



Preventive Effects of Pregabalin on Neuropathic Pain in Head and Neck Cancer Patients Undergoing Radiotherapy

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ABSTRACT

Introduction: Neuropathic pain is a common and debilitating complication in patients with head and neck cancers undergoing radiotherapy. Pregabalin, a gabapentinoid, has shown efficacy in treating neuropathic pain, but its prophylactic role in radiotherapy-induced neuropathic pain remains underexplored.

Materials and Methods: This randomized, double-blind, placebo-controlled trial was conducted at Tabriz University of Medical Sciences involving 70 patients with head and neck cancer scheduled for radiotherapy. Participants were randomly assigned to receive either pregabalin or placebo throughout the radiotherapy course. Pain intensity and neuropathic pain features were assessed using the Visual Analog Scale (VAS) and Douleur Neuropathique 4 (DN4) questionnaire. Rescue analgesic consumption was recorded.

Results: Pregabalin significantly reduced pain intensity and neuropathic symptoms compared to placebo at multiple time points during and after radiotherapy ($p < 0.001$). Additionally, the pregabalin group required less rescue analgesics, indicating better pain control.

Conclusion: Prophylactic administration of pregabalin effectively decreases radiotherapy-induced neuropathic pain severity and analgesic consumption in patients with head and neck cancer. Further studies are warranted to confirm these findings and optimize treatment protocols.

Introduction

Head and neck cancers (HNCs) represent a diverse group of malignancies that arise in the oral cavity, pharynx, larynx, nasal cavity, and salivary glands [1]. These cancers are often associated with aggressive treatment modalities, including surgery, chemotherapy, and most notably, radiotherapy. While radiotherapy is a cornerstone in the management of many patients with HNCs, it is not without complications [2]. One of the most challenging and distressing side effects is neuropathic pain (NP), which can significantly impair quality of life, compromise nutritional status, and hinder treatment compliance [3].

Neuropathic pain resulting from radiotherapy is primarily caused by nerve damage secondary to radiation-induced inflammation, fibrosis, and ischemia. Unlike nociceptive pain, which stems from tissue injury and inflammation, NP arises from direct injury or dysfunction of the somatosensory nervous system [4]. This type of pain is often described as burning, shooting, or electric shock-like, and is frequently accompanied by sensory abnormalities such as allodynia and hyperalgesia [5]. In patients undergoing radiotherapy for head and neck malignancies, neuropathic pain can emerge early during treatment or develop gradually, sometimes persisting long after completion of

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therapy. The prevalence of NP in this population ranges from 20% to 50%, depending on treatment intensity and anatomical location of the tumor [6]. Despite its significant impact, neuropathic pain remains underrecognized and undertreated in many cancer care settings [7]. Conventional analgesics such as non-steroidal anti-inflammatory drugs (NSAIDs) and opioids often fail to provide adequate relief, particularly when NP is a dominant component. Consequently, adjuvant medications that target neuropathic mechanisms are increasingly being considered as part of a multimodal pain management strategy. Among these, pregabalin has emerged as a promising candidate [8].

Pregabalin, a structural analog of gamma-aminobutyric acid (GABA), binds selectively to the $\alpha 2\delta$ subunit of voltage-gated calcium channels in the central nervous system. This binding results in decreased calcium influx at nerve terminals, thereby reducing the release of several excitatory neurotransmitters including glutamate, norepinephrine, and substance P [9]. The pharmacological profile of pregabalin underpins its effectiveness in treating various neuropathic conditions such as diabetic peripheral neuropathy, postherpetic neuralgia, and spinal cord injury-related pain [10]. Moreover, pregabalin has demonstrated efficacy in preventing and attenuating chemotherapy-induced peripheral neuropathy (CIPN), suggesting a potential role in prophylaxis as well as symptom management [11].

The prophylactic use of pregabalin in the context of radiation-induced neuropathic pain in HNC patients is a relatively unexplored area. Early intervention with agents like pregabalin may modulate central sensitization and prevent the establishment of chronic pain pathways [12]. Prophylactic strategies could be particularly valuable in HNC patients, who often undergo high-dose radiotherapy to anatomically complex and sensitive regions, resulting in heightened risk of nerve damage [13]. The potential of pregabalin to reduce the severity and incidence of NP, if initiated before or early during radiotherapy, may represent a critical advancement in supportive cancer care [14].

Several small-scale studies and anecdotal reports have hinted at the benefits of pregabalin in managing radiation-induced pain syndromes; however, robust evidence is still lacking [15]. The timing, dosage, and duration of pregabalin therapy in this preventive context require further investigation. Importantly, any preventive strategy must also consider the safety and tolerability profile of pregabalin, which, although generally well tolerated, may cause side effects such as dizziness, somnolence, and peripheral edema—potentially limiting its use in some patients [16].

Given the pressing need for effective management strategies for NP in HNC patients and the theoretical and preliminary clinical basis for pregabalin's use, a

systematic evaluation of its prophylactic efficacy is warranted [17]. This study aims to assess the preventive effects of pregabalin on the development and severity of neuropathic pain in patients with head and neck cancer undergoing radiotherapy. By targeting the onset of NP before it becomes entrenched, this approach may offer significant benefits in pain control, functional outcomes, and overall quality of life.

Materials and Methods

Study Design

This study was designed as a randomized, double-blind, placebo-controlled clinical trial conducted at a tertiary oncology center. The primary objective was to evaluate the prophylactic efficacy of pregabalin in preventing or reducing the severity of neuropathic pain in patients with head and neck cancer undergoing radiotherapy. The study protocol was approved by the institutional ethics committee and adhered to the principles outlined in the Declaration of Helsinki.

Inclusion Criteria

Eligible participants were adult patients (aged 18 years and older) diagnosed with histologically confirmed head and neck cancer, scheduled to undergo curative or adjuvant radiotherapy with or without concurrent chemotherapy. Additional inclusion criteria included:

- Eastern Cooperative Oncology Group (ECOG) performance status of 0–2,
- Ability to provide informed consent,
- No pre-existing neuropathic pain in the head and neck region,
- Adequate renal and hepatic function.

Exclusion Criteria

Patients were excluded if they met any of the following criteria:

- Prior use of pregabalin, gabapentin, or other antiepileptic drugs within the last 30 days,
- History of hypersensitivity to pregabalin,
- Pre-existing neurological disorders associated with chronic pain,
- Cognitive impairment that precluded reliable self-reporting,
- Ongoing opioid therapy at the time of enrollment,
- Pregnancy or lactation.

Sampling Method

A total of 60 participants were selected using purposive sampling and randomly allocated into two groups using a computer-generated block randomization sequence: one receiving pregabalin and the other receiving a placebo. Allocation concealment was maintained using sequentially numbered, opaque, sealed envelopes. Both

participants and investigators were blinded to group assignments.

Intervention and Procedures

Participants in the intervention group received pregabalin 75 mg orally twice daily, starting two days before the initiation of radiotherapy and continued throughout the treatment period (typically 6–7 weeks). The control group received identical placebo capsules following the same schedule.

All patients underwent standard radiotherapy protocols based on tumor staging and institutional guidelines. Weekly clinical assessments were conducted to monitor pain severity, adverse events, and compliance. Neuropathic pain was evaluated using the Douleur Neuropathique 4 (DN4) questionnaire and a visual analogue scale (VAS), administered at baseline and weekly until two weeks after completion of radiotherapy.

Patients were allowed to use acetaminophen as rescue analgesia, and its use was documented. Opioids or other adjuvant analgesics were not permitted unless deemed clinically necessary, in which case the patient was withdrawn from the study.

Statistical Analysis

Data were analyzed using SPSS version 26.0 (IBM Corp., Armonk, NY). Continuous variables were expressed as mean $\pm$ standard deviation (SD) or median with interquartile range (IQR), depending on

data distribution. Categorical variables were summarized as frequencies and percentages.

Intergroup comparisons were performed using the independent t-test or Mann-Whitney U test for continuous variables, and the chi-square or Fisher's exact test for categorical variables. Repeated measures ANOVA was used to assess changes in VAS and DN4 scores over time between the two groups. A p-value of <0.05 was considered statistically significant.

Ethical Considerations

This clinical study was conducted at Tabriz University of Medical Sciences and involved a total of 70 patients with head and neck cancer undergoing radiotherapy. Patients were randomly assigned to receive either pregabalin ($n = 35$) or placebo ($n = 35$) to evaluate the preventive effect of pregabalin on the development and severity of neuropathic pain. The study was ethically approved under IR.TBZMED.REC.1401.436 and registered with the Iranian Registry of Clinical Trials (IRCT2020050204763N1).

Results

Baseline demographic and clinical variables were well balanced between the two groups. There were no statistically significant differences in age, gender, primary tumor site, radiotherapy dose, or ECOG performance status. This confirms the effectiveness of randomization and ensures comparability of the treatment arms.

Table 1: Baseline Demographic and Clinical Characteristics

Variable	Pregabalin Group ($n = 35$)	Placebo Group ($n = 35$)	p-value
Mean Age (years)	58.69 $\pm$ 7.84	59.23 $\pm$ 8.51	0.742
Gender (Male/Female)	23 / 12	22 / 13	0.796
Tumor Location (%)			
- Oral cavity	34.29%	31.43%	0.781
- Oropharynx	40.00%	42.86%	0.856
- Larynx	25.71%	25.71%	1.000
Mean Radiotherapy Dose (Gy)	66.98 $\pm$ 3.22	67.41 $\pm$ 3.07	0.634
ECOG Performance Status (0–1)	30 (85.71%)	31 (88.57%)	0.713

The VAS (Visual Analog Scale) scores, which assess the overall pain intensity, were significantly lower in the pregabalin group at each follow-up time point during and after radiotherapy. This suggests

that pregabalin effectively reduces the development and progression of radiotherapy-induced pain in patients with head and neck cancer.

Table 2: Pain Intensity Measured by VAS Scores at Multiple Time Points

Time Point	Pregabalin Group (Mean $\pm$ SD)	Placebo Group (Mean $\pm$ SD)	p-value
Baseline (Pre-RT)	1.18 $\pm$ 0.59	1.24 $\pm$ 0.61	0.597
Week 3 of RT	2.84 $\pm$ 1.11	4.89 $\pm$ 1.32	<0.001
End of RT	3.37 $\pm$ 1.24	6.08 $\pm$ 1.58	<0.001
2 Weeks Post-RT	2.65 $\pm$ 1.19	5.37 $\pm$ 1.43	<0.001

DN4 (Douleur Neuropathique en 4 Questions) scores, used to evaluate neuropathic components of pain, were significantly lower in the pregabalin group at both assessment points, indicating its

effectiveness in preventing neuropathic pain features. Additionally, the total amount of rescue analgesics (acetaminophen) used during the treatment course was substantially less in the

pregabalin group, reinforcing its clinical benefit in pain management.

Table 3: Neuropathic Pain Scores (DN4) and Analgesic Use

Parameter	Pregabalin Group (Mean $\pm$ SD)	Placebo Group (Mean $\pm$ SD)	p-value
Week 3 DN4 Score	2.14 $\pm$ 0.78	4.79 $\pm$ 1.12	<0.001
End of RT DN4 Score	2.62 $\pm$ 1.03	5.33 $\pm$ 1.19	<0.001
Total Rescue Analgesic Use (mg)	284.71 $\pm$ 62.45	487.93 $\pm$ 79.66	<0.001

Discussion

The findings of this randomized controlled trial demonstrate that pregabalin is effective in alleviating radiotherapy-induced neuropathic pain in patients with head and neck cancer. The significantly lower Visual Analog Scale (VAS) scores observed in the pregabalin group at week 3, end of radiotherapy, and 2 weeks post-radiotherapy indicate a substantial reduction in overall pain intensity compared to the placebo group [18-20]. This aligns with previous literature suggesting that pregabalin can modulate nociceptive processing through binding to the $\alpha 2\delta$ subunit of voltage-gated calcium channels, thereby reducing the release of excitatory neurotransmitters [21-23].

Additionally, the DN4 scores, which assess neuropathic features of pain, were significantly lower in the pregabalin group at all evaluated time points. This supports the hypothesis that pregabalin not only reduces general pain but also specifically mitigates neuropathic components commonly seen in patients receiving radiotherapy for head and neck cancer [24-26]. This is consistent with earlier findings demonstrating pregabalin's efficacy in reducing neuropathic pain in other cancer-related settings, including chemotherapy-induced peripheral neuropathy [27-29].

Moreover, the significantly lower use of rescue analgesics, including acetaminophen, in the pregabalin group further highlights its clinical value in reducing overall analgesic burden. Patients receiving pregabalin required nearly 200 mg less rescue analgesia compared to the placebo group, indicating more effective baseline pain control [30-32]. Reducing the need for frequent or high-dose use of analgesics can help prevent side effects such as hepatotoxicity and gastrointestinal disturbances [33-35].

The tolerability of pregabalin is another strength noted in this study. No serious adverse effects were observed, and the majority of patients completed the planned radiotherapy without dose modification or interruption. This supports earlier findings that pregabalin, at appropriate doses, is safe and does not significantly interfere with the oncologic treatment regimen [36-38]. Maintaining treatment continuity is crucial in head and neck cancers where delays or dose reductions in radiotherapy can negatively impact tumor control and survival outcomes [39-41].

Pain management is a cornerstone of supportive care in oncology, particularly for head and neck cancers where radiotherapy often causes mucositis, neuropathic pain, and functional impairment. Traditional analgesics, including opioids, are associated with considerable side effects, dependency risks, and limited efficacy in neuropathic pain [42]. The observed superiority of pregabalin in both pain reduction and analgesic-sparing effects suggests it can serve as a valuable adjunct to standard pain management protocols [43]. However, the study is not without limitations. The sample size, although adequately powered, remains relatively small and may limit generalizability. Also, the follow-up period was limited to 2 weeks post-radiotherapy for pain assessment, and long-term outcomes, including the persistence of pain relief or delayed neuropathic symptoms, were not evaluated. Future studies should incorporate longer follow-up durations and assess quality-of-life metrics to further validate these findings [44].

Conclusion

In conclusion, this study provides strong evidence that pregabalin is effective in managing radiotherapy-induced neuropathic pain in patients with head and neck cancer. It reduces both the intensity and neuropathic quality of pain and significantly decreases the need for rescue analgesics. These results suggest that pregabalin can play a pivotal role in improving patient comfort and adherence to radiotherapy without compromising treatment integrity.

Disclosure Statement

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Authors' Contributions

All authors contributed to data analysis, drafting, and revising of the paper and agreed to be responsible for all the aspects of this work.

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