

ORIGINAL RESEARCH ARTICLE

Radiation therapy in head and neck with telecobalt beam quality: Tolerance to 70 Gy dose in a five-week overall treatment time

Ravi Kannan¹, Ramamoorthy Ravichandran^{2*}, Kapil Malik¹, Tarani Mondal², Gopal Datta², Subramania Vijayakanth¹, Talagadadeevi V.S.S.K. Bharath¹, Abhishek Kesha¹, LamLynti Dkhar², and Soumya Brata Deb²

¹Department of Surgical Oncology, Cachar Cancer Hospital and Research Centre, Silchar, Assam, India

²Department of Radiation Oncology, Cachar Cancer Hospital and Research Centre, Silchar, Assam, India

Abstract

Head and neck malignancies are associated with accelerated tumor repopulation when overall treatment time (OTT) extends beyond 28 days, potentially compromising the effectiveness of radiotherapy. To address this limitation, a treatment strategy was developed to reduce OTT by delivering a total radiation dose of 70 Gy over five weeks. In a pilot study involving high-grade head and neck malignancies, a total dose of 70 Gy was delivered using cobalt radiotherapy with tissue compensation at 2 Gy per fraction, administered either 7 fractions/week or 6 fractions/week. Good compliance with the full 70 Gy treatment course was observed. Radiation sequelae in the 7 fractions/week group included Grade III skin reactions in 16% of patients and Grade III mucositis in 26%, both considered acceptable. Based on these results, a randomized non-inferiority trial was conducted to compare acute toxicities between the 7 fractions/week and 5 fractions/week treatment arms, both delivering a total dose of 70 Gy. A total of 107 patients receiving concomitant chemoradiotherapy (CTRT) and 34 patients receiving neoadjuvant chemotherapy followed by concomitant chemoradiotherapy (NACT-CTRT) were treated with 70 Gy over five weeks. Another 99 CTRT patients and 42 NACT-CTRT patients received the same total dose of 70 Gy over seven weeks. In the 7 fractions/week arm, the observed Grade III–IV skin toxicity was 1.6%, and Grade III–IV mucosal toxicity was 12.7%, both significantly lower than the literature-reported value of 69% ($p < 0.0001$). For the 5 fractions/week arm, Grade III–IV skin toxicity was 3.2%, while Grade III–IV mucosal toxicity was <2.0%. Patient compliance was good in the 7 fractions/week study arm. As the tumor biologically effective dose increased by 19.4% (77.7 Gy [7 fractions/week] vs. 65.1 Gy [5 fractions/week]), improved local control is expected. Objective follow-up of this cohort is necessary to evaluate local control.

Keywords: Head and neck radiotherapy; Reduction in overall treatment time; Changed fractionation; Biologically effective dose; Telecobalt

***Corresponding author:**
Ramamoorthy Ravichandran
(ravichandranrama@rediffmail.com)

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1. Introduction

Head and neck squamous cell carcinoma constitutes a major oncologic burden in India, with most patients presenting at an advanced stage requiring multimodality treatment. These patients are treated either with concomitant chemoradiotherapy (CTRT) or with surgical resection followed by adjuvant radiotherapy. Radiotherapy is also used for organ preservation, allowing avoidance of laryngectomy through the use of chemoradiotherapy. Chemotherapeutic drugs provide additive tumor cell killing with a synergistic effect when administered concurrently with megavoltage radiotherapy. However, they also increase treatment-related toxicity, thereby altering the therapeutic index of the overall treatment. Platinum-based agents are the most commonly used chemotherapeutic drugs for advanced head and neck cancers.^{1,2} The current standard of care for locally advanced head and neck squamous cell carcinoma is CTRT, consisting of conventionally fractionated radiotherapy (70 Gy in 35 fractions, 5 fractions per week over 7 weeks) with concurrent cisplatin chemotherapy. This protocol includes a 2-day break on Saturdays and Sundays. For head and neck cancers, radiotherapy is administered using high-energy electron linear accelerators with 6 MV photons. Despite its efficacy, prolonged treatment duration often leads to compliance issues, particularly in resource-constrained settings with limited radiotherapy machine availability and high patient load.

Altered fractionation schedules, including hyper-fractionation, hypo-fractionation, and accelerated fractionation, have been investigated to improve tumor control by reducing the effect of accelerated repopulation.^{3,4} Hyper-fractionation exploits the difference in the rate of repair between normal tissue and tumor, with improvements in the radiobiology of re-oxygenation and re-distribution. Accelerated fractionation, in particular, has demonstrated improved loco-regional control in several trials, though often at the cost of increased acute toxicities. The rationale is to counteract accelerated repopulation in terms of radiobiology. In a controlled, randomized trial⁵, the effect of five fractions per week and six fractions per week at the same total dose of 66–68 Gy, with 2 Gy fractions, was investigated along with the hypoxic radiosensitizer nimorazole. The reduction in treatment time improved primary tumor control from 64% with five fractions per week to 76% with six fractions per week, representing a statistically significant improvement. Different altered radiation fractionation schemes have been shown to improve locoregional control rates in patients with squamous cell carcinoma of the head and neck compared with standard fractionation of 70 Gy.⁶

When combined with chemotherapy, however, the survival benefit of altered fractionation compared to conventional regimens is less clear.

At our center, nearly 60% of patients belong to socioeconomically disadvantaged groups, where reduction in total treatment time could translate into lower indirect costs, reduced treatment default rates, and improved compliance. Radical management in head and neck malignancy by radiation therapy has been an established practice for many decades. The problem in not achieving local control of disease is due to incomplete completion of the planned dose within the planned treatment duration. The main reason for this is radiation reactions in terms of skin and mucosal morbidity, giving rise to interruptions of the radiotherapy course.

Telecobalt therapy has been used in India since the 1960s and continues to remain an important radiotherapy modality. Approximately 150 telecobalt machines are currently operational across various regions of the country.⁷ Many experts recommend continuing cobalt radiotherapy because of similar radiobiological effectiveness, simplicity, and lower maintenance costs.⁸ The literature indicates that, for the tissue thickness encountered in the head and neck region, cobalt beam quality can offer satisfactory dose delivery patterns for managing these malignancies. The entire neck should be irradiated to the full prescribed dose, as treatment failures may occur when certain regions are shielded from the radical dose. In telecobalt radiotherapy, parallel-opposed beam arrangements help spare critical structures, such as the spinal cord, from the primary radiation field while maintaining setup reproducibility across multiple fractions, thereby ensuring accurate dose delivery. A review of the literature comparing telecobalt and linear accelerators.^{9,10} shows that cobalt photon quality has special advantages in head and neck cancers. A study of 1,452 patients showed that local control rates in the neck improved for high-risk patients (extra capsular extension, more than two nodes positive, and/or T4 primary).⁹ A comparative study¹⁰ involving 392 patients evaluated the effects of different photon beam qualities, including Co-60, 4 MV, and 6 MV beams. The results showed no apparent differences in acute or late toxicity and no significant variation in loco-regional control among the different beam qualities. These findings supported the continued use of telecobalt machines for clinical treatment of head and neck cancers.

Previously, we investigated the effect of thermoplastic immobilization devices placed within the radiation beam path during head and neck radiotherapy.¹¹ Patients were divided into four groups: (i) those treated with thermoplastic casts alone, (ii) those treated with

thermoplastic casts and aluminum tissue compensation (ATC), (iii) those treated with thermoplastic casts with a cut-out window in the radiation field, and (iv) those treated with cut-window immobilization combined with ATC. Two important findings were observed: (i) the use of cut-window immobilization with ATC significantly reduced skin and mucosal reactions, and (ii) patients in this group were able to complete the planned radical radiotherapy course of 35 fractions within the intended overall treatment time (OTT) of seven weeks.

Based on these results¹¹, we recommended that cobalt beam quality could be used to deliver radical doses to the head and neck region with tissue compensation to reduce hot spots, while preserving dose build-up through the use of cut-window thermoplastic immobilization. In a pilot study, it was demonstrated that a total dose of 70 Gy could be delivered using accelerated fractionation schedules of 6 fractions/week or 7 fractions/week, with acceptable morbidity comparable to conventional fractionation of 5 fractions/week over an OTT of seven weeks.¹² Among the 92 patients treated with 7 fractions/week, chemo-radiation demonstrated manageable acute toxicities, with Grade III mucositis and skin reaction occurring in only about 10% of patients.¹²

In the same study, the impact of accelerated fractionation on biological dose was evaluated using the linear quadratic model. Reducing the OTT from 49 days to 42 and 35 days increased the tumor biologically effective dose (BED) by approximately 9.7% and 19.4%, respectively, compared with the conventional 5 fractions/week regimen. For a total dose of 70 Gy, the estimated BED_{tumor} values were 65.1 Gy₁₀, 71.4 Gy₁₀, and 77.7 Gy₁₀ for the 5, 6, and 7 fractions/week schedules, respectively. The corresponding BED_{acute} values were 71.8 Gy₁₀, 73.5 Gy₁₀, and 75.3 Gy₁₀, while the BED_{late} remained constant at 116.7 Gy₃ across all schedules because the fraction size was maintained at 2 Gy per fraction. Accordingly, the BED_{acute}/BED_{tumor} ratio decreased from 1.103 for the 49-day OTT regimen to 1.029 and 0.969 for the 42- and 35-day regimens, respectively, suggesting a progressive improvement in the therapeutic ratio with increasing treatment acceleration. These findings supported the feasibility of delivering 70 Gy using 6 or 7 fractions/week schedules while maintaining acceptable normal tissue toxicity. The 92 patients treated with a 7 fractions/week regimen demonstrated manageable acute toxicities, with no Grade IV skin reactions or mucositis observed. Grade III skin reactions and mucositis occurred in 16% and 26% of patients, respectively, supporting the feasibility of accelerated fractionation with acceptable acute morbidity.

These toxicities were comparable to those observed with conventional 5 fractions/week fractionation using the

same total dose and treatment technique, including tissue compensation with parallel-opposed fields, in our earlier patient cohort.¹³ Skin and mucosal morbidities were also compared with earlier linear accelerator studies.^{14,15} A comparative linac-based study using a total dose of 63 Gy at 1.8 Gy/fraction delivered at 1.8 Gy/fraction over 5 weeks (7 fractions/week; 139 patients) versus the same total dose delivered over 7 weeks (5 fractions/week; 140 patients) demonstrated acceptable acute and late toxicities in the accelerated 7 fractions/week arm.¹⁵ However, confluent mucositis was more frequent in the 7 fractions/week arm (60%) compared with the 5 fractions/week arm (33.3%). Similarly, another randomized linac study involving 140 patients reported significantly higher rates of confluent mucositis in the 7 fractions/week group (94%) compared with the 5 fractions/week group (53%).¹⁶ When 2 Gy/fraction was used, radiation necrosis developed in 22% of 7 fractions/week test arm patients, as a late effect at five years. In contrast, our pilot study¹² using cobalt-based parallel-opposed treatment plans did not demonstrate an increased incidence of confluent mucositis with accelerated fractionation.

Another study used an accelerated fractionated concomitant boost treatment plan that was applied in a randomized group of head and neck radiotherapy patients.¹⁷ The conventional arm was administered a 66 Gy total dose at 5 fractions/week with a daily fraction of 2 Gy, completing in 6.5 weeks. The test arm was given a total dose of 67.5 Gy in 40 fractions over five weeks. In the first five weeks, a dose of 45 Gy in 25 fractions/5 weeks (phase I) was delivered, followed by 22.5 Gy/15 fractions added as a second daily fraction after a six-h gap (phase II) in three weeks. Grade III mucositis was reported in 35% of patients in the concomitant boost arm compared to a 19% incidence in conventional arm treatments.

These results¹² formed the foundation for designing a “phase III randomized non-inferiority trial” comparing accelerated (7 fractions/week) and conventional (5 fractions/week) CTRT schedules in locally advanced head and neck squamous cell carcinoma. Both treatment arms used cobalt-60 beam quality, with all other parameters, including treatment technique, concomitant chemotherapy, and neoadjuvant chemotherapy (NACT-CTRT), kept identical between the two groups. This study summarizes the short-term outcomes, treatment compliance, and treatment-related toxicities.

2. Materials and methods

2.1. Radiation therapy with cobalt machine

A Theratron 780E rotational-type cobalt machine (MDS Nordion, Canada) was used with a dose rate of 120 cGy/

min at an 80 cm isocenter. The radiotherapy technique used for treatment of these patients is a simple pair of parallel, opposed rectangular fields. Tumor localization and staging were performed using X-ray computed tomography (Siemens Healthineers, Germany). Radiotherapy fields were confirmed using a conventional isocentric simulator X-ray machine (Panacea Medical Technologies, India). Field sizes used were around $10 \times 20 \text{ cm}^2$ for 22 fractions (to 44 Gy); $7 \times 20 \text{ cm}^2$ for 6 fractions (to 56 Gy); and the remaining $7 \times 7 \text{ cm}^2$ for 7 fractions (to completion of 70 Gy). The entire treatment was delivered using custom-built ATC filters (Figure 1) mounted on the shadow tray at 45 cm from the source. The Orfit immobilization mold was cut in the primary radiation field area to preserve the build-up advantage of the cobalt beam. This approach provided physical intensity modulation to compensate for variations in tissue thickness and contour while maintaining dose uniformity.



Figure 1. Custom-built aluminum tissue compensator

2.2. Assessment of assembled aluminum tissue compensation filter accuracy

Each patient has a grid of tissue-deficiency values measured using a special jig and bamboo sticks. For a few randomly selected patients, the custom-built ATC plate was kept in the shadow tray, and measurements were performed with/without the tray radiation field analyzer. Measured attenuation in radiation profiles was multiplied by excess transmission factors, and efficacy of the ATCs was checked. Figure 2 shows the verification radiation field analyzer plots, which show the accuracy of the assembled ATC filter.

2.3. Chemotherapy

All patients received weekly cisplatin at 40 mg/m^2 intravenous infusion concurrently with radiotherapy. Cisplatin was administered with standard pre- and post-hydration protocols and appropriate antiemetic prophylaxis (5-hydroxytryptamine 3 antagonist, corticosteroid, with or without NK1 receptor antagonist for delayed emesis). In the

7 fractions/week group, five cycles of weekly cisplatin were administered. In the 5 fractions/week group, seven cycles of weekly cisplatin were administered. Dose modifications were implemented according to the protocol in the event of hematological, renal, neurological, or other treatment-related toxicities. Chemotherapy was withheld if absolute neutrophil count was $<1,200/\text{mm}^3$, platelets $<75,000/\text{mm}^3$, serum creatinine $>1.5 \text{ mg/dL}$ or creatinine clearance $<40 \text{ mL/min}$, or in case of grade $\geq \text{III}$ non-hematological toxicities attributable to cisplatin. Radiation was continued wherever feasible.

2.4. Study protocol

This study was approved by the Institutional Research Board (IRB) of CCHRC (Approval No. CCHRC/IRB/017/2021), dated March 5, 2021. Patients were randomly allocated by the clinical trial department to the 7 fractions/week or 5 fractions/week arms after obtaining informed consent. The required sample size was determined based on statistical requirements. A total of 530 patients (265 per arm) were planned, based on an expected acute toxicity rate of 69% from the GORTEC study¹⁴ and an additional 12% allowance for accrual loss ($n = 64$). This study followed a similar comparative approach to the earlier GORTEC trial, which reported 69% acute toxicity in the 7 fractions/week arm.¹⁴ The inclusion criteria for patients are shown in Table 1. An interim analysis was conducted to assess radiation sequelae in the two treatment arms after accrual of 282 patients (141 patients in each arm) from 2022–2024. This sample size was comparable to that of a previous 7 fractions/week study, which included 279 patients.¹⁵ Due to radioactive decay, the dose rate output in the cobalt machine was reduced, requiring increased treatment time per field. Therefore, the trial was discontinued despite the planned accrual of 530 patients. Skin and mucosal reactions were assessed using Radiotherapy Oncology Group grading, recorded in the respective case records and subsequently reviewed during analysis.

Table 1. Details of selected patients in this research study

Criterion	Classification	Details
A	Sites	Oropharynx, hypopharynx, larynx
B	Age	>18 years and <70 years
C	Histology	Squamous cell carcinomas only
D	Stage	American Joint Committee on Cancer Stage III or IV a/b
E	TNM	T2, N1–2, M0; T3–4, N1–2–3, M0;
F	Performance	Karnofsky Performance Status >60
G	Prior treatments	No prior radiotherapy or surgery, except for diagnostic biopsy

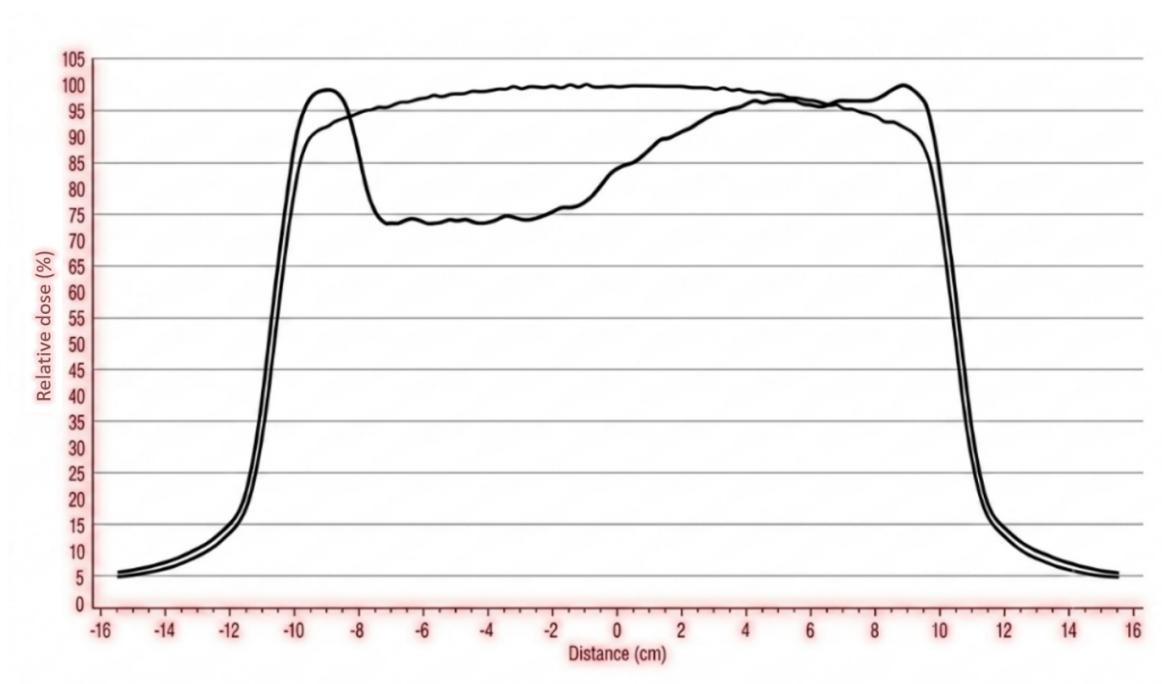


Figure 2. Cobalt radiation beam profile with aluminum tissue compensation after applying transmission factors for tissue thickness variations. Restoration of the original beam profile confirms the quality assurance of the manually assembled aluminum compensating blocks.

2.5. Details and distribution of patients

The total number of patients analyzed was 282, of whom 236 (83.7%) were males, and 46 (16.3%) were females. A total of 107 CTRT and 34 NACT-CTRT patients received treatment with 70 Gy over five weeks, at 7 fractions/week (Arm A), while 99 CTRT and 42 NACT-CTRT patients received the same dose of 70 Gy over seven weeks, at 5 fractions/week (Arm B) (total 141 each). There was no difference in the planned total dose of 70 Gy. Patient classification is summarized in [Table 2](#).

The male patients ranged in age from 31 to 73 years, with a mean age of 56 years, while female patients ranged from 35 to 70 years, with a mean age of 54 years. Histologically, the distribution of primary tumor sites was as follows: in the CTRT group, 43.2% had oropharyngeal cancer, 41.7% had hypopharyngeal cancer, and 15.0% had laryngeal cancer; in the NACT-CTRT group, 59.2% had oropharyngeal cancer, 35.5% had hypopharyngeal cancer, and 5.3% had laryngeal cancer. Overall, 206 patients (73%) received CTRT, while 76 patients (27%) received NACT-CTRT. Patient selection was based on histopathological classification of clinically high-grade head and neck malignancies. The study population comprised 131 (46.4%) patients with stage 3 disease and 151 (53.6%) patients with stage 4 disease, out of total of 282 patients.

Table 2. Patient classification in the phase III clinical trial

Variables	Number of patients	
	CTRT (n = 206)	NACT-CTRT (n = 76)
Patient classification		
Male	107 (51.9%)	34 (44.7%)
Female	99 (48.1%)	42 (55.3%)
Total	206 (100%)	76 (100%)
Site		
Oropharynx	89 (43.2%)	45 (59.2%)
Hypopharynx	86 (41.7%)	27 (35.5%)
Larynx	31 (15.0%)	4 (5.3%)
Stage		
3	124 (60.2%)	7 (9.2%)
4	82 (39.8%)	69 (90.8%)

Note: Total number of patients included is 282 (236 males and 46 females).

Abbreviations: CTRT: Concomitant chemoradiotherapy; NACT-CTRT: Neoadjuvant chemotherapy followed by concomitant chemoradiotherapy.

3. Results

During the analysis, there were variations in the OTT to complete the planned dose of 70 Gy. Tables 3 and 4 show the actual OTT in both arms. It was observed that 79.7% in the CTRT group and 77.0 % in the NACT-CTRT group (Table 3) finished their treatment within 34–40 days (about 5 weeks). A total of 84.4% in the CTRT group and 80% in the NACT-CTRT group finished their treatment within 47–50 days (7 weeks) (Table 4). This clearly showed that patient compliance is satisfactory in both arms. The acute toxicities in both arms were comparable.

Figure 3 shows the texture of skin at the completion of 70 Gy in the 5 fractions/week group during the initial use of ATC in head and neck cobalt treatments. Tables 5 and 6 show the grading of toxicities observed in the 7 fractions/week and 5 fractions/week arms. Grade III skin toxicity was observed in 1.6% of patients in the 7 fractions/week arm and 3.2% in the 5 fractions/week arm, with no Grade IV skin toxicity in either arm. Grade III mucosal toxicity was observed in 12.7% of patients in the 7 fractions/week

arm compared with <1.0% in the 5 fractions/week arm. Pneumonia occurrence in the total cohort is presented in Table 7, with similar incidence in both arms. A total of 26 deaths were recorded during the trial, with the cause of death documented in 11 patients. The causes of death appeared unrelated to radiation treatment (Table 8).



Figure 3. Patient's skin status at completion of 70 Gy. He received the full dose of 70 Gy without breaks in seven weeks overall treatment time, at a daily dose of 2 Gy/fraction.

Table 3. Actual overall treatment time observed in the 7 fractions/week (Arm A) patients

Actual overall treatment time days	CTRT group patients		NACT-CTRT group patients	
	Number	%	Number	%
<30 days	6	5.8%	0	0
30–33 days	3	2.9%	2	5.9%
34 days	54	52.5%	1	2.9%
35 days	8	7.8%	16	47.1%
>35 days	20	19.4%	9	26.5%
>40 days	12	11.7%	6	17.6%

Note: Number of patients correspond to available patients who were treated/assessed, excluding deaths.

Abbreviations: CTRT: Concomitant chemoradiotherapy; NACT-CTRT: Neoadjuvant chemotherapy followed by concomitant chemoradiotherapy.

Table 4. Actual overall treatment time observed in the 5 fractions/week (Arm B) patients

Actual overall treatment time days	CTRT group patients		NACT-CTRT group patients	
	Number	%	Number	%
<40 days	6	6.7%	5	12.8%
<47 days	46	51.1%	19	48.7%
47 days	19	21.1%	7	17.9%
>50 days	11	12.2%	6	15.4%
>55 days	8	8.9%	2	5.1%

Note: Number of patients correspond to available patients who were treated/assessed, excluding deaths.

Abbreviations: CTRT: Concomitant chemoradiotherapy; NACT-CTRT: Neoadjuvant chemotherapy followed by concomitant chemoradiotherapy.

Table 5. Acute toxicities recorded in Arm A (7 fractions/week) patients

Grades	Acute toxicity skin		Grades	Acute toxicity mucosa	
	Patients	%		Patients	%
0	1	<1.0%	0	1	<1.0%
I	82	65.1%	I	15	11.9%
II	41	32.5%	II	94	74.6%
III	2	1.6%	III	16	12.7%
IV	0	0.0%	IV	0	0.0%
Missing	15	–	Missing	15	–

Note: Number of patients correspond to available patients who were treated/assessed, excluding deaths.

Table 6. Acute toxicities recorded in Arm B (5 fractions/week) patients

Grades	Acute toxicity skin		Grades	Acute toxicity mucosa	
	Patients	%		Patients	%
0	5	4.0%	0	2	1.6%
I	70	55.6%	I	23	18.3%
II	47	37.3%	II	99	78.6%
III	4	3.2%	III	1	<1.0%
IV	0	0.0%	IV	1	<1.0%
Missing	15	–	Missing	15	–

Note: Number of patients correspond to available patients who were treated/assessed, excluding deaths.

Table 7. Pneumonia toxicity record

Arm	Number	Remarks
A		
Yes	9	9/49 (18.4%) evaluable patients developed pneumonia
No	40	
Missing	92	
B		
Yes	11	11/52 (21.1%) evaluable patients developed pneumonia
No	41	
Missing	89	

Table 8. Both Arms A and B recorded deaths

Total deaths	Reasons recorded	Reasons available in case records
26/282 (9.2%)	11	Advanced disease ($n = 3$)
		Tumor bleed ($n = 1$)
		Cardiac arrest ($n = 2$)
		Sepsis ($n = 3$)
		Respiratory failure ($n = 1$)
		Aspiration pneumonia ($n = 1$)

4. Discussion

The study evaluated whether accelerated telecobalt radiotherapy, delivered as 7 fractions/week to 70 Gy over five weeks, is tolerable for locally advanced head and neck cancers. It compared skin and mucosal toxicities with conventional schedules, emphasizing tissue compensation, patient compliance, shortened treatment time, and future local-control assessment. Our clinical trial has shown patient compliance with 7 fractions/week radiotherapy treatments, with very low short-term morbidities both for entrance skin and the mucosa, suggesting that this could be practiced for high-grade head and neck malignancies. Short-term follow-up for 1–2 years has shown that patients tolerated their full course well. With cobalt teletherapy, a total dose of 70 Gy could be delivered within an OTT of 35 days, which may enhance tumor control through an increased BED_{tumor} resulting from the reduction in OTT by two weeks. As the fraction size was maintained at 2 Gy, no additional late effects would be expected solely from the increased number of fractions per week; however, long-term follow-up of patients in this trial arm is required to confirm this. The findings also suggest that weekend treatment interruptions unnecessarily prolong the cumulative interfraction interval and may adversely affect tumor control in head and neck radiotherapy. A

24-h interval between 2-Gy fractions appeared to allow adequate repair of acute tissue damage.

There is no overlap between the previous pilot group of patients and the current patients. The pilot study grouped 92 patients into the 7 fractions/week arm and 24 patients into the 6 fractions/week arm, with no patients in the 5 fractions/week arm. The present cohort of patients was randomly grouped into the 7 fractions/week (141 patients) arm and the 5 fractions/week (141 patients) arm.

Oncological outcomes for the two groups of 141 patients are not reported for two reasons: (i) the objective of this report is to evaluate treatment tolerance, compliance, and toxicity with 7 fractions/week versus 5 fractions/week, reducing the overall treatment time from 49 to 35 days while maintaining the same total dose of 70 Gy; and (ii) the follow-up period was insufficient to assess outcomes such as local control and survival, as the study concluded only in 2024. However, the earlier pilot study has reported some data on outcomes¹³: mean survival: 1,005 days (2.75 years); median survival: 841 days (2.3 years). The survival rates at 6 months, 1 year, and 2 years were 80.2%, 71.4%, and 53.8%, respectively. At three months post-treatment, 50% of patients demonstrated complete clinical response at both the primary site and neck, and 12% had residual disease at the primary site with complete response in the neck.

In an earlier study¹⁴, conducted on patients recruited between 1994 and 1998, 268 patients were randomly assigned to two regimens: (i) 70 Gy in 35 fractions of 2 Gy over 49 days; or (ii) 62–64 Gy in 30–32 fractions of 2 Gy, delivered as two fractions per day over 22–23 days. The accelerated regimen showed a 24% improvement in locoregional control. However, no significant differences

in disease-free survival or overall survival were observed between the two arms, and no difference in late effects was reported.

A previous study on 7 fractions/week with a linear accelerator (with a 6 MV photon beam) was conducted with Orfit thermoplastic material immobilization, which is obligatory to compensate for the 15 mm dose build-up of 6 MV. A total dose of only 63–64 Gy at 1.8 Gy/fraction (about 10% reduced total dose) was prescribed. The previous study reported a mucosal reaction incidence of about 69%¹⁴, whereas in our present results, it did not exceed 13% in the 7 fractions/week arm compared to 1.0% in the 5 fractions/week arm. The difference between the present morbidity results and reported morbidity with linac treatments is highly statistically significant ($p < 0.0001$). A meta-analysis of hyper-fractionated and altered fractionation regimens showed survival benefits, but all the reviewed studies were executed only with linacs and with intensity modulation.¹⁸ This report emphasizes that the method applied uses simple radiation field placements and can be implemented with a telecobalt machine. Table 9 compares our pilot trial and present phase III trials in terms of radiation sequelae. Both studies showed that Grade III skin and mucosal morbidities are comparable in 7 fractions/week and 5 fractions/week. Compared with the clinical experience of conventional radiotherapy using 5 fractions/week, the low incidence (1%) of mucosal toxicity may be attributed to the open window in the Orfit thermoplastic material and the use of tissue compensation. Skin morbidity was also low, possibly because the 5-mm build-up region of the cobalt beam was preserved. The superficial skin layers receive a reduced dose within the build-up region, with the absorbed dose increasing to approximately 90% at a depth of 2–3 mm for a cobalt-60 beam.

Table 9. Comparison of morbidity in present cohort phase III study and previous pilot study¹²

Grades	Present cohort		Pilot study	
	7 fractions/week (n = 141)	5 fractions/week (n = 141)	7 fractions/week (n = 92)	5 fractions/week (n = 178)
Skin reaction				
I	65.1%	55.6%	46.7%	No data
II	32.4%	37.3%	25.0%	No data
III	1.6%	3.2%	16.3%	10.7%
IV	0.0%	0.0%	0.0%	1.1%
Mucosal reaction				
I	11.9%	18.3%	31.5%	No data
II	74.6%	78.6%	38.0%	No data
III	12.7%	<1.0%	26.1%	26.4%
IV	0.0%	<1.0%	0.0%	2.4%

The findings from this study demonstrate that a total dose of 70 Gy could be delivered within an OTT of 35 days, representing an accelerated treatment approach in head and neck radiotherapy. Based on the observed treatment tolerance, cobalt radiotherapy may be considered a feasible option for high-grade head and neck malignancies. A limitation of this approach is that, unless patient-specific tissue compensators are prepared manually or by automated methods, its application with conventional cobalt machines may not be feasible for all head and neck malignancies. At the time of this report, local control and survival outcomes could not be adequately assessed because of the limited follow-up period since completion of treatment for the last cohort of patients.

Our results may contribute to addressing the radiotherapy needs of the North-Eastern regions of India, where head and neck malignancies account for a substantial proportion of patients receiving radiotherapy. The 7 fractions/week schedule reduces the treatment period by approximately two weeks and may increase annual treatment capacity by allowing treatment to continue on weekends. We also plan to continue evaluating this approach using the newly designed Bhabhatron 3i Indian cobalt machine equipped with a multileaf collimator, with multiple-field forward planning to potentially replace laborious patient-specific tissue compensators. These findings support the continued role of telecobalt radiotherapy, particularly in resource-limited settings where head and neck malignancies represent a substantial proportion of the radiotherapy workload and disproportionately affect socioeconomically disadvantaged populations.^{19,20}

5. Conclusion

This study shows that skin and buccal mucosa sequelae have a lower incidence when using ATC. Experience with 7 fractions/week demonstrated the feasibility of delivering 70 Gy within a five-week OTT. Cobalt-60 treatment may offer advantages over 6-MV linac beams in head and neck radiotherapy because of its reduced dose build-up and the improved treatment tolerance observed with simple beam-directed cobalt treatment combined with ATC. Long-term follow-up of this cohort is necessary to assess treatment outcomes and determine whether dose adjustments are required to optimize local control.

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Conflict of interest

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Author contributions

Conceptualization: Ravi Kannan, Ramamoorthy Ravichandran, Gopal Datta

Formal analysis: Kapil Malik, Ravi Kannan, Ramamoorthy Ravichandran

Investigation: Kapil Malik, Subramania Vijayakanth, Talagadadevi V.S.S.K. Bharath, Abishek Kesha

Methodology: Ramamoorthy Ravichandran, Kapil Malik, Tarani Mondal, LamLynti Dkhar, Soumya Brata Deb

Writing—original draft: Ramamoorthy Ravichandran

Writing—review & editing: Ravi Kannan, Ramamoorthy Ravichandran

Ethics approval and consent to participate

This study was approved by the Institutional Research Board (IRB) of CCHRC (Approval No. CCHRC/IRB/017/2021), dated March 5, 2021. All participants provided informed consent to participate in this study.

Consent for publication

All participants provided informed consent for their data to be published.

Availability of data

All the data supporting the findings of this study are not publicly available due to patient confidentiality, but could be allowed with specific request in writing to the corresponding author.

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