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Research Article

Pretreatment serum albumin: a prognostic indicator of survival in oral cancer

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ABSTRACT

Background: Malnutrition has been recognized as a poor prognostic indicator for cancer. In recent years, the role of serum albumin as a predictor of survival in cancer has received considerable attention. Therefore, the present study was carried out to investigate whether the pretreatment serum albumin can predict the prognosis of patients with oral cancer.
Methods: Medical records of 433 pathologically proven oral cancer patients diagnosed and treated from 01st January 2006 to 31st December 2008 were retrospectively analyzed. We used Receiver operating characteristic curve analysis to establish most appropriate cut-off for serum albumin, Kaplan-Meier method for survival analysis and the Cox proportional hazard models to investigate the prognosticators.
Results: The overall 5 year's survival of the cohort was found to be 54.4%. On univariate analysis, serum albumin of ≤4.34 g/dl was associated with poor overall survival (OS) (p=0.029). Multivariate Cox proportional hazard analysis revealed that lower serum albumin (<4.35g/dl) was a significant independent predictors for worse OS (HR=1.350, 95% CI = 1.013 - 1.817; P< 0.038). Lymph nodal involvement was also found to be independent indicator for poor OS. Furthermore, serum albumin was found to be positively correlated with both body weight (r=0.142, p=0.003) and heamoglobin (r=0.304, p=0.000).
Conclusion: Pretreatment serum albumin levels are of useful prognostic significance in oral cancer patients. Thus, this easily accessible variable may not only serve as a potent marker to predict the outcomes, but more importantly as an indicator for initiating aggressive nutrition intervention in oral cancer patients.

Key words: Serum albumin, Oral cancer, Survival, Nutrition

INTRODUCTION

In India, because of cultural, ethnic, geographic factors and the popularity of addictive habits, oral cancer is a significant public health problem. Although globally oral cancer is eleventh leading site of cancer, in India, it ranks number one in terms of incidence among men and third among women.[1]

Annually 80,000 cases are diagnosed and 50,000 deaths occur due to oral cavity cancer in India. A vast majority (>70%) of more than one billion population of India lives in rural areas, which have inadequate access to trained providers and limited health services. As a result, most of the cases are diagnosed at later stages which result in low treatment outcomes and poor 5-year survival rate of approximately 37% (26-45).[2] Various clinical, biochemical, and histological prognostic factors have been identified in the literature, some generic to all cancers and some specific for oral cavity cancer.

Some of the key factors determining oral cancer survival are age, stage, grade, degree of lymph node involvement and tumor histological characteristics.[3-7] In addition, nutritional status has been hypothesized to be of prognostic value in patients with oral cancer.[8]

Malnutrition in cancer patients is a significant problem due to a variety of mechanisms involving the tumor, the host response to the tumor, and anticancer therapies.[9,10]

Malnutrition has been associated with a number of clinical consequences, including deteriorated quality of life, decreased response to treatment, increased risk of chemotherapy-induced toxicity and a reduction in cancer survival.[11,12]

There are various methods of assessing nutritional status in cancer, the most commonly used tools are subjective global assessment (SGA), bioelectrical impedance analysis (BIA), and laboratory measurements of serum albumin, pre-albumin and transferrin.[13-18] Others include anthropometric parameters such as weight loss, arm muscle circumference and skin-fold thickness.[19-21]

Serum albumin is generally used to assess the nutritional status, severity of disease, disease progression and prognosis. In cancer it has been described as an independent prognosticator of survival in lung cancer, pancreatic cancer, gastric cancer, colorectal cancer and breast cancer.[22-28]

With respect to head and neck neoplasm nutritional status has been documented to be a prognostic factor. However, the studies were not limited to primary oral cancer and focused on pre-operative weight and calculation of nutritional status score.[29-31] Therefore, the present study was carried out to investigate whether pretreatment serum albumin levels could be simple predictors for the survival of patients with oral cancer.

METHODS

This was a retrospective hospital records based study. Medical records of 662 pathologically proven oral cavity cancer patients, who were residents of Mumbai, diagnosed and treated surgically at Tata Memorial Hospital from 01st January 2006 to 31st December 2008 were analyzed.

Those who had no pathologic report, did not have record of pretreatment weight or had inadequate chart records were excluded. After these exclusions, 433 patients fulfilled the requirements and were included for further analyses.

The patient information recorded for this study was age at presentation, sex, lifestyle habits (tobacco and alcohol use), pretreatment weight, pretreatment serum albumin level, pretreatment hemoglobin level, tumor location, tumor staging and types of treatment received.

Disease in all patients was staged according to the sixth edition of the UICC/AJCC TNM classification system.[32,33] The study had the approval of the Research Ethics Committee of the hospital.

Data analysis and statistical methods

Patient survival was defined as the time interval between date of diagnosis and date of death or date of last contact/last known to be alive. The Kaplan-Meier or product-limit method was used to calculate survival. The log-rank test statistic was used to evaluate the equality of survival distributions across different strata.

Receiver operating characteristic (ROC) curve analysis to select the most appropriate cut-off points for serum albumin was performed to stratify patients at a high risk of malignancy-related death. The score at the point with both maximum sensitivity and specificity was selected as the best cut-off value. The Cox proportional hazards model was applied for univariate and multivariate (backward method) analysis to identify prognostic factors. Statistical analyses were performed using SPSS software v17.0 (SPSS, Chicago, IL). Statistical significance was considered at $p < 0.05$.

RESULTS

The patient's characteristics are summarized in Table 1. As shown, the median age was 50 years (range: 24-85 years), and the percentage of males and females were 70.2% and 29.8% respectively. Out of the 433, patients 303 (69.97%) were diagnosed at late stages (III and IV), and the other 130 patients (30.03%) were at early stages (I and II).

At the time of this analysis (March 2015), 190 patients had expired, and 243 were censored. The median follow-up period was 40 months (range, 1 to 103 months). The 5-year Overall survival of the cohort was 54.4% and stage-wise survival rate for TNM stage I, II,III and IV patients was found to be 79.7%, 66.4%, 52.4% and 43.1% ($p< 0.00$) respectively (Figure 1).

The cut-off value of serum albumin for survival outcome was determined by ROC curve analyses. A cut-off point of 4.35 was selected for the survival analyses and all patients were divided into either high (≥4.35 g/dl) or low (≤4.34 g/dl) serum albumin groups.

Univariate and multivariate analysis of serum albumin as prognostic factor for overall survival

Analyzed factors included age, gender, overall stage, lymph node involvement, treatment modality and serum albumin. Univariate analysis revealed that lower serum albumin (≤4.34g/dL; p=0.029), advanced disease (TNM stage, III+IV; p= 0.000) and lymph nodal involvement (p= 0.000) were associated with poorer prognosis. Other factors such as age, gender and treatment received were not found to be significantly associated with survival of oral cavity cancer patients. Furthermore, factors influencing the survival were examined by the multivariate Cox proportional hazard model using the backward regression method. The analysis showed that

lower serum albumin level (≤4.34g/dL) (HR=1.350, 95% CI=1.013-1.817; P<0.038) and lymph node involvement (HR=2.311, 95% CI=1.700-3.142; p<0.000) were found to be independent predictors for poor overall survival of oral cavity cancer patients (Table 2).

Table 1: Patients' characteristics.

Parameter	Number of patients	Percentage (%)
Age		
median	50 Years	
Range	24-85 Years	
Sex		
Male	304	70.2
Female	129	29.8
T Classification		
T1	61	14.1
T2	139	32.1
T3	43	9.9
T4	190	43.9
N Classification		
N0	200	46.2
N+	233	53.8
Tumor Stage, AJCC		
I	43	9.9
II	87	20.1
III	79	18.2
IV	224	51.7
Tumor Sites		
Lip	15	3.4
Tongue	128	29.6
Gum	68	15.7
Floor of mouth	9	2.0
Hard Palate	7	1.6
Cheek Mucosa	153	35.3
Vestibule of mouth	46	10.6
Retromolar Trigone	7	1.6
Treatment modalities		
Surgery alone	148	34.2
Surgery + radiotherapy	187	43.2
Surgery + chemotherapy	04	0.9
Surgery + chemoradiotherapy	94	21.7

Table 2: Univariate and multivariate analysis of prognostic factors for overall survival in patients with oral cavity

	Univariate		Multivariate	
Parameter	HR (95% CI)	p value	HR (95% CI)	p value
Age, >65 y	1.148 (0.754 - 1.748)	0.521		
Sex, (male)	1.129 (0.819 - 1.556)	0.458		
TNM stage (III+IV)	2.205 (1.539 – 3.159)	0.000	1.370 (0.813- 2.130)	0.237
Lymph node mets	2.277 (1.678 - 3.089)	0.000	2.311 (1.700 - 3.142)	0.000**
Serum Albumin <4.35 g/dl	1.388 (1.031 - 1.868)	0.031	1.350 (1.013 – 1.817)	0.038**
Treatment (single/ multi-modality)	0.990 (0.729 – 1.344)	0.947		

**Significant (p<0.05), Abbreviations: HR-hazard ratio; CI-confidence interval

Survival rates and categorization of patient characteristics according to high/ low serum albumin

The 5 years survival rate of patients with low serum albumin (≤4.34g/dL) was found to be 48.9% which was significantly (p<0.029) lower to survival rate of 59.2% for patients with higher serum albumin (Figure 2). Patient characteristics including pretreatment weight and hemoglobin were categorized as per high / low serum albumin levels (Table 3).

Table 3: Baseline clinical characteristics of the oral cavity carcinoma patients according to high/ low serum albumin.

Characteristic	Serum Albumin ≤4.34 (n=249)	Serum Albumin ≥4.35 (n=182)	p Value
Mean age (years)	50.50±11.78	51.84±12.48	0.245
Body weight, Kg	53.39±13.58	60.06±13.59	**0.006****
Hemoglobin, g/dL	12.43±1.95	13.61±1.91	**0.000****
Tobacco, no. (%)			
Non-user	76 (30.5)	43 (23.6)	0.114
users	173 (69.5)	139 (76.4)	
Alcohol, no. (%)			
Non-drinker	208 (83.5)	144 (79.1)	0.242
Drinker	41 (16.5)	38 (20.9)	
T-classification			
T1–T2	109 (43.8)	89 (48.9)	0.292
T3–T4	140 (56.2)	93 (51.1)	
N-classification			
N0	111 (44.6)	88 (48.4)	0.438
N+	138 (55.4)	94 (51.6)	
Overall stage			
I–II	67(26.9)	62 (34.1)	0.109
III–IV	182 (73.1)	120 (65.9)	
Treatment			
Uni-modality	89 (35.7)	57 (31.3)	0.338
Dual/ Multi-modality	160 (64.3)	125 (68.7)	

**** Significant (p<0.05), Abbreviations: Data are means±SD.

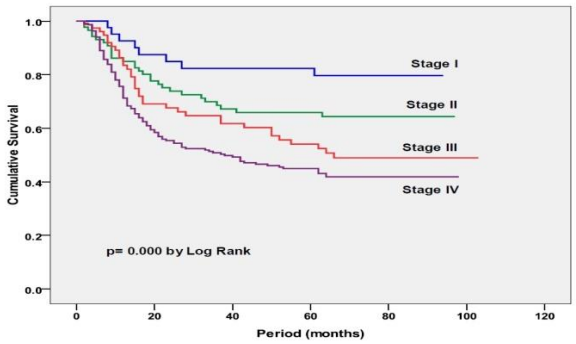

Figure 1: Kaplan-Meier curves for survival outcomes in all patients stage-wise.

The mean weight and hemoglobin of patients with higher serum albumin (≥4.35g/dL) was found to be significantly more than patients with lower serum albumin (p=0.006 and p=0.000 respectively). Lifestyle factors such as tobacco and alcohol consumption was not found to be associated with serum albumin (p>0.05). Furthermore, serum albumin also found to be positively correlated with both body weight (r=0.142, p=0.003) and hemoglobin (r=0.304, p=0.000).

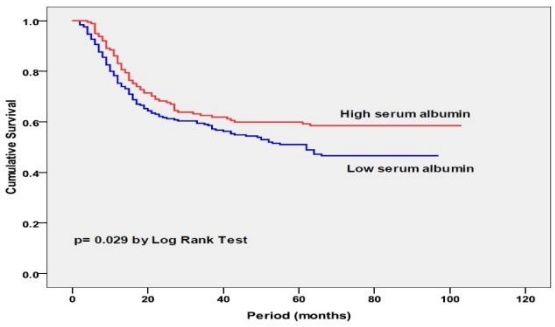

Figure 2: Kaplan–Meier survival curves of cumulative survival rates in patients with oral cavity cancer classified into 2 groups according to serum albumin.

DISCUSSION

The identification of factors influencing survival in oral cancer is of considerable importance for clinical management of the disease. Although nutritional status has been hypothesized to have an association with survival, the published literature documenting its prognostic significance in oral cancer remains sparse. Despite the number of nutrition assessment tools used for research purposes, a consensus has not been reached on what may be an ideal tool for nutritional assessment in cancer. The current study was undertaken to investigate if pretreatment serum albumin, a potential indicator of nutritional status, could predict survival in oral cancer.

In the present study, we found that serum albumin was an independent prognostic factor for patients with oral cavity cancer. Patients with serum albumin levels of ≥4.35g/dL had a statistically significantly better survival than those with levels of ≤4.34g/dL independent of age, sex and stage of disease.

Brooks GB et al, first reported the role of serum albumin as a part of nutritional status in prognostication of head and neck cancers.[31] Liu S et al also demonstrated that pretreatment serum albumin levels are independent indicator of prognosis for patients with oral cavity cancer.[34]

A prospective cohort study of 170 patients with advanced cancer, where lung (34%), liver (14%), and lower gastrointestinal tract (14%) malignancies accounted for almost two thirds of the primary cancers, enrolled into the palliative care unit of a regional hospital in Hong Kong demonstrated that serum albumin is an independent predictor of survival.[35]

Furthermore, these findings have also been reproduced in carcinoma of lung cancer, pancreatic cancer, gastric cancer, colorectal cancer and breast cancer with increasing evidence that serum albumin can be a prognostic factor in cancer.[22-29]

The mechanisms explaining the independent association between cancer prognosis and serum albumin lies in the fact that malnutrition and inflammation suppress albumin synthesis.[36] As part of the systemic inflammatory response to the tumor, proinflammatory cytokines and growth factors are released and have a profound catabolic effect on host metabolism.[37] Interleukin-6, produced by the tumor or surrounding cells, stimulates liver production of acute-phase reaction proteins (such as CRP and fibrinogen) in both the fasted and fed states.[37]

This increases the demand for certain amino acids, which if limited in the diet, may be obtained from breakdown of skeletal muscle.[38] The lower serum albumin concentration may be due to the production of cytokines such as IL-6, which modulate the production of albumin by hepatocytes.[39,40]

Alternatively, tumor necrosis factor may increase the permeability of the microvasculature, thus allowing an increased trans-capillary passage of albumin.[41] In addition, presence of micrometastatic tumor cells in liver may induce the kuppfer cells to produce a variety of cytokines (IL-Ib, IL-6, TNF), may modulate albumin synthesis by hepatocytes.[39,42] Thus, as disease progresses due to presence of chronic systemic inflammatory response, albumin levels drop significantly and serve as good indicators of prognosis of cancer.[9,43,44]

In the present study, we also demonstrated that patients with higher serum albumin (≥4.35g/ dl) had higher mean bodyweight and hemoglobin as compared to patients with lower serum albumin (≤4.34g/dl). In addition, serum albumin was also found to have significant positive correlation with both these parameters ($p<0.05$). Previous studies have suggested similar significant positive correlation of serum albumin with body weight and hemoglobin levels.[45-47]

The interrelationship between albumin, body mass, hemoglobin and the inflammatory response is consistent with the concept that the presence of an ongoing inflammatory response contributes to the progressive loss of these vital protein components of the body and the subsequent death of patients with advanced cancer.[47] Furthermore, our results also confirmed the previous finding that presence of nodal involvement is associated with poor prognosis for oral cavity cancer patients.[48,49]

There were several limitations of our study which need to be acknowledged. The study was conducted at a single institution, was of retrospective nature and relies on data not primarily meant for research. Hence, instead of body mass index (BMI) serum albumin was correlated to weight as for majority of cases height was not available for calculation of BMI. Furthermore, this study did not evaluate the effectiveness of nutritional intervention on survival as it was difficult to gather this information accurately from the patient's medical record. Finally, serum albumin levels also depends on many other medical conditions such as dehydration, marasmus, ascites, hepatic failure, metabolic stress, burns, trauma etc. these conditions should be ruled out when assessing the serum albumin levels. These drawbacks emphasize the need for conducting multicenter prospective studies to completely understand the role of serum albumin in oral cancer survival.

CONCLUSION

In conclusion, present study has demonstrated the prognostic significance of serum albumin in oral cancer. The potential advantage of pretreatment serum albumin level as a pretreatment prognostic factor in cancer patients is that it is inexpensive and reproducible. Thus, it can be used as an independent indicator of the need for aggressive nutritional intervention, which would perhaps lead to improvement in outcome of oral cancer patients.

However, the critical question whether raising albumin levels by means of intravenous infusion or by hyper alimentation decreases the excess risk of mortality in oral cancer, needs to answered by prospective studies/ Clinical trials.

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