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Original Article

Comparative Effectiveness and Tolerability of Topical Capsaicin Versus Pregabalin in Chemotherapy-Induced Peripheral Neuropathy: A Prospective Observational Study

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Abstract

Background: Chemotherapy-induced peripheral neuropathy (CIPN) is a frequent and debilitating complication of neurotoxic chemotherapy, significantly affecting quality of life and treatment adherence in cancer patients. Pharmacological management remains challenging, with limited efficacy and tolerability of commonly used systemic agents.

Objective: To compare the effectiveness and safety of topical capsaicin and oral pregabalin in patients with CIPN receiving neurotoxic chemotherapy.

Methodology: This prospective, observational comparative study was conducted from January to December 2023 at the Clinical Oncology Department of Swat Institute of Nuclear Medicine Oncology and Radiotherapy, Pakistan. A total of 117 patients who developed new-onset CIPN during or after chemotherapy were included. Patients received either topical capsaicin 0.075% (Group-A, n = 77) or oral pregabalin (Group-B, n = 40). Symptom improvement was assessed at two and six weeks. Adverse events, treatment compliance, and discontinuation rates were also recorded. Statistical analysis included chi-square tests, independent t-tests, and logistic regression adjusted for chemotherapy regimen.

Results: Both groups demonstrated symptom improvement; however, response rates were significantly higher in the capsaicin group at both two weeks (85.7% vs. 32.5%, p = 0.005) and six weeks (93.5% vs. 32.5%, p = 0.001). Logistic regression confirmed superior efficacy of capsaicin [OR 6.2; 95% CI 2.8–13.5]. No systemic adverse events were reported with capsaicin, whereas pregabalin was associated with dizziness, edema, and sleepiness, leading to high treatment discontinuation.

Conclusion: Topical capsaicin demonstrated superior efficacy and better tolerability compared with pregabalin in the management of CIPN. These findings suggest that topical capsaicin may represent a safer and more effective alternative for symptomatic relief in patients receiving neurotoxic chemotherapy.

Keywords: Antineoplastic Agents, Capsaicin, Neuralgia, Peripheral Nervous System Diseases, Pregabalin.

Introduction

Cancer is one of the most common causes of morbidity and mortality worldwide [1]. With advances in medical science and the availability of improved diagnostic techniques, cancer has become increasingly treatable, and global cancer-related mortality rates have shown a declining trend [2]. Cancer is managed using multiple therapeutic modalities, including chemotherapy, surgery, radiotherapy, stem cell therapy, targeted therapy, nanoparticles, ablation therapy, ferroptosis-based therapy, sonodynamic therapy, natural antioxidants, radionics, and chemodynamic therapy [3]. Among these, chemotherapy has been extensively used over the past few decades as a frontline treatment option for advanced cancers, particularly in cases where surgery and/or radiotherapy are not feasible due to specific clinical considerations [4]. For most cancers, chemotherapy remains one of the most effective and widely utilized treatment modalities [5], as it can cure cancer, control tumor growth, or alleviate cancer-related symptoms [4].

Despite its effectiveness, chemotherapy is associated with several adverse effects, including nausea, vomiting, diarrhea, pain, sexual dysfunction, blurred vision, gastrointestinal distress, bleeding, hair loss, and peripheral neuropathy [6]. Chemotherapy-induced peripheral neuropathy (CIPN) is one of the most common and disabling dose-dependent adverse effects associated with neurotoxic chemotherapeutic agents. CIPN may necessitate substitution of the drug of choice, reduction in therapeutic dose, or, in severe cases, discontinuation of chemotherapy. Chemotherapeutic agents commonly associated with CIPN include taxanes, platinum derivatives, bortezomib, and vinca alkaloids. CIPN is defined as impaired sensory nerve function resulting from exposure to chemotherapeutic agents and is characterized by numbness, pain, and tingling sensations in the extremities. CIPN may present as an acute or chronic condition depending on patient-related factors and chemotherapy protocols [7].

Chemotherapy affects sensory, motor, and autonomic nerves, leading to axonal damage and demyelination, which results in pain and burning sensations in the extremities. In CIPN, disease progression typically begins in the toes, extends to the feet and ankles, and may subsequently involve the lower legs. Genome-wide association studies have demonstrated the involvement of single nucleotide polymorphisms in the development of CIPN. Several studies report that 50–90% of cancer patients receiving neurotoxic chemotherapy experience CIPN [7,8]. Other contributing factors include diabetes, alcoholism, HIV infection, nutritional deficiencies, and immunosuppressive disorders [9]. Reported incidence rates of CIPN range from 50% to 90% among patients treated with neurotoxic chemotherapy. In rare cases, patients may also develop paraneoplastic neuropathies, such as paraneoplastic encephalomyelitis, asymmetric sensory neuropathy, or carcinomatous or lymphomatous sensory neuropathy [10]. Currently, there are no established prophylactic or preventive guidelines for the management of CIPN, as highlighted by the American Society of Clinical Oncology (ASCO) clinical practice guidelines released in 2014 and updated in 2020 [11].

Based on available clinical data, both pharmacological and non-pharmacological approaches are employed for the management of CIPN. Pharmacological agents such as antidepressants, serotonin–noradrenaline reuptake inhibitors (SNRIs), tricyclic antidepressants, antiepileptics, and opioids have demonstrated varying degrees of effectiveness. Among the SNRIs, duloxetine has shown clinically documented efficacy in the treatment of CIPN [12]. Pregabalin, an antiepileptic agent, is frequently prescribed for CIPN; however, its use is often limited by systemic adverse effects, including dizziness and sedation [13]. Neurotoxic chemotherapeutic agents increase the expression of the alpha-2-delta subunit of calcium channels, contributing to peripheral neuropathy and neuropathic pain. Oral pregabalin inhibits this alpha-2-delta subunit in neuronal cells and has been shown to be effective in neuropathic pain management [14].

Topical therapies, including high-concentration capsaicin (8%) patches, offer localized analgesia with minimal systemic exposure. Capsaicin induces nociceptor desensitization by depleting substance P and modulating transient receptor potential vanilloid 1 (TRPV1) receptors, resulting in analgesic effects [15]. Topical agents represent a favorable treatment option for CIPN and include lidocaine patches (700 mg) and capsaicin patches (179 mg) available in various formulations. The capsaicin patch (179 mg) is recommended for the treatment of peripheral neuropathic pain, either as monotherapy or in combination with other pharmacological interventions [16,17]. Patients were diagnosed with CIPN if they reported new-onset pain or numbness in their extremities following exposure to neurotoxic chemotherapy [18]. However, evidence regarding the effectiveness of topical capsaicin specifically in CIPN remains limited. Therefore, this study aimed to evaluate the therapeutic potential of topical capsaicin in comparison with oral pregabalin in cancer patients experiencing CIPN.

Methodology

Study Design

This study was designed as a prospective, observational, comparative study conducted over a one-year period from January to December 2023. The objective was to compare the effectiveness and tolerability of topical capsaicin versus oral pregabalin in patients who developed chemotherapy-induced peripheral neuropathy (CIPN) following exposure to neurotoxic chemotherapy agents. As an observational study, treatment allocation was based on clinical decision-making rather than randomization, reflecting real-world clinical practice.

Ethics

Ethical approval for the study was obtained from the institutional publication committee of the Swat Institute of Nuclear Medicine Oncology and Radiotherapy (SINOR), Saidu Sharif, Swat, Khyber Pakhtunkhwa, Pakistan (Approval/Record No. EA-SINOR/001, dated 28-10-2024). All participants were informed about the study objectives, treatment options, potential benefits, and risks. Written informed consent was obtained prior to enrollment, and confidentiality of patient information was maintained throughout the study.

Setting

The study was conducted at the Clinical Oncology Department of Swat Institute of Nuclear Medicine Oncology and Radiotherapy, Saidu Sharif, Swat, KP, Pakistan. This tertiary care oncology center provides comprehensive cancer treatment services, including chemotherapy, radiotherapy, and supportive care, and manages a large number of patients receiving neurotoxic chemotherapy regimens.

Participants

A total of 117 patients diagnosed with cancer who developed new-onset peripheral neuropathy symptoms during or after treatment with neurotoxic chemotherapy were included. Neuropathic symptoms were defined as pain, numbness, or tingling sensations attributable to chemotherapy exposure. Patients were divided into two treatment groups: Group-A (n = 77) and Group-B (n = 40). Exclusion criteria included the presence of pre-existing neuropathy unrelated to chemotherapy, uncontrolled diabetes mellitus, or refusal to provide informed consent.

Variables

The primary independent variable was the type of neuropathy treatment administered (topical capsaicin versus oral pregabalin). Dependent variables included improvement in neuropathic symptoms at two and six weeks following treatment initiation. Secondary variables included the occurrence of adverse events, treatment discontinuation, and patient compliance. Chemotherapy regimen type (taxane-based versus vinca alkaloid-based therapy) was considered a potential confounding variable and was accounted for in adjusted analyses.

Data Sources/Measurement

Neuropathic symptom improvement was assessed using patient-reported outcome measures based on subjective symptom relief as reported during follow-up visits at two and six weeks. Frequency of topical application and tolerability of capsaicin were monitored in Group-A, while dose escalation, tolerability, and adherence to pregabalin were recorded in Group-B.

Adverse events and treatment discontinuation were documented through clinical evaluation and patient interviews. Validated neuropathy assessment tools such as the Numeric Rating Scale (NRS) or EORTC-CIPN20 questionnaire were not utilized, which represents a methodological limitation of this study.

Bias

As a non-randomized observational study, there is potential for selection bias due to treatment allocation based on clinical discretion. Reporting bias may also be present, as symptom improvement was based on patient self-report rather than standardized validated instruments.

Efforts were made to minimize bias by using consistent follow-up intervals and applying uniform inclusion and exclusion criteria across both groups.

Study Size

The study included a total of 117 participants, with 77 patients receiving topical capsaicin and 40 patients receiving oral pregabalin. The sample size was determined based on patient availability during the study period and reflects routine clinical practice rather than a priori power calculation.

Quantitative Variables

Quantitative variables included age, treatment duration, and symptom improvement status at two and six weeks. Categorical variables included treatment group, chemotherapy regimen type, presence or absence of symptom improvement, adverse events, and treatment discontinuation.

Statistical Methods

Statistical analysis was performed using appropriate comparative methods. Categorical variables were compared between groups using the chi-square test, while continuous variables were analyzed using independent sample t-tests. Logistic regression analysis was conducted to adjust for potential confounding by chemotherapy regimen (taxane versus vinca alkaloid). Results were expressed as odds ratios with corresponding 95% confidence intervals. A p-value of less than 0.05 was considered statistically significant.

Results

Participants

A total of 117 patients who developed chemotherapy-induced peripheral neuropathy were included in the analysis. Of these, 77 patients were assigned to Group-A (topical capsaicin) and 40 patients to Group-B (oral pregabalin). Baseline demographic and clinical characteristics were comparable between the two groups, with no statistically significant differences observed in age, sex distribution, or type of neurotoxic chemotherapy regimen received, indicating adequate baseline comparability (Table 1).

Descriptive Data

The mean age of patients in Group-A was 60.1 ± 13.5 years, while in Group-B it was 63.4 ± 8.2 years (p = 0.33). In Group-A, 48 patients were male and 29 were female, whereas Group-B included 18 males and 22 females (p = 0.48). With regard to chemotherapy exposure, the majority of patients in both groups had received taxane-based regimens (paclitaxel or docetaxel) or vinca alkaloids (vincristine). In Group-A, 65 patients (84.4%) received taxanes and 12 (15.6%) received vinca alkaloids, whereas in Group-B, 10 patients (25%) received taxanes and 30 (75%) received vinca alkaloids. The distribution of neurotoxic chemotherapy regimens did not differ significantly between groups (p = 0.68), as summarized in Table 1.

Outcome Data

Both treatment groups demonstrated clinical response; however, the magnitude and consistency of improvement differed substantially. At the two-week follow-up, 66 of 77 patients (85.7%) in the capsaicin group reported improvement in neuropathic symptoms compared with 13 of 40 patients (32.5%) in the pregabalin group, a difference that was statistically significant (p = 0.005). At six weeks, symptom improvement was reported by 72 patients (93.5%) in Group-A, whereas only 13 patients (32.5%) in Group-B continued to report improvement, maintaining a highly significant difference between groups (p = 0.001).

Regarding safety outcomes, no systemic adverse events were reported among patients receiving topical capsaicin. In contrast, adverse events were observed in 14 patients (35%) in the pregabalin group, including dizziness, peripheral edema, and sleepiness. Additionally, treatment discontinuation was common in Group-B, with 21 patients (52.5%) discontinuing pregabalin due to either inadequate symptom relief or intolerance. High treatment compliance was observed in Group-A, with most patients completing therapy as prescribed.

Main Results

Topical capsaicin demonstrated significantly superior efficacy compared with pregabalin in reducing symptoms of chemotherapy-induced peripheral neuropathy at both two and six weeks. Logistic regression analysis adjusting for chemotherapy regimen type (taxane versus vinca alkaloid) confirmed this finding, showing a markedly higher likelihood of response in the capsaicin group [odds ratio (OR) 6.2; 95% confidence interval (CI) 2.8–13.5].

While adverse events such as dizziness, edema, and sleepiness were observed in the pregabalin group, these did not reach statistical significance when compared collectively (p = 0.43), and no adverse events were reported in the capsaicin group (Table 2). These findings highlight both the superior efficacy and favorable tolerability profile of topical capsaicin in this patient population.

Table 1: Comparison of patient characteristics and clinical background for both groups.

Variables		Group-A (n=77)	Group-B (n=40)	p-value
Age in years		60.1 ± 13.5	63.4 ± 8.2	0.330
Gender	Male	48 (62.3)	18 (45.0)	0.480
	Female	29 (37.7)	22 (55.0)	
Neurotoxic regimen, n (%)	Texans	65 (84.4)	10 (25.0)	0.680
	Vinca alkaloids	12 (15.58)	30 (75.0)	

Table 2: Information of adverse events noted for all patients in both groups.

Adverse events	Group-A (n = 77)	Group-B (n = 40)	p-value
Dizziness	0	04%	0.430
Edema	0	04%	
Sleepiness	0	06%	

Discussion

Chemotherapy-induced peripheral neuropathy (CIPN) remains a major dose-limiting toxicity of neurotoxic chemotherapeutic agents and significantly compromises patients' quality of life and functional status. In this prospective, observational comparative study, a substantially higher proportion of patients treated with topical capsaicin reported improvement in neuropathic symptoms at both 2 weeks (85.7%) and 6 weeks (93.5%) compared with those receiving pregabalin (32.5% at both time points). Importantly, this benefit remained statistically significant after adjustment for chemotherapy regimen, indicating that the observed superiority of capsaicin was independent of differences in neurotoxic exposure. These findings are consistent with previous reports demonstrating the efficacy of high-concentration capsaicin in the management of peripheral neuropathic pain, including CIPN, across both controlled trials and real-world clinical settings [8,15,16,19].

The enhanced efficacy observed with capsaicin may be attributed to its localized mechanism of action. Capsaicin selectively activates and subsequently desensitizes transient receptor potential vanilloid 1 (TRPV1)–expressing nociceptive fibers, leading to reduced peripheral pain transmission without systemic drug exposure [1,15]. In contrast, pregabalin exerts its analgesic effect through central inhibition of the α2δ subunit of voltage-gated calcium channels, a mechanism commonly associated with systemic adverse effects such as dizziness, peripheral edema, and sedation [13,14]. In the present study, 35% of patients receiving pregabalin experienced adverse events, and more than half discontinued therapy due to intolerance or inadequate symptom control. Comparable tolerability concerns associated with pregabalin use in oncology populations have been reported previously [13].

High treatment adherence was observed in the capsaicin group, likely reflecting its favorable safety profile and ease of topical administration. This finding is clinically relevant, as patients with cancer frequently experience polypharmacy and are particularly vulnerable to cumulative drug toxicity and clinically significant drug–drug interactions. The absence of systemic adverse effects associated with topical capsaicin represents a meaningful therapeutic advantage in this population and supports its consideration as a practical and patient-centered option for CIPN management [8,16].

Several limitations of this study warrant consideration. The non-randomized, open-label design introduces the potential for selection and reporting bias. In addition, group sizes were unequal, and chemotherapy regimens differed between treatment arms; however, adjusted regression analyses were performed to mitigate the impact of these differences. Pregabalin dosing in this study remained below guideline-recommended therapeutic ranges, which may have underestimated its potential efficacy; nonetheless, dose escalation was limited by poor tolerability, reflecting real-world clinical constraints and findings reported in prior studies [13]. Furthermore, validated neuropathy assessment tools such as the EORTC-CIPN20 or numerical rating scales were not utilized, and symptom improvement was assessed using patient-reported outcomes, which limits direct comparability with other published studies [18].

Despite these limitations, the present study provides meaningful real-world evidence supporting topical capsaicin as an effective and well-tolerated treatment option for CIPN. Given the limited pharmacological therapies currently recommended by ASCO guidelines and the absence of established preventive strategies for CIPN [11,18], topical capsaicin may represent a valuable alternative or adjunctive therapeutic approach in routine clinical practice.

Future randomized controlled trials incorporating standardized neuropathy assessment instruments, longer follow-up durations, and direct comparisons with guideline-endorsed therapies are warranted to further clarify the role of topical capsaicin in the management of CIPN.

Conclusion

Both topical capsaicin and oral pregabalin demonstrated clinical benefit in improving symptoms of chemotherapy-induced peripheral neuropathy; however, topical capsaicin showed superior efficacy and a more favorable safety profile in this cohort. These findings should be interpreted as exploratory and hypothesis-generating. Further well-designed randomized controlled trials using standardized outcome measures are required to validate the role of topical capsaicin as a therapeutic option for CIPN.

Authors' Contributions:

All authors meet the ICMJE criteria for authorship.

Author 1: Substantial contribution to conception and design, drafting the manuscript, final approval, agreed to be accountable for all the work.
Author 2: Substantial contribution to conception and design, data acquisition, drafting the manuscript, final approval, agreed to be accountable for all the work.
Author 3: Analysis and interpretation of data, drafting the manuscript, final approval, agreed to be accountable for all the work.
Author 4: Analysis and interpretation of data, critical revision, final approval, agreed to be accountable for all the work.
Author 5&6: Substantial contribution to conception and design, drafting the manuscript, final approval, agreed to be accountable for all the work.
Author 7&8: Substantial contribution to conception and design, data acquisition, drafting the manuscript, final approval, agreed to be accountable for all the work.

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