International Journal of Community Medicine and Public Health
Joshi PS et al. Int J Community Med Public Health. 2025 Jul;12(7):3113-3119
http://www.ijcmph.com
pISSN 2394-6032 | eISSN 2394-6040

DOI: https://dx.doi.org/10.18203/2394-6040.ijcmph20252105

Original Research Article

Clinico-demographic profile and survival analysis of oral cancer patients: results from tertiary cancer care hospital in western Maharashtra, India

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Received: 08 April 2025
Accepted: 04 June 2025

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ABSTRACT

Background: Oral cancer has a significant public health importance in India. The overall survival rate is below 50% and has remained so for many decades in spite of immense research ongoing in the field of oncology. This lays the foundation for the search of prognostically relevant factors in order to customize the individual management of oral squamous cell carcinoma (OSCC) patients. Objective was to evaluate and corelate clinico-demographic features and survival of selected OSCC cases.
Methods: This retrospective hospital based cohort study was carried out at Mahatma Gandhi Cancer Hospital, Miraj, Maharashtra, India. A total of 1100 OSCC patients enrolled to the hospital's registry for management of OSCC with curative intent in the period from January 2011 to December 2016 were considered. The primary outcome measure was set as overall survival. Secondary outcome included disease-specific and disease-free survival. Student t test and chi-square test was used for categorical variables. Kaplan-Meier survival curves were plotted for survival analysis. The Cox proportional hazards regression model was used to assess the role of predictors.
Results: The mean overall survival for the entire cohort of patients was 33.96±31.19 (month's ±SD). Buccal mucosa was the commonest location and significantly less mean survival was observed for lesions located on alveolar ridges, retromolar trigone and floor of mouth and lesions in clinical stage IV.
Conclusions: It is the extreme need of hour to increase public awareness about the harmful effects of tobacco consumption and early detection of oral cancer.

Keywords: Disease free survival, Disease specific survival, Oral squamous cell carcinoma, Overall survival, Tobacco

INTRODUCTION

India faces a major health problem of communicable and non-communicable diseases. Non-communicable diseases together are grouped as modern epidemics. Among these modern epidemics, cancer is tenth commonest cause of mortality in developing countries including India.[1] Among all cancers, oral cancer ranks among the top three types of cancer in the country. GLOBOCAN, a project of the International Agency for Research on Cancer (IARC) has projected that oral cancer crude incidence in India in both genders will increase by 2030.[2] Among all oral cancers, squamous Cell Carcinoma (OSCC) is the sixth most common cancer with over 300,000 new cases

arising annually. Regional differences in the prevalence of risk factors are the main reason for variation in incidence and pattern of oral cancer. The increased prevalence of the oral cancer in the Indian subcontinent is due to the usage of various tobacco products (smokeless or smoking), alcohol consumption, spicy food, high exposure to sunlight due to farming and neglect of overall oral health.[3]

In India, oral cancer has a significant public health importance. There are multiple reasons to this like-diagnosis at advanced stages resulting in high treatment cost, poor treatment outcomes; inadequate access to trained health care providers and limited health care services in rural areas; high exposure to risk factors such as the use of tobacco in any form. The overall survival (OS) rate for oral cancer is below 50% and has remained so for many decades in spite of immense research ongoing in the field of Oncology. This lays the foundation for the search of prognostically relevant factors in order to customize the individual management of oral squamous cell carcinoma (OSCC) patients.

Literature search reveals few comprehensive studies exploring clinico-demographic profile of OSCC patients as independent risk factor and correlation to survival in Oncology centers in Western Maharashtra, India. Hence this present hospital based retrospective cohort study was planned to report findings of OSCC cases from single tertiary cancer care center located in Western Maharashtra, India. The primary objective was to evaluate and analyze the association between clinico-demographic features and survival outcomes of selected OSCC cases.

METHODS

The present retrospective hospital-based cohort was carried out at Mahatma Gandhi Cancer Hospital, Miraj, Maharashtra, India. This hospital is a tertiary cancer care centre located in Sangli- Miraj- Kupwad Municipal Corporation area and is registered under section 5 of Bombay Nursing Homes Registration Act 1949. Necessary permissions were duly obtained from hospital authorities for collecting and analyzing patient's medical records from hospitals registry. Since the patient's data was to be collected from archival records of the hospital there was a waiver to informed written consent as per ICMR guidelines.[4] Institutional ethics committee (IEC) approval was obtained prior to beginning of the study. (ECR/885/Inst/MH/2017). A total of 1100 OSCC patients enrolled to the hospital's registry for management of OSCC with curative intent in the period from January 2011 to December 2016 were considered in this cohort study. Patients surgically treated for primary oral squamous cell carcinoma (conventional) followed by either/or radiotherapy and chemotherapy were included in this study. All histopathologic variants of OSCC, patients treated for secondary or recurrent oral squamous cell carcinoma, patients with non-malignant lesions or oral cancers other than OSCC and patients with metastatic lesions to oral cavity were excluded from study. Patient's demographic, clinical, histopathological diagnosis, type of treatment received and follow up record was collected from hospitals registry. In cases where follow up record was incomplete, telephonic conversation was carried out. The primary outcome measure was set as overall survival. Secondary outcome included disease specific and disease-free survival. Disease specific survival (DSS) was analyzed by plotting survival curves to display pattern of survival rates over time (5-year survival) for-age, gender, risk factors, site and clinical stage specific.

Statistical analysis

Statistical analysis was performed using STATA, software version 10.1, 2011 by Stata Corp. TX 77845, USA. Descriptive analysis was employed to summarize patient baseline characteristics. Continuous data was expressed by using mean±standard deviation and categorical data by using frequency counts and percentages. Student t test and chi-square test was used for categorical variables. Kaplan-Meier survival curves were plotted to estimate median survival time and proportion of survived subjects. The Cox proportional hazards regression model was used to assess the role of predictors (age-group, gender, habits, site, clinical stage, treatment modality). Significance level was set at $p<0.05$.

RESULTS

The basic characters evaluated for all 1100 OSCC patients are shown in Table 1.

Patients were grouped age wise in four age groups <40 years; 41-50 years; 51-60 years; >60 years. Maximum number of patients was noticed in age group of 51-60 years (28.82%). The mean age±SD was 51.13±12.04 years for males and 55.42±11.90 years for females. There was statistically significant difference in average period of survival in different age groups (p=0.0001) (Table 2). Kaplan Meier survival estimates exhibit the influence of age on overall survival experiences and confirm that older individuals have lower mean survival and higher mortality rate (Figure 1A). The mean overall survival in months for males was 36.17 and in females it was 24.63 (Figure 1B). The result of difference in survival between males and females (static) was statistically significant (p=0.0001) (Table 2).

Table 1: Patient record.

Variables	Number	Percentage
Age groups (years)		
<40	223	20.27
41-50	306	27.82
51-60	317	28.82
>60	254	23.09
Gender		
Male	890	80.91
Female	210	19.09
Residential status		
Rural	1035	94.10
Urban	65	5.90
Socio economic status		
Low	936	85.09
Medium	162	14.72
High	2	0.18
Habits		
Chewing tobacco	561 (M=558)	51
Chewing ghutka	296	26.91
Chewing tobacco+ either/or smoking /alcohol	14	1.27
Only mishri	174 (F=172)	15.82
Betel nut and\or betel quid chewing	5	0.45
None	50	4.55
Topographic distribution of lesions		
Buccal mucosa	395	35.91
Lateral tongue	227	20.64
Gingivobuccal sulcus	112	10.18
Lower alveolar ridge	113	10.27
Retromolartrigone	45	4.09
Upper alveolar ridge	61	5.55
Floor of mouth	31	2.82
Lower lip	23	2.09
Upper lip	3	0.27
Palate	20	1.82
Gingiva	2	0.18
Multiple sites	68	6.18
Clinical staging		
I	141	12.82
II	252	22.91
III	177	16.09
IV	530	48.18
Treatment modality		
only surgery	724	65.82
Surgery + RT	220	20.00
Surgery + CT	48	4.37
Surgery + RT + CT	108	9.81
Histologic grade of differentiation		
Well	988	89.82
Moderate	100	9.09
Poor	12	1.09
Patient status		
Alive	465	42.27
Dead	576	52.36
Lost to follow up	59	5.36
Recurrence	71	6.45

Table 2: Survival outcome and age groups, gender, habits, site and clinical staging.

Variables	Mean	SD	Median	Alive	Dead	Lost to follow up	Total		P value
Age group (years)									
<40	47.358744	30.510765	60	145	64	14	223	*F (3, 1096) =63.84	P=0.0001*
41-50	43.908497	29.587627	48	186	105	15	306		
51-60	29.334385	30.27608	12	105	193	19	317		
>60	15.998031	24.090512	6	29	214	11	254		
Total	33.963182	31.19118	17.51100	465	576	59	1100		
Gender									
Male	36.16685	31.44266	24	405	440	45	890	*t (1098) =4.8736	P=0.0001, S (p<0.05*)
Female	24.62381	28.32360	9	60	136	14	210		
Total	33.963182	31.19118	17.5	465	576	59	1100		
Habits									
1	33.904635	33.615556	13	206	325	30	561	*F (5, 1094) =8.47. Pearson $\chi^2(10)$ = 104.0747	P=0.0001, S, P value = 0.0001 (Significant)
2	40.972973	26.603414	45	185	101	10	296		
3	23.214286	33.094686	6	2	9	3	14		
4	23.16092	27.69419	8	46	119	9	174		
5	9	2.8284271	10	-	3	2	5		
6	36.22	28.864419	34.5	26	19	5	50		
Total	33.963182	31.19118		465	576	59	1100		
Site									
1-BM	34.05443	31.010481	No	169	199	27	35.91	*Pearson $\chi^2(22)$ = 40.1438	P = 0.010
2- lateral tongue	35.955947	34.214418	No	86	127	14	227		
3-GBS	35.419643	29.524654	No	57	52	3	112		
4-L ALV	27.929204	26.952245	No	43	66	4	113		
5-RMT	30.311111	26.746981	No	21	22	2	45		
6-U ALV	23.868852	26.399795	No	14	44	3	61		
7-FOM	28.129032	25.404385	No	13	17	1	31		
8-lower lip	41.608696	35.177135	No	11	10	2	23		
9-upper lip	48	34.597688	No	2	-	1	3		
10-palate	29.9	34.520627	No	7	11	2	20		
11-gingiva	69	57.982756	No	1	1	-	2		
12-multiple sites	45.5	32.885827	No	41	27	-	68		
Total				465	576	59	1100		
Clinical staging									
1				92	42	7	141	*Pearson $\chi^2(6)$ =149.3870	P value = 0.001 (Significant)
2				153	88	11	252		
3				87	73	17	177		
4				133	373	24	530		
Total				465	576	59	1100		

*Clinically significant

There was a statistically significant (p=0.0001) difference in average survival (month's) on comparison with usage of different forms of tobacco (Table 2, Figure 1C). Buccal mucosa (35.91%) was the commonest site of lesion and statistical significance (p=0.010) was noticed between survival outcomes and OSCC lesions located clinically at different sites (Table 2). There was significantly less mean survival (months) for OSCC lesions located at lower and upper alveolar ridges (27.929204, 23.868852), retromolartrigone (30.311111) and floor of mouth (28.129032) (Figure 1D). Maximum numbers of patients were in clinical stage IV and statistically significant difference was noted between survival outcomes and clinical staging (p=0.0001) (Table 2). Overall survival

rate in months was lowest in clinical stage IV (23.59434) followed by stage III (41.848315), stage II (43.839286) and stage I (45.414286) (Figure 1E). Patients were managed with different treatment modalities and only surgical management was the most preferred treatment followed by surgery + radiotherapy (RT), surgery+ (RT)+ chemotherapy (CT) and surgery + CT. The mean overall survival in month's ±SD for the entire cohort of patients (n=1100) was 33.96±31.19. Disease specific survival was 19.85±18.99 months and disease-free survival was 34.31±31.10 months. Mean survival time was reduced significantly by 14.5 months (±SD) in cancer patients who had recurrence (p=0.0001*). Cox proportional hazard model identified that Men (HR=1.87) and tobacco consumption habits (HR=1.22) had significantly higher (almost double) risk of mortality when adjusted for effect of other variables (95% CI was narrow and excludes unity). Type of treatment received (HR=0.82) was a protective factor for risk of hazards of cancer, those who received surgical treatment with RT + CT have significantly lesser risk of hazards when adjusted for effect of other variables.

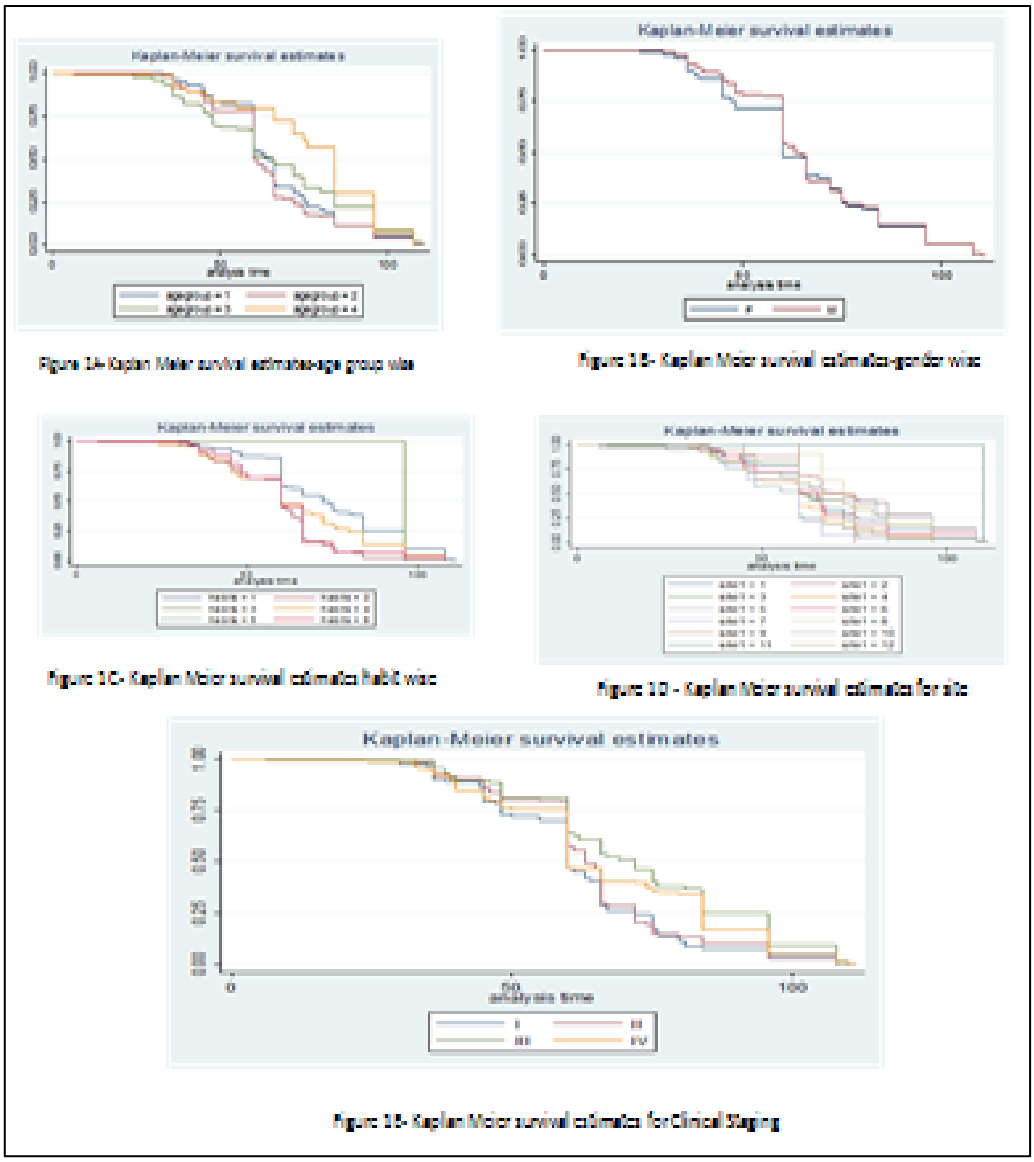

Figure 1: Kaplan Meir survival estimates for age groups, gender, habits, site and clinical staging: A) Kaplan Meir survival estimates for age groups; B) Kaplan Meir survival estimates for gender; C) Kaplan Meir survival estimates for habits; D) Kaplan Meir survival estimates for site; E) Kaplan Meir survival estimates for clinical staging.

DISCUSSION

Oral cancer is of immense public health importance to India. Western Maharashtra is one of the important hubs of tobacco manufacturing and informal surveys have revealed increasing number of` oral cancer cases. Very few comprehensive studies in oncology centers in western Maharashtra have explored the combined effect of socio-demographic profile and clinical features affecting survival in OSCC. We have presented a comprehensive retrospective analysis of socio-demographic profile, clinical features, treatment modality and survival

outcomes in 1100 patients from single tertiary cancer care center located in western Maharashtra.

Age is an important co-variable affecting prognosis and survival in OSCC. It is generally agreed that OSCC in older individuals have a more aggressive course and worse prognosis than in younger individuals and we also confirm this trend. Least survival experience was noticed in age group above 60 years and similar results are shared by other studies.[5-7] Our study showed a male preponderance and this is in agreement with various studies conducted over the years.[1, 7-10] We identified male gender (HR=1.87) as significant predictor of mortality on multivariate analysis. Low survival rate in men has also been implied by other studies.[5,7] Poor survivals in males is probably due to the prevailing risk factors and advanced stage at diagnosis. Major risk factors for oral cancer like tobacco, alcohol, and betel quid are very well established in the published literature. International Agency for Research on Cancer (IARC) has extensively evaluated various cohort and case-control studies and supported the evidence of etiology.[11,12] Our results are comparable with results of reported literature and show a strong association between consumption of smokeless tobacco and OSCC. [9,10] We have an interesting observation that, in this western Maharashtra region, chewing tobacco was more prevalent in males than smoking tobacco and that in rural areas among females, applying mishri (roasted tobacco; 82%) to teeth and gums was more prevalent. Multivariate analysis using Cox proportional hazard identified habits as significant predictor of mortality. Similar results are shared by Liao et al.[13]

The difference in occurrence of OSCC at different intraoral sites is largely due to variation in regional endemic practices of tobacco habits prevalent in different geographic locations. We noticed buccal mucosa (35.91%) to be the commonest site for the lesion followed by lateral tongue (20.64%) in both the genders. Similar results are shared in many studies.[14-17] Kaplan Meier survival estimates show that the probability for survival at 5 years was lowest for two sites namely retromolar trigone (23.81%) and floor of mouth. (24.04%) Similar results are shared in other studies.[6,7]

It is undoubtedly a known fact that advanced clinical staging is associated with poor prognosis and survival in OSCC. This may occur due to absence of early symptoms leading to late diagnosis, lack of awareness, poverty and fear of diagnosis. We observed lowest overall survival rate in months for clinical stage IV, followed by stage III, stage II and stage I. Similar results are shared by many authors.[5-7,18,19] The mean OS in month's ±SD for the entire cohort of 1100 patients in our study was 33.96±31.19. DSS was 19.85±18.99 months and DFS was 34.31±31.10 months. Comparable results are shared by many researches from various countries.[7,18,20] On the contrary, higher OS rates of over 60% have been reported by many researches.[6,19] There can be multiple reasons for improvement of survival over time like young age patients, better oral cancer awareness and health care facilities, rapid referral to oncology centers and prompt treatment, aggressive management of post operative complications, and adherence to uniform treatment protocols. Exclusive strength of our study is that we have analyzed a huge cohort of 1100 OSCC cases from western Maharashtra region with a long follow up period. This is a very useful addition to database of Cancer Registry and is of immense public health importance. We do reinforce the fact that awareness of early detection and diagnosis of OSCC, prompt and adequate health care facilities, affordable treatment options with implementation of Government schemes will definitely improve the overall survival associated with OSCC.

Since our study design was retrospective cohort type, it may have the limitations inherent to this type of study design. The robust statistical analysis carried out in our study helped to overcome this limitation and our results are not compromised. Our study was a hospital based and not population based, so sample may not be representative of all OSCC cases in Maharashtra. We advocate multi-centric prospective longitudinal studies of this kind so as to increase the database and acquire more knowledge of characteristics of OSCC.

CONCLUSION

The mean overall survival in month's ±SD for the entire cohort was 33.96±31.19. Older individuals (>60 years) had lower mean survival and higher mortality rate. Male gender, tobacco abuse are adverse factors and Surgery+RT+CT are protective factors for survival. It is the extreme need of hour to increase public awareness about the harmful effects of tobacco consumption and early detection of oral cancer.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee (ECR/885/Inst/MH/2017)

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Cite this article as: Joshi PS, Dive AM, Desai SS, Patil DB, Hormuzdi DM. Clinico-demographic profile and survival analysis of oral cancer patients: results from tertiary cancer care hospital in western Maharashtra, India. Int J Community Med Public Health 2025;12:3113-9.