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Research Article

AN EVALUATION OF QUALITY OF LIFE IN PATIENTS ON CONCURRENT CHEMO RADIOTHERAPY WITH CISPLATIN IN HEAD AND NECK CANCER- A PROSPECTIVE OBSERVATIONAL STUDY

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A B S T R A C T

Head and neck cancers usually begin in the squamous cells that line the moist, mucosal surfaces in the head and neck (for example, inside the mouth, the nose, and the throat). These squamous cell cancers are often referred to as squamous cell carcinomas of the head and neck.
The aim of the study is to evaluate quality of life in patients on concurrent chemo radiotherapy with cisplatin in head and neck cancer.
The objective of the study is to measure the quality of life and pharmaceutical care and toxicity profile of cisplatin with radiotherapy in head and neck cancer.
The methodology involves subjects, who satisfy the study category taken into study and patient consent form was taken. Subject information was collected using data collection forms and details of the subject were secured. FACT-H&N (Version 4) was filled by subject before and after the treatment.
Data collected by using questionnaire FACT- H&N for assessing the quality of life by using various scales such as emotional, additional, social, functional, and physical well being patients on concurrent chemoradiotherapy with cisplatin and P value found to be <0.0001 and toxicity profile also studied, patients more suffered with weight loss, anemia, thrombocytopenia and neutropenia and radiation toxicity also found to be patients more suffered with dermatitis and mucositis.
Patients on CCRT have improved the quality of life rather than radiotherapy alone. Even toxicity also more with CCRT than radiotherapy.

INTRODUCTION

Head and Neck Cancers

Definition

Head and neck cancers usually begin in the squamous cells that line the moist, mucosal surfaces in the head and neck (for example, inside the mouth, the nose, and the throat). These squamous cell cancers are often referred to as squamous cell carcinomas of the head and neck).

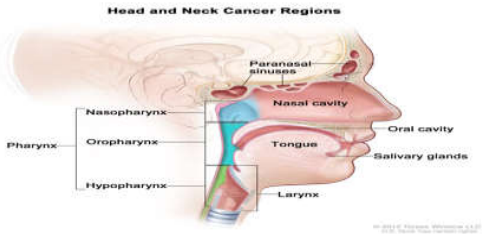

Fig 1

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Aim and Objectives

Aim

To evaluate quality of life in patients on concurrent chemoradiotherapy with cisplatin in head and neck cancer.

Objective

To measure the quality of life and pharmaceutical care and toxicity profile of cisplatin with radiotherapy in head and neck cancer.

Plan of work

The work is planned to carry out as follows:

- To include head and neck cancer patients.
- To design a patient data collection form and standard questionnaire H & N 35.
- To collect all the data required for the study from radiotherapy out -patient and inpatient department.
- To analyze the data and provide the feedback of results to the physician (prescriber) and submit the safety data of cisplatin and adverse reactions of the drug.

- To counsel the patients regarding the usage and effects of medications.

METHODOLOGY

Study site: A Non experimental prospective observational study was conducted on head and neck cancer patients in radiotherapy department, GOVERNMENT GENERAL HOSPITAL, Guntur, Andhra Pradesh.

Study duration

The study was carried out between December 2016 and May 2017.

Inclusion criteria

- A patient who suffered from various types of head and neck cancer.
- Consented males and females above age 18 years.
- A patient who is concurrent chemoradiotherapy with cisplatin for any cancer of head and neck cancer.

Exclusion criteria

- Patients who suffered from cancers, other than head and neck cancers.
- Patients with head and neck cancer under 18 years are excluded.
- Patients who have recurrent and remission of head and neck cancers.
- Female patients with pregnancy are excluded.
- Patients with severe heart disease and lung disease are excluded.

Study design: A Non Experimental prospective observational study.

Study Method

- The study is conducted in the Government General Hospital, Guntur, a1300 bedded tertiary care hospital.
- All patients with head and neck cancer patients will be included in the study.
- Most of the patients visiting the hospital are from rural areas
- Patients were screened for RFT/LFT/RBS/CBP were considered.
- Evaluation of clinical symptoms, RFT/LFT/RBS/CBP levels in patients on cisplatin, safety parameters was assessed.
- The baseline knowledge of the patients on the disease, complications, regular blood glucose monitoring, diet, lifestyle modifications and medication adherence is assessed using a questionnaire.
- Patients are then counseled about disease, diet, lifestyle modifications and medication adherence.
- Patients are reviewed periodically (i.e., Every 3 months) for the improvement in their prognosis of cancer and improvement in general condition.

OBSERVATIONS AND RESULTS

Age Wise Distribution of Patients with Head and Neck Cancer

Table 1: Describes age wise distribution of Patients with Head and Neck Cancer that shows that between age group 51-70 (25.675%) are more suffered with head and neck cancer.

Table 1 Age wise Distribution of Patients with Head and Neck Cancer

S. No	Age Group	Number of Patients	Percentage (%)
1.	<30	2	2.702
2.	31-40	10	13.513
3.	41-50	14	18.918
4.	51-60	19	25.675
5.	61-70	19	25.675
6.	>70	10	13.513

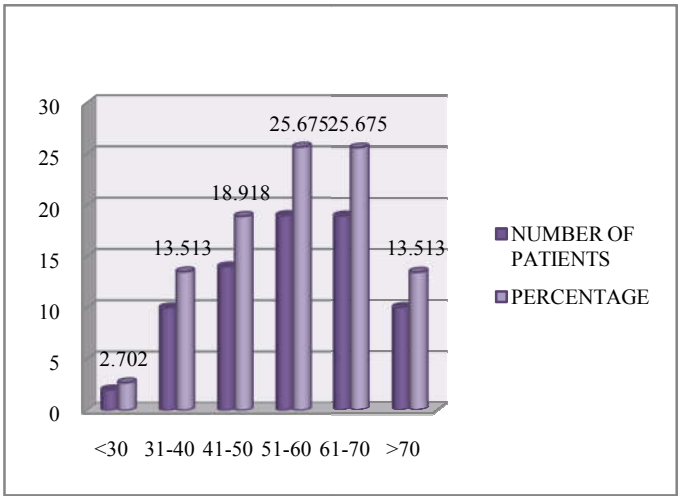


Fig 1 age wise distribution of Patients with Head and Neck Cancer

Distribution of Patients by Stage of Head and Neck Cancer

Table 2 Distribution of Patients with Stage of Cancer

S.No	Stage	No of Patients	Percentage (%)
1.	I	1	1.351
2.	II	20	27.027
3.	III	29	39.189
4.	IV A	11	14.864
5.	IV B	13	17.567
6.	IV C	0	0

Table 2-: In distribution of patient with stage of cancer describes that patient are more diagnosed with stage II (27.027%) and stage III (39.189%) cancer

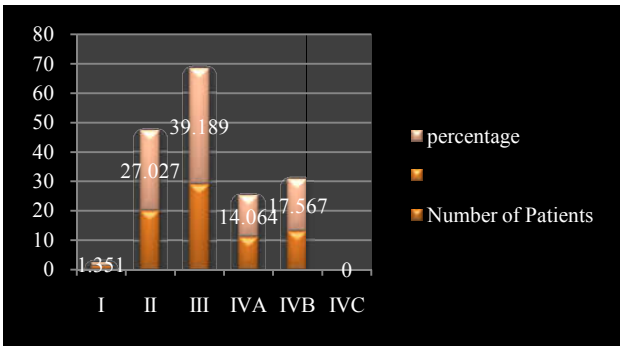


Fig 2 Distribution of Patients with Stage of Cancer

Distribution of Patients Based on Educational Status

Table 3 Distribution of patients based on Educational status

S. No.	Educational status	No. Of patients	Percentage (%)
1.	Illiterates	60	81.108
2.	Primary education	10	13.513

3.	Secondary education	3	4.054
4.	Graduates	1	1.351

Table3: describes the who are suffering from head and neck cancer are illiterate (81.1) and primary education (13.531%)

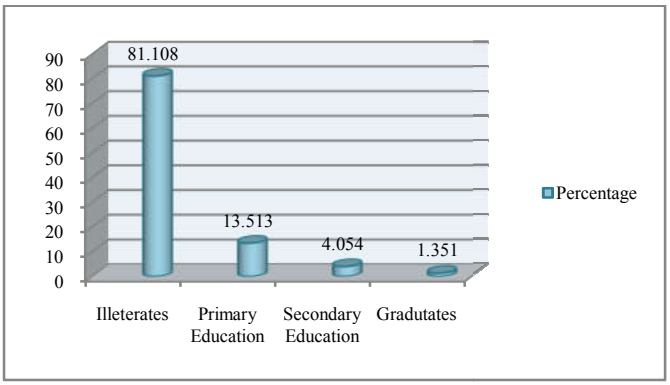


Fig 3 Distribution of patients based on Educational status

Distribution of Patients Based on Food Habits

Table 4 Distribution of Patients Based on Food Habits

S. No	Food habits	No. Of. Patients	Percentage (%)
1.	Vegetarian	2	2.702
2.	Mixed diet	72	97.29

Table 4**:** table describes most of patients are having the habit of taking mixed diet (2.702%) rather than vegetarian (97.29%)

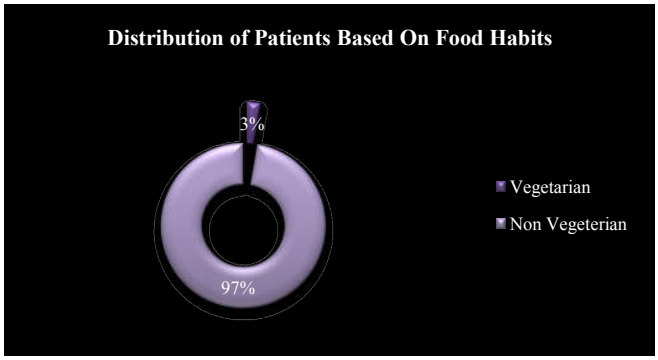


Fig 4 Distribution of Patients Based on Food Habits

Distribution of Patients Based On Location

Table 5 Categorization of patients based on Locality

S. No	Location	No. Of Patients	Percentage (%)
1.	Urban	14	18.918
2.	Rural	60	81.081

The table describes that 14 (18.918%) of patients belongs to Urban area & about 60 (81.08%) of patients are from Rural area.

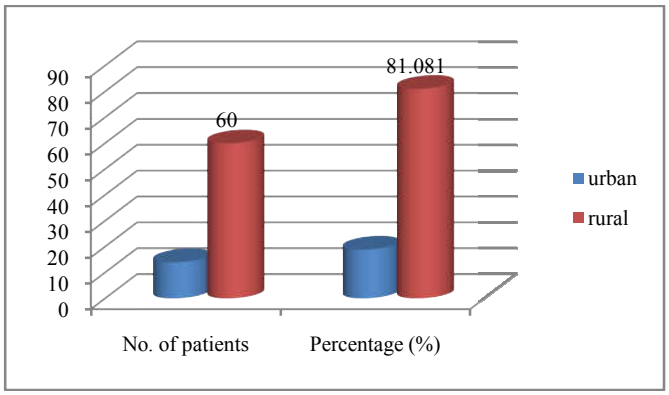


Fig 5 Distribution of patients based on location

Type Wise Distribution of Head and Neck Cancer In Females

Table 6 Distribution of patients based on different cancer

S. No	Diagnosis	Number of Patients	Percentage (%)
1.	Tongue	5	27.77
2.	Parotid	1	5.55
3.	Lower lip	1	5.55
4.	Oral cavity	1	5.55
5.	Alveoli	1	5.55
6.	Post cricoid	9	50

This table describes about different types of cancers in female patients suffering mostly with postcricoid (50%) out of 18 females.

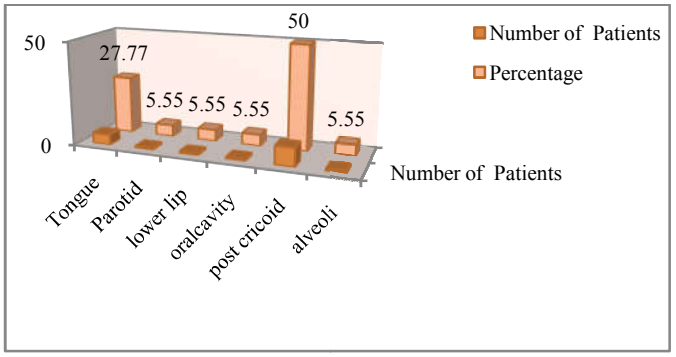


Fig 6 Distribution of patients based on different cancer in females

Type Wise Distribution of Head and Neck Cancer in Males

Table 7 Distribution of patients based on different cancer

S. No	Diagnosis	Number of Patients	Percentage (%)
1.	Tongue	7	12.28
2.	Parotid	1	1.75
3.	Supraglottis	12	21.05
4.	Nasopharynx	3	5.26
5.	Oral cavity	2	3.50
6.	Oropharynx	1	1.75
7.	Post cricoids	4	7.01
8.	RMT	2	3.50
9.	Glottis	1	1.75
10.	Vocal cord	2	3.50
11.	Tonsils	1	1.75
12.	Angle of mouth	1	1.75
13.	Hypopharynx	3	5.26
14.	MUO neck	3	5.26
15.	Hard palate	3	5.26
16.	Soft palate	2	3.50
17.	Buccal mucosa	7	12.28
18.	Larynx	1	1.75
19.	Cheek	1	1.75

This table describes about different types of cancers in male patients suffering mostly with supraglottis (21.05%) out of 57 males.

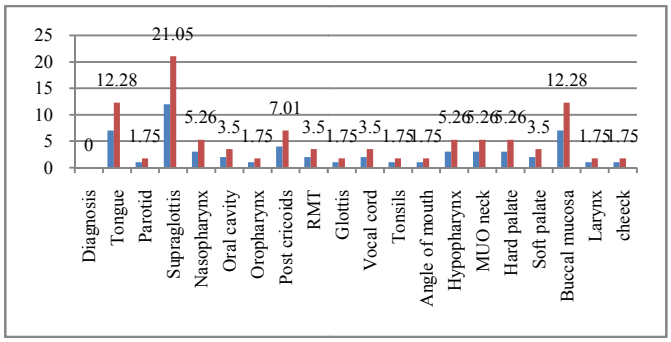


Fig 7 Distribution of patients based on different cancer

Distribution of Head and Neck Cancer Patients Based On Hbs Ag Status & None

Table 8 Categorization of patients based on viral status

Viral status	No of Patients	Percentage
HBs Ag	1	1.35
None	73	98.6

The above table describes that 1 (1.35%) of patients are HBs Ag positive.

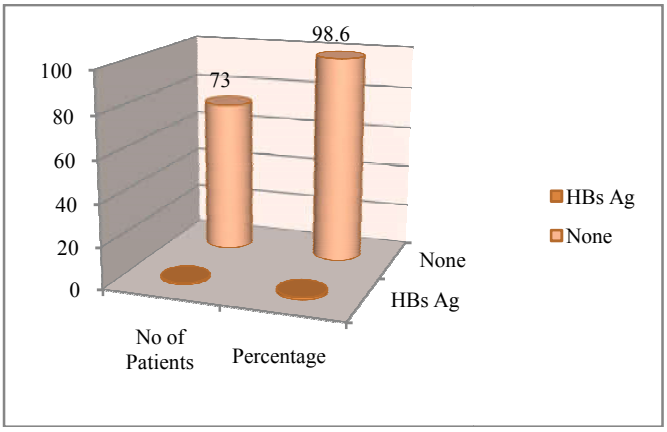


Fig 8 Distribution of head and neck cancer patients based on Hbs Ag status & none

Categorization Based on Family History in Head and Neck Cancer Patients

Table 9 Distribution of patients based on Family history

S. No	Family history	No. of Patients	Percentage (%)
1.	Yes	0	0
2.	No	63	85.13
3.	Not known	11	14.86

From the above table, we can know that no patient had a family history of head and neck cancer. About 11 (14.12%) of patients don't know about their family history of cancer.

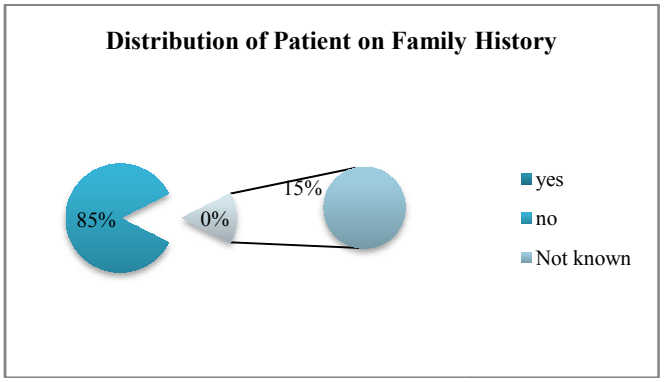


Fig 9 Distribution of patients based on Family history

Categorization of Occupational Status in Head and Neck Cancer Patients

Table 10 Categorization of patients based on occupational status

S. No	Occupational status	No. Of Patients	Percentage (%)
1.	Employee	2(%)	2.702
2.	Self employed	20(%)	27.02
3.	Daily wage	34(%)	45.94
4.	Not working	18(%)	24.32

The above table describes that 34 (45.94%) of patients are daily wagers and only about 2 (2.702%) patients are employees.

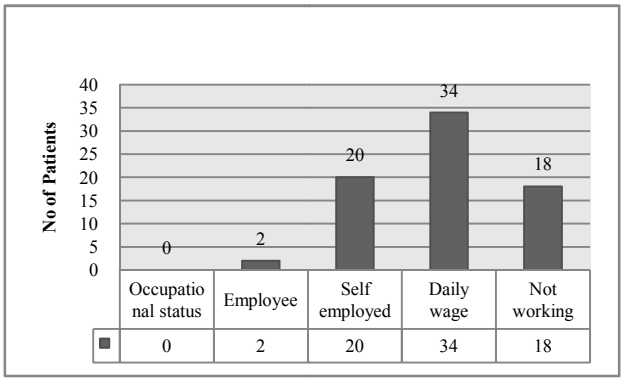


Fig 10 Categorization of patients based on occupational status

Categorization of Study Participants Based on Social Habits in Head and Neck Cancer Patients

Table 11 Categorization of study participants based on social habits

S. No	Social history	Number of patients	Percentage (%)
1.	Smoking	42	56.756
2.	Alcohol	12	16.216
3.	Betel nut	10	13.513
4.	Occupational Exposure	10	13.513

From the **Table11-;** About 42 (56.75%) patients have the habit of smoking and about 12 (16.216%) patient have habit of alcohol and 10 (13.513%) patients don't have any history of social habits.

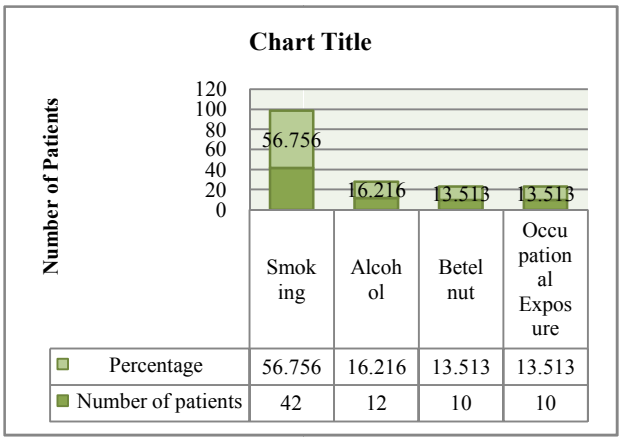


Figure 11 Categorization of study participants based on social habits

Categorization Based on Histopathological Class of Head and Neck Cancer

Table 12 Categorization Based on Histopathological Class of Head and Neck Cancer

S. No	Histopathological class	No. of patients	Percentage (%)
1.	Squamous cell carcinoma	74	100

Table 12-describes the categorization of Patients Based on their Histopathological Class of Head and Neck Cancer; Out of 74 patients 74 (100%) were diagnosed as Squamous cell carcinoma.

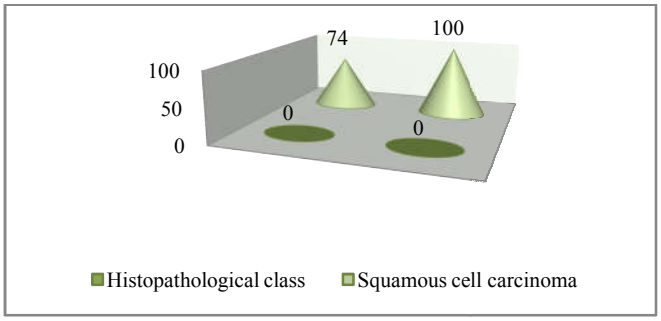


Fig 12 Categorization Based On Histopathological Class of Head and Neck Cancer

Categorization of Patients Based on Mode of Treatment

Table 13 Categorization of Patients Based on Mode of Treatment.

S. No	Mode of treatment	No. Of patients
1.	Concurrent	20
2.	Radiation	54

The above table describes that patients on concurrent are 20 and radiation are 54

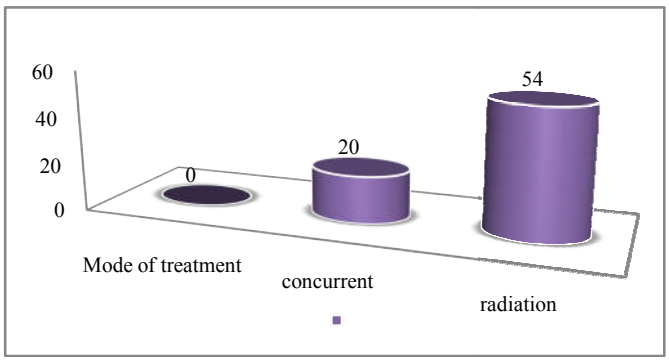


Fig 13 Categorization of Patients Based on Mode of Treatment

Categorization of Patients Based on Recurrence of Cancer

Table 14 Categorization of patients based on recurrence of cancer

S. No	Recurrence	No. of patients
1.	Yes	4
2.	No	71

The table describes about No of recurrence, patients are 4 and without recurrence are 71 in six months of duration

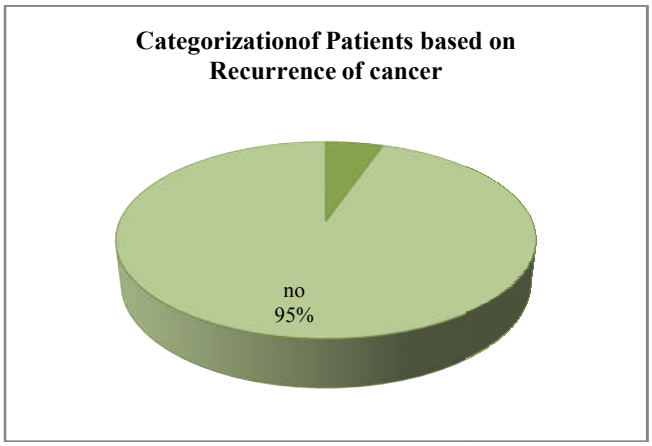


Fig 14 Categorization of patients based on recurrence of cancer.

Assessment of Quality of Life

- Quality of life was assessed by using the FACT- H&N QLQ Questionnaire.
- The FACT-
  H&N QLQ incorporates five functional scales (addition al, physical, functional, emotional, and social), three symptom scales (fatigue, pain, and nausea and vomiting).
- And a number of single items assessing additional symptoms commonly reported by cancer patients (dyspnoea, loss of appetite, dysphagia, constipation and diarrhea) and perceived financial impact of the disease

Functional Scale Domains in Eortc Qlq C-30

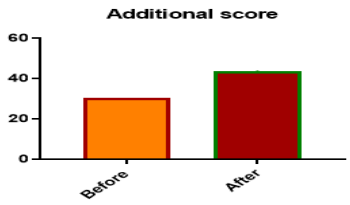
Table 15 Functional Scale

S.No.	Domains	Mean ± Standard Deviation		
		Before Treatment	After Treatment	P-Value
1.	Additional concerns	13.16±11.8	20.16±16.7	<0.0001
2.	Emotional well-being	20.63±15.18	35.75±18.23	<0.0001
3.	Functional well-being	13.66±11.60	28.63±16.53	<0.0001
4.	Physical well-being	7.16±4.70	25.80±15.03	<0.0001
5.	Social Functioning	10.50±1.76	32.90±10.90	<0.0001

Additional Concerns

Before Treatment: - 13.16±11.8
After Treatment: - 20.16±16.7 P-Value: <0.0001

Fig 15



Social Functioning

Before Treatment: - 10.50±1.76
After Treatment: - 32.90±10.90
P-Value: - <0.0001

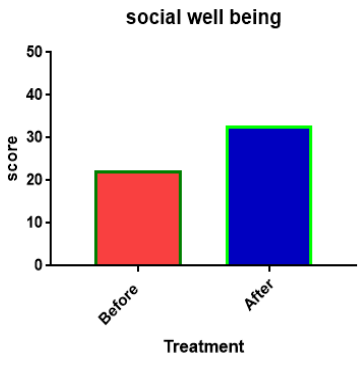


Fig 16

Physical Well-Being

Before Treatment: - 7.16±4.70
After Treatment: - 25.80±15.03 P-Value: <0.0001

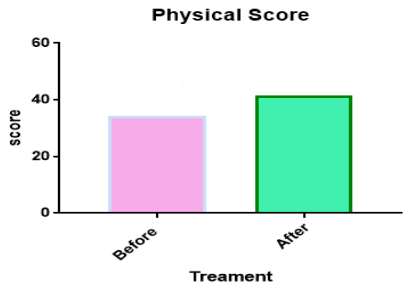
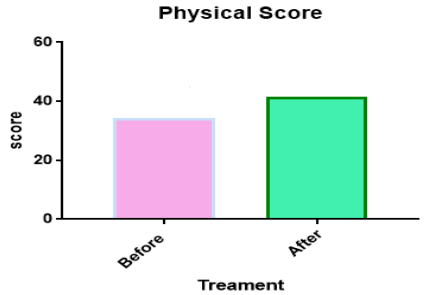


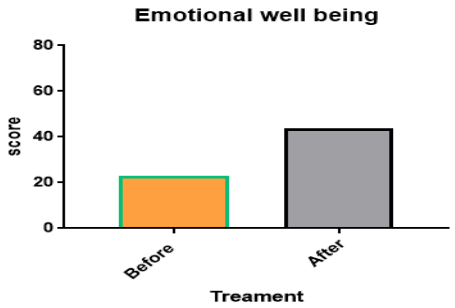
Fig 17



Emotional well-being

Before Treatment: - 20.63±15.18
After Treatment: - 35.75±18.23
P-Value: <0.0001

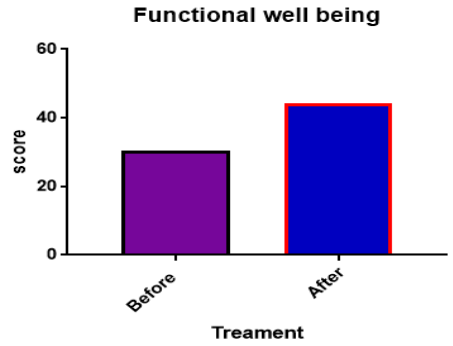
Fig 18



Functional Well-Being

Before Treatment: - 13.66±11.60
After Treatment: - 28.63±16.53
P-Value: <0.0001

Fig 19



DISCUSSION

Head and neck cancers usually begin in the squamous cells that line the moist, mucosal surfaces in the head and neck (for example, inside the mouth, the nose, and the throat). These squamous cell cancers are often referred to as squamous cell carcinomas of the head and neck).

During a 6 months study, 74 patients who were diagnosed with head and neck cancer and who met the inclusion criteria were taken as study subjects. The prevalence of ADRs varies from subject to subject because of the inter subject variability towards the drugs administered

Subjects were recruited based on criteria that were set in the protocol. Subjects for concurrent chemoradiotherapy were selected based on performance status of the patient that assess the capability of the patient to withstand the chemotherapy drugs and their ADR's. ECOG (Eastern Cooperative Oncology Group) performance status scale, which provides with the grading and relative description is used in this study.

As similar to the study, which is conducted by SusanUrba, *et al*., (2012) - Advanced head and neck cancer patients to assess the overall survival rate using the quality assessment scale score as prognostic factors by giving treatment as cisplatin monotherapy. The study population of 795 out of which 704 subjects are suitable for the study. It was conducted during the year 2012. They have used FACT – H & N questionnaire to assess the quality of life. Age above 65 yrs, site of disease, ECOG are considered as prognostic factor for survival as were baseline scores on four FACT-H&N subscales (physical well-being, emotional well-being, functional well-being, additional concerns-H&N; HRs = 0.82–0.94; all $P \leqslant 0.002$) and prior surgery/radiotherapy (HR = 0.76); and baseline scores of the FACT-H&N subscales of physical well-being, social/family well-being, and additional concerns-H&N (HRs = 0.89–0.94; all $P \leqslant 0.014$ per table).

In our study to assess quality of life of the patient, we used FACT-H&N questionnaire (version-9), ECOG performance status. The patients who met the inclusion criteria set by us are started giving treatment with cisplatin and five days radiation in a week of age above 18 years and assessed quality of life in both radiation and concurrent chemo radiation patients by filling the questionnaire FACT - H & N which consist of several parameters related to quality of life viz., emotional well being, physical score, social well being, functional well being and additional concerns. We obtained an overall significance of P<0.0001 both prior to treatment and after the treatment.

As compared to the above study, their P value is found to be <0.002 and in the present study the P value is <0.0001that shows that the present study conducted by us is highly significant. The patients who are involved in our study have achieved better quality of life when compared to the above said study.

During the history collection it was found that smoking consumption and alcohol consumption were the main reasons for head and neck cancers than other related etiologies as said in a study by Cristina Hernández-Vila, *et al*., (2017).

Hence a supportive therapy for symptomatic relief was suggested to the patients whereby the physician accepted the suggestions of the clinical pharmacist prescribed the supportive medications for ADR'swhich helped the patient to cope up with them. This had a major hand in improving the QoL of the patient and progression on the performance status. Apart from this, we, clinical pharmacists counseled the patients regarding disease, medication and diet that could take viz., Buttermilk, porridge, malts, non-irritant juices like cane

sugar, banana, etc, they helped the patient to gain physical strength and cooperate with the treatment. This made patient to recover faster.

CONCLUSION

Our study concluded that the incidence of ADRs associated with drug toxicities in concurrent chemotherapy patients and patients with radiotherapy alone. Regular follow up and provision of pharmaceutical care is a key factor to manage the ADRs and complications. By creating awareness and providing pharmaceutical care on disease and usage of drugs, medication adherence and quality of life of the patient was improved.

The need for provision of pharmaceutical care is necessary to improve quality of life of both concurrent chemotherapy patients and patients with radiotherapy alone to manage all the possible ADRs and complications associated with the drugs and disease progression. Prescription errors, administration errors, possible ADRs were avoided due to strict follow-up by the pharmacist. Along with physicians, nurses and clinical pharmacists have a great role in the management of ADRs and improvement of patient's quality of life.

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