



## Research Article

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### PATIENT REPORTED OUTCOMES ON BIOGETICA FORMULATIONS IN TRIGEMINAL NEURALGIA

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#### ABSTRACT

Background: Trigeminal neuralgia (TN) is a chronic disorder, characterized by unbearable, sudden facial pain, often leads people to suicide. Thus TN is referred to as suicide disease. Aim: The ability of four formulations based on natural medicine, homeopathic, dietary supplements and ayurvedic herbs in different combinations to reduce the complications of TN was investigated with comparative evaluation. Materials & Methods: The study was performed through survey. Questionnaire related to demographic and illness information with TN patient's feedback on the formulations after use, was prepared and randomly sent to the patients, who have received the treatment at the clinic. The responses were collected electronically and detailed statistical analysis was carried out to evaluate the outcome of the treatment. Results: Combinations of all four Biogetica® formulations showed more potential in reducing the disease complications. The treatment with these formulations also displayed improvement in the patient's ability to perform physical activities. Furthermore, no side effects were observed for these formulations after treatment. The combination of 4 biogetica formulas improved the health rate of 68% TN patients. Such results have not been seen in any Drug treatment or gamma knife Surgery. Maximum number of patients (26) got the positive result in about 15 to 45 days. But, interestingly, 21 patients got their pain relieved within 15 days of time. Conclusion: The combination of natural medicine, homeopathic, dietary supplements and ayurvedic herbs are effective in alleviating the complications of TN without any adverse effects. Therefore, Biogetica® formulations can be used safely in the treatment of TN.

**Keywords:** Trigeminal neuralgia; Herbal medicine; Neuropathic pain

#### INTRODUCTION

Trigeminal neuralgia (TN), also referred as tic douloureux, is a chronic pathological disorder characterized by lancinating and sudden facial pain.<sup>1</sup> Such pains are often convulsive and excruciating, having a substantial detrimental effect on the quality of life.<sup>2</sup> Most of the times, simple act such as speaking or chewing triggers the pain, which is episodic in nature.<sup>1</sup> The prevalence of TN is about 0.015% in the general population.<sup>3</sup> Neuralgia commonly affects elderly people, especially above 50 years of age, women being more susceptible.

The pathogenesis of this rare, facial pain syndrome is attributed to the age associated degeneration and vascular compression in trigeminal nerve.<sup>4</sup> About 80-90% of the TN are idiopathic, with nerve compression considered as the primary cause. However, multiple sclerosis and tumors (vestibular schwannoma, tuberculoma, meningioma, epidermoid cyst, etc.) are the etiological factors of neuralgia observed in about 10% of patients.<sup>2,5-7</sup> Many reports also put forward the theories of the possible role of arachnoiditis, diabetes mellitus, sinusitis, aneurysm and inflammatory diseases in causing TN.<sup>2</sup> Alongside the pain, compression of trigeminal nerve also leads to other associated complications such as facial swelling, skin redness, running nose, nasal congestion, lacrimation and muscle contractions.<sup>8</sup>

The most commonly used therapeutic modalities of TN include the use of anticonvulsants. Starting from the first neuralgia drug, phenytoin, so far, various anticonvulsant drugs such as carbamazepine (CBZ), oxcarbazepine (OXC), baclofen and

gabapentin have been used.<sup>2,9,10</sup> Though these drugs showed the potential to reduce and control pain attacks, due to severe adverse effects and pain relapses, Clinicians are keen about finding safe and effective alternative medicines. Natural products and their formulations can be considered as the better candidates, as their side effects are relatively less frequent compared to synthetic compounds.<sup>11</sup> Also, it is well known that herbal medicines are more useful in the management of neuropathic pains.<sup>12</sup> Therefore, in this study, we sought to analyze the efficacy of four formulations of Biogetica® in different combinations among TN patients. The study was performed through survey and the outcome of the treatments was evaluated by analyzing the data provided by the patients.

#### MATERIALS AND METHODS

##### Site and study design

This study was carried out at Dr. Vijay Kumar Kamat's clinic, Belagavi, Karnataka. A questionnaire with 29 questions was carefully prepared (given in Supplementary Information). The questionnaire is divided into three domains containing demographic information, illness information and the patient's feedback on Biogetica® formulations, respectively. The TN patients who were earlier treated via telemedicine at the clinic were considered as the study subjects. The questionnaire was arbitrarily sent to the study subjects and their responses were collected electronically for a period of 3 months. The data received from the TN patients were then tabulated, before being subjected to detailed analysis using appropriate statistical methods.

### Study subjects

A total of 76 individuals participated in the study, out of which, 49 were female and 27 were male. The consent of all the subjects to participate in the study was taken at the beginning of the questionnaire, by providing complete information about the study and the resulting publication of the data.

### Formulations

Four formulations of Biogetica® were used in the study. The composition of all the formulations was tabulated in Table 1.

### Treatment details

Different participants have taken the four formulations in different combinations. More than 65% patients (50 individuals) have taken all the four formulations, where as 11 participants received the TN formula alone. Further, 4 subjects have taken a combination of neuralease, OM 13 and TN Formula. Table 2 shows the details of the formulations received by the participants. Overall, majority (71 participants) have received TN formula, followed by OM 13 (61 patients), neuralease (60 patients) and HoloRam Cronisol-D (55 patients).

Around 60% study participants were using the Biogetica® formulations for less than 1 year time. A total of 16 (21.1%) patients have been taking the formulations for about 1-3 years, and 15 (19.7%) have been using the Biogetica® formulations for more than 3 year duration.

Alongside these formulations, 56 individuals have taken various other alternative medicines or therapeutic methods including acupuncture, physiotherapy and drugs such as CBZ and baclofen. Mainly, thirteen study subjects have received tegretol treatment, while lyrica and gabapentin were taken by 10 and 9 patients, respectively. In addition, 6 patients taken a well known TN drug, carbamazepine. Further, 14 participants have also used formulations other than Biogetica® formulations.

### Ethical considerations

The approval from the ethics committee was not obtained, as the study is based on the survey of patients outcome measure for previously approved Ayurvedic and Homeopathic Products.

### Statistical analysis

The data was entered in MS Excel 365 and analysed by using the SPSS software version 22. The data was represented in the form of frequency, percentages and graphs. Cross tabulation was used to study the relationship between two variables.

## RESULTS

### Demographic details

Out of 76 participants, large portion (40.8%) were of the age between 65-75 years (31 patients). 18 patients (23.7%) were more than 75 year old, whereas 14 subjects (18.4%) were aged between 55-65 years. A small fraction of people were below 55 years with 8 participants aged between 45-55 years and only 5 (6.6%) study participants were between 35-45 years, respectively (Figure 1).

### Disease details

Among 76 participants, 33 patients (43.4%) were suffering from TN from less than 5 years (Table 3). One fourth of the study subjects (19 patients) were under diseased state from 5-10 years, followed by 13 (17.1%) participants, who are suffering from a period of 10-15 years. Whilst, 11 patients (14.5%) were suffering from long term TN (more than 15 years). Most of the subjects (46.1%) were not suffering from conditions such as multiple sclerosis, trigeminal nerve injury or tumor. However, 27 participants (35.5%) were known to be suffering from trigeminal nerve injury. Subjects with multiple sclerosis and tumor were found to be 6 (7.9%) and 3 (3.9%), respectively.

### Clinical effectiveness

**Pain relief score:** The efficacy of the Biogetica® formulations was analyzed based on the responses of patients. After using Biogetica® formulations, more than 50% study participants (40 patients) have achieved pain relief score more than 5. Among 50 patients, who have received the combination of all four drugs (neuralease, OM 13, TN Formula and HoloRam Cronisol-D), 27 have rated pain relief score of >5. All the four patients who took the combination of neuralease, OM 13 and TN Formula, have rated the formulation with >5 pain relief score. The response for the combination of OM 13, TN Formula and HoloRam Cronisol-D was 50:50. Interestingly, TN formula alone had the pain relief score of more than 5 by approximately 27% patients. The response of patients for different combinations is depicted in Table 4. It is very significant that, higher number of study subjects (53) experienced very mild to moderate pain during the past 4 weeks of the study, compared to 23 patients with severe or very severe pain.

**Time response:** Maximum number of patients (26) got the positive result in about 15 to 45 days. But, interestingly, 21 patients got their pain relieved within 15 days of time. The time taken by the different combinations of Biogetica® formulations to show their results on TN patients are tabulated (Table 5). Neuralease alone showed its effect between 15-45 days. Two patients expressed that the combination of neuralease with OM 13 has displayed the results within 45 days. The combination of all the 4 Biogetica® formulations showed its result at different time intervals i.e., less than 15 days in 22% of the TN subjects; between 15-45 days in 36% of patients; 45-90 days in 20% of the subject and more than 90 days in rest 22% of participants. But, 45.5% of the subject opined that TN formula alone was effective within 15 days of treatment, whereas in 36.40% of subjects, it exhibited results beyond 90 days.

**Health improvement:** Improvement in the quality of the health was assessed in TN patients after using Biogetica® formulations. About 61% of the patients expressed that they there is improvement in their health after consuming the different combinations of Biogetica® formulations. About 32.90% of patients did not experience any changes in their health. Feedback from the patients showed that compared to other combinations, the combination of all the four formulas of Biogetica was more effective in improving the health rate of about 68% TN patients. Only 4 participants (5.2%) were feeling worse than before.

**Overall effect:** Information on overall effectiveness of different formulations of Biogetica was gathered from all 76 subjects and divided in to two categories,  $\leq 5$  and  $> 5$ . In accordance with other results, the combination of all 4 formulations of Biogetica was more effective in 34 patients out of 50, who used these combinations. 4 (36.4%) out of 11 patients found the TN formula alone as effective and rated with a score of  $> 5$ . All the patients

(4) who took the combination of neuralease, OM 13, TN formula rated its effectiveness more than 5. In general, more than 65% of the patients rated the effectiveness of Biogetica formula with >5, while only 34.2% rated with a score of ≤5.

**Effect on daily and physical activities:** Biogetica® formulations have considerably improved various activities of the patients. More than 50% of patients were able to do activities such as lifting or carrying groceries, climbing one flight of stairs and bathing or dressing without any limitation. However, 64 of 76 study participants had problem doing vigorous activities such as running, lifting heavy objects and participating in strenuous sports. Other activities like bending or kneeling and walking more than a mile, were moderately affected. Further, more than 50%

respondents have confirmed that, after treatment with Biogetica® formulations, their work or other daily activities were not affected either by physical or emotional problems. Nevertheless, 75% of the study subjects have reported that their social activities were affected slightly to extremely due to physical or emotional problems. This is almost in agreement with the interference of pain in their normal work. Biogetica® formulations have also enhanced the confidence among patients in getting good health. Almost three-fourth of study participants considered that they don't get sick easier than other people, and accepted that they were as healthy as anybody else. More than 50% of the patients were confident that their health will not deteriorate in future also.

**Table 1: Composition of Biogetica® formulations**

Formulation	Ingredients
Homeopathic Trigeminal Neuralgia CM (TN Formula)	Aconite 30; <i>Hypericum</i> 200; Hekla Lava 30; <i>Spigelia</i> 30 - Homeopathy Potency
Homeopathic OM 13 Trigeminal	Potent bioenergetic impressions of: Peripheral Nerve Endings, Trigeminal Nerve – Homeopathy Potency
Herbal Neuralease	<p>Each tablet of 850 mg comprises concentrated aqueous extracts of:</p> <p>Ayurvedic classical formulation – Varanadi Kasayam            Ayurvedic classical formulation – Drakshadi Kasayam            Brahmi (<i>Bacopa monnieri</i>) – 200 mg            Rasna (<i>Pluchea lanceolata</i>) – 15 mg            Kharjura (<i>Pheonix farinifera</i>) – 200 mg            Excipient – 60 mg</p> <p>Composition of Varanadi Kasayam: 240 mg            Varana (<i>Crataeva religiosa</i>), sairyaka (<i>Strobilanthes ciliatus</i>), shatavari (<i>Asparagus racemosus</i>), dahana (<i>Plumbago zeylanica</i>), morata (<i>Chenomorpha fragrans</i>), bilwa (<i>Aegle marmelos</i>), vishanika (<i>Aristolochia bracteolata</i>), brihati (<i>Solanum melongena</i>), bhadra (<i>Aerua lanata</i>), karanja (<i>Pongamia glabra</i>), pootikaranja (<i>Holoptelia integrifolia</i>), jaya (<i>Premna corymbosa</i>), pathya (<i>Terminalia chebula</i>), bahalappallava (<i>Moringa olifera</i> / drum stick), darbha (<i>Desmostachya bipinnata</i>) and agnimukhi (<i>Semecarpus anacardium</i>) – 15 mg each</p> <p>Composition of Drakshadi Kasayam: 135 mg            Draksha (<i>Vitis vinifera</i>), madhooka (<i>Madhuca longifolia</i>), yashtimadhu (<i>Glycyrrhiza glabra</i>), lodhra (<i>Symplocos laurina</i>), mustha (<i>Cyperus rotundus</i>), amalaki (<i>Emblica officinalis</i>), aravinda (<i>Nelumbo nucifera</i>), chandana (<i>Santalum album</i>), usheera (<i>Andropogon muricatus</i>) – 15 mg each</p> <p>Dosage:            Prophylaxis – 2 tablets two times daily for 6-8 weeks.            Maintenance – 2 tablets once daily at bedtime for over 2-3 months.</p>
Nutraceutical Capsules CRONISOL-D	<p>Group I:            Activated substrate micronutrient: Gamma-aminobutyric acid (GABA) – 15 mg, Sodium hyaluronate – 2.5 mg</p> <p>Group II Fungi:            Lion's mane extract dry (<i>Hericium erinaceus</i>) – 30 mg.</p> <p>Group III Herbal remedies:            Cat's claw dry extract (<i>Uncaria tomentosa</i>, bark &gt; 3% alkaloids oxi indolicos) – 50 mg, Ginkgo biloba (Dry extract, leaves 24% ginkgo flavonols) – 45 mg, Devil's claw dry extract (<i>Harpagophytum procumbens</i> root &gt; 2% harpagoside) – 45 mg, Aloe vera extract (nebulized) – 35 mg, Dry extract black currant (<i>Ribes nigrum</i>, leaves, &gt; 1% flavonoids) – 35 mg, Powder willow (<i>Salix alba</i>, cortex) – 35 mg, Poppy california dry extract (<i>Eschscholzia californica</i>, aboveground, &gt;2% flavonoids) – 20 mg, Horsetail (<i>Equisetum arvense</i>, aboveground, dry extract &gt; 10% silica) – 20 mg, Hypericum dry extract (<i>Hypericum perforatum</i>, aboveground &gt; 0.3% hypericin) – 20 mg</p> <p>Group IV Amino acids:            L-tryptophan – 25 mg, Leucine – 20 mg, L-methionine – 20 mg, Phosphatidyl-L-serine powder (20%) – 20 mg</p> <p>Group V vitamins and minerals:            Magnesium gluconate (5.86% magnesium) – 25 mg, Vitamin B6 (pyridoxine hydrochloride) – 0.7 mg, Vitamin B12 (cyanocobalamin) – 1.25 mcg</p>

**Table 2: Formulation(s) taken from Biogetica**

Biogetica Formulation(s)	No. of Participants	Percent
Neuralease Tablets, OM 13, TN Formula, HoloRam Cronisol-D	50	65.8
Neuralease Tablets, OM 13	2	2.6
Neuralease Tablets, OM 13, TN Formula	4	5.3
Neuralease Tablets	1	1.3
Neuralease Tablets, TN Formula	1	1.3
Neuralease Tablets, TN Formula, HoloRam Cronisol-D	2	2.6
OM 13	1	1.3
OM 13, HoloRam Cronisol-D	1	1.3
OM 13, TN Formula	1	1.3
OM 13, TN Formula, HoloRam Cronisol-D	2	2.6
TN Formula	11	14.5
Total	76	100.0

**Table 3: Distribution of participants according to duration of suffering from TN**

How long have you been suffering?	No. of Participants	Percent
<5	33	43.4
5-10	19	25.0
10-15	13	17.1
>15	11	14.5
Total	76	100.0

**Table 4: Cross tabulation between type of Biogetica formulation(s) and Pain relief score**

Which formulation(s) have you taken from Biogetica?	Pain Relief Score		Total
	≤5	>5	
Neuralease Tablets	0 0.0%	1 100.0%	1 100.0%
Neuralease Tablets, OM 13	0 0.0%	2 100.0%	2 100.0%
Neuralease Tablets, OM 13, TN Formula	0 0.0%	4 100.0%	4 100.0%
Neuralease Tablets, OM 13, TN Formula, HoloRam Cronisol-D	23 46.0%	27 54.0%	50 100.0%
Neuralease Tablets, TN Formula	1 100.0%	0 0.0%	1 100.0%
Neuralease Tablets, TN Formula, HoloRam Cronisol-D	2 100.0%	0 0.0%	2 100.0%
OM 13	1 100.0%	0 0.0%	1 100.0%
OM 13, HoloRam Cronisol-D	0 0.0%	1 100.0%	1 100.0%
OM 13, TN Formula	0 0.0%	1 100.0%	1 100.0%
OM 13, TN Formula, HoloRam Cronisol-D	1 50.0%	1 50.0%	2 100.0%
TN Formula	8 72.7%	3 27.3%	11 100.0%
Total	36 47.4%	40 52.6%	76 100.0%

Table 5: Cross tabulation between type of Biogetica formulation(s) and duration

Which formulation(s) have you taken from Biogetica?	How long did it take to see results?				Total
	<15 days	15 days to 45 days	45 days to 90 days	>90 days	
Neuralease Tablets	0	1	0	0	1
	0.0%	100.0%	0.0%	0.0%	100.0%
Neuralease Tablets, OM 13	1	1	0	0	2
	50.0%	50.0%	0.0%	0.0%	100.0%
Neuralease Tablets, OM 13, TN Formula	1	1	0	2	4
	25.0%	25.0%	0.0%	50.0%	100.0%
Neuralease Tablets, OM 13, TN Formula, HoloRam Cronisol-D	11	18	10	11	50
	22.0%	36.0%	20.0%	22.0%	100.0%
Neuralease Tablets, TN Formula	1	0	0	0	1
	100.0%	0.0%	0.0%	0.0%	100.0%
Neuralease Tablets, TN Formula, HoloRam Cronisol-D	1	1	0	0	2
	50.0%	50.0%	0.0%	0.0%	100.0%
OM 13	0	1	0	0	1
	0.0%	100.0%	0.0%	0.0%	100.0%
OM 13, HoloRam Cronisol-D	1	0	0	0	1
	100.0%	0.0%	0.0%	0.0%	100.0%
OM 13, TN Formula	0	1	0	0	1
	0.0%	100.0%	0.0%	0.0%	100.0%
OM 13, TN Formula, HoloRam Cronisol-D	0	0	0	2	2
	0.0%	0.0%	0.0%	100.0%	100.0%
TN Formula	5	2	0	4	11
	45.5%	18.2%	0.0%	36.4%	100.0%
Total	21	26	10	19	76
	27.6%	34.2%	13.2%	25.0%	100.0%

Table 6: Cross tabulation between type of Biogetica formulation(s) and Side effects

Which formulation(s) have you taken from Biogetica?	Have you experienced any side-effects with Biogetica Formulation(s)?		Total
	Yes	No	
Neuralease Tablets	0	1	1
	0.0%	100.0%	100.0%
Neuralease Tablets, OM 13	0	2	2
	0.0%	100.0%	100.0%
Neuralease Tablets, OM 13, TN Formula	0	4	4
	0.0%	100.0%	100.0%
Neuralease Tablets, OM 13, TN Formula, HoloRam Cronisol-D	6	44	50
	12.0%	88.0%	100.0%
Neuralease Tablets, TN Formula	0	1	1
	0.0%	100.0%	100.0%
Neuralease Tablets, TN Formula, HoloRam Cronisol-D	1	1	2
	50.0%	50.0%	100.0%
OM 13	0	1	1
	0.0%	100.0%	100.0%
OM 13, HoloRam Cronisol-D	0	1	1
	0.0%	100.0%	100.0%
OM 13, TN Formula	0	1	1
	0.0%	100.0%	100.0%
OM 13, TN Formula, HoloRam Cronisol-D	0	2	2
	0.0%	100.0%	100.0%
TN Formula	2	9	11
	18.2%	81.8%	100.0%
Total	9	67	76
	11.8%	88.2%	100.0%

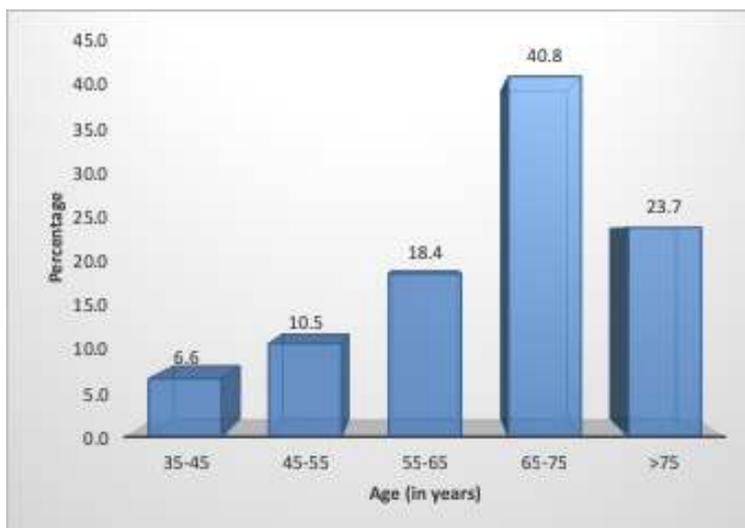


Figure 1: Distribution of participants according to age

**Adverse events:** Promisingly, about 90% study participants have not experienced any side-effects after using Biogetica formulation(s). Table 6 depicts the response of TN patients on the side effects of various formulations of Biogetica. Among the 11 different combinations of Biogetica® formulations, 8 formulations were free from side effects. The combination of all the 4 formula of Biogetica showed very low side effect. About 88% of patients have not experienced any side effects after using this formulation. Similarly, treatment with TN formula alone has very subtle side effect. Only 9 out of 76 have experienced some sort of side effects.

## DISCUSSION

Currently, neuropathic pain is considered as the major health concern worldwide. Many reports have showed the potential activities of various drugs in overcoming this chronic neurological disorder. CBZ and OXC were earlier recommended as the first line of drugs against TN.<sup>13-15</sup> But, CBZ led to some common side effects such as drowsiness, diplopia, nausea, dizziness, ataxia, elevation of transaminases and hyponatremia to few severe complications like myelosuppression, hepatotoxicity, lymphadenopathy and systemic lupus erythematosus.<sup>13</sup> Further, it is also reported that about 6-10% of patients receiving CBZ cannot tolerate the drug.<sup>16</sup> Therefore, OXC is a better alternative as it is more safe well tolerated.<sup>17</sup>

There are also reports that, currently, antidepressant drugs such as gabapentin, amitriptyline or pregabalin were also considered for neuropathic pains.<sup>18</sup> Botulinum toxin type A (BTX-A) was also reported to reduce the pain intensity among TN patients.<sup>19,20</sup> A second line of drugs for TN include lamotrigina and baclofen, and many more being developed. Along with the chemotherapy, several therapeutic modes are developed and being used against TN. However, none of these are reliable or satisfying due to their adverse effects. Procedures like microvascular decompression (MVD) and gamma knife radiosurgery also not showed promising outcome by affecting the quality of the patient's life due to reoccurrence of pain and numbness feel in that area.

Use of herbal alternatives to relieve neuropathic pains has been explored earlier with positive effects.<sup>21</sup> Leaf extract of *Ginkgo biloba* is reported to increase the ability of patient suffering from

neuropathic pain, to do physical activities.<sup>22</sup> Other plants which are able to cure the neuropathic pains include *Aconitum carmichaeli*, *Acorus calamus*, *Cannabis sativa*, *Artemisia dracunculul*, *Nigella sativa* and *Allium sepa*.<sup>23</sup> Also, many plant based topical pain relievers were developed, suggesting that the role of phytotherapy in alleviating pain.<sup>24</sup>

In this retrospective study, we investigated the role of four herbal formulations of Biogetica® as a therapeutic approach against the neuropathic pain syndrome, TN. Different combinations of the our study formulations have yielded positive effects of the disease. Out of all the combinations, patients who have received all the four formulations (TN formula, OM 13, neuralease and CRONISOL-D) showed potent activity followed by TN formula alone. These formulations were able to reduce the pain significantly, with more than half of the patients achieving the successful pain relief. 54% of patients who have received all the four Biogetica® formulations showed pain relief score above 5 with overall effectiveness of 68%. This is better than the results obtained for gamma knife surgery, which resulted in pain relief among only 44% of the patients.<sup>25</sup>

The time taken to get the result is also significantly less. Most of the patient's pain was relieved in less than 15 days of time. The test formulations have also considerably improved the daily activities of the patients, with less interference of physical or mental health. More importantly, all these effect were observed without adverse effects. Therefore, these formulations are much safer than procedure like microvascular decompression, which lead to severe complications such as meningitis, haematomas, cerebrospinal fluid (CSF) leakage, sensory loss and hearing loss.<sup>13</sup>

The formulations could not able to improve the patients ability to do vigorous activities. Further, social activities of three fourth of the patients were also affected due to physical or emotional problems. But, the improvement of psychological confidence among the patients were very promising. Therefore, these formulations of Biogetica® can be a new candidate in the TN therapy. This study has led to a safe and better therapeutic herbal based formulations. Thus, use of Biogetica® formulations is more improved and effective herbal based therapeutic approach to overcome TN.

A Survey to Assess Efficacy of Biogetica Formulation in Trigeminal Neuralgia(TN)

## A Survey to Assess Efficacy of Biogetica Formulation in Trigeminal Neuralgia(TN)

We invite you to participate in the survey "to assess efficacy of Biogetica Formulation(s) in Trigeminal neuralgia(TN)".

If you agree to participate, please fill up the questionnaire. The questions are pertaining to the disease status before and after consumption of Biogetica Formulation(s) and your experiences while taking it for TN. The answers to the questions will be analyzed and results would be published in a reputed medical journal.

The information provided by you will remain strictly confidential and only the researchers involved in the study will have access to it. The data or results that arise from this study will be used only for scientific purpose(s). Your identity will not be revealed in any information released or published.

Your participation in the study is voluntary but we would appreciate your responsiveness in the study as this will help to find a cure for TN. Hence, we request you to spend some time in filling up the questionnaire.

\*Required

1. Email address \*

\_\_\_\_\_

### A. CONSENT

---

2. 1. Do you agree to participate in this survey and use the data for publication? \*

Mark only one oval.

- Yes      Skip to question 2.  
 No      Stop filling out this form.

### B. DEMOGRAPHICS

3. 2. What is your name? \*

\_\_\_\_\_

4. 3. What is your age? \*

\_\_\_\_\_

5. 4. What is your sex? \*

Mark only one oval.

- Male  
 Female

6. 5. Email address \*

\_\_\_\_\_

## C. ILLNESS

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7. 6. Suffering/suffered from TN ? \*

Mark only one oval.

- Yes Skip to question 7.  
 No Stop filling out this form.

## A Survey to Assess Efficacy of Biogetica Formulation in Trigeminal Neuralgia(TN)

8. 7. How long have you been suffering? \*

\_\_\_\_\_

9. 8. Suffering/suffered from any of the following conditions? \*

Tick all that apply.

- Multiple sclerosis  
 Tumour  
 Arteriovenous malformation  
 Trigeminal nerve injury  
 HIV positive  
 History of Hepatitis C  
 Current hepatitis B  
 None of the above  
 Others

10. 9.(a) Taken any other treatment/medicine for TN except Biogetica formulation(s)? \*

Mark only one oval.

- No  
 Yes

11. (b). If yes, please specify

\_\_\_\_\_

## D. BIOGETICA FORMULATION

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12. 10. (a). Which formulation(s) have you taken from Biogetica? \*

*Tick all that apply.*

- Neuralease Tablets/Niargim
- OM 13
- TN Formula
- HoloRam Cronisol-D

13. (b). If others, please specify

\_\_\_\_\_

14. 11. How long have you been using Biogetica Formulation(s) for TN? \*

\_\_\_\_\_

15. 12. How much pain relief did you achieve with Biogetica Formulation(s). Please rate it out of 10 (1- less pain relief, 10 - more pain relief) \*

*Mark only one oval.*

1	2	3	4	5	6	7	8	9	10
<input type="radio"/>									

16. 13. How long did it take to see results? \*

*Mark only one oval.*

- < 15 days
- 15 days to 45 days
- 45 days to 90 days
- > 90 days

17. 14. Have you experienced any side-effects with Biogetica Formulation(s)? \*

*Mark only one oval.*

- No
- Yes

18. If yes, please specify,

\_\_\_\_\_

19. 15. How much bodily pain did you have during the past 4 weeks? \*

Mark only one oval.

- Very mild
- Mild
- Moderate
- Severe
- Very severe

20. 16. How would you rate your health in general now after taking Biogetica Formulation (s)? \*

Mark only one oval.

- Much better than before
- Somewhat better now than previous
- About the same
- Somewhat worse now than before
- Much worse now than before

21. 17. How would you rate the overall effectiveness of the Biogetica formulation on a scale of 1 to 10? (1- less effective, 10 - more effective) \*

Mark only one oval.

1	2	3	4	5	6	7	8	9	10
<input type="radio"/>									

22. 18. The following items are about activities you might do on a typical day. Does your health now limit you in these activities? If so, how much? \*

Mark only one oval per row.

	Yes, limited a lot	Yes, limited a little	No, not limited at all
Vigorous activities, like running, lifting heavy objects, participating in strenuous sports	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Lifting or carrying groceries	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Climbing a one flight of stairs	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Bending or kneeling	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Walking more than a mile	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Walking several blocks	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Bathing or dressing yourself	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

23. **19. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? \***

Mark only one oval per row.

	Yes	No
Cut down the amount of time you spent on work or other activities	<input type="radio"/>	<input type="radio"/>
Accomplished less than you would like	<input type="radio"/>	<input type="radio"/>
Had difficulty performing the work or other activities (for example, took extra effort)	<input type="radio"/>	<input type="radio"/>

24. **20. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)? \***

Mark only one oval per row.

	Yes	No
Cut down the amount of time you spent on work or other activities	<input type="radio"/>	<input type="radio"/>
Accomplished less than you would like	<input type="radio"/>	<input type="radio"/>
Didn't go to work or other activities carefully as usual	<input type="radio"/>	<input type="radio"/>

25. **21. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friend, neighbours, or group? \***

Mark only one oval.

- Not at all
- Slightly
- Moderately
- Quite a bit
- Extremely

26. **22. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)? \***

Mark only one oval.

- Not at all
- A little bit
- Moderately
- Quite a bit
- Extremely

27. **23.How much time during the past 4 weeks: \***

Mark only one oval per row.

	All the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
Did you feel full of pep?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Have you been a very nervous person?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Have you felt so down in the dumps that nothing would cheer you up?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Have you felt calm and peaceful?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Did you have a lot of energy?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Have you felt downhearted and blue?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Did you feel worn out?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Have you been a happy person?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Did you feel tired?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

28. **24.How TRUE or FALSE is each of the following statement to you? \***

Mark only one oval per row.

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
I seem to get sick a little easier than other people	<input type="radio"/>				
I am as healthy as anybody else I know	<input type="radio"/>				
I expect to get my health worse	<input type="radio"/>				
My health is excellent	<input type="radio"/>				

29. **25.Which of the following best suits your current status? \***

Mark only one oval.

- No pain, no medications
- Occasional pain, no medications required
- Some pain, adequately controlled with medications
- Some pain, not adequately controlled with medications
- Severe pain or no pain relief

**THANK YOU**

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## CONCLUSION

In an attempt to develop new herbal based therapeutic medicines for TN, this retrospective study of four herbal and homeopathic formulations of Biogetica® was carried out. The formulations have showed considerable potential to relieve the pain in TN. Out of different combinations, combination of all four Biogetica® formulations exhibited higher level of positive effects in reducing the disease complications, followed by TN formula. Other combinations have also yielded moderate result in alleviating the pain. These formulations displayed their activity in considerably less time. The treatments improved the ability of patients to do daily activities. Taken together, this study shed light on the role of Biogetica® herbal and homeopathic formulations in treating TN, which can be safely used by patients without any adverse effects.

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