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A First- In- Class Curative Drug for Diabetic Neuropathy and Neuropathic Pain Management: Limb Salvage Through Targeting Underlying Pathophysiology

Javid MJ*
Department of Anesthesiology and Pain management, Tehran University of Medical Sciences, Iran

***Corresponding author:** Javid MJ, Department of Anesthesiology and Pain management, Tehran University of Medical Sciences, Imam Khomeini Complex, Tehran, Iran
Tel: +989121216524;
Email: jafarija@tums.ac.ir/mihanjavidj@gmail.com

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Abstract

Diabetic peripheral neuropathy (DNP) is a debilitating complication of diabetes with no known curative treatment to date. Current therapeutic approaches primarily focus on symptom management rather than addressing the underlying pathophysiology.

This study introduces a Novel Regenerative Compound (NRC) designed to target the root cause of DPN, microvascular ischemia and neuroinflammation.

Nerve stimulation and action potential activation has been proposed by the author as the mechanism of action to investigate in the future.

In our volunteer candidates who were candidate for amputation and involved with diabetes type I and type II and severe peripheral neuropathy, the drug demonstrated significant neuro-regenerative and angiogenic effects offering a new vision of treatment that extends beyond symptomatic relief.

These findings suggest a potential paradigm shift in the management of DPN and even other neuropathic disorders toward disease-modifying therapies.

Keywords: Diabetic neuropathy; Nerve regeneration; Disease-modifying therapy; Limb salvage; Novel regenerative drug; Neuropathic Pain management; Phase III clinical trial

Abbreviations

DPN: Diabetic Peripheral Neuropathy; BCC: Boron Containing Compound; NRC: Novel Regenerative Compound; NCV: Nerve Conduction Velocity.

Introduction

Diabetic peripheral neuropathy (DPN) is a common, disabling complication of diabetes mellitus, significantly impairing quality of life due to pain, numbness, and risk of foot ulcers and amputations [1,2]. Traditional treatments primarily target symptomatic relief without addressing underlying pathophysiological mechanisms, including microvascular ischemia, oxidative stress, and chronic inflammation [3,4]. Recent research emphasizes that targeting these mechanisms may halt or even reverse nerve damage, offering disease-modifying potential [5,6].

The novel therapeutic agent evaluated in this phase III study is a *Topical Regenerative Boron Contained Compound* (Orthoboric acid) and designed to restore microvascular circulation, reduce neuroinflammation, and stimulate nerve regeneration. Paraclinical and clinical observations, demonstrated neuroprotective and angiogenic properties, suggesting that this approach may address the root causes of DPN rather than merely alleviating symptoms [7,8]. This Novel Regenerative Compound (NRC) represents a potential paradigm shift in the management of diabetic neuropathy, consistent with emerging trends in regenerative and molecular therapies for neuropathic conditions [9,10].

Material and Methods

Study was conducted as a compassionate study, in 60 patients with diabetes type I and type II who were suffering from long term severe neuropathy (cold and pale skin), lack of sensation, impaired circulation (lack of dorsalis pedis pulsation) and refractory foot ulcers. All patients had received routine ulcer care and antibiotic therapy for at least 3 months, with no response to the standard traditional treatments and all of them were candidate for amputation. In fact,

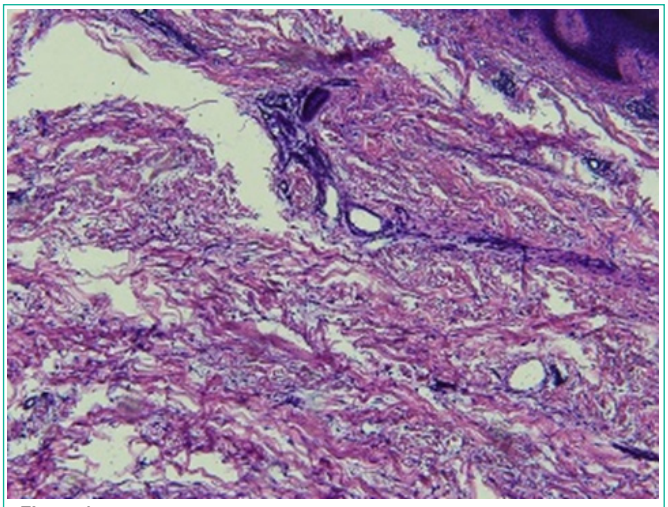

Figure 1:

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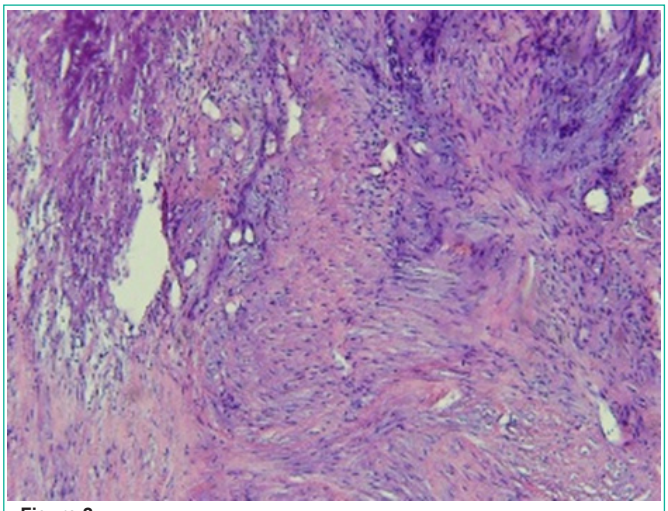
the novel drug was the last chance to limb salvage in the volunteer patients.

Approval from Iran Food and Drug Organization for topical usage had been obtained before starting the study.

Written informed consent was obtained from all patients or their legal representatives.

Boron Containing Compound was prepared as a solution for topical usage and the involved limb was immersed into the solution for 15 minutes, twice a day. Duo to ongoing intellectual property protection (application number: 17/799,901) and pending international patent applications, the precise composition and molecular structure of the drug remain confidential. However, its pharmacodynamic profile has been characterized by neuroprotective, anti-inflammatory and angiogenic properties, contributing to both symptomatic relief and disease modification. The primary goal was to measure changes in nerve conduction velocity, which reflects nerve function. Secondary goals included measuring neovascularization in the affected tissue and skin and finally cell regeneration effect of BCC (Figures 1,2,3,4).



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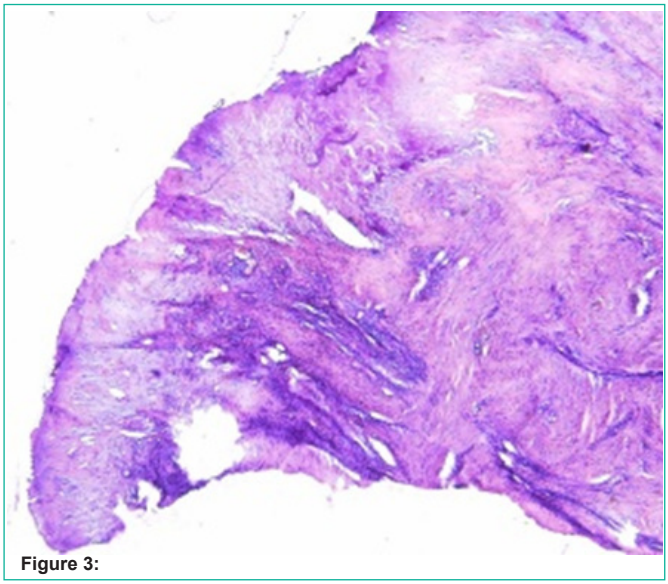

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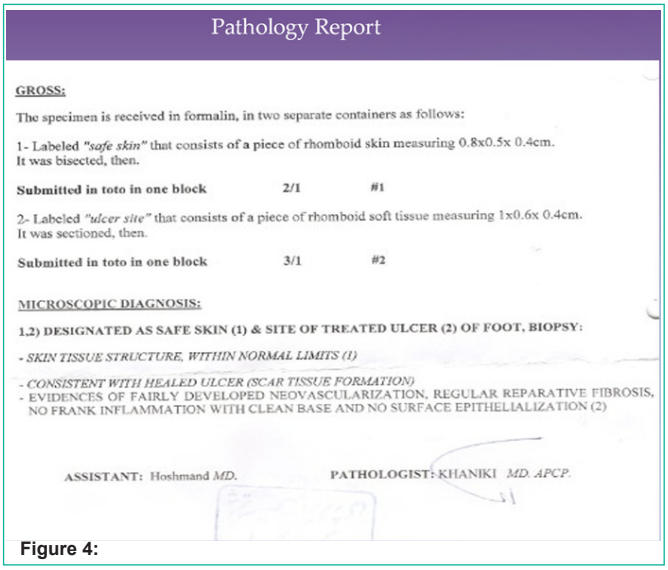

Figure 4:

Safety was monitored through adverse event reports and lab tests.

Results

Evaluation of the patients after 7 days, showed considerable reestablishment of circulation.

All patients exhibited palpable dorsalis pedis pulsation and restoration of previously lost sensation. The affected limb showed normal warmth and color.

A biopsy from the affected area, 10 days after administering the Novel BCC, reported fairly developed neovascularization and no frank inflammation.

After 3 weeks, 10% of patients were randomly evaluated for Nerve Conduction Velocity.

The nerve conduction velocity (NCV) assessment, demonstrated a significant improvement in nerve conduction velocity.

This improvement corresponded with a clinical downgrade in neuropathy severity, from a severe to a moderate stage.

Such findings suggest a meaningful recovery of nerve function in the affected patients over the study period.

No adverse effect reported during and after the novel BCC topical therapy.

Discussion

Our phase III trial demonstrates that targeting the underlying pathophysiology of DPN can result in substantial improvements in both subjective symptoms and objective measures of nerve function. Patients previously considered for amputation exhibited restoration of sensation, improved limb perfusion, and enhanced nerve conduction velocity, indicating meaningful recovery of nerve function [1,5,7].

The investigational compound utilized in this study is a Boron Based Compound. A novel therapeutic agent developed to target the underlying pathophysiology of diabetic peripheral neuropathy.

Current pharmacologic options, such as duloxetine, pregabalin, and gabapentin, provide symptomatic relief but fail to modify disease

progression [2,4]. In contrast, the BCC leverages a multimodal mechanism, combining angiogenic stimulation, anti-inflammatory activity, and neuro-regeneration. Such a disease-modifying approach aligns with recent findings on exosome therapy, neuromodulation, and molecular regenerative agents, which highlight the feasibility of reversing neuropathic damage in select patient populations [8,9,10].

At present, this compound has Iran Food and Drug Association approval for topical usage.

Evaluation of the topical BCC in pure diabetic neuropathy (without ulcer) in a pilot study showed similar clinical and paraclinical results.

Regarding the scientific evidences discussed above, as a first-in-class curative drug, targeting underlying cause, rapid healing of diabetic ulcers and *preventive effect on the occurrence of ulcers are expected from the novel compound*. Screening planning for diabetic neuropathy and treatment with this novel compound, *promises an ulcer free world in the future for diabetic patients and the substantial alleviation of financial burden on the healthcare system.*

This novel breakthrough in diabetic neuropathy not only signifies a farewell to diabetic ulcers and related limb amputation but also heralds a new era in the management of unmet neurodegenerative disorders.

As the author proposed the role of Boron containing Compounds as a novel potential for treatment of neurodegenerative diseases, in 2019 (Patent application filed in USPTO), this novel potential investigated by Mónica Barrón-González et al. in 2023 [11].

Chemical nerve stimulation and restoration of normal membrane action potential is the probable mechanism of action of Novel Regenerative Compound / Boron Containing Compound.

According to the author, in disabling neuropathic disorders, neurons do not die; rather their function is impaired due to ischemia and lack of blood circulation. Restoration of blood flow, together with membrane potential stimulation, can lead to recovery of neuronal action and revitalize neurons.

Future investigations would clarify exact mechanism of action.

The effect of Boron in nerve stimulation effect has been reported in literature [12].

Positive outcomes have been reported from Electrical Nerve Stimulation in peripheral nerve injury [12].

These findings underscore a paradigm shift in DPN treatment from symptom management toward curative and regenerative strategies. The 3-year follow up of patients indicated sustained efficacy of treatment with this drug.

Long-term follow-up studies are required to evaluate the durability of clinical improvement, impact on diabetic foot complications, and integration into standard clinical practice. Nevertheless, the results suggest that early intervention targeting the root pathophysiology can substantially improve outcomes and potentially reduce the burden of DPN on patients and healthcare systems [3,6,9].

The Novel Regenerative Compound has been approved by Iran Drug and Food Organization for topical usage.

Conclusion

This study, underscore a paradigm shift in DPN treatment from symptom management toward curative and regenerative strategies. This first-in-class curative drug heralds a new era in the management of diabetic neuropathy, enabling rapid wound healing, preventing diabetic ulcers and related amputations and promise a world, free of diabetic ulcers.

Moreover, it represents a pivotal turning point in the therapeutic landscape of neurodegenerative diseases and vascular disorders as unmet dilemmas.

Acknowledgment

I am very grateful to professor Hamid Reza Fathi and Professor Babak Mirzashahi for their sincere collaboration in cases requiring debridement and reconstructive procedures.

Limitations of the Study

The study faced certain systemic and administrative constrains during the regulatory evaluation of the proposed therapeutic agent. The constrains which included extended review timelines and limited operational coordination and the timely initiation of clinical investigation. Ultimately, the project did not received approval from related organization.

Ultimately the new compound received approval from Iran Food and Drug Organization for topical use.

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