Regeneration, Reconstruction & Restoration **Case Series**

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Photobiomodulation as a Coadjutant in Management of Trigeminal Neuralgia: A Case Series Study and Review of the Literature

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Background and objectives: Trigeminal Neuralgia (TN) is a disabling neuropathic pain that can severely compromise the quality of life the patient. The current standard treatments for TN lack enough safety and efficacy; therefore, utilizing new remedies is mandatory. Photobiomodulation (PBM) is a novel treatment suggested for neuropathic pain, but we need more studies on using low-level laser to manage TN.

Materials and methods: 7 cases of primary confirmed TN were enrolled in this study. Diode laser (InGaAs) was utilized with 980 nm wavelength to irradiate the involved painful areas and trigger zones. Painful areas were irradiated intra and extraoral with the duration of 20 seconds and in osculation condition in continual wave (CW). The energy density of intra and extraoral irradiation was 4 j/cm^2 and 6 j/cm^2 respectively. Duration of treatment was about 3 weeks. VAS (Visual analogue scale) score was used as an outcome measure before and after treatment. Prior to enrollment, the VAS of self-reported pain of subjects was 10.

Results: VAS scores gradually decreased from the 4th session in all patients, as far as following 15th session. VAS scores in all patients were 1-2 degree at the end of third week of study. Along with PBM therapy, the dose of carbamazepine for pain management was reduced until the pain intensity was so low that it was not needed.

Conclusion: It seems that the PBM could be employed as adjuvant therapy for TN, but further study with precise laser dosing and more outcome measures are needed to apply this technology confidently.

Keywords: Photobiomodulation; Low-level Laser therapy; Laser biostimulation; Phototherapy; Trigeminal Neuralgia.

1. Introduction

Trigeminal Neuralgia (TN) is a common form of orofacial pain that is distinguished by recurrent, brief, unilateral attacks of electric shock-like pain that are provoked by innocuous stimuli, have an abrupt onset and end, and are confined to the distribution of one or more branches of the trigeminal nerve. It can manifest spontaneously or be a consequence of another recognized condition. TN is an excruciating chronic orofacial pain that could disable the patient and directly impact daily activity (1). TN is classified under painful cranial neuropathies according to the International Classification of Headache Disorders (ICHD, version 3) published by the International Headache Society (IHS) and has the following diagnostic criteria (2).

Classical TN refers to cases with an apparent vascular lesion in imaging or surgical assessment, which compresses the trigeminal root nerve. Secondary TN is caused by an underlying disease such as the Varicella-Zoster virus, vascular malformation, tumor, or an autoimmune disorder such as Multiple Sclerosis. Conversely, in Idiopathic TN, the underlying etiology cannot be identified (2). The most common sites of involvement include the peri-oral and peri-nasal region, vermilion, gums, and alveolar mucosa. Some facial and intra-oral areas may also serve as trigger zones. Innocuous stimuli of these trigger points can fire the pain, and the patients abstain from fingering them (3).
Various types of facial pain were mistakenly grouped along with trigeminal neuralgia, however they are actually separate conditions, sometimes classified as "atypical facial pain" or "painful trigeminal neuropathy". “Persistent idiopathic facial

pain" (PIFP), previously known as "Atypical facial pain", is one of the most common differential diagnoses of TN (1, 4).

Wide ranges of treatments are used to treat TN and its subtypes, including anti-epileptic drugs, antidepressant agents, antipsychotic drugs, cholinergic medications (bethanechol), interventional procedures (microvascular decompression, alcohol injections, thermocoagulation, mechanical decompression, or stereotactic radiosurgery, and psychological treatments (1, 5).

The gold standard and first-line pharmacological treatment is a voltage-gated sodium channel blocker: Carbamazepine (CBZ) and its alternative "Oxcarbamazepine". These two main anticonvulsant agents can control paroxysmal pain in almost all kinds of TN in nearly 90% of patients (3,11,12). Long-term uses of these medications are not easily tolerable and have some side effects (1). The treatments cause only moderate pain relief and have adverse effects and meaningful risks in most cases. Thus, it is crucial to look for more potent and safer remedies (1).

Photobiomodulation (PBM), formerly referred to as Low-Level Laser Therapy (LLLT) or cold laser therapy, includes the light interaction with biological tissues to enhance cellular changes without temperature alteration (6). PBM refers to the utilization of red (600–700 nm) and near-infrared light (NIR) (700–1100 nm) that is generated by low-to-mid power coherent lasers or non-coherent light-emitting diodes [LED]. The power density (irradiance) of this light ranges from 1 mw to 5 W/cm2 (7).

PBM conducts three various clinical effects, including healing promotion, anti-inflammatory impact, and lowering the acute or chronic pain (8). The painkilling is via the reduction of histamines, bradykinin, prostaglandins, and acetylcholine (9).

Following 24 hours of exposure to the 980 nm laser, there was an observed enhancement in mitochondrial activity.

At an energy density of 25 J/cm2, this increase was the highest (126.6%). However, it has not been shown that this increase was statistically significant compared to the control group.

According to Wang et al. (10) the study found that at the investigated settings, 980 nm had an impact on temperature-gated calcium ion channels but did not affect mitochondrial cytochrome c oxidase, in comparison to 810 nm. Water has the potential to be considered as a chromophore for longer wavelengths of NIR, based on its absorption spectra.

Amaroli et al. demonstrated the initial capability of the 980 nm diode laser light to engage with the mitochondria from the bovine liver. The interaction exhibited a window effect and affected Complexes III and IV, as well as ATP synthesis and oxygen consumption. On the other hand, a power of 0.8W maintained the connection between mitochondria and caused an increase in ATP synthesis through the activities of Complex III and IV (11).

Additionally, an increase in oxidative stress was seen, possibly due to the higher oxygen consumption and the specific conditions of the mitochondrial isolation experiment. The lower powers (0.1–0.2 W) of the 980 nm Diode laser shown an inhibitory effect, while the intermediate values (0.3–0.7 W) did not have any noticeable impact. On the other hand, the higher powers (0.8–1.1 W) resulted in an increase in ATP production.

Amaroli et al. extracted mitochondria from bovine liver and found that exposing them to a low intensity of PBM at 980 nm could uncouple the respiratory chain, resulting in increased oxidative stress and the suppression of adenosine triphosphate (ATP) synthesis. On the other hand, higher doses of PBM could maintain mitochondrial coupling and enhance ATP production by activating mitochondrial complexes III and IV.

In 2016, Arduino et al. conducted a study to assess the impact of 980 nm PBM (300 mW, 10 J/cm2, 10 s/point, 2 mm light-tissue distance, twice a week for five consecutive weeks) compared to clonazepam in individuals diagnosed with Burning Mouth Syndrome. The findings demonstrated that PBM outperformed clonazepam in enhancing pain relief and exhibited statistical significance throughout the three-month observation period, however there was no meaningful improvement in anxiety or depression (12).

In a rat model nerve injury, 980 nm diode laser could rehabilitate mechanical hypersensitivity (12).

PBM is a non-invasive, low cost modality that demonstrates few contraindications and rare side effects (12,18).

The purpose of this study is to evaluate the effect of PBM in reducing symptoms of the patients with TN in conjunction with pharmacotherapy.

2. Case presentation

The study protocol was approved by the Ethics Committee of Kermanshah University of Medical Sciences (approval No: IR.KUMS>RES.1400.766). Written consent was taken from all patients prior to the treatmen. The diagnosis of Trigeminal Neuralgia for 7 patients was confirmed by neurologists, oral and maxillofacial surgeons, and otolaryngologists separately according to the usually accepted criteria based on ICHD version 3 and suffering from TN pain for at least 6 months (1, 2). Every patient was labored from unilateral orofacial paroxysmal pain radiating to the upper/lower jaw or nasal ala or the temporal/forehead region of the head. The duration of pain episodes was brief and sharp in quality. Misdiagnoses of pain with odontogenic pain led to the extraction of the teeth of the involved side of the jaw in all patients prior to definitive diagnosis (Figure 1). All patients were receiving anti-epileptic drugs, mainly CBZ (400-600 mg daily), since the disease was diagnosed definitively (Table 1), but the pharmacotherapy could not improve the pain completely, and the drug doses must be increased to a threshold point. The included patients did not have any contraindications such as gestation to receive laser irradiation. All patients received PBM from October 2020 to January 2021 at a private clinic in the Lorestan province of Iran that was consecutively included in the study. The age of the patients ranged from 37 to 83 (Mean= 58.42) years, 3 patients

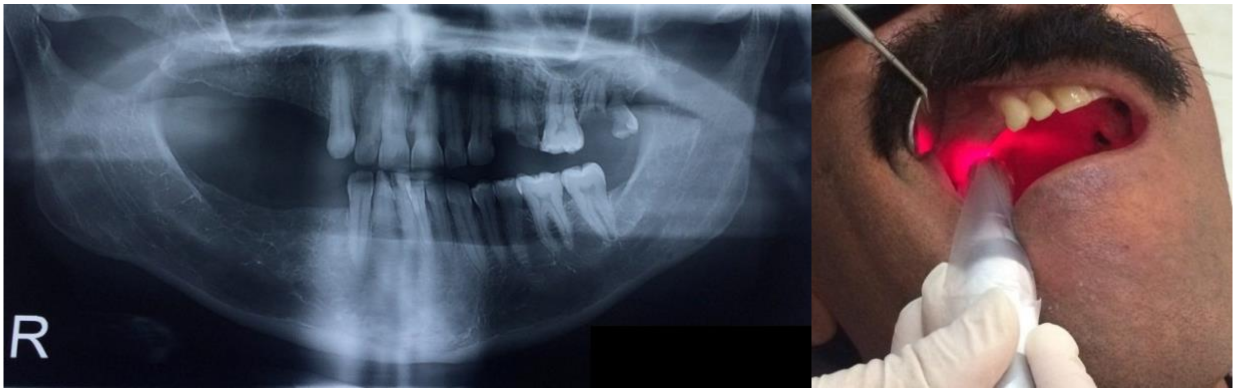

Figure 1. Extraction of the teeth of the right side of a 45-year-old patient could not relieve the severe unilateral lower face pain. After establishment of TN diagnosis, PBM of the involved area decraesed the quantity and episodes of the TN pain significantly. 980 nm diode laser by continuous wave mode were used intraoral and extraoral with 5 J radient energy totally.

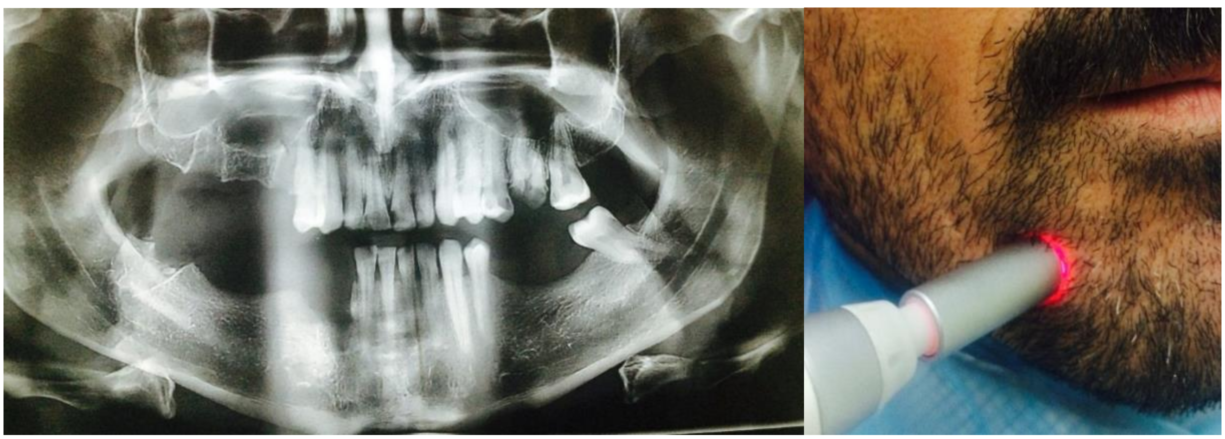

Figure 2. A 37-year-old male with the history of the whole right-side tooth extraction due to misdiagnosis of odontogenic pain. TN was confirmed and extraoral sites were irradiated by diode laser with a power of 0.3 W and 20 seconds in continuous wave contact mode.

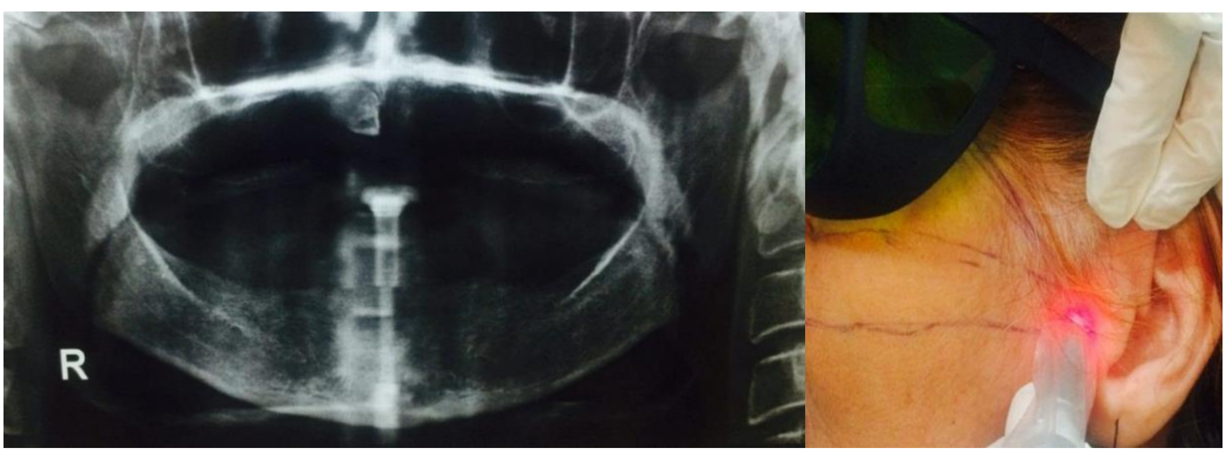

Figure 3. LLLT of right side of the face of a 65-year-old patient with TN with V1 to V3 branch involvement. The same extaoral parametrs of the 908 nm laser for other cases were aplied.

were male, and 4 patients were female (Table 1). The participants were alert and conscious, free from psychological disorders or sensory disabilities. None of the patients had received neurosurgery or any other invasive treatments (such as ethanol or glycerin injection, radiofrequency, Gama-knife microvascular decompression, etc.). For measuring the pain, the VAS score was used before and after treatment. The pain degrees were registered in a questionnaire. The range of VAS was from 0-10; 10 pointed out the most severe pain conceivable while 0 denoted no pain. VAS score of patients before laser treatment was 10 degrees. The patient reported every VAS score, and the clinician was not blind to the VAS results. The main outcome of the intervention was pain reduction which was assessed by VAS at the end of the 15th session of laser therapy.

Diode laser [Indium gallium arsenide (InGaAs)] was applied in all subjects with 980 nm wavelength (Wiser, Doctor Smile, Italy), a power of 0.3 W for extraoral and 0.2 W for intraoral sites, and the diameter of the beam spot size was approximately 1 cm^2 (0.9 mm^2). Extraoral and intraoral irradiance was 300 and 200 mw/cm^2 respectively. The duration of exposure at each point was 20 seconds in CW and contact mode. Hence, extraoral and intraoral energy densities were 6 and 4 J/cm^2, respectively. Moreover, the delivery system of the laser beam was permanent fiber with a low-level tip, and the application technique was stationary contact (single contact point). The power of the laser diode device used in this study was checked by a power meter (PFM-300 Exfo) and no loss of output power was observed.

Some parameters such as the number of points irradiated, whole area irradiated (cm^2), and total radiant energy were varied among the patients due to different painful areas and diversity of pain distribution. The patients were treated by laser every other day for 15 sessions. Thereafter, the reminder dose was delivered monthly for one year. Trigeminal large branches (V1-V3) are deeply seated beneath the maxillofacial bones; therefore, laser delivery to these large branches is nearly impossible. We need to irradiate almost all involved regions point to point. The biggest trunk of the Trigeminal nerve which we can access through the skin is the Auriculotemporal nerve which turns posteriorly around the condylar neck. The device probe was disinfected and covered with disposable covers before use.

3. Discussion

TN is a weary neuropathic pain with a widespread burden. Severe episodic pain can compromise the function and quality of life of the patients yet sometimes could lead to suicide (1-3). PBM was widely used to rehabilitate numerous painful conditions as well as TN (13).

Results of this case series showed that the VAS subjective measurements of TN pain were significantly reduced following 15 sessions of PBM by a 980 nm diode laser. Noninvasiveness, non-pharmacotherapeutic with minimal adverse effects, made PBM an interesting treatment approach in TN patients (14). Meanwhile, according to the two recent systematic reviews by Ibarra et al. and De Pedro et al., the studies about the effect of PBM on trigeminal neuralgia are sparse and heterogeneous in the aspect of laser parameters, laser wavelengths, frequency of the light emission, inclusion criteria, and outcome measures (Table 3) (1, 6). Various protocols of laser therapy weaken the outer validity of the previous research, so it is very difficult to define specific parameters for PBM. The common point of former research has been the use of infra-red light (above 700 nm wavelength), using continuous wave (CW) and contact mode in most studies and irradiation of trigger painful points (Table 3). One of the problems of previous research was not reporting the number of irradiated points (9, 15-18).

Regardless of the paucity of literature about PBM in TN treatment, the majority of clinical trials have positive results in the aspect of pain reduction (Table 3).

Among different researches, like ours, only one study by Amanat et al. used 980 nm (GaAs laser) to alleviate the pain of 12 patients with TN. They received 10 separate PBM sessions with 420 mW/cm2 irradiance at the target and the 3.6 J radiant energy per irradiation site in addition to medication (CBZ). In comparison with our study, PBM adjunct to the medication in the study by Amanat et al. (9), could not significantly reduce VAS records following the treatment; but in the present study, the results were meaningful in terms of VAS pain reduction, and the laser parameters for extraoral points was 300 mW/cm^2 and 200 mW/cm^2 for intraoral regions.

In another study by Ebrahimi et al., they compared co-adjunctive photobiomodulation with pharmacotherapy and medication therapy alone. They used an 810 nm GaAlAs diode laser with 5 J energy during 9 sessions and found that PBM could significantly decrease pain severity compared to the pharmacotherapy alone in TN patients (3).

Some of the limitations of our study were the low number of included patients, short-term follow up, and considering the VAS as the only main result of the intervention. Therefore, it is suggested to add the frequency and duration of pain to the main results of future research.

After 10 sessions of Photobiomodulation, Walker et al. found that 7 out of 9 TN patients experienced pain alleviation, as measured by a decrease in urine 5-HIAA, a metabolite of serotonin that has analgesic effect (19).

Pinheiro et al. examined 241 people experiencing persistent maxillofacial discomfort; 53 were found to have TN within 1 and 2 years. These patients received a total of 12 sessions and were observed at two distinct intervals. Approximately 20 patients were asymptomatic during the first year following treatment, and 30 patients were asymptomatic during the second year. The authors report that the symptomatic patients have symptoms throughout both follow-up periods and that they were emotionally distressed (17).

Table1. Clinical charactristics of 7 patients included in the study.

Patient number	1	2	3	4	5	6	7
Age	37	45	65	68	53	83	58
Sex	M	M	F	F	F	M	F
Side	R	R	R	L	L	R	R & L
Prior treatments	CZN* + GAB*	CZN + GAB	CZN + GAB	CZN + GAB	CZN + GAB	CZN + GAB	CZN + GAB
Neurovascular conflict	Non	Non	Non	Non	Non	Tearing	Non
The affected Trigeminal branch(es)	V2+V3	V1+V2 +V3	V1+V2+V3	V1+V2	V1+V2+V3	V1+V2+V3	V1+V2+V3
Medical history	None	None	None	None	None	None	None

Table 2. Before and after VAS scores of the patients.

Patient number	1	2	3	4	5	6	7
VAS at the first session	10	10	10	10	10	10	10
VAS after 15th session	1	2	1	1	2	1	2

Therapeutic combinations to control TN pain were examined; PBM and Gasserian ganglion block surgery resulted in decreased pain intensity and resulted in pain alleviation and the rate of carbamazepine consumption 7 days after surgery; this reduction persisted throughout all follow-up periods. 85.7% of patients in the therapy combination group were symptom-free after six months (20).

The observed therapeutic benefit may have been due to the oxygenation of damaged neuronal cells during surgery, which activated a neuroprotection process supported by PBM and neurogenesis (21).

A study that evaluated PBM as an adjunct to oxcarbazepine treatment also found that medication consumption was reduced (22).

Two studies examined the effect of carbamazepine in combination with PBM . In both studies, patients ameliorated immediately after therapy; However, no difference was seen between the PBM and pharmacotherapy groups at the end of the study or during the first (9) , second and fourth months of follow-up (3). Patients recovered throughout therapy, but no therapeutic benefits were shown in the follow-up session, suggesting that prolonged, continuous treatment may enhance the result of this therapeutic relevance (17).

In just one study, PBM was compared to TENS (transcutaneous electrical nerve stimulation) The patients were randomly assigned to either the photobiomodulation or electromagnetic stimulation groups, then they were treated with either an infra-red helium-neon laser with an intensity of 150–170 mW/cm2 or 10 Hz for 20 minutes, depending on which group they were in. Both therapies resulted in comparable pain control and reduction after the treatment (18).

Intriguingly, the electromagnetic stimulation group also observed a decrease in muscular tension, which wasn't seen in the PBM group. This may have been due to the different points applied by the two therapies, as PBM's effect occurs in the targeted tissue, but for a complete assessment of a muscular effect, the protocol points should have also included the impacted muscular tissue (18). While photobiomodulation (PBM)

Table 3. High quality clinical trials on TN treated by PBM (adopted from Ibarra and De Pedro et al. (1,14)).

Author/ year	Equipment	Wavelength (nm)	Dose (J/cm^2)	Power density (mW/cm2)	Time of exposure	Spot size	Points	Session's schedule	Method of irradiation
Walker 1983 (19)	Helium-neon laser	632	NI	1	20 seconds	4mm^2	NI	30 sessions	Pulse mode (20 Hz) & CM
Pinheiro 1998 (17)	Diode laser	632.8 670 830	0.2J 0.8J 3.9J	NI	Varied according to the output power of each laser	NI	NI	12 sessions	CW & CM
Agha mohammadi 2012 (15)	Diode laser	890	3-10 J	NI	NI	NI	NI	12 sessions	CW & CM
Amanat 2013 (9)	GaAs laser	980	12.73 J	120	5 minutes at each trigger point	0.2826 cm^2	NI	10 sessions	Pulse mode (3000 Hz) And CM
Seada 2013 (18)	Helium-neon laser	830	NI	150-170	1-2 min intraorally at the full path of the branch and 10 min at extraorall trigger points	NI	NI	24 sessions	CW & CM
Antonic´ et al 2017 (16)	GaAlAs laser	660 810	3.0 J	30	100 second	2 mm	NI	20 sessions	CW & CM
Ebrahimi 2018 (3)	GaAlAs diode laser	810	5	200	25 seconds	NI	2-3 points	9 sessions	CW & CM

NI: not informed, CW: continuous wave, CM: contact mode.

muscular tissue (18). While photobiomodulation (PBM) treatment shows promise as an adjuvant therapeutic technique, (3, 9, 15, 22).

There may be inconsistency across studies due to these mistakes, even when they may not meet the criteria for a high risk of bias. There was no agreement since each study used unique parameters.

Previous work by Jenkins and Caroll et al. established a streamlined recommendation for reporting PBM parameters, which includes the following eight pieces of information: wavelength, power or irradiance, radiant exposure, time, area of the light beam when in contact with the target (which may not always match the area of the equipment's output spot), type of devices pulse (continuous light or in fragmented pulses), anatomical site of the target, and therapies schedule (23).

An agreement on the optimal parameters of PBM or the clinical regimen for TN patients cannot be proposed in the absence of uniformity in documented parameters and results.

The only constant parameter was the wavelength, which ranged from 810 to 980 nanometers in five of the six investigations. It is essential to note that the effectiveness was observed in a pattern of continuous sessions; furthermore, the long-term follow-up data was inadequately reported.

4. Limitation

In general, the number of patients who meet the criteria of classic trigeminal neuralgia is very low, in addition the regular follow-up of these patients and the full cooperation of the patients are one of the problems and limitations of this type of study.

5. Conclusion

The photobiomodulation adjuvant to the standard pharmacotherapy of the primary Trigeminal Neuralgia seems to be effective in the pain reduction, and therefore, decreasing the dose of anti-epileptic drugs. More similar research with larger sample size is needed to determine the best therapeutic window for PBM in TN treatment.

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Authors' contribution

Nahid Derikvand: Original Draft, Project Administration
Masoud Hatami: Conceptualization, Writing-Review & Editing, Supervision
Seyed Amir Hossein Ghasemi: Writing -Review
Nima Fallahnia: Writing -Review

Conflict of Interest

The authors declare that they have no conflicts of interest related to this article

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