	
	2	0	0.0%	1	100.0%	
	2b	4	33.3%	8	66.7%	
	2c	1	33.3%	2	66.7%	
	3b	0	0.0%	3	100.0%	
RT Iniation less than 6 weeks	No	13	40.6%	19	59.4%	0.018
	Yes	11	78.6%	3	21.4%	

Discussion

Oral cavity squamous cell carcinoma (OCSCC) remains a significant health burden in India, with tobacco use being a well-established etiological factor. In our study, nearly half of the patients reported smoking and tobacco chewing, consistent with national patterns reported in previous studies from India. Smoking demonstrably compromises outcomes in surgical and radiotherapy patients. In surgical contexts, it heightens morbidity, while in radiotherapy, it exacerbates treatment toxicities [8]. Smoking significantly increases the risk of postoperative complications, cancer recurrence, and mortality in oral cavity cancer patients, and quitting smoking before surgery can reduce these risks. Current smokers are at much higher risk for complications such as delayed wound healing, surgical site infections, pulmonary complications (including pneumonia and failure to wean from a ventilator), and longer hospital stays. Meta-analytic data show increased odds for necrosis (OR 3.60), wound complications (OR 2.27), delayed healing (OR 2.07), and infections (OR 1.79) in smokers undergoing cancer surgery [9]. Patients who continue to smoke have an 86% higher risk of cancer recurrence and a two-fold decrease in 5-year survival, compared to those who quit smoking at diagnosis. Ongoing smoking is linked to increased overall and cancer-specific mortality. These combined effects contribute to prolonged treatment duration and an overall poorer prognosis, underscoring smoking's dual role as a causative factor and a negative prognostic indicator.

The present study highlights key clinicopathological and treatment-related factors influencing the treatment package time (TPT)—a surrogate indicator for overall treatment efficiency and quality. Although the National Cancer Grid of India and NCCN guidelines recommend completing definitive treatment within 100 days to optimize treatment outcomes, ^[10] almost 48% of our patients exceeded this threshold. Delay in Treatment Package Time have been linked with inferior locoregional control and overall survival in head and neck cancers.

One of the most critical observations in this study was the significant association between radiotherapy initiation delay and prolonged Treatment Package Time. Patients who commenced adjuvant radiotherapy within 6 weeks of surgery were significantly more likely to complete treatment within 100 days ($p = 0.018$). Only 30% of the study population were able to initiate radiotherapy within 6 weeks, rest couldn't due to various factors which is comparable with global data. This shows any factors like post op morbidity, other factors like financial, social and emotional factors which delays early radiotherapy initiation, ultimately have impact on delayed TPT. Insurance authorizations and operational logistics within hospitals delays radiotherapy initiation which ultimately prolongs the TPT.

Additionally, advanced T-stage (T_{4a}) and higher nodal burden were significantly associated with prolonged TPT. 75% of our study population presented with locally advanced disease which mandates complex planning and treatment. These patients often require more extensive resections and complex reconstructions, which may lead to longer recovery periods, delayed wound healing, and consequently, deferred early initiation of adjuvant therapy and net effect of prolonged TPT. Our data resembles data from other part of our country. Interestingly, flap reconstruction, although expected to lengthen recovery time, did not show a statistically significant impact on TPT in our cohort ($p = 0.129$). In fact, a majority of patients who received flap coverage were still able to complete treatment within 100 days. This suggests that with standardized perioperative care and efficient rehabilitation protocols, reconstructive surgery need not be a barrier to timely adjuvant therapy. Tumor site also significantly influenced TPT. Tongue cancers had the highest rate of timely treatment completion, possibly due to earlier symptom recognition and relatively straightforward access for surgery and surveillance. Conversely, tumors of the alveolus, floor of mouth, and retromolar trigone were uniformly associated with delayed TPT, potentially due advance disease and need for extensive resection and delay in postoperative recovery.

Counselling the patients about the significance of adjuvant radiotherapy, particularly its role in achieving optimal locoregional control, is essential to enhance treatment compliance and facilitate completion of therapy within the recommended timeframe. Counselling and rehabilitation of the patient should be done before initiation of treatment and continued during the course of treatment to accomplish the optimal outcome. This study is limited by its small sample size. Furthermore, long-term oncologic outcomes such as recurrence-free survival and overall survival were not assessed in this interim analysis.

Conclusion

This study highlights the multifactorial contributors to treatment delays in oral cavity squamous cell carcinoma (OCSCC) managed with surgery followed by adjuvant radiotherapy. Nearly half of the patients in our study experienced a prolonged treatment package time (TPT >100 days), which is known to adversely affect oncologic outcomes. Delayed initiation of radiotherapy beyond six weeks post-surgery, advanced tumor size and high nodal burden, and tumor subsite were significantly associated with prolonged TPT. In contrast, variables such as sex, age and the use of flap reconstruction did not show a statistically significant impact on treatment duration. Adhering to recommended treatment timelines should be prioritized to optimize disease control and to improve survival in OCSCC patients.

Compliance with ethical Standards

Research involving human participants: Human participants were enrolled into the study with informed written consent as per Institutional Ethical Committee Norms

Conflict of Interest: None

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