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Research Article

JOURNAL OF CANCER SCIENCE AND CLINICAL THERAPEUTICS

ISSN: 2637-5079

HEXASHOT: A Short Course Palliative Radiation Therapy of 21Gy in 6 Fractions Over 3 Days in Locally Advanced, Un-Resectable Head and Neck Cancers

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Abstract

Background: Head and neck cancer is one of the most common malignancies in developing countries like India with males being the most implicated ones. 60-80% patients present in advanced stage compared to 40% in developed nations. Most of such locally advanced head and neck cancer patients need some form of urgent palliation and palliative radiation therapy is an effective way in mitigating these cases. This pilot study of palliative radiation therapy using 3 days schedule of total 6 fractions (HEXASHOT) was performed to evaluate the response rates, toxicities and quality of life post treatment in these patients.

Materials and Methods: Fifty six patients with locally advanced (Stage IVA-IVB), un-resectable, squamous cell carcinoma of head and neck region were recruited under this study. Radiation therapy was delivered by Co60 teletherapy machine. Response rates and quality of life were assessed at 1 and 3 months post treatment, and toxicities at baseline and 1 month using appropriate standard tools.

Results: Median age of these 56 patients (51 male and 5 female) in the study was 57 years. Post completion of radiation therapy Response rateswere statistically significant in patients, with 16.1% patients showing a partial response and 75.0% remaining with stable disease after 1 month. At 3 months, 19.6% had a partial response and 62.5% maintained stable disease. Two patients undergone radical conversion to upto 66Gy total dose, after 1 month in view of near complete response. There was a statistically significant improvement in quality of life and other presenting symptoms post treatment. Only four patients reported Grade 2 oral mucositis at 1 month post treatment with no evidence of xerostomia, dysphagia and hematological toxicities post treatment.

Conclusion: In developing countries like India with busy, government hospital settings with long dates of radiation therapy and excessive patient load, "HEXASHOT" is an effective palliative radiation therapy schedule providing optimum symptom relief with minimal toxicities within a short period of 3 days, thus mitigating logistics issues.

Keywords: Palliative; Radiation therapy; Head and neck cancer; Cancers.

Introduction

In the 21st century, cancer is a significant social, medical, and financial issue that accounts for almost 1 in 6 deaths (16.8%) and 1 in 4 deaths (22.8%) from non-communicable diseases worldwide. According to

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Citation: Subhrajit Das, Vikas Yadav, Jaspreet Kaur, Rajiv Sharma, Rajashekhar CHT. HEXASHOT: A Short Course Palliative Radiation Therapy of 21Gy in 6 Fractions Over 3 Days in Locally Advanced, Un-Resectable Head and Neck Cancers. Journal of Cancer Science and Clinical Therapeutics. 9 (2025): 83-86.

Received: April 06, 2025
Accepted: April 14, 2025
Published: April 28, 2025

Subhrajit Das, et al., J Cancer Sci Clin Ther 2025
DOI:10.26502/jcsct.5079267

GLOBOCAN (Global cancer observatory) 2022 data, head and neck squamous cell cancer is one of the most common malignancies in developing nations, including India, where 2,69,797 new cases are expected to be diagnosed with the disease in 2022 [1]. A number of factors, including lack of access to healthcare, illiteracy, poverty, and limited resources for health care, contribute to the majority of head and neck cancer patients presenting at an advanced stage. Infact, 60% to 80% patients present with advanced disease in India compared to 40% in developed countries [2]. Late stage presentation, lack of access to cancer care centers and failure to complete treatment all lead to the decreased overall survival of head and neck cancer patients in India irrespective of gender. Locally advanced, non-metastatic group of patients are treated by concurrent chemo-radiation or altered fractionation. However, patients who are unfit for radical concurrent chemo radiotherapy need some form of palliative treatment for loco regional control and improved quality of life [3]. Numerous studies have examined the efficacy of radiation therapy to reduce pain, enhance breathing, speaking, swallowing, and breathing abilities in patients, as well as to lessen continuous bleeding and tumor ulceration. Although such studies advocate for the use of radiotherapy in palliative setting but no standard palliative regime exists in the current scenario [4]. After extrapolation from above discussion and considering the long queue of patients in government hospital settings, patient compliance and the need for short hospital stays, we plan to assess clinical response and palliation of symptoms post HEXASHOT palliative radiation therapy i.e., 21 Gy in 6 fractions over 3 days with 6 hours interval in between 2 fractions with BED of 28Gy for locally advanced head and neck cancer patients.

Materials and Methods

A total of 56 histologically proven, locally advanced (Stage IVA,IVB) un-resectable, non-metastatic squamous cell carcinoma cases of head and neck region were recruited in this study after proper, informed consent. Patients' exclusion criteria were nasopharyngeal tumors and metastatic disease. Fifty one male and five female cases with median age of 57 years were included under this study. External beam radiation was delivered by parallel opposing fields in all of the patients. Radiation therapy was delivered by Cobalt-60 external beam teletherapy machine Bhabatron-II, using the fields generated as above to the primary tumor and involved nodes to a dose of 21Gy in 6 fractions over 3 days, two fractions per day, 6 hours apart. The biologically equivalent dose for this HEXASHOT regimen for tumor is 28Gy which is equivalent to the B.E.D of commonly used palliative radiation therapy schedule 20Gy/5fractions over 5 days by Mohanti et al [5]. Patients were called after completion of treatment, then at 1 month and 3 months duration for proper assessment.

Patient's detailed clinical history and clinical examination with the complete evaluation of the primary tumor, neck nodes and metastasis was done. The decision to consider the patient for palliative treatment was taken by guide and other consultants with experience in treating head and neck cancer cases. Patients who fulfilled the inclusion criteria were then given palliative radiotherapy of 21Gy in 6 fractions over 3 days. Patients were assessed for clinical response at 1 month and after 3 months by clinical evaluation and contrast enhanced computed tomography (CECT) (base of skull to T4 vertebra) wherever indicated and by using RECIST (Response evaluation criteria in solid tumors) version 1.1. Treatment toxicities were assessed at treatment completion and at 1 month after completion of treatment by CTCAE version 5.0. Quality of life was assessed at 1 month and 3 months after treatment and compared from baseline by EORTC HN35 and EORTC QLQ C30 questionnaire.

Results

In our study response rates were assessed clinically and radiologically using RECIST 1.1 criteria at 1 month and 3 months following treatment. At 1 month, 16.1% showed a partial response, 8.9% had progressive disease, and 75.0% remained with stable disease. At 3 months, 19.6% had a partial response, 17.9% showed progressive disease, and 62.5% maintained stable disease (Figure 1). Two patients were converted into curative conventional fractionation schedule of 66Gy in 33 fractions over 6.5 weeks in view of near complete response rates. The p value is significant <0.001.

In our study quality of life was assessed by QLQ-C30 and HN35 questionnaires at 1 and 3 months post treatment. Overall global quality of life score was improved in about 40% patients by more than or equal to 50% (p<0.001). This was statistically significant at 1 and 3 months. There were various domains of HN-35 questionnaire. Significant observations which were also studied in other palliative head and neck radiation therapy studies were pain, swallowing/ dysphagia and mouth opening. At 1 month there was a statistically significant improvement in pain by about 50% and above in 50% of patients (p<0.001) (Figure 2). Also, there was a statistically significant improvement in swallowing by

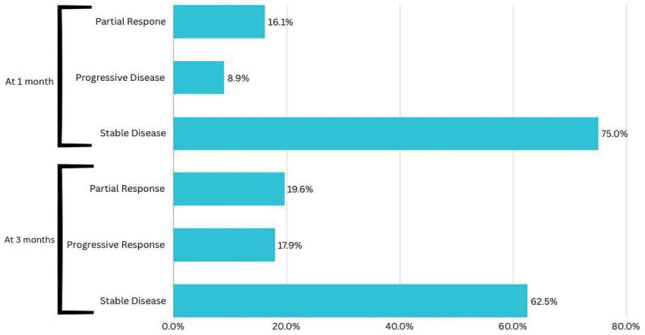

Figure 1: Response to Treatment completion

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DOI:10.26502/jcsct.5079267

about 50% and above in 36% of patients (p<0.001) (Figure 3). There was no statistical difference in mouth opening, salivation, dry mouth etc.

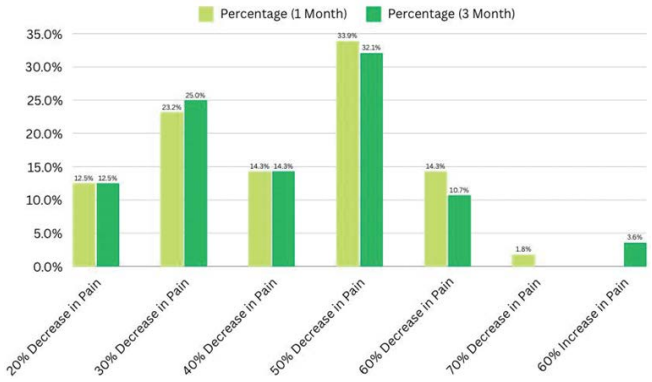

Figure 2: Comparison between decrease in pain at 1 and 3 months.

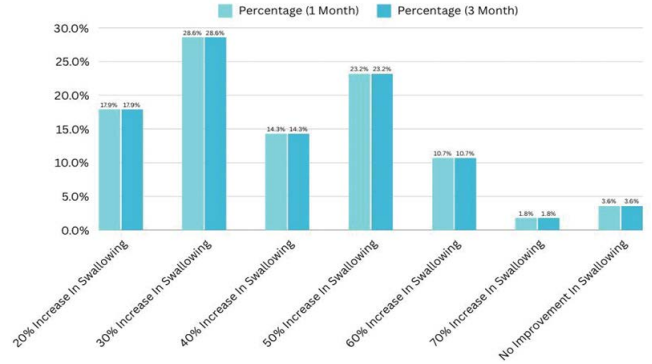

Figure 3: Comparison between improvement in swallowing at 1 and 3 months.

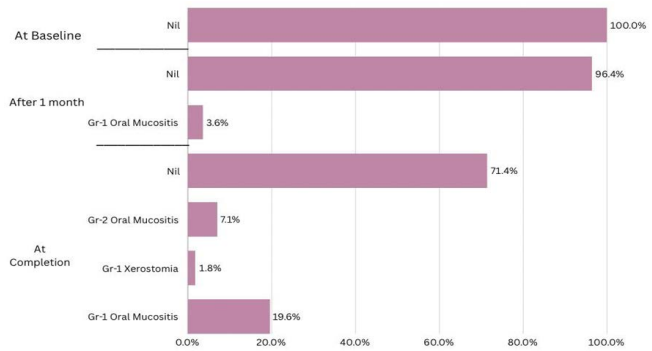

Figure 4: Reactions at Baseline, Completion and after 1 month.

The study HEXASHOT was well tolerated by most of the patients with 7.1% (4 patients) developing grade-2 oral mucositis at treatment completion and 3.6% (2 patients) developing grade-1oral mucositis after 1 month (Figure 4). There was no evidence of dermatitis, dysphagia, xerostomia and hematological toxicities in any of the patients. In a similar study by Mohanti et al all patients developed patchy mucositis at 1 month follow up [5]. In QUAD-SHOT study by Corry et al 33% patients developed grade 1 mucositis and 11% grade 2 [6]. In the OCTA- SHOT study by Jakhar et al, there were 63% patients developing grade 2 oral mucositis at 15th day, with subsequent healing of all reactions after 1 month [7]. These findings demonstrate the good tolerability of HEXASHOT regime.

Discussion

In developing countries like India, head and neck cancers are the most common type of malignancy encountered in cancer centers. Majority of patients present in advanced stage. Even at their first presentations patients are having locally advanced disease with large neck nodes, ulceration, bleeding which urgently calls for the need of palliative radiation therapy [8]. The main intent of management of such cases is to provide urgent symptomatic relief and improved quality of rest of their life with minimal toxicity to the patient. The long queues, busy government settings, shortage of radiation therapy machines all put up to the fact that patients are not started upfront palliative radiation therapy or they are lost to follow up in long schedules. The two most commonly used regimen in palliative radiation therapy in Indian settings are 20Gy/5 fractions over 5days by Mohanti et al5 and 30Gy in 10fractions by Ghoshal et al [9]. In the regimens mentioned above sometimes patients lose to follow up for 1 or 2 weeks and hinder the potential benefits of the radiation therapy. Our study effectively delivered similar biologically effective dose of 28 Gy, similar to study of 20Gy in 5 fractions over 5 days in just three days period by altered hypofractionation.

Considering above limitations, we tried to explore the response rates, toxicities and quality of life using HEXASHOT palliative radiation therapy regime of 21Gy in 6fractions delivered over 3 days in 56 patients in a tertiary cancer care centre in India. This study had a long follow up period of 3 months post treatment to assess the response rates, quality of life and toxicities and the clinical response of radiation therapy was sustained during the 3 months follow up both clinically and by imaging and toxicities were very less during the 3 months follow up with sustained palliation of symptoms. However, a large sample size is needed to test this study in the near future with more longer follow up period to study for overall survival and long term toxicities. If compared with other palliative radiation therapy schedules, this study can be used as an induction radiation therapy regime in medically unfit/poor performance status patients who can be converted to radical treatment later on providing minimal toxicities to those patients also.

Financial support and sponsorship: Nil

Conflicts of interest: There are no conflicts of interest.

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Declarations

Ethical approval and consent to participate

This study was conducted at the department of Radiation Oncology, VMMC and Safdarjung Hospital, New Delhi after due certification from the Institutional Review Board (IRBB) and Institutional Ethics Committee (IEC) in accordance with the Declaration of Helsinki.

All consecutive consenting patients (written, informed consent form) meeting the inclusion and exclusion criteria, coming to the department of Radiation Oncology at VMMC and Safdarjung Hospital were enrolled in the study.

Consent for publication

This study doesn't contain any personal, private information of any subject/patient. Institutional written consent form was used for written consent before participation and publishing of study.

Funding

No funds were received or granted for conducting this study from any source.

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