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# COMPARING THE EFFECTIVENESS OF TOPICAL LIGNOCAINE SKIN PATCH AND LIGNOCAINE SPRAY IN PATIENTS WITH ACUTE TRIGEMINAL NEURALGIA

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**ABSTRACT** **Background and Aim:** Lignocaine primarily works by blocking voltage-gated sodium channels in the nerve membranes and helps to stabilize the hyperexcitable nerve activity associated with trigeminal neuralgia. This study was conducted to know the effect of lignocaine skin patch and lignocaine mucosal spray in acute trigeminal neuralgia.**Methods:** Eighty four diagnosed cases of trigeminal neuralgia affecting 2nd and 3rd division were selected for the study. The patients were divided into two groups of 42 patients in each group. The Group P received lignocaine skin patch and Group SP received lignocaine spray. Each patient was observed in pain clinic over 2 hours after applying skin patch and lignocaine spray. The patients were asked to grade the pain per NRS pain score just before applying medication i.e at baseline and at 15 min, 30 min, 60 min and 2hours after medication. After that each patient were telephoned by study coordinator to assess the pain (NRS pain score), any changes in the patient's drug therapy since the prior contact, number of patients who took rescue analgesia and to determine if there had been any adverse effects. **Results:** The demographic characteristics of the two groups were comparable and nonsignificant in terms of age, weight and gender ($p > 0.005$). We found that in both groups, patients experienced significant pain relief but the patients who received lignocaine spray (Group SP), the NRS pains score was significantly lower than the patients who received lignocaine skin patch (Group P). Lignocaine spray significantly decreased the NRS score from baseline 8.0±1.3 to 5.1±2.0 at 15 min , 1.2±0.4 at 30min, 3.2±2.1 at 60min and at 2 hour 3.5±1.6 in Group SP, whereas in lignocaine skin patch patients the NRS score changed from baseline 8.1±0.5 to 7.2±0.6 at 15min, 7.3±1.1 at 30 min, 6.7±1.4 at 60min and at 2 hour 6.1±2.0 in Group P. The NRS pain score reduction from day 1 to day 10 was also significantly lower in Group SP as compared to Group P. Even at 15 day and at 30 day the NRS pain score were lower in Group SP when compared to Group P. Six patients in Group SP (25.7%) took recue analgesia and ten patients (25%) in Group P took rescue analgesia which was statistically nonsignificant.**Conclusion:** Both lignocaine skin patch and lignocaine spray decreases pain in trigeminal neuralgia but lignocaine spray provide significant pain relief in acute exacerbations of trigeminal neuralgia.

**KEYWORDS :** lignocaine spray, lignocaine skin patch, trigeminal neuralgias

## INTRODUCTION

Lignocaine primarily works by blocking voltage-gated sodium channels in the nerve membranes, which inhibits the generation and conduction of nerve impulses. [1, 2] This action helps to stabilize the hyperexcitable nerve activity associated with trigeminal neuralgia. Lignocaine (lignocaine) is not a first-line treatment for trigeminal neuralgia (trigeminal neuralgia), but it is a useful option for managing acute exacerbations and refractory cases when standard medications like carbamazepine fail or cause intolerable side effects.[3, 4] It can be administered in several ways: Intravenous (IV) Infusion, this is used for short-term, transitional pain control but it needs hospital stay and under intense monitoring and needs trained staff which limits its use in OPD settings.[5] An ideal treatment for trigeminal neuralgia exacerbations would be one that achieves complete and rapid analgesia, as much as possible, without any severe complications and could be easily administered. The lignocaine skin patch is a safe, local, non-invasive adjunctive treatment option for trigeminal neuralgia patients who have pain or trigger points on the external skin of the face, especially those who cannot tolerate the side effects of systemic medications. [6,7] Similarly lignocaine spray is an effective anesthetic of mucous membranes. [8] The analgesic effect of this spray occurs within five minutes will be useful in trigeminal neuralgia. [9] Studies have shown that 8% lignocaine spray applied on nasal or oral mucosa produces prompt analgesia without serious adverse reactions in patients with trigeminal neuralgia of second and third division. So far, few studies have been conducted to show the effect of lignocaine sprayed directly on the oral and/or nasal mucosa or applied directly as skin patch for trigeminal neuralgia exacerbation. In the present study, we analyzed the efficacy of lignocaine skin patch and intraoral and/or intranasal 8% lignocaine aerosol to explore a safe, fast-acting, and convenient option for the relief of acute trigeminal neuralgia exacerbations.

## Methods

This is a single-center, observational study conducted in the period of January 2024 to October 2025 in pain relief center Sonwar, Srinagar , Jammu and Kashmir , India. After a written consent, 84 adult patients of diagnosed cases of trigeminal neuralgia affecting 2nd and 3rd division of age group 30-70years of either sex were selected for the study. The inclusion criteria of patients includes:

- Occurrence of episodes of intense facial paroxysmal pain in the distribution(s) of one or more divisions of the trigeminal nerve, triggered by innocuous stimuli.
- Normal neurologic examination.
- Normal neuroimaging analysis.

The Patients excludes from the study were:

- Atypical pain location (e.g. no specific trigger points) or trigger zones in the mouth.
- Proposed surgical intervention due to preference of the patient.
- Any condition known to interfere with the correct execution of the sensory tests (e.g peripheral or central neurological dysfunction or cognitive impairments).
- Presence of any other acute or chronic pain disorder with the need of systemic analgesic medication for more than 10 days in the last 3 months.
- Inability to discontinue the use of another lignocaine-containing products or a class I anti-arrhythmic drug during the study period.
- History of hypersensitivity to an amide-type local anesthetic agent, or other contents of the lignocaine or vehicle patch.
- History of surgical intervention or neurological ablation to treatment trigeminal neuralgia.
- Any patient who was judged to be unreliable or unable to understand the protocol procedures.
- Any abnormality of the skin or of vascular origin at application site.
- Pregnancy or breast feeding.

The patients were divided into two groups of 42 patients in each group. The Group P received lignocaine skin patch and patients were instructed to apply the lignocaine patch over the most painful area for seven days. Each painful area was determined by the most painful trigger point which was mapped by the study physician. Up to three patches could be applied at one time, but only once for up to 12 hours within a 24-hour period for 7 days. The Group SP received lignocaine spray (8%) 4-5 times a day for 7 days. When receiving the aerosol, patients were asked to be in a sitting position with the neck extended and head slightly back to spray the aerosol on patients' nasal mucosa, and mouths opened to spray the aerosol on patients' oral mucosa.

Physicians sprayed patients with two presses of 8% lignocaine aerosol; each spray lasted for one second on each specific area according to different affected division of the trigeminal nerve. Each patient was observed for two hours in pain clinic after applying skin patch and lignocaine spray. The patients were asked to grade the pain per NRS just before applying medication i.e at baseline and at 15 min, 30 min, 60 min and at 2hr after medication. The patient's concomitant medications (Carbamazipine 800mg twice daily plus oral analgesic tramadol and paracetomol as rescue analgesia in case of severe pain) were maintained throughout this study. After that each patient were telephoned on the days 1-14 by study coordinator to assess the pain (NRS), the number of patients who took rescue analgesia (%), any changes in the patient's drug therapy and to determine if there had been any adverse effects. The patients were also asked to visit clinic personally on day 7th, day 15th and on day 30th to complete pain assessment and report concomitant medications and adverse events. Patients were also advised to record their pain intensity daily on the 0 to 10 scale at the same time each day in a diary that they received at their first clinic visit.

### Statistical Analysis

In order to reach a power of 90%, 30 patients were required for this study. Probability (p)-values of 0.05 or less were considered significant. No corrections for multiple comparisons were applied. Power analysis was completed using SPSS-PC, Version 11.0, and the following parameters: A change of 20% on the 0 to 10 pain intensity scale of the NRS (With 0 being no pain and 10 being pain as severe as the patient can imagine) was considered clinically meaningful.

## RESULTS

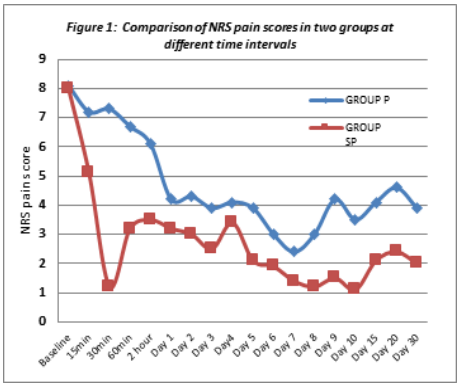
Eighty four patients were enrolled in the study. Six patients were lost during follow-up, four patients in Group SP and two patients in Group P and excluded from the study. The demographic characteristics of the two groups were comparable and non-significant in terms of age, weight, and gender (Table 1) ($p > 0.005$). We found that in both groups, patients experienced significant pain relief but the patients who received lignocaine spray, the pain reduction scores were significantly lower as compared to patients who received lignocaine skin patch. Lignocaine spray significantly decreased the NRS score from baseline 8.0±1.3 to 5.1±2.0 at 15 min, 1.2±0.4 at 30min, 3.2±2.1 at 60min and at 2 hour 3.5±1.6 in Group SP, whereas in lignocaine skin patch patients the NRS score changed from baseline 8.1±0.5 to 7.2±0.6 at 15min, 7.3±1.1 at 30 min, 6.7±1.4 at 60min and at 2 hour 6.1±2.0 in Group P. The NRS pain score reduction from day 1 to day 10 was also significantly lower in Group SP when compared to Group P (Table 2). Even at the 15th day and 30th day the NRS pain score were lower in Group SP when compared to Group P. Six patients in Group SP (25.7%) took recue analgesia and ten patients (25%) in Group P took rescue analgesia ($p > 0.005$) which was statistically nonsignificant (Table 1).

**Table 1: Comparison of Demographic Data**

| Parameter | Group SP | Group P | P Value |
|---|---|---|---|
| Age (years) | 59.5±6.5 | 62.7±8.2 | 0.0593 |
| Gender M/F | 30/10 | 29/9 | >0.005 |
| Weight ( kg) | 67.5±12.1 | 70±9.6 | 0.3169 |
| Rescue analgesia | 10 (25%) | 6(15.7%) | 0.3120 |
| Values are expressed as mean ± SD/ numbers /percentage | | | |

**Table 2: Numeric Pain rating Scale (NRS) in two Groups**

| Time | Group P | Group SP | P value | Time | Group P | Group SP | P value |
|---|---|---|---|---|---|---|---|
| Baseline | 8.1±0.5 | 8.0±1.3 | 0.6521 | Day 5 | 3.9±2.3 | 2.1±1.1 | <0.0001 |
| 15 min | 7.2±0.6 | 5.1±2.0 | <0.0001 | Day 6 | 3.0±0.3 | 1.9±0.7 | <0.0001 |
| 30 min | 7.3±1.1 | 1.2±0.4 | <0.0001 | Day 7 | 2.4±1.4 | 1.4±0.9 | 0.0004 |
| 60 min | 6.7±1.4 | 3.2±2.1 | <0.0001 | Day 8 | 3.0±1.0 | 1.2±0.7 | <0.0001 |
| 2 hour | 6.1±2.0 | 3.5±1.6 | <0.0001 | Day 9 | 4.2±0.6 | 1.5±1.3 | <0.0001 |
| Day 1 | 4.2±1.3 | 3.2±1.1 | <0.0005 | Day 10 | 3.5±1.2 | 1.1±0.3 | <0.0001 |
| Day 2 | 4.3±1.3 | 3.0±0.5 | <0.0001 | Day 15 | 4.1±0.7 | 2.1±1.0 | <0.0001 |
| Day 3 | 3.9±1.6 | 2.5±0.3 | <0.0001 | Day 20 | 4.6±1.7 | 2.4±1,3 | <0.0001 |
| Day4 | 4.1±0.6 | 3.4±1.1 | 0.0008 | Day 30 | 3.9±1.1 | 2.0±0.5 | <0.0001 |
| Values are expressed as mean ± SD | | | | | | | |




## DISCUSSION

While carbamazepine is the first-line and most effective medication for trigeminal neuralgia (TN), its use is limited by several significant shortcomings, primarily related to its side effect profile, potential for drug interactions, and reduced long-term efficacy which can affect daily function and quality of life. Due to these limitations, many patients ultimately require adjuvant therapies or surgical interventions to manage their pain effectively. Use of adjuvants not only reduces pain intensity but also improves associated symptoms like anxiety, depression, and functional problems (eating, sleeping), enhancing the patient's overall quality of life. Common adjuvants include: baclofen. lamotrigine, gabapentin and pregabalin, botulinum toxin type a (botox) injections, tizanidine, antidepressants and lignocaine. But use of these adjuvants has their own limitations and side effects. Among the adjuvants, lignocaine when used topical is safe and have minimal side effects. Lignocaine is primarily used in two forms in trigeminal neuralgias: topical and intravenous. Lignocaine blocks voltage-gated sodium channels in the nerve endings, reducing abnormal nerve firing and the transmission of pain signals to the brain. The topical application targets the pain locally, directly over the affected area. The primary advantage in topical lignocane is that very little of the drug is absorbed systemically, meaning it provides pain relief with a significantly lower risk of the systemic side effects. It is available as a 5% medicated plaster (patch) or as an 8% solution/spray for pain in the mouth or nose. In this study we used lignocaine as skin dermal patch and the lignocaine spray forms in acute trigeminal neuralgia patients. In both forms lignocaine significantly improves acute pain without any serious side effects. But the pain reduction was significantly much better controlled who received lignocaine sprays as compared to lignocaine dermal patch. Similar type of study was conducted by Yuriko Niki [12] and co workers. They examined the response to intraoral application of 8% lignocaine (LDC) in patients with oral trigeminal neuralgias pain. **They concluded that intraoral** application of 8% LDC produced prompt analgesia without serious side effects in patients with trigeminal neuralgias who presented with severe intraoral pain. Similarly A.Kanai et al. [13] conducted a study on intranasal lignocaine 8% spray on paroxysmal pain in second-division trigeminal neuralgia. Twenty-five patients were randomized to receive two sprays (0.2 ml) of either lignocaine 8% or saline placebo in the affected nostril using a metered-dose spray. And they found that Intranasal lignocaine 8% spray significantly decreased VAS [baseline: 8.0 ±2.0 cm, 15 min post spray: 1.5 ±1.9 cm], whereas the placebo spray did not. Moreover, pain was described as moderate or better by 23 patients of the lignocaine spray and 1 of the placebo group. The effect of treatment persisted for 4.3 h (range 0.5–24 h). in an another study conducted by **Xiangjun zhou** and coworkers [14] , they sprayed lignocaine aerosol on oral and nasal mucosa for recue of acute trigeminal neuralgia exacerbations. They found that lignocaine aerosol sprayed on oral and/or nasal mucosa is beneficial for immediate pain relief in patients with acute trigeminal neuralgia exacerbation and they expected that in future lignocaine aerosol to become a promising treatment option for patients with V2 and/or V3 trigeminal neuralgia. Similarly, **Chunmei Zhao and co authoirs** [15] conducted a study to explore the efficacy and safety of 5% lignocaine mediated plaster in trigeminal neuralgia in 25 patients for 28 days and they observed that lignocaine mediated plaster produced partial relief of pain symptoms in trigeminal neuralgias and concluded that for

responders, lignocaine mediated plaster may be used as an add-on therapy in a multidrug treatment protocol. In conclusion, both the lignocaine skin patch and the lignocaine spray offer targeted, topical approaches to managing trigeminal neuralgia pain with fewer systemic side effects compared to traditional oral medications. They can be considered valuable **adjuncts** to standard treatment regimens (which typically start with carbamazepine) rather than first-line monotherapies in most clinical guidelines, though recent studies advocate for their use as a first step in some patients due to their excellent safety profiles.

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