

Original Research Article

Received : 05/10/2025
 Received in revised form : 17/11/2025
 Accepted : 09/12/2025

Keywords:
Topical Lidocaine, Local Anaesthetic.

Corresponding Author:
Dr. Vimal Hastimal Jain,
 Email: docjvh@gmail.com

DOI: 10.47009/jamp.2025.7.6.193

Source of Support: Nil,
 Conflict of Interest: None declared

Int J Acad Med Pharm
 2025; 7 (6); 1039-1042



THE EVALUATION OF TOPICAL LIDOCAINE USE

Vimal Hastimal Jain¹

¹Associate Professor, Department of Anesthesia, SSPM Medical College and Lifetime Hospital, Padve, Sindhudurg, India.

ABSTRACT

Background: Pain treatment without systemic absorption is growing with topical analgesics. Post-herpetic neuralgia can be treated with lidocaine patches. Dentists utilise topical anaesthetics with 5% lidocaine to lessen injection discomfort, however maintaining extended contact and avoiding periosteum contact is difficult. Innovative DentiPatch lidocaine transoral patches provide efficient local anaesthesia with minimal systemic influence during recurrent injections. **Aim and Objectives:** This study aims to evaluate the efficacy and safety of topical lidocaine. **Materials and Methods:** Lidocaine 5% gel and ice tested for orthodontic discomfort in this clinical experiment. From August 2021 to July 2023, two dentists at a community dentistry clinic collected data with ethical approval. Lidocaine 5% gel or ice was given to eligible participants as topical anaesthesia. Visual analogue scales (VASs) measured heart rates and pain. To compare the two groups' results, paired t-tests and chi² tests were used. **Result:** Table 1 displays VAS ratings for pain and discomfort during needle insertion and lidocaine 5% gel was applied. The Control group (ice application) had lower mean VAS pain ratings at 1 and 2.5 minutes than the Study group (lidocaine 5% gel) ($p = 0.015$). Pain ratings were comparable at 5 minutes ($p = 0.08$). The study group had more buccal injection pain ($p = 0.039$) but less discomfort ($p = 0.002$). Palatal injection ratings were comparable across groups ($p = 0.249, 0.641$). **Conclusion:** In conclusion, ice as topical anesthesia before oral mucosa relieves pain like lidocaine 5% gel. It is affordable and well-tolerated and data was scarce, the sample size was comparable to earlier studies.

INTRODUCTION

Topical analgesic is used to reduce both acute and long-term pain, targeting periphery nociceptive pathways without minimising plasma absorption. 5% well-tolerated for the therapy of "post-herpetic neuralgia (PHN), is non-toxic.^[1] Lidocaine permeates the skin for soothing effect. Both 5% and 1.8% topical lidocaine systems were authorised by the FDA in 1999 and 2018 respectively in order to relieve PHN-related discomfort.^[2] With a 19-fold reduced drug loading (36 mg versus 700 mg) & improved adhesion, the 1.8% system delivers lidocaine more effectively and is similar to 5% lidocaine regions, allows the patch for 12 hour stay in skin.^[3] Many illnesses that react to the literature, including PHN, pain in the lower back, carpal tunnel syndrome, and diabetic neuropathy, to topical lidocaine in the legs, also joint pain. Topical lidocaine and other painkillers may help with different neuropathic & nociceptive pain conditions.^[4] Also dentists administer topical anaesthetics to the mouth mucosa to reduce discomfort.^[5]

Using needles of 27 gauge, staying away from the periosteum, and topical anaesthetics containing 5%

lidocaine are common elements. The application of 25-gauge needles, the infusion of a local anaesthetic solution following needle penetration, interaction with the periosteum, and 15 to 45 seconds of contact between the topical agent and the intestinal mucosa when phenol^[6] or benzocaine^[7] is used as the active topical agent.^[6] 25-gauge needles are required for injections into mandibular blocks and some regional anaesthetic procedures, such as infraorbital nerve blocks of data, lingual nerve blocks, posterior upper alveolar blocks containing data, and mental nerve blocks.^[7] Mostly, topical anaesthetics are gel, get diluted in mouth for anaesthesia. Dentists cannot avoid touching the periosteum.^[8]

Thus, topical anaesthetic system which adhered to the oral mucosa is effective local anaesthetic concentrations.^[9] Topical drug shouldn't increase the systemic local anaesthetic concentrations attained by consecutive injections.^[11] Approval for the U.S. FDA anaesthetic patches employing a bioadhesive matrix to apply lidocaine directly to the oral mucosa (Noven Pharmaceuticals Inc.'s DentiPatch lidocaine transoral mode of administration) is received containing 23 & 46 mg of lidocaine base every 2 square centimetres.^[12]

MATERIALS AND METHODS

Research design

The purpose of this clinical trial is to evaluate the efficacy of lidocaine 5% gel and ice for the management of orthodontic-related discomfort. The Ethical Review Board and the Medical Products Agency both gave their clearance. From August 2021 to July 2023, two general dentists collected data in a community dental clinic. The individuals who fulfilled the inclusion criteria and gave informed consent were randomly assigned to one of two groups. Topical anaesthesia was applied to the first group with lidocaine 5% gel and to the second group with ice. The patient's heart rates and pain levels were monitored using "visual analogue scales (VASs)". The taste preference was a qualitative evaluation which was marked during the procedure from each patient. The result of the two groups was compared using statistical analysis, specifically paired t-tests and chi² tests.

Inclusion and Exclusion Criteria

Inclusion

- Patients planning orthodontic therapy that includes the extraction of two contralateral maxillary premolars without pathology.
- Patients under the age of 20 are considered to be in excellent health by the "American Society of Anesthesiologists (ASA)".
- People who don't get anxious about visiting the dentist.
- Participants' willingness to take part in the study, as well as the willingness of their parents or guardians if the subject is under the age of 18.

Exclusion

- Patients with medical problems that may compromise study safety or quality.
- Hypersensitivity to amide-type local anesthetics or topical anesthesia drugs.

- Non-compliance with the study protocol prevented the comparison of the two topical anaesthesia medications.
- Patients without explicit consent from them and their parents/guardians.
- Patients or legal guardians who discontinue or withdraw from the research.

Statistical Analysis

The data were evaluated by statistical analysis employing appropriate methods, such as paired t-tests, to compare the average pain scores between the groups administered with lidocaine 5% gel and ice. Chi-squared tests are utilized to evaluate the disparity in proportions pertaining to discomfort and mucosal irritation. The Pearson correlation tests are utilized to assess potential relationships between variables. Descriptive statistics, namely the mean \pm standard deviation (SD), are employed as a means of summarizing the data. A significance level of 0.05 is utilized for all statistical tests.

Ethical Approval

The Regional Ethical Review Board recommended that the study obtain ethical approval.

RESULTS

Table 1 shows VAS ratings for pain and discomfort during needle insertion and lidocaine 5% gel injection. Compared to the Study group (lidocaine 5% gel application), the Control group (ice application) had decreased mean VAS pain ratings at 1 and 2.5 minutes ($p = 0.015$). At 5 minutes, the two groups had similar pain ratings ($p = 0.08$). The Study group had higher mean VAS pain ratings for buccal injection than the Control group ($p = 0.039$). Buccal injection discomfort was considerably reduced in the study group ($p = 0.002$). Both groups had similar VAS ratings for palatal injection ($p = 0.249$) and pain ($p = 0.641$). Lidocaine 5% gel may relieve needle insertion pain better than ice but may induce more buccal injection discomfort.

Table 1: VAS ratings after needle insertion and injection after ice and lidocaine 5% gel

Intervention/variable measured (application time)	Control group Ice mean \pm SD (mm)	Study group Lidocaine 5% gel mean \pm SD (mm)	p-value
VAS pain buccal needle insertion (1 min)	8.9 \pm 8.5	7.8 \pm 8.7	0.587
VAS pain buccal needle insertion (2.5 min)	10.9 \pm 8.8	8.4 \pm 9.5	0.015
VAS pain buccal needle insertion (5 min)	10.9 \pm 12.5	8.3 \pm 6.9	0.08
VAS pain buccal injection	13.0 \pm 11.1	15.8 \pm 13.6	0.039
VAS discomfort buccal injection	9.8 \pm 9.9	4.0 \pm 4.0	0.002
VAS pain palatal injection	18.9 \pm 10.9	20.9 \pm 15.11	0.249
VAS discomfort palatal injection	6.7 \pm 7.7	6.0 \pm 8.9	0.641

DISCUSSION

In the Cochrane review, destruction to peripheral neurons, the dorsal root ganglia, or the dorsal Horn of the vertebral column due to herpes zoster infections is the primary cause of postherpetic neuralgia for brain hyperexcitability and peripheral nociceptor

sensitization.^[13] Other studies can evaluate the effectiveness of topical lidocaine.^[14]

Currently, a range of pain disorders is treated using topical lidocaine. The review of literature provides the information for the absorption and the absence of systemic side effects.^[15] Topical lidocaine is efficient to manage osteoarthritis, neuropathy caused by diabetes, and post-herpetic neuralgia. For the best

pain management and multimodal analgesia, topical lidocaine is effective either alone or with systemic medications and non-pharmacological methods.^[16] The external viscous 2% lidocaine gel reduces pain during instrumentation for maxillary third molar extraction locations identified as having alveolar osteitis as well as for pain relief. Alveolar osteitis is treated by topical thick 2% lidocaine jelly, at the first hour or post-instrumentation.^[17]

A study was conducted to describe the comparison of the in vitro penetration and in vivo anaesthetic effectiveness of liposomal-lidocaine formulations with formulations of lidocaine on the oral mucosa. The discovery of 5% lidocaine gel can be considered a substitute for other topical anaesthetics on oral mucosa. ^[18,19] A prospective RCT compared to assess the effectiveness of a thermosetting cream containing 2.5% prilocaine & 2.5% morphine, eugenol was applied to a gauze strip.

The present investigation used non-scarring laser pulses which were reproducible pain inducers with high reproducibility for evaluating topical anaesthetics with minimal intra-individual variability. Results shown 40% lidocaine ointment was ineffective than EMLA 5% cream.^[19]

A study was conducted to assess the efficacy of topical “tetracaine-adrenaline-cocaine (TAC)” & lidocaine infiltration during the treatment of paediatric laceration injuries in comparison to four topical anaesthetics without cocaine. It is a useful substitute for TAC and lidocaine infiltration, particularly on the face and scalp.^[20,21] Because TAC is prone to touch mucosal membrane on the face and produces systemic toxicity. The trial estimates Bupivacaine's efficacy in comparison to lidocaine infiltration.^[22] Locally, 5% lidocaine medicinal bandage is effective to treat neuropathic and pain.^[23] NSAIDs, aspirin-based rubefacients, capsaicin, and lidocaine are nonsteroidal anti-inflammatory drugs. Lower NNT levels resolve topical diclofenac & ketoprofen formulations to treat acute pain including sprains and strains.^[24] Topical high-concentration capsaicin, topical diclofenac, and topical ketoprofen cannot address postherpetic neuralgia and chronic musculoskeletal diseases.^[25]

CONCLUSION

In conclusion, oral mucosal injections made with ice as topical anaesthesia prior to the procedure result in pain alleviation during the insertion of the needle comparable to that achieved with lidocaine 5% gel, with the onset of the topical anaesthetic effect occurring as quickly as 1 minute after application. Study participants also reported that the lidocaine 5% gel had a less pleasant taste than ice. Therefore, using ice as topical anaesthesia before injection is a practical, inexpensive, and readily accessible substitute for the commercially available lidocaine 5% gel. This discovery may have far-reaching consequences for dental practises by giving patients

a reliable, easily available, and well-tolerated option for dealing with dental discomfort. The dentistry community and their patients would both benefit from further study and clinical application of this strategy to improve patient satisfaction and comfort during dental operations. The lack of sufficient data was a problem. However, the sample size is considered to be sufficient because equivalent numbers of patients have been included in similar research in the past.

REFERENCES

1. Gudin J, Nalamachu S. Utility of lidocaine as a topical analgesic and improvements in patch delivery systems. *Postgrad Med.* 2020 Jan;132 (1):28-36. doi: 10.1080/00325481.2019.1702296. Epub 2020 Jan 3. PMID: 31900074.
2. Malamed SF. *Handbook of local anesthesia*. 3rd ed. St. Louis: Mosby; 1991.
3. Yaacob HB, Noor GM, Malek SN. The pharmacological effect of Xylocaine topical anaesthetic - a comparison with a placebo. *Sing Dent J* 1981;6(2):55-7.
4. Holst A, Evers H. Experimental studies of new topical anaesthetics on the oral mucosa. *Swed Dent J* 1985;9(5):185-91.
5. Rosivack RG, Koenigsberg SR, Maxwell KC. An analysis of the effectiveness of two topical anesthetics. *Anesth Prog* 1990;37:290-2.
6. Pollack S. Pain control by suggestion. *J Oral Med* 1966;21(2):89-95. 6. Gill CJ, Orr DL. A double-blind crossover comparison of topical anesthetics. *JADA* 1979;98(2):213-4.
7. Keller BJ. Comparison of the effectiveness of two topical anesthetics and a placebo in reducing injection pain. *Hawaii Dent J* 1985; 16 (12) :10-1.
8. Kincheloe JE, Mealiea WL, Mattison GD, Seib K. Psychophysical measurement on pain perception after administration of a topical anesthetic. *Quintessence Int* 1991;22(4):311-5.
9. Martin MD, Ramsay DS, Whitney C, Fiset L, Weinstein P. Topical anesthesia: differentiating the pharmacological and psychological contributions to efficacy. *Anesth Prog* 1994;41 (2):40-7.
10. Hersh EV, Heipin ML, Evan OB. Local anesthetic mortality: report of case. *ASDC J Dent Child* 1991;58(6):489-91.
11. Moore PA. Preventing local anesthesia toxicity. *JADA* 1992;123(9):60-4.
12. Hersh EV, Hermann DG, Lamp CJ, Johnson PD, MacAfee KA. Assessing the duration of mandibular soft tissue anesthesia. *JADA* 1995; 126(11):1531-6.
13. Brennan MJ. The effect of opioid therapy on endocrine function. *Am J Med.* 2013;126(3 Suppl 1):S12-18. doi:10.1016/j.amjmed.2012.12.00123414717
14. Cohen SP, Mao J. Neuropathic pain: mechanisms and their clinical implications. *BMJ.* 2014;348:f7656. doi:10.1136/bmj.f765624500412
15. Dworkin RH, O'Connor AB, Audette J, et al. Recommendations for the pharmacological management of neuropathic pain: an overview and literature update. *Mayo Clin Proc.* 2010; 85(3 Suppl):S3-14. doi:10.4065/mcp.2009.0649
16. GO Kruger Oral and Maxillofacial Surgery (ed 6), Mosby, St. Louis, MO (1984), pp. 102-103
17. Franz-Montan M, Baroni D, Brunetto G, Sobral VR, da Silva CM, Venâncio P, Zago PW, Cereda CM, Volpato MC, de Araújo DR, de Paula E, Groppe FC. Liposomal lidocaine gel for topical use at the oral mucosa: characterization, in vitro assays and in vivo anesthetic efficacy in humans. *J Liposome Res.* 2015 Mar;25(1):11-9. doi: 10.3109/08982104.2014.911315. Epub 2014 May 7. PMID: 24807821.
18. Burgoyne CC, Giglio JA, Reese SE, Sima AP, Laskin DM. The efficacy of a topical anesthetic gel in the relief of pain associated with localized alveolar osteitis. *J Oral Maxillofac*

Surg. 2010 Jan;68(1):144-8. doi: 10.1016/j.joms.2009.06.033. PMID: 20006169.

19. Hernández E, González S, González E. Evaluation of topical anesthetics by laser-induced sensation: comparison of EMLA 5% cream and 40% lidocaine in an acid mantle ointment. *Lasers Surg Med.* 1998;23(3):167-71. doi: 10.1002/(sici)1096-9101(1998)23:3<167::aid-lsm6>3.0.co;2-n. PMID: 9779651.

20. Smith GA, Strausbaugh SD, Harbeck-Weber C, Shields BJ, Powers JD, Hackenberg D. Comparison of topical anesthetics without cocaine to tetracaine-adrenaline-cocaine and lidocaine infiltration during repair of lacerations: bupivacaine-norepinephrine is an effective new topical anesthetic agent. *Pediatrics.* 1996 Mar;97(3):301-7. PMID: 8604261.

21. Mick G, Correa-Illanes G. Topical pain management with the 5% lidocaine medicated plaster--a review. *Curr Med Res Opin.* 2012 Jun ;28(6):937-51. doi: 10.1185/03007995.2012.690339. Epub 2012 May 24. PMID: 22551228.

22. Derry S, Wiffen PJ, Kalso EA, Bell RF, Aldington D, Phillips T, Gaskell H, Moore RA. Topical analgesics for acute and chronic pain in adults - an overview of Cochrane Reviews. *Cochrane Database Syst Rev.* 2017 May 12;5 (5):CD008609. doi: 10.1002/14651858.CD008609.pub2. PMID: 28497473; PMCID:PMC6 481750.

23. Derry S, Moore RA, Gaskell H, McIntyre M, Wiffen PJ. *Cochrane Database Syst Rev.* 2015 Jun 11;2015(6):CD007402. doi: 10.1002/14651858.CD007402.pub3.

24. Derry S, Conaghan P, Da Silva JA, Wiffen PJ, Moore RA. *Cochrane Database Syst Rev.* 2016 Apr 22;4(4):CD007400. doi: 10.1002/14651858.CD007400.pub3.

25. Gaskell H, Derry S, Wiffen PJ, Moore RA. *Cochrane Database Syst Rev.* 2017 May 25; 5(5):CD007355. doi:10.1002/14651858. CD0 07355.pub3.