

## ORIGINAL ARTICLE

# A Comparative Analytical study of Chemo-Radiotherapy with either weekly Docetaxel or weekly Cisplatin for Treatment of Locally advanced Head and Neck Cancer

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**HOW TO CITE THIS ARTICLE:**

Ayush Jain, Dipshi Agrawal, Virendra Bhandari, et al. A Comparative Analytical study of Chemo-Radiotherapy with either weekly Docetaxel or weekly Cisplatin for Treatment of Locally advanced Head and Neck Cancer. Indian Journal of Cancer Education and Research. 2025; 13(1): 07-16.

**ABSTRACT**

**Purpose:** To compare and analyse chemoradiotherapy with either weekly docetaxel or weekly cisplatin for treatment of locally advanced head and neck cancer in terms of tumor response and toxicities.

**Methods:** This was a comparative analytical study. Adult patients (age  $\geq 18$  years) with LAHNSCC planned for chemoradiation and Karnofsky performance status of  $>70\%$  were randomly assigned in 1:1 to either radiation with concurrent docetaxel 20mg/ once weekly or concurrent cisplatin 30mg/ m<sup>2</sup> for a maximum of six cycles. Comparison of treatment response and acute and late toxicities were done.

**Results:** A total of 50 patients were enrolled in the study between September 2022 and February 2024. The overall response rate was slightly higher in the Docetaxel-RT arm compared to the Cisplatin-RT arm (87% vs. 80%). Complete response rates were 34.8% in the Docetaxel-RT group and 20% in the Cisplatin-RT group ( $P = 0.25$ ), while partial response rates were 52.8% and 60%, respectively ( $P = 0.58$ ).

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➤ Received: 25-04-2025 ➤ Accepted: 08-05-2025



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In terms of toxicity, Grade III mucositis was significantly more common in the Docetaxel-RT arm (65.2%) compared to the Cisplatin-RT arm (28%). Additionally, the incidence of grade 3 acute skin reactions was higher with Docetaxel-RT (28.1% vs. 4%), as was the occurrence of subcutaneous fibrosis at six months post-treatment (13% vs. 8%).

**Conclusion:** Weekly Docetaxel (20 mg/m<sup>2</sup>) administered concurrently with radiotherapy in patients with locally advanced head and neck cancer demonstrates a favorable toxicity profile and comparable efficacy to weekly Cisplatin. Further validation through larger phase II/III trials and multicentre studies is warranted to optimize dosing strategies and assess long-term outcomes, including survival benefits.

## KEYWORDS

• Chemoradiation • Docetaxel • Head and Neck cancer

## INTRODUCTION

Head and neck cancer encompasses a range of cancers affecting the oral cavity, larynx, nasopharynx, oropharynx, hypopharynx, and sinonasal tract<sup>1</sup> Globally, it is among the most prevalent types of cancer. According to the GLOBOCAN2022 report, there were 1,99,76,499 new cancer cases worldwide. In India, lip and oral cavity cancer is notably prevalent, ranking as the second most commonly occurring cancer overall with 143759 new cases reported in 2022 and most common cancer in Indian males with 107812 new cases.<sup>1</sup>

In cases of locally advanced HNC, combined modality therapy with chemotherapy and radiotherapy as majority of patients following single modality develop locoregional recurrence. A meta-analysis of individual patient data from over 17,346 participants in 93 trials conducted from 1965 to 2000 (Meta-Analysis of Chemotherapy in Head and Neck Cancer) demonstrated that combining radiotherapy (RT) with concurrent chemotherapy resulted in a 19% reduction in the risk of death and an overall 6.5% improvement in 5-year survival compared to RT alone ( $P < .0001$ ).<sup>2</sup> This benefit was mainly due to a 13.5% improvement in locoregional control. Various radiotherapy schedules have been used alongside concurrent chemotherapy, showing similar results in terms of feasibility and toxicity profiles.<sup>3</sup>

Chemotherapeutic agents that have demonstrated efficacy in the treatment of squamous cell carcinoma of the head and neck when combined with radiation include Methotrexate, Bleomycin, Mitomycin C, 5-fluorouracil, Carboplatin, and Cisplatin.

Among these, **Cisplatin** is the most frequently used agent in the majority of studies due to its potent radiosensitizing properties. However, its use is often limited by significant toxicities, particularly nephrotoxicity and vestibulocochlear side effects. These adverse effects can hinder the completion of essential concurrent Cisplatin cycles during radiotherapy and make it unsuitable for patients with impaired renal function or pre-existing hearing loss.

Taxanes have demonstrated encouraging response rates for the management of locally advanced and metastatic head and neck cancers in early clinical studies.<sup>4</sup> **Docetaxel**, a semisynthetic derivative, exerts its antitumor effect by promoting tubulin polymerization and inhibiting microtubule depolymerization. This mechanism leads to cell cycle arrest in the G2/M phase, which is known to be approximately 2.5 times more sensitive to radiation than the G1/S phase<sup>5</sup> The radiosensitizing potential of Docetaxel has been confirmed in vitro, and is thought to be primarily mediated through this cell cycle synchronization effect.

Notably, Docetaxel exhibits a 1.9-fold higher affinity for tubulin-binding sites compared to Paclitaxel and possesses an intracellular half-life approximately three times longer. This pharmacokinetic advantage contributes to higher intracellular concentrations at steady state.<sup>6</sup>

The **maximum tolerated dose** of Docetaxel is 100 mg/m<sup>2</sup> administered every 21 days, with transient neutropenia identified as the principal dose-limiting toxicity.<sup>7</sup> Other commonly reported adverse effects include alopecia, mucositis, fatigue, sensory neuropathy, fluid

retention, rash, and hypersensitivity reactions.

In phase II trials, single-agent Docetaxel has shown response rates ranging between 27% and 43% in patients with squamous cell carcinoma of the head and neck (SCCHN).<sup>8</sup> Given the established survival benefit of concurrent chemoradiotherapy in head and neck cancer<sup>9</sup>, and the comparable outcomes observed with low-dose weekly chemotherapy regimens<sup>10</sup>, weekly administration of Docetaxel alongside radiotherapy has been explored as a viable therapeutic option.

Multiple phase I and II studies have demonstrated that conventional radiotherapy can be safely combined with weekly Docetaxel at doses ranging from 10 to 20 mg/m<sup>2</sup>, yielding acceptable toxicity profiles and promising activity.<sup>11,12</sup> This regimen may serve as an effective alternative to Cisplatin, particularly in patients with contraindications such as renal dysfunction or pre-existing ototoxicity.

Based on these findings, a cross-sectional analytical study was undertaken to compare the clinical outcomes and toxicity profile of concurrent radiotherapy with either weekly Docetaxel (20 mg/m<sup>2</sup>) or weekly cisplatin (30 mg/m<sup>2</sup>) in patients with locally advanced head and neck cancer.

## MATERIALS AND METHODS

A cross-sectional analytical study of radiotherapy with either concurrent weekly Docetaxel or weekly cisplatin for locally advanced inoperable head and neck cancer was conducted after obtaining approval from Institutional Research Committee and Ethics Committee. All patients with locoregionally advanced squamous cell carcinoma of oral cavity, oropharynx, hypopharynx and larynx (stage 3 and 4), seen from September 2022 to February 2024 who fulfilled the inclusion and exclusion criteria were included in the study. All patients were informed about the treatment protocol and written informed consent was obtained to participate in the study.

### Pre-treatment evaluation

Detailed history and physical examination was done in all patients. Biopsy of the primary tumor site or fine needle aspiration of clinically significant nodes was done. Necessary blood investigations (haemoglobin, blood counts, hepatic and renal function) and radiological

evaluation like chest x-ray, soft tissue of neck, barium swallow and orthopantomogram were done in selected cases. ECG and ECHO were done prior to administration of chemotherapy. CT scan or MRI scan of head and neck were done in relevant situations only. All patients had pre-RT dental check up and dental clearance was obtained before starting radiotherapy.

### Inclusion criteria

Patients with histologically proven inoperable squamous cell carcinoma of larynx, laryngopharynx, oropharynx and oral cavity of stages III and IV (T3-4 and N0-3, T1 N2-3 and N2-3 and T2 N1-3) with KPS score >70% with normal liver, renal and bone marrow function were included in the study.

### Exclusion criteria

Patients with metastatic disease, previous history of treatment with radiotherapy, chemotherapy or surgery, more than one site of malignancy, chronic medical illness which would compromise treatment and any co-existing medical problems with contraindication for Docetaxel were excluded from the study.

### Treatment Radiotherapy

Patients in both Group A and Group B underwent radiation therapy following immobilization with a thermoplastic mask. **Planning CT scans** were performed using a Siemens SOMATOM Definition AS scanner (Siemens Medical Systems, Germany), acquiring 3 mm axial slices. The images were transferred to the **Eclipse Treatment Planning System (Version 13.7, Varian Medical Systems, Palo Alto, CA)** for contouring and planning.

Target volumes—**GTV, CTV, and PTV**—along with **organs at risk (OARs)** such as the parotid glands, spinal cord, and brainstem, were delineated on the planning CT. **Intensity Modulated Radiotherapy (IMRT)** was employed for all patients. Radiation plans were developed by medical physicists and reviewed by a team of radiation oncologists. **Dose-volume histograms (DVHs)** were used to evaluate target coverage and OAR sparing, and the optimal plan was selected for treatment.

Treatment was delivered using **megavoltage photon and electron beams** on a **Clinac DMX Linear Accelerator** (Varian Medical Systems

Inc., USA), equipped with **Millennium 80 MLC**. Patients received conventional fractionation—**200 cGy per fraction, once daily, five days a week**, to a total dose of **66-70 Gy over 6-7 weeks**. Photon energies of **6 MV and 15 MV**, and electron energies of **6, 9, 12, and 15 MeV** were utilized based on tumor location and depth.

### Chemotherapy

**Docetaxel:** Concurrent chemotherapy with Docetaxel was administered at a dose of 20 mg/m<sup>2</sup> on days 1, 8, 15, 22, 29, and 36 alongside conventional fractionated radiotherapy. Premedication included granisetron, dexamethasone, ranitidine, and promethazine. Docetaxel was diluted in 500 mL of fluid and infused over 3 hours, followed by 1 liter of post-hydration. Intravenous antiemetics were continued on day 2, with oral antiemetics maintained for 3-4 days post-infusion.

**Cisplatin:** Cisplatin was administered at 30 mg/m<sup>2</sup> on the same schedule (days 1, 8, 15, 22, 29, and 36) with concurrent radiotherapy. Pre-hydration included granisetron, dexamethasone, and ranitidine in 500 mL fluid. Forced diuresis was induced with 20% mannitol over 15 minutes. Cisplatin was infused in 500 mL of chloride-containing fluid over 2.5 hours, followed by 1.5 liters of post-hydration fluids supplemented with potassium and magnesium. Day 2 intravenous antiemetics were followed by a 3-4 day course of oral antiemetics.

### Evaluation during treatment

All patients were evaluated weekly during treatment clinically and blood investigations (haemoglobin, blood counts, hepatic and renal functions) were done prior to each cycle of chemotherapy. Docetaxel was not administered if the serum bilirubin was greater than 2 times the upper limit of normal (ULN). Dose of Docetaxel was reduced by 20% in patients who developed grade 3 or 4 diarrhea, liver enzymes greater than five times the ULN, and grade 2 palmar-plantar toxicity.

Chemotherapy was not administered if any focal signs of infection, total blood counts <3000/cubicmm, absolute neutrophil count < 1500/cubicmm, platelet count < 100000/cubicmm. Chemotherapy administration was delayed or omitted and radiotherapy was interrupted / stopped when patients developed

grade III mucositis or skin reactions. Minor side effects were managed symptomatically.

### Weekly assessment

All patients were monitored weekly and assessment was done according to common toxicity criteria (Cancer Therapy Evaluation Program Common Toxicity Criteria, Version 5.0).

### Response assessment and Follow up

Response assessment was done by clinical evaluation. In suspicious cases CT scan was done for confirmation of the response (Response Evaluation Criteria for Solid Tumours, RECIST version 1.1). All patients were advised to come for follow up four weeks after treatment and every 3 months in the first year, every six months in the second year, and every year thereafter. During follow up visits patients had clinical assessment and endoscopies to assess locoregional disease and also assessment for late radiation toxicities.

### Statistical Analysis

Data were entered in **MS Excel 2010** and analyzed using appropriate statistical software. Results were presented as frequency tables and graphical representations (pie or bar charts) for qualitative variables. **Descriptive statistics** were computed as mean  $\pm$  standard deviation for continuous variables and frequencies with percentages for categorical data.

Normality of quantitative data was assessed using the **one-sample Kolmogorov-Smirnov test**. Based on the distribution, appropriate statistical tests were applied: **Independent t-test** for normally distributed data and **Mann-Whitney U test** for non-parametric comparisons between two groups. For repeated measures, **repeated measures ANOVA** was used. A **p-value < 0.05** was considered statistically significant.

## RESULTS

### Patient characteristics

Total 50 patients were enrolled in the study, 25 patients were randomly assigned in each group. 1 patient in Group A defaulted the treatment in middle and 1 patient was lost to follow up after treatment, hence both were excluded from the study. Mean age of the patients was 48 years (range 29-74 years) in

group A while 47.6 years (Range 31-73) in Group B as shown in Table 1.

**Table 1** showing the patient characteristics, including the age, performance status, clinical stage group and site of primary

Characteristics	Docetaxel (n=23)		Cisplatin (n=25)	
	Mean	Range	Mean	Range
Age, years	48	29-74	47.6	31-73
<b>Performance Status</b>	Total	%	Total	%
KPS 90	17	73	19	76
KPS 80	6	26	6	24
<b>Stage Group</b>				
Stage IVA	20	87	20	80
Stage IVB	3	13	5	20
<b>Site of Primary</b>				
Oral cavity	15	65.2%	15	60%
Oropharynx	4	13%	4	16%
Larynx	2	8.6%	2	8%
Hypopharynx	2	8.6%	2	8%
Nasopharynx	1	4.3%	2	8%

### Treatment Compliance

Total 50 patients were recruited for this study. All the patients were selected according to the inclusion and exclusion criteria as mentioned earlier.

In group A 1 patient left the treatment in middle while 1 patient was lost to follow up after treatment completion and hence were excluded from evaluation, while no such events were observed in the group B.

Head and neck cancer patients undergoing radiotherapy often experience significant acute toxicities that can disrupt their treatment schedule. These interruptions and subsequent prolongation of treatment duration can impact the overall effectiveness of the therapy as shown in Table 2.

**Table 2:** Depicting overall treatment duration and mean days of gap

Treatment Compliance	Group A	Group B
Overall Treatment Duration Range, days	50-72	49-65
Mean days of gap, days	7.3	4.4

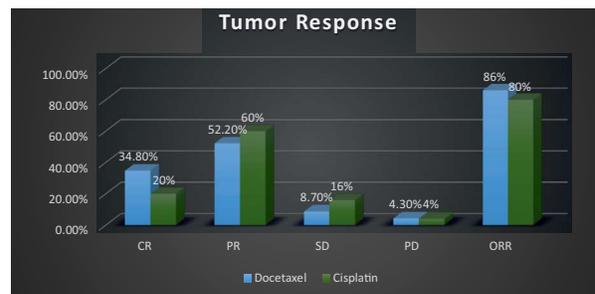
### Response to treatment

Treatment response was evaluated one month after the end of treatment as per RECIST criteria version 1.1.

Evaluation after concurrent chemo-radiation showed that complete response was seen in 34.8% in group A and 20% in group B. Partial response was 52.2% in group A and 60% in group B. The overall response was 86% in group A while 80% in group B as depicted in Table 3 and Graph1.

Tumor Response	N	Group A	N	Group B	P Value
Complete Response	8	34.80%	5	20%	0.25
Partial response	12	52.20%	15	60%	0.58
Stable disease	2	8.70%	4	16%	0.95
Progressive disease	1	4.30%	1	4%	0.45
Total	23	100%	25	100%	
ORR	20	86%	20	80%	0.52

**Table 3:** Response to treatment in two groups (as per RECIST v1.1)



**Graph 1:** Treatment response: Complete response was achieved in 8 (34.8%) patients in group A and 5(20%) patients in group B. Partial response was observed in 12(52.2%) patients in group A and 15(60%) patients in group B, while group A and group B both had 1(4.3% in group A and 4% in group B) patients each with progressive disease.

## TOXICITY

### Locoregional Toxicities

The most common acute toxicities were mucositis and skin reactions. **Grade III mucositis** occurred in **65.2%** of patients in the Docetaxel arm compared to **28%** in the Cisplatin arm. Skin toxicity typically developed from the third week of treatment, with **Grade III skin reactions** observed in **26.1%** of Docetaxel-treated patients versus **4%** in the Cisplatin group.

Late toxicities primarily included **xerostomia** and **subcutaneous fibrosis**. In Group A (Docetaxel), **Grade I xerostomia** was reported in 26.1% and Grade II in 69.6%

of patients. In Group B (Cisplatin), **Grade I xerostomia** occurred in **56<sup>0</sup>%** and **Grade II** in **44<sup>0</sup>%** of patients. The difference between the two groups was not statistically significant.

For **subcutaneous fibrosis**, **Grade I** reactions were seen in **21.8%** and **Grade II** in **65.2%** of Group A patients, whereas Group B had **Grade I** fibrosis in **48<sup>0</sup>%** and **Grade II** in **44<sup>0</sup>%**. Again, no statistically significant difference was noted

between the groups. Refer Table 4

#### Systemic Toxicities:

In the Docetaxel group, **Grade II lymphopenia** occurred in **1 patient**, and **Grade III anemia** was seen in **3 patients**. In contrast, the Cisplatin group had **no cases of Grade III lymphopenia** and **only 1 case of Grade III anemia**. Refer Table 4.

**Table 4:** Locoregional and Systemic toxicities

Toxicities		None	Grade I	Grade II	Grade III	Grade IV
Anemia	Docetaxel	12 (52%)	8 (34.8%)	3 (13%)	–	–
	Cisplatin	18 (72%)	6 (24%)	1 (4%)	–	–
Vomiting	Docetaxel	19 (82.6%)	4 (17.4%)	–	–	–
	Cisplatin	17 (68%)	7 (28%)	1 (4%)	–	–
Lymphopenia	Docetaxel	4 (17.4%)	16 (69.6%)	2 (8.7%)	1 (4.3%)	–
	Cisplatin	15 (65.2%)	9 (36%)	1 (4%)	–	–
Renal toxicity	Docetaxel	20 (87%)	3 (13%)	–	–	–
	Cisplatin	11 (44%)	12 (48%)	2 (8%)	–	–
Febrile Neutropenia	Docetaxel	20 (87%)	–	–	3 (13%)	–
	Cisplatin	24 (96%)	–	–	1 (4%)	–
Diarrhoea	Docetaxel	9 (39.1%)	11 (47.8%)	3 (13%)	–	–
	Cisplatin	19 (76%)	5 (20%)	1 (4%)	–	–
Acute Mucositis	Docetaxel	–	–	8 (34.8%)	15 (65.2%)	–
	Cisplatin	–	–	18 (72%)	7 (28%)	–
Acute Skin Reactions	Docetaxel	–	6 (26.1%)	11 (44.8%)	6 (26.1%)	–
	Cisplatin	–	8 (32%)	16 (64%)	1 (4%)	–
Subcutaneous Fibrosis	Docetaxel	–	5 (21.8%)	15 (65.2%)	3 (13%)	–
	Cisplatin	–	12 (48%)	11 (44%)	2 (8%)	–
Xerostomia	Docetaxel	–	6 (26.1%)	16 (69.6%)	1 (4.3%)	–
	Cisplatin	–	7 (28%)	18 (72%)	0	–
Peripheral Sensory neuropathy	Docetaxel	17 (74%)	4 (17.4%)	–	–	–
	Cisplatin	23 (92%)	2 (8%)	–	–	–

## DISCUSSION

Newly diagnosed cases of locally advanced head and neck cancer, which have unresectable nodal disease or individuals who are unfit for surgery, concurrent systemic therapy is considered the standard modality of treatment. Most randomized clinical trials show the superiority of combined RT and chemotherapy to RT alone for the treatment of locally advanced, nonmetastatic HNC and

review of the literature showed a 11% overall reduction in mortality.<sup>13</sup>

Meta-Analysis of Chemotherapy in Head and Neck Cancer has recognized the benefit of use of radiotherapy and concurrent chemotherapy reducing the risk of death and overall improvement in 5-year survival compared to treatment with RT alone.<sup>3</sup> An update of the MACH-NC meta-analysis confirmed the superiority of concurrent

chemoradiotherapy compared with RT alone across all HNC primary sites. The choice of systemic therapy must be individualized based on the patient characteristics. Though the preferred chemoradiotherapy approach in locally advanced disease remains the combination of Cisplatin and radiation,<sup>14,15,16</sup> several clinical trials have been conducted which have explored the use of other chemotherapeutic agents but limited data are available comparing the efficacy of different chemoradiotherapy regimens.

Several Phase I and Phase II trials have explored the use of combining Docetaxel with radiation in treatment of HNC.<sup>17,18</sup> In these studies, it was observed that docetaxel can be used in conjunction with RT with comparable clinical outcome and manageable toxicity profile. In this study, we evaluated the response efficacy and acute as well as late toxicities of two different chemotherapeutic drugs including Docetaxel and Cisplatin given along with RT. The baseline characteristics of patients in our study were alike in both the groups and no significant difference was seen in terms of age, site and disease site.

In group A (Docetaxel+RT), complete response was seen in 34.8% of the patients, partial response in 52.2%, whereas 4.3% of the patients had progressive disease. The overall response achieved was 86%. These results obtained were somewhat similar to phase II clinical trial conducted at Dana-Farber Cancer Institute (Boston, MA),<sup>19</sup> where complete response was seen in 57% of the patients, partial response in 16% and progressive disease in 5% of the patients. The overall response was 86% which was comparable to that obtained in our study. In GORTEC phase II trial (98-02), in carcinoma oropharynx stage III and IV<sup>17</sup> the locoregional control was of 64% which is similar to that seen in our study.

Another study conducted at Christian Medical College (Vellore, India) by Jomon *et al*<sup>20</sup> showed the overall locoregional response at first follow up to be 85% which is similar to that obtained in our study. In group B (Cisplatin+RT), 20% of the patients received complete response whereas partial response was obtained in 60% of the patients and progressive disease was observed in 4% of the total patients. The overall response was 80% in group B. The locoregional disease clearance obtained in our study was better than that

obtained in study conducted by Kumar S *et al*<sup>21</sup> where overall response was 59%. The weekly administration of cisplatin appeared to be well tolerated with less toxicity as compared to intermittent high dose cisplatin reported in phase II RTOG trial.<sup>22</sup> Study conducted by Kang MH *et al*<sup>23</sup> showed overall response to be comparable to that obtained in our study with better toxicity tailoring with weekly Cisplatin as seen in our findings.

The complete response observed in Group A was 34.8%, compared to 20% in Group B, though this difference was not statistically significant (p value 0.25). The partial response rates were 52.2% in Group A and 60% in Group B, also showing no statistical significance (p=0.58). Additionally, the overall response rates in both groups did not show statistical significance (P=0.52). These results align with the data obtained in the study conducted by Liao JF *et al*<sup>24</sup> and Wei *et al*<sup>25</sup>, who analyzed records of 73 stage III-IVA NPC patients to compare the efficacy of chemoradiotherapy with docetaxel and cisplatin, also found no significant difference between the two groups, similar to our findings.

Toxicity evaluation and analysis of study showed that Docetaxel can be used in clinical setting for concurrent chemoradiation with manageable toxicities. Non-haematological toxicities consisted of acute mucositis, peripheral sensory neuropathy, diarrhoea, xerostomia, skin and subcutaneous tissue reactions. The difference in acute mucositis in both the groups was statistically significant (P=0.01) with grade III mucositis seen more in patients who received docetaxel (65.2%) as compared to cisplatin group (28%). This result was in range and comparable to observation of increased incidence of grade III mucositis with Docetaxel as seen in studies conducted by Jomon *et al* (57%)<sup>20</sup> and Liao *et al* (74.5%).<sup>24</sup>

Peripheral sensory neuropathy was found to be more in patients of group A, where grade II neuropathy was observed in 17.4% (4 of 23) of the total patients and the observation was statistically significant (P=0.03). This observation was similar to the correlation of docetaxel and development of peripheral sensory neuropathies at a wide range of dose levels of 10 to 115 mg/m<sup>2</sup> seen in study conducted by New *et al*.<sup>26</sup> Another important toxicity of cisplatin is renal

function impairment, which was measured by monitoring weekly serum creatinine levels.

Creatinine levels were found to be deranged in 56% of the patients of group B, most of whom had grade I renal toxicity (48%). Renal toxicity was found to be higher in cisplatin group of our study as compared to other studies where weekly cisplatin was given concurrently with radiation with only 15.1%<sup>24</sup>, 16.6% and 4.8%<sup>20</sup> (grade II) patients suffered from renal impairment. Also, the difference between group A and B was found to be statistically significant ( $P=0.007$ ) with renal toxicity seen more in group B as was observed in Liao et al study.<sup>24</sup>

In group A, grade II vomiting occurred in 17.4% patients whereas in group B, it was seen in 28% which was comparable to a study conducted in China<sup>24</sup> where vomiting was observed more in patients who received cisplatin than docetaxel. Other non-haematological toxicities like diarrhoea, skin reactions and xerostomia were comparable in both the groups with no significant difference seen in our study.

Haematological toxicity observed were not severe and were manageable. Neutropenia was observed only in 3 (13.1%) patients who received docetaxel. This observation was higher than the incidence seen in GORTEC phase II trial<sup>17</sup> where neutropenia was observed in 3 out of 61 patients whereas the results were comparable to Jomon et al study<sup>20</sup> 13% (n=4) patients suffered from grade III anaemia and none from grade IV anaemia and the incidence in both the groups was statistically insignificant.

The main toxicity observed more in docetaxel group was grade III acute mucositis and acute skin reactions (dermatitis) which were statistically significant, while renal toxicities were markedly less than the cisplatin group which was also statistically significant. All the toxicities were acceptable and manageable and none of the patients dropped out of the treatment due to intolerable adverse reactions.

The use of low dose weekly docetaxel for concurrent chemoradiation in LAHNC patients has slightly better or comparable locoregional response and toxicities with significantly reduced risk of renal complications and vomiting makes it a feasible alternative to cisplatin in patients with impaired renal

functions with only caution of acute mucositis and acute skin reactions

## CONCLUSION

Our study indicates that weekly Docetaxel (20 mg/m<sup>2</sup>) administered concurrently with radiotherapy in patients with locally advanced head and neck cancer demonstrates a favorable toxicity profile and comparable efficacy to weekly Cisplatin. Acute toxicities, primarily mucositis and skin reactions, were consistent with previously reported findings and did not necessitate treatment interruption or dose reduction.

While no significant difference in disease response was observed between the two regimens, toxicity patterns aligned with the respective chemotherapeutic drug classes. The results suggest that Docetaxel may serve as a viable alternative for patients ineligible for Cisplatin, particularly those with renal impairment or ototoxicity risk.

However, due to the limited sample size and follow-up duration, these findings should be interpreted with caution. Further validation through larger phase II/III trials and multicentre studies is warranted to optimize dosing strategies and assess long-term outcomes, including survival benefits.

**Conflict of Interest:** NIL

**Funding:** NIL

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