

Original Research Article

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Hypofractionated radiotherapy with weekly paclitaxel and carboplatin versus conventional fractionation radiotherapy with weekly cisplatin in carcinoma of the larynx and hypopharynx for response and toxicity assessment

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ABSTRACT

Background: Conventional fractionated radiotherapy (CFRT) with weekly cisplatin is the standard of care for locally advanced laryngeal and hypopharyngeal carcinoma but is often limited by significant toxicity. This study evaluates hypofractionated radiotherapy (HFRT) combined with weekly low-dose paclitaxel and carboplatin as a more tolerable alternative. Objective of the study was to compare the tumor response and toxicity profiles of HFRT plus paclitaxel/carboplatin versus CFRT plus cisplatin.

Methods: Sixty-four patients with stage III–IVB carcinoma were randomized into two arms. Arm 1 received HFRT (63 Gy in 28 fractions) with weekly paclitaxel (30 mg/m²) and carboplatin (AUC 1.5). Arm 2 received CFRT (70 Gy in 35 fractions) with weekly cisplatin (30 mg/m²). Response was assessed via RECIST 1.1; toxicities were graded using RTOG/CTCAE criteria.

Results: At 6 weeks post-treatment, the complete response (CR) rate was 71.9% in arm 1 and 68.8% in arm 2. Arm 1 demonstrated a significantly improved safety profile, with lower rates of grade 3 mucositis (28.1% versus 43.8%) and grade 3 leukopenia (15.6% versus 28.1%). Additionally, grade 2 skin reactions (25% versus 37.5%) and nausea/vomiting (31.3% versus 53.1%) were less frequent in arm 1, leading to higher treatment compliance.

Conclusions: HFRT with weekly low-dose paclitaxel/carboplatin offers non-inferior efficacy and superior tolerability compared to standard CFRT. It is a viable therapeutic strategy for elderly or renal-compromised patients and in resource-constrained settings.

Keywords: HFRT, CFRT, CCRT, Low dose paclitaxel and carboplatin, Laryngeal and hypopharyngeal carcinoma, HNSCC, RECIST

INTRODUCTION

Head and neck squamous cell carcinoma (HNSCC) is a major global health challenge, with the larynx and hypopharynx among the most affected subsites.¹ A significant proportion of these patients present with advanced disease requiring aggressive multimodal therapy for optimal outcomes.²

The current standard for locally advanced cases is concurrent chemoradiotherapy (CCRT) with cisplatin, which offers survival benefits of 6.5% (5YOS) compared with radiotherapy alone (meta-analysis MACH-NC, 2009 update) and 37% versus 23% with RT alone (intergroup trial (1998)) but is frequently associated with substantial toxicities renal, hematological, gastrointestinal, and neurotoxic effects leading to treatment delays or discontinuation in many patients.^{3,4}

Hypofractionated radiotherapy (HFRT) which delivers larger doses per fraction over a shorter period, is increasingly being explored in head and neck cancers.^{5,6} This approach potentially counters accelerated tumor repopulation, reduces overall treatment time, improves patient compliance, and optimizes healthcare resource utilization.⁷ Moreover, alternative chemotherapeutic agents like low dose Paclitaxel and Carboplatin have demonstrated radiosensitizing properties with more favorable toxicity profiles than cisplatin.⁸

This study aims to address the limitations of conventional cisplatin-based CCRT by evaluating a new approach. The central hypothesis is that a regimen combining HFRT with weekly low dose Paclitaxel and Carboplatin could provide a viable therapeutic strategy with comparable efficacy but reduced toxicity and improved patient compliance.

Study objectives

The specific objectives of this prospective comparative study are to compare tumor response rates between HFRT with weekly low dose Paclitaxel/Carboplatin versus conventional radiotherapy with weekly cisplatin, assess and compare toxicity profiles of the two regimens and evaluate treatment compliance and tolerability in both treatment arms.

METHODS

Study design and setting

This was a prospective, comparative study conducted at a State Cancer Institute, Chhatrapati Sambhaji Nagar, Maharashtra, India. The primary endpoint was tumor response at 6 weeks, 3,6,12 and 18-months post-treatment, assessed using RECIST 1.1 criteria. Secondary endpoints included the assessment of toxicities using RTOG and CTCAE scoring systems, as well as treatment compliance and tolerability.

Study duration

This study was conducted in between May 2022 to February 2024.

Participants

The study was conducted in accordance with the Declaration of Helsinki, with approval obtained from the Institutional Ethics Committee of the State Cancer Institute, Chhatrapati Sambhaji Nagar. Written informed consent was obtained from all participants before enrollment.

A total of 64 patients were enrolled, with histologically confirmed, non-metastatic squamous cell carcinoma of the larynx or hypopharynx (stage III–IVB), aged ≤ 70 years, with an Eastern Cooperative Oncology Group (ECOG) performance status of 0–2. Patients with prior

chemotherapy or radiotherapy, recurrent disease, distant metastases were excluded.

Randomization and treatment arms

Participants were divided into two treatment arms.

Arm 1 (hypofractionated RT + Pacli/Carbo)

External beam radiotherapy (IMRT) delivering 63 Gy in 28 fractions (2.25 Gy/fraction) over 5.5 weeks, with weekly low dose Paclitaxel (30 mg/m²) and Carboplatin (AUC 1.5).

Arm 2 (conventional RT + Cisplatin)

External beam radiotherapy (IMRT) delivering 70 Gy in 35 fractions (2 Gy/fraction) over 7 weeks, with weekly cisplatin (30 mg/m²).

Radiotherapy technique and target volume delineation

Simulation and immobilization

All patients underwent contrast-enhanced computed tomography (CT) simulation in the supine position with a thermoplastic head-and-shoulder immobilization mask. Axial CT images were acquired at 3-mm slice thickness from the skull base to the carina.

Target delineation

Gross tumor volume (GTV) - included the primary tumor (GTV-P) and involved lymph nodes (GTV-N), as identified on clinical examination, endoscopy, and radiological imaging (CECT/MRI). Clinical target volume (CTV)- CTV was defined as GTV + 5–10 mm margin to account for microscopic spread, modified respecting anatomical barriers. Elective nodal regions were included according to the primary subsite: larynx- levels II–IV (and level VI if subglottic extension) and hypopharynx- levels II–V (with level VI if post-cricoid involvement). Planning target volume (PTV)- generated by adding a uniform 5 mm isotropic margin around CTV to compensate for setup errors and patient motion.

Organs at risk

The spinal cord, brainstem, parotid glands, oral cavity, pharyngeal constrictors, larynx (for hypopharyngeal cases) and mandible were delineated as organs at risk (OARs).

Treatment technique

All patients were treated with IMRT using 6 MV photons delivered on a linear accelerator. Dose constraints for OARs were applied in accordance with QUANTEC and other published recommendations wherever feasible- spinal cord: maximum dose (Dmax) <45 Gy, brainstem: Dmax <54 Gy, parotid glands: mean dose <26 Gy (to at

least one parotid, ideally both), oral cavity: mean dose <40 Gy (to reduce mucositis/xerostomia), pharyngeal constrictors: mean dose <50 Gy (associated with reduced dysphagia), larynx (for hypopharynx cases): mean dose <45 Gy (to minimize edema and dysfunction), mandible: Dmax <70 Gy (to prevent osteoradionecrosis) dose prescription, arm 1 (HFRT + Pacl/Carbo): 63 Gy in 28 fractions (2.25 Gy/fraction), 5 fractions/week over 5.5 weeks, arm 2 (CFRT + Cisplatin): 70 Gy in 35 fractions (2.0 Gy/fraction), 5 fractions/week over 7 weeks. Treatment was delivered once daily, and patients were monitored with weekly clinical examination and toxicity scoring.

Outcome measures

Tumor response

Assessed using RECIST 1.1 via contrast-enhanced computed tomography (CECT) and endoscopic evaluation at 6 weeks, 3, 6, 12 and 18 months post-treatment.

Toxicity evaluation

Toxicities were recorded weekly during treatment and at 6 weeks, 3, 6, 12 and 18 months post-treatment. Toxicities were graded using RTOG radiation morbidity criteria and CTCAE v5.0.

Follow-up schedule

Patients were followed weekly during treatment, then at 6 weeks, 3, 6, 12 and 18 months post-treatment. Supportive measures were provided as needed, including IV fluids, analgesics, feeding tubes, and antibiotics.

Statistical analysis

Categorical variables were analyzed using the Chi-square test. A $p<0.05$ was considered statistically significant. Data were analyzed using appropriate biostatistical software.

RESULTS

A total of 64 patients were enrolled (32 in each arm). The mean age was comparable between the two groups (arm 1: 59.5 ± 9.8 years; arm 2: 59.0 ± 8.9 years). Both groups were well-matched in terms of gender distribution, ECOG performance status, tumor subsite (larynx versus hypopharynx), and TNM staging ($p>0.05$ for all) (Figure 1 and Table 1).

Mucositis: grade ≥ 3 mucositis was observed in 28.1% of patients in arm 1 versus 43.8% in arm 2 ($p=0.18$). Skin reaction: grade ≥ 2 skin toxicity was lower in arm 1 (25%) than in arm 2 (37.5%). Hematologic toxicity: grade ≥ 3 leukopenia occurred in 15.6% of Arm 1 versus 28.1% in

arm 2 ($p=0.22$). GI toxicity: grade ≥ 2 nausea/vomiting was higher in the cisplatin group (arm 2), with more frequent hydration support required (Figure 2 and Table 2).⁹ At 6 months, both groups maintained similar disease control rates. No treatment-related deaths were recorded. Late toxicities, including dysphagia and xerostomia, were comparable between groups (Figure 3 and Table 3). All patients completed planned radiotherapy. Chemotherapy compliance was higher in arm 1, with 90.6% receiving ≥ 5 cycles of low dose Paclitaxel/Carboplatin compared to 78.1% completing ≥ 5 cycles of cisplatin in arm 2. Fewer unplanned treatment interruptions were noted in arm 1 (Figure 4).

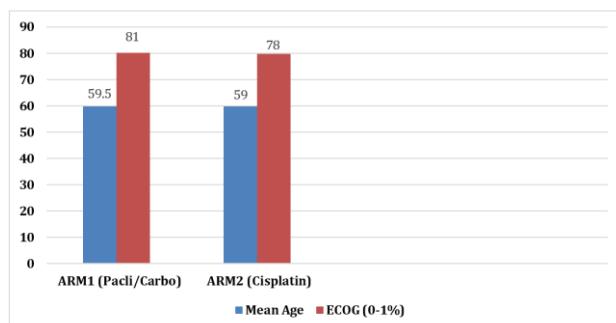


Figure 1: Baseline demographic and clinical characteristics.

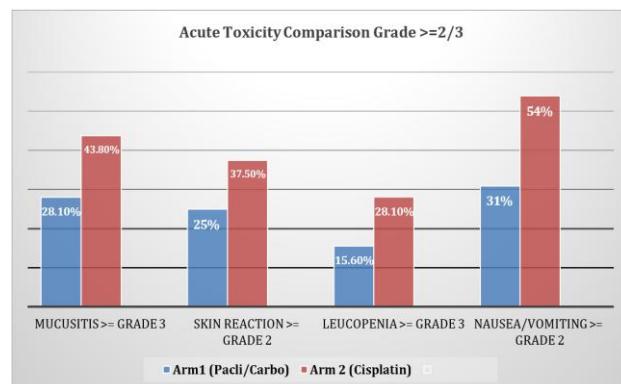


Figure 2: Toxicity grade.

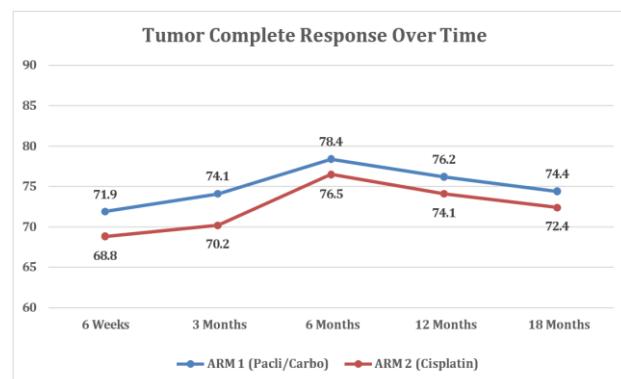


Figure 3: Tumor response comparison (RECIST 1.1).

Table 1: Baseline demographic and clinical characteristics.

Variables	Arm 1 (Pacli/Carbo + HFRT)	Arm 2 (Cisplatin + CFRT)	P value
No. of patients	32	32	
Mean age (years)	59.5±9.8	59.0±8.9	0.94
Gender (M/F)	26/6	25/7	0.77
ECOG 0–1 (%)	81	78	0.68
Tumor site (larynx/hypopharynx)	18/14	20/12	0.63
TNM stage III/IV (%)	62.5 / 37.5	59.4/40.6	0.80

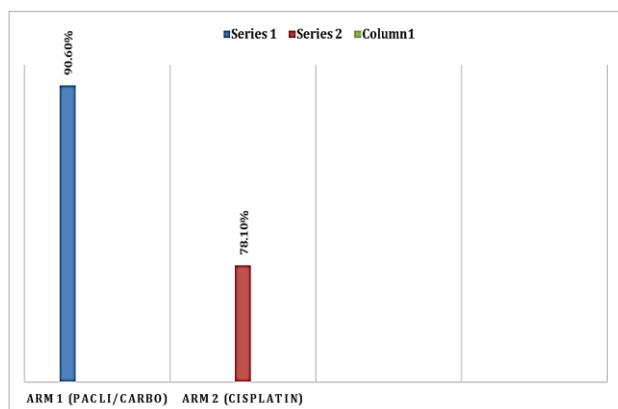
Table 2: Toxicity profile (grade ≥2 or ≥3).

Toxicity type	Grade	Arm 1 (%)	Arm 2 (%)	P value
Mucositis	≥3	28.1	43.8	0.18
Skin reaction	≥2	25.0	37.5	0.29
Leucopenia	≥3	15.6	28.1	0.22
Nausea/vomiting	≥2	31.3	53.1	0.04*
Dysphagia	≥2	34.4	40.6	0.59

*:Statistically significant

Table 3: Tumor response comparison (RECIST 1.1) follow-up.

Time point	Response type	Arm 1 (%)	Arm 2 (%)	P value
6 weeks	CR	71.9	68.8	0.77
	PR	21.9	25.0	
	PD	3.1	3.1	
3 months	CR	74.1	70.2	0.78
6 months	CR	78.4	76.5	1
12 months	CR	76.2	74.1	1
18 months	CR	74.4	72.4	1

**Figure 4: Treatment compliance.**

DISCUSSION

This prospective comparative study evaluated the efficacy, toxicity, and compliance outcomes of HFRT with weekly low dose Paclitaxel and Carboplatin (Pacli/Carbo) versus CFRT with weekly cisplatin in patients with locally advanced squamous cell laryngeal and hypopharyngeal carcinoma. The results demonstrated non-inferior tumor response rates between the two arms, with a favorable trend in toxicity profile and treatment adherence in the HFRT + low dose Paclitaxel/Carboplatin arm.

Hypofractionation involves the delivery of higher radiation doses per fraction over a reduced number of treatment sessions. This approach is increasingly being explored in HNSCC due to its radiobiological advantages, such as countering accelerated tumor repopulation and improving convenience for patients and resource-limited healthcare systems. In the present study, patients in arm 1 received 63 gray (Gy) in 28 fractions (2.25 Gy/fraction), compared to 70 Gy in 35 fractions (2.0 Gy/fraction) in arm 2. The reduced overall treatment time in arm 1 (5.5 weeks versus 7 weeks) can be advantageous, especially for patients in remote areas or with limited socio-economic support.

Tumor response was assessed using the RECIST version 1.1, and complete response (CR) rates were comparable between both arms (71.9% in arm 1 versus 68.8% in arm 2; $p=0.77$). These findings suggest that the hypofractionated regimen, in combination with low dose Paclitaxel and Carboplatin, does not compromise oncologic efficacy.¹⁰

The toxicity profile is a critical determinant of treatment compliance in CCRT. In this study, toxicities such as grade ≥ 3 mucositis (28.1% in arm 1 versus 43.8% in arm 2) and hematological toxicities including leukopenia (15.6% versus 28.1%) were significantly lower in the

hypofractionated arm. These results are consistent with existing literature reporting higher toxicity rates with cisplatin-based CCRT, particularly renal, hematologic, and gastrointestinal (GI) side effects.^{11,12} Furthermore, more patients in arm 1 completed ≥ 5 cycles of chemotherapy (90.6%) compared to arm 2 (78.1%), indicating better tolerability and fewer treatment interruptions.

The choice of chemotherapy agents is another important factor. Low dose Paclitaxel and Carboplatin are known to have radiosensitizing properties with a more favorable toxicity profile than cisplatin. The combination is especially useful in patients who are elderly, have pre-existing renal dysfunction, or cannot tolerate cisplatin due to comorbidities.^{13,14} While cisplatin remains the standard of care, these results highlight the potential role of alternative agents in patients unsuitable for cisplatin.

Rationale for using low dose Paclitaxel and Carboplatin

Low dose weekly Paclitaxel and Carboplatin were selected as concurrent agents in this study due to their established radio sensitizing properties and more manageable toxicity profile compared to cisplatin. Low dose Paclitaxel promotes radio sensitization by arresting tumor cells in the G2/M phase—the most radiosensitive phase of the cell cycle—thereby enhancing radiation-induced cytotoxicity. Carboplatin complements this effect through the formation of DNA adducts, which inhibit DNA repair after irradiation.

The use of low weekly doses (low dose Paclitaxel 30 mg/m² + Carboplatin AUC 1.5) has been supported in multiple phase II trials demonstrating effective tumor control with reduced nephrotoxicity, neurotoxicity, and ototoxicity compared to high-dose cisplatin.¹⁵ This regimen is particularly advantageous for patients with borderline performance status, elderly patients, or those with renal dysfunction who cannot tolerate cisplatin.

Additionally, low-dose weekly scheduling improves compliance by minimizing severe toxicities (such as mucositis, nausea, and hematologic suppression) and reducing the need for intensive supportive care. The better tolerability translates into fewer unplanned treatment interruptions, ensuring that the therapeutic intensity of concurrent chemoradiation is maintained. Even at low doses low dose Paclitaxel/carboplatin shown to maintain their radio sensitizing properties.

The use of low dose Paclitaxel and Carboplatin as concurrent radiosensitizers was initially explored in carcinoma esophagus, particularly in the landmark CROSS trial, where weekly low dose Paclitaxel (50 mg/m²) and Carboplatin (AUC 2) with concurrent radiotherapy demonstrated significant improvements in pathological complete response and overall survival, with a favorable toxicity profile compared to traditional cisplatin/5-FU-based chemoradiation.¹⁶

This success in esophageal cancer provided the biological and clinical basis for extrapolating the regimen to other squamous cell carcinomas of the aerodigestive tract, including laryngeal and hypopharyngeal cancers, which share similar radiosensitivity and histopathological characteristics.

Based on these results, it was hypothesized that low-dose weekly low dose Paclitaxel + Carboplatin could achieve effective radio sensitization in head and neck squamous cell carcinoma, while reducing renal, ototoxic, and gastrointestinal toxicities commonly associated with cisplatin. This rationale underpins the design of the current study.

Our findings align with previous studies such as those by Rawal et al and Gupta et al which reported equivalent response rates with hypofractionated schedules and improved toxicity profiles.^{17,18} Importantly, our study contributes real-world evidence from a government cancer center in a resource-limited setting, underlining the practicality of HFRT in daily oncology practice.

Comparison with cisplatin-based chemoradiotherapy in literature

Concurrent chemoradiation with cisplatin remains the standard of care for locally advanced laryngeal and hypopharyngeal carcinoma. Reported complete response (CR) rates with conventional fractionated radiotherapy (70 Gy in 35 fractions) and weekly or 3-weekly cisplatin range from 65% to 80% in published series.

RTOG and MACH-NC meta-analyses have shown that cisplatin-based CCRT provides an absolute survival benefit of 6–8% at 5 years, with locoregional control rates translating into CR rates around 70% in laryngeal/hypopharyngeal subsites.^{19,20}

Indian and Asian studies (Agarwal et al and Gupta et al) also reported CR rates between 68–75% at 3–6 months post-treatment, albeit with high rates of grade ≥ 3 mucositis and hematologic toxicity.^{21,22}

In our study, the cisplatin arm achieved a CR rate of 68.8% at 6 weeks, consistent with published literature. Importantly, the hypofractionated low dose Paclitaxel/Carboplatin arm achieved a comparable CR rate of 71.9%, with similar disease control up to 18 months, but with a trend toward lower grade ≥ 3 mucositis (28.1% versus 43.8%) and leukopenia (15.6% versus 28.1%).

These findings suggest that while cisplatin-based CCRT remains highly effective, weekly low-dose low dose Paclitaxel/Carboplatin with HFRT offers non-inferior tumor response rates with a more favorable toxicity profile and better treatment compliance, making it an attractive alternative in selected patients (elderly, renal dysfunction, or cisplatin-ineligible cases).

In addition to clinical outcomes, the implications for healthcare resource utilization are noteworthy. HFRT can reduce the burden on radiotherapy machines and personnel, increase patient throughput, and decrease overall treatment cost.²⁸ In low- and middle-income countries (LMICs), where radiotherapy infrastructure is often overburdened, this could improve accessibility to timely cancer care.

However, some limitations must be acknowledged. The study's follow-up duration was limited to eighteen months, which is insufficient for assessing long-term outcomes such as locoregional control, disease-free survival, and late radiation-related toxicities. Furthermore, the study was single-institutional, which may introduce biases in patient selection and treatment administration. Larger, multicentric trials with extended follow-up are required to validate these findings and establish HFRT + Pacl/Carbo as a potential standard in suitable patient populations.²⁴

Several prior studies have suggested that hypofractionated regimens may offer logistical and radiobiological advantages, particularly in resource-constrained settings. In our study, although complete response rates at 6 weeks, 3, 6, 12 and 18 months post-treatment were not statistically different, the slightly higher compliance and lower incidence of severe toxicities in the HFRT arm suggest a potential clinical benefit. Notably, grade ≥ 3 mucositis and leukopenia were more common in the cisplatin group, aligning with known toxicity profiles of platinum-based chemoradiation.

The combination of low dose Paclitaxel and Carboplatin demonstrated acceptable radio-sensitizing efficacy with a more favorable side effect profile, supporting its consideration as an alternative in patients. This is particularly relevant given the challenges of maintaining nutritional status, hydration, and renal function in head and neck cancer patients undergoing treatment.^{25,26}

Our findings also reaffirm the practical benefits of hypofractionation, including reduced overall treatment time, improved patient throughput, and possibly better compliance—an important factor in low- and middle-income countries where radiotherapy access may be limited.^{27,28}

Despite these limitations, the results support the feasibility and safety of using hypofractionated chemoradiotherapy with low dose Paclitaxel and Carboplatin as a viable alternative to the conventional cisplatin-based regimen in patients with locally advanced laryngeal and hypopharyngeal cancers.

CONCLUSION

HFRT with weekly low dose Paclitaxel and Carboplatin has demonstrated favorable tolerability and non-inferior efficacy as compared to CFRT with cisplatin in locally advanced laryngeal and hypopharyngeal carcinoma,

especially in resource-constrained settings. The favorable tolerability of this regimen suggests it may be a valuable option for elderly or renal compromised patients.

Given its shorter treatment duration and manageable side effects, this approach may be particularly advantageous in settings with limited healthcare resources, in elderly patients, and in those with renal compromise who are often ineligible for cisplatin. Further large-scale, randomized studies with extended follow-up are warranted to confirm long-term outcomes and establish the role of HFRT as a standard treatment option in locally advanced laryngeal and hypopharyngeal carcinoma.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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