Prevalence of Functional Problems after Treatment of Oral Cavity Malignancy: A Single Tertiary Care Centre Study

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ABSTRACT
Background: Oral cancer is major public health problem in the Indian subcontinent, where it ranks among the top three types of cancer in the country. Prevalence of functional problems in terms of eating in public, understandability of speech & normalcy of diet in oral cavity cancer patients following the completion of index treatment using Performance Status Scale for Head & Neck cancers has not been well studied in Indian patients. This study was conducted to assess the prevalence of functional deficits in Indian patients as defined in the prevalidated Performance Status Scale for Head and Neck PSS-HN questionnaire.
Methodology: This was a prospective observational study conducted in a tertiary care teaching hospital on patients diagnosed as a case of Oral Cavity malignancy and underwent surgery at this centre. The patients were administered the PSS-HN questionnaire in their follow up visit after discharge from the hospital following successful completion of surgical procedure by the study physician.
Results: 110 patients with Head and neck carcinoma undergoing surgery were enrolled. The best preserved function of PSS-HN scale was speech understandability where only 30.9% or 34 respondents were reported to have significant morbidity (score of <50). Public eating was next best with significant morbidity in 41.8% participants followed by worst affected - normalcy of diet at 46.4%.
Conclusion: The worst affected function was normalcy of diet. The general trend was towards taking soupy or liquid diet in higher stages of carcinoma post treatment as these patients were the most debilitated. The morbidity was even higher in patients treated with RT. The most severely affected patients had major surgeries of either tongue or extensive mandibulectomy. There remains an acute need to further study these morbidities in post-surgical management in Indian population with head and neck cancers. It would definitely be prudent to further study them over a longer period of time which was not possible in our study, which was limited by time duration.
Keywords: Enteral feeding, speech understandability, public eating.

INTRODUCTION
Cancer is emerging as a major illness in India with the number of people suffering from the disease is estimated to be around 2.5 million; over 0.8 million new cases and 0.55 million deaths occurring each year.[1] According to the International Agency for Research on cancer (IARC), a group chartered by the World Health Organization to conduct research and develop scientific strategies for cancer prevention and control; cancers of the oral cavity, lungs,

oesophagus, stomach, cervix, and breast are some of the most commonly occurring forms in both male and female population of India. Oral cancer is major public health problem in the Indian subcontinent, where it ranks among the top three types of cancer in the country.[2] The difference in incidence and pattern of oral cancer can be due to an overall effect of ageing of population as well as some regional differences in the prevalence of specific risk factor.[3] The low-income groups in India are affected most due to a wide exposure to risk factors such as tobacco chewing and insufficient exposure to newly diagnostic aids, resulting in a delay in reporting of oral cancer.[4] Surgery is the most well-established mode of initial definitive treatment for a majority of oral cancers, with a longstanding history of being the accepted method of treatment for well over a century. In patients with advanced cancer, radiotherapy is employed in conjunction with surgery, most often offered as post-operative treatment.

The follow-up of patients operated on for oral and oropharyngeal cancer includes the evaluation of recurrent, persistent, and new primary cancers and the provision of psychological and social support to patients and family members. In addition, patients need to be monitored for the development of non-neoplastic morbidity related to treatment.[5] Few studies [2-4] are based on functional outcomes as secondary end points in oral cancer treatment. Speech and swallowing are frequently rated as important by patients after primary surgery for oral and oropharyngeal cancer.[6] Although swallowing and speech are included in several scales of health-related quality of life in oral and oropharyngeal cancer[7], few studies[6] have explored the predictive factors that influence these domains.

Though there is literature on quality of life (QOL); magnitude of functional deficits or morbidities faced by survivors after treatment has not been addressed adequately in the literature. In Indian scenario where oral cancer is a common health problem with reasonable survival after treatment, it becomes extremely important to assess these morbidities for optimal utilization of resources. Study by Gliklich et al,[8] highlighted the importance of site-specific quality of life measures and these should include domains that reflect eating/swallowing, speech/communication, and physical appearance. Studies have demonstrated that overall QOL improved towards pre-treatment baseline by 12 months on an average after curative treatment.[9] However, the head and neck cancer specific problems remain important throughout and these functional problems should remain a higher priority. To assess the unique domains of dysfunction experienced by head and neck cancer patient population, List et al.[10] designed and validated Performance Status Scale for Head and Neck (PSS HN). It is a clinician-rated instrument that provides detailed information on the type of diet taken and where and how people choose to eat. The measure has been shown to have good inter-rater reliability as well as sensitivity to changes in performance over time. As well as recording oral intake, a record is kept of enteral feeding status. The PSS HN has been found to discriminate the levels of functioning across the broad spectrum of head and neck cancers particularly for oral cancers, and has demonstrated good reliability as well as sensitivity to differences in performance and change over time.[11] Apart from a single study which evaluated the PSS HN scale after concomitant chemoradiation in head and neck cancer, no work performed in Indian population where oral cancer predominates could be found. Hence the present study was done at our tertiary care centre to assess the extent of functional problems in oral cavity cancer patients following the completion of index treatment and functional deficits in terms of eating in public, understandability of speech & normalcy of diet following treatment using Performance Status Scale for Head & Neck cancers.

MATERIAL & METHODS

This cross-section observational study was conducted in the department of Surgery in a tertiary care teaching hospital for a period of two years from Sept 2019 till Sept 2021. All

patients diagnosed as a case of Oral Cavity malignancy who underwent surgery in this centre during this period were recruited in the study after written informed consent. Permission for the study was granted from the Institutional Ethics Committee. Patients who have unresectable disease, with distant metastasis, requiring NACT/Radiotherapy, non-compliant and non-consenting patients were excluded.

Socio-demographic factors such as age, gender etc. were noted. All the baseline data about patients was collected prior to the start of treatment including socio-demographic characteristics and tumour stage. The patients were administered the PSS-HN questionnaire in their follow up visit after discharge from the hospital following successful completion of surgical procedure by the study physician. The PSS-HN questionnaire was administered in a structured interview format where three domains were inquired into viz., normalcy of diet; score of public eating and understandability of speech. Score < 50% were considered to indicate significant morbidity.

The criteria of normalcy of diet were inquired about first. Foods that were difficult to eat were asked about. In case patient indicated he/she ate everything then soft chewable food i.e., 50 upwards were inquired and the final score was assigned just below the level where patient indicated in negative.

To prevent undefined scores for public eating, only discharged patients on follow-up visits were interviewed. The description best suited to the patient was taken as the score. Any patient even on restricted diet choosing to join others in public eatery was rated 75.

Understandability of speech was decided by the interviewer based on his ability to understand the speech of the patient while looking away from the patient.

Table 1: Performance Status Scale for Head and Neck Cancer Patients: PSS-HN

Normalcy OF Diet	Public Eating	Understandability of Speech
100 Full diet (no restrictions)	100 No restriction of place, food or companion (eats out at any opportunity)	100 Always understandable
90 Full diet (liquid assist)	75 No restriction of place, but restricts diet when in public (eats anywhere, but may limit intake to less "messy" foods (e.g., liquids)	75 Understandable most of the time; occasional repetition necessary
80 All meats	50 Eats only in presence of selected persons in selected places	50 Usually understandable; face-to-face contact necessary
70 Raw carrots, salads	25 Eats only at home in presence of selected persons	25 Difficult to understand
60 Dry bread and crackers	0 Always eats alone	0 Never understandable; may use written communication
50 Soft chewable foods	999 In-patient	
40 Soft foods requiring no chewing(e.g., mashed potatoes, apple sauce, pudding)		
30 Pureed foods(in blender)		
20 Warm liquids		

10 Cold liquids		
0 Non-oral feeding(tubefed)		

For maximum sample size, a level of confidence 95% with absolute error of margin 5% was taken.The required sample came out as 06 patients for each group with a minimum total sample size required as 12. However, to increase the strength of the study, sample size of atleast 25 was planned under each group.

Accepting redundancies, a total sample size of 60 patients were taken for this study. The two-sample t-test (Student's t) was used for analysing the quantitative variables with normal distribution. The Chi (χ^2) square test was used where distribution was skewed and for categorical variables. In comparisons using Student's t test, 80% confidence intervals for the mean difference in response provided a range of likely values to assess clinical significance and for all tests of significance, p-values <0.05 were considered statistically significant.

RESULTS

A total of 110 patients were included out of 126 patients evaluated for the study (9 patients fulfilled exclusion criteria, 3 refused consent and 4 did not complete the study). The majority of the patients in the group of participants were males. The M:F ratios were thus skewed towards male gender with values of 5.47. The distribution of the patients according to the age in decades showed no statistical difference. The maximum representation in both the genders was in the age of 60 to 69 years with almost 24.5% participants. The type of carcinoma, stage, site and surgeries used for management are detailed below in table 1.

Table 1: Demographic profile and morphology of carcinoma

Variables	Female (N=17)	Male (N=93)	p-value
Age distribution			0.52
20-40	1	27	
41-60	8	36	
60-80	8	30	
Type of Ca			0.17
SCC	16	92	
ACC	01	01	
Stage	F	M	0.93
I	6	30	
II	4	26	
III	6	34	
IV	1	3	
Subsite			0.16
Buccal Mucosa	3	26	
FOM	4	5	
Lower Alveolus	1	21	
Lower Lip	1	3	
Oral Tongue	5	28	

RMT	3	10	
Surgery	**(N = 110)**	**%**	-
Buccal mucosa composite resection	35	31.8	
Buccal mucosa marginal mandibulectomy/ upper alveolectomy	17	15.4	
Buccal mucosa and lip wide excision	25	22.7	
Tongue wide excision/ hemi glossectomy	18	16.4	
Total glossectomy	15	13.6	

The maximum representation was from stage I in oral tongue and buccal mucosa followed by stage II Ca in oral tongue and Stage III Ca in buccal mucosa.

The management done for the enrolled patients is detailed in table 2.

Table 2: Management of patients depending upon the Stage of Cancer and Subsite

Variables	Values	I	II	III	IV	p-value
1. Subsite	Buccal Mucosa	11	8	10	0	0.96
	FOM	3	3	2	1	
	Lower Alveolus	5	4	9	1	
	Lower Lip	1	1	1	0	
	Oral Tongue	12	10	9	2	
	RMT	3	3	7	0	
	Upper Alveolus	1	1	2	0	
2.Reconstruction used	Free Flap	4	4	12	1	
	Local Flap	8	7	1	1	
	Pedicled Flap	10	6	24	2	
	Primary Closure	14	13	3	0	
3. Adjuvant therapy	Chemo-radiation	4	8	21	4	
	Radiation	32	22	19	0	

The best preserved function of PSS-HN scale was speech understandability where only 30.9% or 34 respondents were reported to have significant morbidity (<50). Public eating was next best with significant morbidity in 41.8% participants followed by worst affected - normalcy of diet at 46.4%.

Table 3: Functional Deficit vs tumour stage

Functional deficit PSS-HN scale	Public eating		Speech understandability		Normalcy of diet	
	≤50	>50	≤50	>50	≤50	>50
I	8	28	4	32	9	27
II	7	23	4	26	11	19

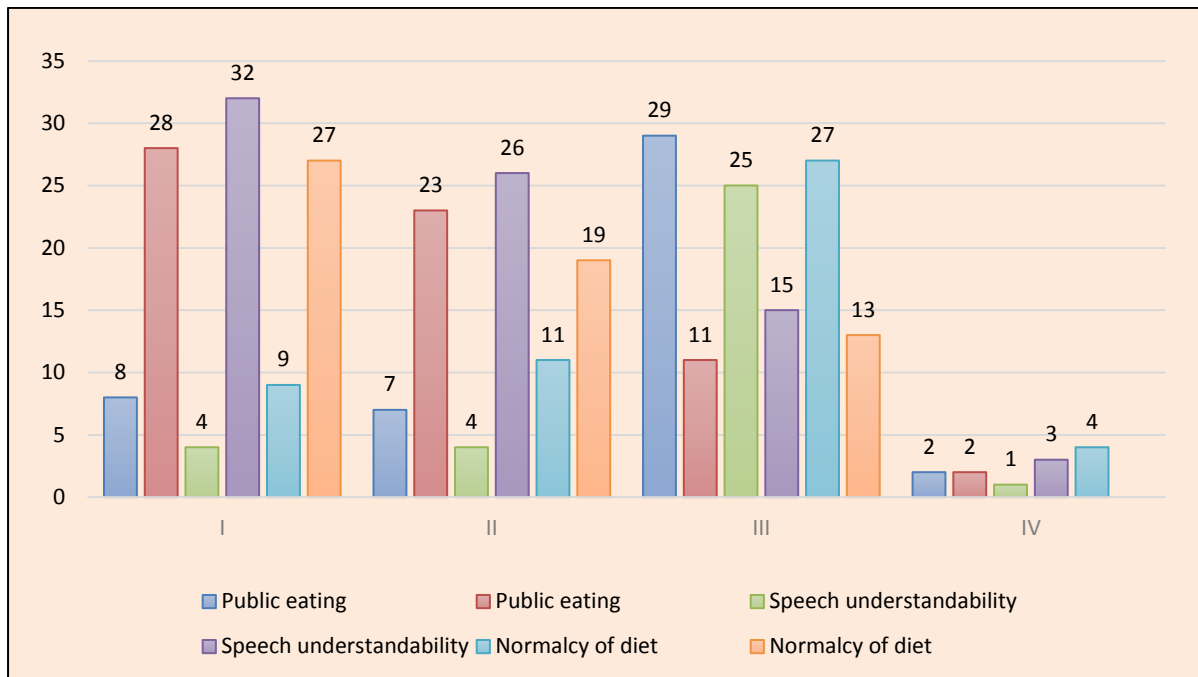| III | 29 | 11 | 25 | 15 | 27 | 13 |
| IV | 2 | 2 | 1 | 3 | 4 | 0 |
| Total (%) N=110 | 46 (41.8) | 64 (58.2) | 34 (30.9) | 76 (69.1) | 51 (46.4) | 59 (53.6) |

Figure 1: Functional Deficit vs tumour stage

DISCUSSION

Oral carcinoma has significant burden in India due to the habit of tobacco consumption both in smoked and well as chewable forms. It is one of the leading causes of cancer related mortality especially in males. The prevalence of oral carcinoma in Indian scenario is complicated by the fact that it usually presents in lower strata of the society, hence presents in advanced stages with extensive lesions resulting in poor treatment outcomes. The result being morbidity patterns is typically worse than other countries, necessitating a focus on validating scales of morbidity and implementation of their use in treatment of these patients.

The treatment comprises of disfiguring extensive surgeries especially if carcinoma is well advanced in concurrence with radio and chemotherapy which in turn leads to significant morbidities. Whereas the surgeons earlier were usually only concerned with survival of patients, there was a felt need to look into the morbidity due to these surgeries and reconstruction methods used. Many Quality of Life (QOL) indicators are being evaluated and validated now for oral cancer patients including health related quality of life questionnaires (HRQOL) and PSS-HN scale with the central aim being identification of surgeries preserving more significant functions, reducing morbidity due to treatment and in general improving the lives of these patients.

The surgical treatment of these lesions involve usually wide resection with or without extensive neck dissection along with adjuvant therapies either radiation alone or combined chemo-radiation. The morbidities due to the procedures continued to evolve and increase over a period of time as brought out by study by de Graeff et al.[12] in Dutch patients using European Organization for Research and Treatment of Cancer (EORTC) Core Questionnaire,

along with EORTC Head and Neck Cancer Module, and the Center for Epidemiological Studies Depression Scale before treatment, and till 3 years. They found worse morbidity pattern and depression just after the treatment which improved in further follow-ups. Similarly, study by Bjordal et al.[13] in Norwegian and Swedish patients used the above questionnaires and reported that health-related quality of life (HRQL) of these patients significantly deteriorated following surgery and only gradually recovered after a period of one year. Since these HRQL are usually not studied during and after treatment in our patient population, our study was done to address these concerns in the immediate aftermath of debilitating oncological treatment.

The present study had 110 participants who had been operated upon in our hospital and had been recently discharged. This was comparable to the earlier study by Yadav et al.[14] (reporting on PSS-HN) and Borggreven et al.[15] (reporting on EORTC QLQ-C30/QLQ-H&N35) who evaluated a similar number of hundred and eighty participants respectively in their studies. Similarly, Dziegielewski et al.[16] also reported on a comparable number of eighty-one patients but his study was done in patients after trans-oral Robotic Surgery (TORS). In contrast, Scott et al.[17] reported on patients undergoing TORS only in forty-four patients employing EORTC QLQ-C30/QLQ-H&N35 questionnaires for HRQOL.

The studies by Borggreven et al.[15], Dziegielewski et al.[16] and Scott et al.[17] employing EORTC QLQ-C30/QLQ-H&N35 questionnaires for HRQOL reported the salient findings of worsening morbidity patterns in immediate post-operative period with long term follow-ups indicating improvement in scores. Dziegielewski et al.[16] reported overall decline in eating, speech, social and aesthetic functions post-surgery which improved after a period of one year. Borggreven et al.[15] reported that tumour site, stage and comorbidities especially affected the functional outcomes. Scott et al.[17] compared patients undergoing TORS with those treated with radiotherapy (RT) and found that RT group faired worse on all counts of functional outcomes studied i.e., swallowing function, dysphagia and shoulder impairment post neck dissection surgery. A systematic review by Hutcheson et al.[19] comparing studies done on patients undergoing TORS and adjuvant therapies reported primarily on swallowing dysfunction and dysphagia and concluded that TORS had significantly better functional outcomes. The best predictors for swallowing outcomes were tumour at base of tongue, stage, baseline characteristics and adjuvant chemoradiation.

Our study was directly comparable to that by Yadav et al.[14] as both compared functional outcomes as per PSS-HN scale. The worst affected function was normalcy of diet which was subpar in 46.4% of our patients. The deficit was only recorded in 38% in the study by Yadav et al. The general trend was towards taking soupy or liquid diet in higher stages of carcinoma post treatment as these patients were the most debilitated. The morbidity was even higher in patients treated with RT which was comparable to the review by Hutcheson et al.[18] The severely affected patients had major surgeries of either tongue or extensive mandibulectomy. The increased morbidity in higher stages was in contrast to that by Yadav et al.[14] which reported no effect of stage as the study involved only well-functioning stage III and IV patients. It was comparable to another study by Campbell et al.[19] which reported on University of Washington, PSS HN, the FACT-G (functional assessment of cancer therapy general) scale and FACT-HN scales in patients with head and neck cancers. This study also reported that advanced stages of cancer had lower scores but conversely found that patients treated with RT alone fared much better than those treated with multimodality treatment. However, those requiring multi-modality treatments tend to have higher stages and extensive cancers than those who do not.

 The other score of public eating was also comparatively poorer in our study at 41.8% as compared to that reported by Yadav et al.[14] at 28%. This was partly explainable by the fact that we studied our patients in the immediate aftermath of their discharge from the hospital

which did tend to increase our morbidity scores. Similar to the normalcy of diet, this parameter was also affected largely by the stage of the disease as well as the subsite and type of reconstruction and surgery used.

As compared to the other parameters, understandability of speech was much better in our study at 30.9%. However, when compared to the figure reported by Yadav et al.[14] it was almost reaching to double the morbidity. The authors feel that this figure is likely due to the short interval between operative management and the survey and it is likely to be lesser in subsequent period of time. There remains an acute need to further study these morbidities post-surgical management in Indian population with head and neck cancers. It would definitely be then prudent to further study them over a longer period of time which was not possible in our study, which was limited by time duration. The authors hence recommend further studies in the subject population to evaluate and suggest remedial actions needed during treatment of these patients.

CONCLUSION

The best-preserved function of PSS-HN scale was speech understandability where only 30.9% or 34 respondents were reported to have significant morbidity (<50). Public eating was next best with significant morbidity in 41.8% participants followed by worst affected - normalcy of diet at 46.4%.

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