

EVALUATION OF EFFECTIVENESS OF PAIN OUT DENTAL GEL AS A TEMPORARY ANALGESIC IN PROVIDING EXPRESS INSTANTANEOUS RELIEF OF ODONTOGENIC CAUSES OF TOOTH ACHE

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ABSTRACT

Pain has the function of a warning to tissue damage and activation of defensive mechanisms, with the aim of prevention of further damage. The stimulus which damages or threatens to damage a tissue activates the nociceptors which in turn carry the information by a system of neurons to cortex, where it is processed and recognized as pain. Most somatosensory information from the area of orofacial system is transported via n. trigeminus. In order to remove pain, it is necessary to recognize and properly diagnose the cause of pain. This is not always easy, due to numerous variations within the clinical findings, and the latent possibility that pain has referred from odontogenic structure onto the nonodontogenic ones, and vice versa.

Knowing the pathways and mechanisms of pain, possible causes and different characters of orofacial pain, as well as a thorough anamnesis, clinical examination and testing will eventually lead to a proper diagnosis.

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OBJECTIVE:

To evaluate the effectiveness of PAIN OUT DENTAL GEL as a temporary analgesic in relieving odontogenic causes of tooth ache and providing express pain relief after a single professional application. **Materials and methods:** This survey was carried out in 126 patients taken from the OPD of department of periodontology in Ahmedabad dental hospital with age of 12 to 70 years in 2 months period of time duration. They were required to possess a minimum of one tooth which was painful which could be due to caries, dentinal hypersensitivity, faulty restoration, post surgical pain, food impaction, pain due to periodontitis, tooth fracture. Odontogenic pain severity and its relief after application of the pain out gel was evaluated by using the Visual Analog Score (VAS) card in 126 different subjects by a single investigator. **Conclusion:** The in-office dental gel containing clove oil, camphor and extract of mentha arvensis provides significant reduction in acute odontogenic pain instantly after a single professional application of the product

“For there was never yet a philosopher who could endure the toothache patiently.”

–William Shakespeare.

The International Association for the study of pain defines pain as “an unpleasant sensory and emotional experience associated with actual or

potential tissue damage, or described in terms of such damage. It belongs to the sensations that brings information about the state of the organisms and its relation with the environment directly to the brain.¹

It is exactly pain which is the most common reason for patients to come to the dental clinic, this pain usually originates in the tooth itself or its supporting structures. In order to establish a proper diagnosis, it is absolutely important to take anamnesis, i.e. a detailed subjective description of the painful condition of the patient including the quality, duration, volume, frequency and periodicity of pain.

Pain is not a disease and is always subjective, it is manifested, in addition to pain, as the activity of sympathetic, producing fear, anxiety, pupillary dilation, tears, tachycardia, hypertension, nausea, vomiting, sound effects and facial expressions. The level of perception of pain is not constant. The threshold of pain and responses to pain vary under different conditions. Awareness of pain occurs at the thalamocortical level where many complex interactions shape the overall experience and response². Postcentral gyrus determines awareness of the stimuli, temporal lobus, with the help of memory, identifies the nature of the stimuli, frontal lobus and limbic system provide emotional reactions and the hypothalamus and pituitary gland control the autonomic and endocrine response.

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Odontogenic pain has its source in the pulpodentinal complex and / or periapical tissue. These two structures are functionally and embryonically different, and consequently the pain originating in these areas is perceived differently³. Pulp pain, or pulpalgia, is by far the most commonly experienced pain in and near the oral cavity and maybe classified according to the degree of severity and the pathologic process present:⁷

1. Hyperreactive pulpalgia
 - a. Dentinal hypersensitivity
 - b. Hyperemia
2. Acute pulpalgia
 - a. Incipient
 - b. Moderate
 - c. Advanced
3. Chronic pulpalgia
 - a. Barodontalgia
4. Hyperplastic pulpitis
5. Necrotic pulp
6. Internal resorption
7. Traumatic occlusion
8. Incomplete fracture

Inflammation of dental pulp is similar to that in other connective tissues. The inflammatory response of dental pulp involves vascular reaction, neuronal activity and infiltration of immune cells at the site of inflammation.

The pulp is supplied by a rich neurovascular network that regulates various inflammatory mediators; however the dental pulp is enclosed in a non-compliant environment by mineralized dentin and has reduced collateral circulation.

These anatomic restrictions tend to intensify the injury that results from external irritation and the harmful side effects of host inflammatory mediators.

The pain-process involves a number of chemical pain mediators. Thus, it is known that the teeth are innervated by sympathetic nerve fibers, which release norepinephrine as a mediator, and the sensory fibers, which release acetylcholine and substance P. Of other mediators, there are also vasoactive peptides and calcitonin, which participate in the increase of the dentine sensitivity. Nerve fibers that

connect teeth with the central nervous system belong to the fifth brain nerve (N. Trigeminus) and autonomic nervous system (sympathetic nervous system). Sensory nerve fibers in the pulp consist of myelinated A-fibers, which prevail, and non-myelinated C-fibers. Of the former, these are mainly A-delta fibers, which conduct the impulses faster, while, speaking of the latter, C-fibers, which are thinner and slower conducting. A-delta fibers are responsible for strong immediate, sharp, well localized pain and C-fibers for dull, continuous, and irradiating pain.⁴

The effect of a short heat or cold stimulus is explained by the hydrodynamic theory in the following way: the application of hot stimuli on the exposed dentin leads to the expansion of dentinal fluid, whereas the application of cold stimulus causes its contraction. Both types of stimuli cause fluid flow, thus the activation of mechanoreceptors of the sensory nerves.

CAUSES OF TOOTHACHE:

- a) Dental caries
- b) Dental trauma (tooth fracture and /or cracked tooth)
- c) Damaged filling
- d) Post surgical / post extraction
- e) Dentinal hypersensitivity
- f) Food impaction
- g) PDL pain
- h) Non-odontogenic causes (referred muscle pain, trigeminal neuralgia, referred head pain, neuropathic pain, shingles, cardiac toothache, psychological disturbances.

Characteristics of pain:

1. Quality
2. Intensity
3. Episodic or continuous
4. Spontaneous or provoked
5. Aggravating and alleviating factors

Some patients have a low grade, bothersome ache and others experience excruciating pain, described as throbbing, sharp or shooting⁷. The pain can be present all the time or come and go. Unexpectedly, the pain can migrate from one tooth to another and even change sides of the mouth. The pain may be

present from weeks to several years.

A VISUAL ANALOGUE SCALE (VAS) is a measurement instrument that tries to measure a characteristic or attitude that is believed to range across a continuum of values and cannot easily be directly measured. The amount of pain that a patient feels ranges across a continuum from none to an extreme amount of pain.⁵ From the patient's perspective, this spectrum appears continuous; their pain does not take discrete jumps, as a categorization of none, mild, moderate and severe would suggest.

Operationally, VAS is usually a horizontal line 100 mm in length, anchored by word descriptors at each end. The patient marks on the line the point that they feel represents their perceptions of their current state. The VAS score is determined by measuring in mms from the left hand of the line to the point that the patient marks⁸.

These scales are of most value when looking at change within individuals and are of less value for comparing across a group of individuals at one point of time. The VAS is generally regarded as a valid and reliable tool for chronic pain measurement.

Due to a number of factors, patients find it difficult to visit the dentist immediately in case of a painful episode and opt for medications to get temporary symptomatic relief. These medications can be divided into

A: Traditional home remedies:

- a. Clove oil
- b. Neem leaves
- c. Salt gargles

B: Pharmacologic drugs:

- a. Pain killers
 - 1) mild to moderate-Ibuprofen, Diclofenac
 - 2) Strong opioids
- b. Steroids

Most of these medications are used without proper medical consultation and their "abuse" can lead to unwarranted results and serious side effects. Few of their limitations are as follows:

- Delayed onset of action
- Contraindicated in certain group of patients like those suffering with allergies or with reduced

kidney functions.

- Paracetamol at higher doses and with alcohol can cause liver toxicity.
- Opioid pain killers are controlled substances and have greater abuse potential.
- Steroids are immune-suppressants, and hence not suitable for pain management due to dental infections.

It is here that a novel product, Pain Out dental gel, comes into the picture as an effective substitute for temporary relief of pain.

In a study by **Oklješa et al.** conducted within the framework of the scientific research by Faculty of Dental Medicine in Zagreb, it had been investigated how often patients come to the dental clinic because of toothache or generally any pain in the mouth, and what the respective percentages of acute or chronic pain were. The research was conducted on the sample of 2735 respondents over a period of 1 year. Pain was present in the 16.49 % of patients, and the remaining 83.51 % of the patients were without pain. With regard to the duration of pain, acute pain has been significantly higher (about 84 %) than chronic pain (about 16 %). The representation of acute odontalgia with respect to the total number of patients was 12.36 % of patients, chronic odontalgia was represented in 2.38 % of patients.⁶

OBJECTIVES:

- 1) To evaluate difference in measurements of VAS scores before and after application of **PAIN OUT DENTAL GEL**.
- 2) To evaluate perception of patient's level of satisfaction in attaining relief of pain after dental gel application.

MATERIALS AND METHOD:

126 patients were selected from the outpatient department of Periodontology and Oral Implantology for the study. The procedure was explained and a written consent obtained.

INCLUSION CRITERIA:

- (i) Systemically healthy patients who have not undergone any surgery in the recent past.
- (ii) Odontogenic pain caused due to a variety of factors like caries, dental trauma, a damaged filling, dental

hypersensitivity, food impaction, PDL pain.

(iii) Patients willing to participate in the study

EXCLUSION CRITERIA:

- (i) Patients with inability to make an accurate mark on the VAS scale due to motor, cognitive or visual impairment
- (ii) Patients who lack sufficient effort to appropriately complete the task due to pain or cultured and other behavioural characteristics
- (iii) Patients with episodic nature of pain
- (iv) Patients with chronic disease
- (v) Gross oral pathology
- (vi) Non-odontogenic causes of tooth pain which include Trigeminal Neuralgia, Cluster headache, Acute Otitis media, Acute maxillary sinusitis, Cardiogenic jaw pain, TMJ disorders, Sialolithiasis, Atypical facial pain, Allergic sinusitis, Post herpetic neuralgia, Facial pain as a result of malignant neoplasms
- (vii) Patients with known allergy to components of dental gel
- (viii) Pregnant patients
- (ix) Patients on anti-histamines, sedatives, anti-depressants, tranquilizers

126 patients were selected from the outpatient department of PERIODONTICS AND ORAL IMPLANTOLOGY having odontogenic causes of tooth ache. The procedure was explained to them and a written consent form obtained.

The cause of tooth ache was ascertained using history, clinical examination (visual inspection, palpation, percussion and other tests) and radiographic aids when required. An assessment was made about the type, quality, intensity, frequency, duration and periodicity of pain. One tooth or 2 teeth (as the case demanded) was taken for consideration. Patients were asked to rate the intensity of the pain that they were experiencing by pointing to a line in the continuum of values on the VAS score card, a point which represents the analogous score of the level of pain. PAIN OUT DENTAL GEL was applied on the required area of interest using an applicator tip. It was allowed to

stay for 10 minutes during which period, the patient was not allowed to rinse, gargle or perform any movements that might affect the retention of the gel. A repeat scoring on the VAS score was made by the patient 10 minutes after gel application. The mean difference in VAS score values was recorded. (for one tooth or two teeth as the case demanded). Patients were asked to interpret their perception of the level of improvement they observed after usage of the gel.

VAS score difference Effectiveness Quotient

1-2	Low effectiveness
3	Moderate effectiveness
4-5	High effectiveness

The subjects scored pain intensity on a visual analogue scale (VAS) (0=no pain and 10=extreme, unbearable pain). Patients were instructed to point to the VAS. (Difference of 3-5 is considered as significant relief from tooth pain)

Results:

Distribution of study subjects based on etiology:

Etiology	Frequency
Caries	73
Hypersensitivity	15
Trauma to tooth	08
Food impaction	19
PDL pain	11

Mean changes in VAS score before and after application of dental gel in tooth-1

Tooth 1	VAS score at baseline	7	4
	VAS score 10 min after gel application	3	
	VAS score at baseline	7	3
	VAS score 10 days after gel application	4	

EFFECTIVENESS	No. OF SUBJECTS
HIGH (4-5)	67
MODERATE TO LOW (3)	37
NO EFFECTIVENESS (1-2)	22

Results of this survey showed high level of effectiveness of **PAIN OUT DENTAL GEL** in providing express pain relief in maximum number of subjects. Results also showed that dental caries was the primary etiologic factor responsible for pain in maximum number of subjects.

DISCUSSION: Tooth pain is one of the most common dental problems and a recent study conducted to assess attitudes towards dental care showed that 37% of people have suffered from tooth ache in the past 6 to 12 months. Pain out dental gel is one of a kind first aid solution which provides temporary relief so that patients can continue with their routine before going to a dentist for permanent cure. Thus it proves to be effective in buying some time before a permanent solution can be achieved¹⁰.

PAIN OUT DENTAL GEL consists of clove oil, camphor, extract of mentha arvensis. These analgesic oils may be from natural sources or may be synthetic. Clove oil is extracted from the buds,

leaf or stem of the clove plant, *syzygium aromaticum*. Camphor may be extracted from plants, eg. from laurel or *rosemary*, or synthetically produced, eg; from oil of turpentine.⁹

In this study, pain out dental gel was applied to painful tooth/teeth in 126 subjects. 67 of the 126 subjects demonstrated high effectiveness of dental gel, 37 subjects showed moderate to low effectiveness while 22 subjects did not demonstrate any change. This proves the clinical effectiveness of the dental gel in providing temporary express relief of tooth pain.

However, 22 patients did not demonstrate any change in the VAS score before and after application of the gel. Further studies need to be carried out to find the causative factors behind the non-effectiveness of the product and also to determine if its effectiveness stays for a longer duration.

CONCLUSION :

The in-office PAIN OUT dental gel containing clove oil, camphor and extract of mentha arvensis provides significant reduction in odontogenic tooth pain instantly after a single professional application of the product and this reduction is maintained for 10 days without its further application.

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