

Comparative Efficacy of the Polyethylene Glycol Gel and the Varying Concentrations of Benzocaine Gel in Achieving Clinically Meaningful Pain Relief in Patients with Toothache

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Author's Contribution

^{1,2,3}Substantial contributions to the conception or design of the work; or the acquisition, ⁴Drafting the work or revising it critically for important intellectual content, analysis, or interpretation of data for the work,

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ABSTRACT

Objective: To compare meaningful pain relief with Polyethylene glycol gel, 10% and 20% concentrations of benzocaine gel in patients of toothache because of irreversible pulpitis reporting to the department of Operative Dentistry.

Methodology: This comparative study was conducted from Dec 2018-Feb 2020 in the Department of Operative Dentistry, PIMS, Islamabad via stratified random sampling. Sample size was 600, 200 each for propylene glycol gel group, 10% Benzocaine group & 20% Benzocaine group. Inclusion criteria was: Patients of 15 years or more age and with-out any systemic illness, toothache because of ir-reversible pulpitis in 01 permanent mandibular or maxillary tooth having an open cavity, those patients having toothache of at-least moderate intensity as per Visual Analogue Scale (VAS). Whereas exclusion criteria were: Patients having periodontal abscess, those used any systemic or topical analgesic inside 4 hours preceding to the visit. After informed consent from participants, the ethical committee of PIMS/SZABMU approved the study

Results: One-way ANOVA was used to explore the difference in time duration to achieve meaningful pain relief among the three groups, and it was found to be significant statistically ($F=17.193$, $P<0.001$). Post Hoc test was used to explore the pair wise comparisons of the three groups in terms of duration to achieve meaningful pain relief. mean difference of Group B and Group C was 2.719 and the comparison was significant ($P<0.001$) and mean difference of Group C and Group A was -4.029 and the comparison was significant ($P=0.001$).

Conclusion: Benzocaine in both concentrations is more effective in achieving clinically meaningful pain relief than Polyethylene Glycol in patients having toothache.

Keywords: Benzocaine, Gel, Pain, Polyethylene Glycol, Pulpitis, Toothache

Introduction

Oral ailments are a vital public health problem globally, directly impacting the lives of people by triggering pain, suffering, affecting self-esteem and speech.¹⁻³

Health is considered as supreme assets in human life and oral health is immensely imperative for overall physical-health.⁴⁻⁶ Toothache is defined as "a pain that originated from tooth and its supporting structures."⁷

Presence of the bacteria in tooth is the main reason of peri-apical conditions, root canal, and pathological pulp. Bacteria can invade the dentine pulp-complex through different pathways for instance through caries, fractures, cracks, and broken-down-restoration margins. Pulp primarily attempts to wall-off these invading bacteria & their endotoxins with reactionary dentine. Nevertheless, if

this invasion continues, then it results in reversible pulpitis, and if it remains untreated, then it advances to irreversible pulpitis.^{8,9} Prevalence of toothaches was 58% in a recent research. The findings highlight the multifactorial nature of toothache, with sturdy links to sex, age, lifestyle behaviors, oral hygiene habits, and socioeconomic status.¹⁰

The most common form of self-medication for relief of acute toothache includes topical anesthetic agents. Topical anesthesia is effective when applied to the tissue surface due to the pharmacologic effect of anesthetic agents. This helps to reduce the injection discomfort. Besides this use, topical anesthesia can be applied individually or as a component of exclusive formulations for the treatment of symptomatic oral and mucosal ulcers or lesions.¹¹

Several formulations of topical anesthetics are supplied in the form of gels, ointments, solutions, aerosols, pastes, powders, lozenges, tablets and impregnated patches. Topical anesthesia could decrease pain perception and discomfort due to two mechanisms. There may be the pharmacologic action and also an added advantage caused by the psychological effect of the topical anesthetic which should be acknowledged in dental practice.¹²

Because of its quick onset and persistent effects, benzocaine is a topical anesthetic that is frequently used in dentistry. It relieves pain momentarily by obstructing nerve signals in the injured location. Acute toothaches can be effectively treated with benzocaine.¹³

Topical benzocaine is available in formulations with a regular potency of 10% and a maximum potency of 20%. According to the Food and Drug Administration (FDA) of the United States, it is generally described as safe and effective when used externally as an analgesic or anesthetic for the relief of pain temporarily, caused by minor injury or irritation in the mouth and gingivae, teething, ulcers, sore throat, orthodontic appliances, dentures and minor dental procedures.¹⁴ Polyethylene glycol gel provides protective and analgesic effects by forming a film over inflamed mucosa and exposed dentine, and is also used as an alternative to anesthetic gels.

Despite widespread use, there is limited comparative data on clinical efficacy of Polyethylene glycol gel versus different concentrations of benzocaine gel for acute toothache. Therefore, objective of this study was to compare meaningful pain relief with Polyethylene glycol gel, 10% and 20% concentrations of benzocaine gel in patients of toothache because of irreversible pulpitis reporting to the department of Operative Dentistry.

Methodology

This comparative study was conducted from Dec 2018-Feb 2020 in the Department of Operative Dentistry, PIMS,

Islamabad via stratified random sampling. Epi-info software was used to calculate sample size as per following parameters

Margin of error 5%, design effect 1, confidence interval 95%, Anticipated populace proportion (P_1) = 81.00%, Anticipated populace proportion (P_2) = 87.00%, Anticipated populace proportion (P_3)¹⁴ = 70.00%. Ultimate sample size was 600, 200 each for propylene glycol gel group, 10% Benzocaine group & 20% Benzocaine group.

All 03 gels were commercially available. Group-A: Polyethylene glycol gel group, Group-B: 10% Benzocaine Gel, Group-C: 20% Benzocaine Gel. Inclusion criteria was: Patients of 15 years or more age and without any systemic illness, toothache because of irreversible pulpitis in 01 permanent mandibular or maxillary tooth having an open cavity, those patients having toothache of at-least moderate intensity as per Visual Analogue Scale (VAS). Occurrence of pain was appraised by VAS as: No (VAS=0), and "Yes (VAS= 1 to 10) and pain intensity was the highest score recorded (mild=1-3, moderate =4-6, severe =7-10).¹⁵ Whereas exclusion criteria were: Patients having periodontal abscess, those used any systemic or topical analgesic inside 4 hours preceding to the visit, having any allergy or contra-indication to any local anesthetics, including benzocaine, and patients whose pain initiated from multiple hard or soft-tissue regions.

An ethical committee of SZABMU/PIMS approved this study and an informed consent was also taken from all participants afterwards diagnosis of irreversible pulpitis with cold test by means of endo-ice. Patients were asked to estimate their pain & rate it on Ordinal Dental Pain Scale (DPS) as per following criteria; 0=No pain, 1=mild pain, 2=moderate pain, 3=severe pain. Patients who had at-least "moderate pain" on ordinal Dental Pain Scale were designated for this research & were then allotted to either of the 03 Groups, stratified in a ratio of 1:1:1 by means of software (randomizer.org). Assistant investigator & primary investigator supervised an application of gel. A pea sized (standardized) amount of 10% or 20% Benzocaine gel, polyethylene glycol gel of even thickness was placed on glass slab, after giving instructions to the participants. Participants were given gel who then applied it to their tooth & surrounding region properly with finger. Marked instrument was used to measure thickness of gel, in order to guarantee that all the partakers used a same standardized quantity of gel. Upon application, a stopwatch was started by assistant, who wasn't informed of sort of gel applied.

Patients were asked to inform the investigator about any adverse effects. The onset time of meaningful pain relief was noted with the help of stopwatch. Patients were instructed about meaningful pain relief occurring if pain intensity improved at-least 01 point on ordinal Dental Pain

Scale. After completion of data-collection, participants were referred for the definitive dental treatment.

Collected data was entered & analyzed using SPSS version 25. Post-Hoc test was used to explore the pair wise comparisons of the three groups. Whereas, one-way ANOVA was used to explore the difference in time duration to achieve meaningful pain relief among the three groups. P-value ≤ 0.05 was taken as significant.

Results

Out of 600 participants, women were 346 (57.60%) while men were 254 (42.40%). In the group A (Polyethylene Glycol Gel), out of 200 patients, 60 presented with a severe pain & 140 presented with a moderate pain. In 10% Benzocaine Gel (Group B), out of 200 patients, 134 presented with a moderate pain & 66 patients with a severe pain. Whereas, in 20% Benzocaine Gel (Group C), 70 patients presented with a severe pain and 130 presented with a moderate pain. Percentage of patients according to severity of pain upon arrival for dental treatment is shown in figure 1.

		Mean Difference (I-J)	Std. Error	Sig.
Any Pain Relief	Polyethylene Glycol Gel-10% Benzocaine Gel	0.167	.321	.938
	10% Benzocaine Gel-20% Benzocaine Gel	1.40335	.26221	.000
	20% Benzocaine Gel-Polyethylene Glycol Gel	-1.57005	.32114	.000

Post Hoc test was used to explore the pair wise comparisons of the three groups. Mean difference of group A and group B was 0.167 and the comparison was insignificant ($P=0.938$). On the other hand, mean difference of Group B and Group C was 1.403 and the comparison was significant ($P=0.001$) and mean difference of Group C and Group A was -1.570 and the comparison was significant ($P=0.001$) which showed that 20% benzocaine gel has quick pain-relieving effect as compared to 10% benzocaine gel and polyethylene glycol gel. As shown in table I.

		Mean	SD		
Meaningful pain relief	Polyethylene Glycol Gel	11.1278	4.10389	F	Sig.
	10% Benzocaine Gel	9.8176	7.70617	17.193	< 0.001
	20% Benzocaine Gel	7.0987	5.22843		

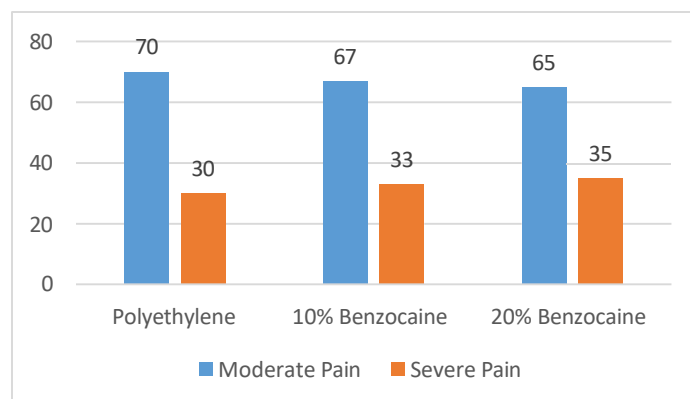


Figure 1. Severity of pain upon arrival for dental treatment.

One-way ANOVA was used to explore the difference in time duration to achieve meaningful pain relief among the three groups, and it was found to be significant statistically ($F=17.193$, $P<0.001$). The mean time of group A to achieve pain relief was 11.128 ± 4.104 , of Group B was 9.818 ± 7.706 and of Group C was 7.099 ± 5.228 . The results revealed that 20% Benzocaine Gel group experienced meaningful pain relief feeling quicker as compared to 10% Benzocaine Gel group and Polyethylene Glycol Gel group. As displayed in table II.

Post Hoc test was used to explore the pair wise comparisons of the three groups in terms of duration to achieve meaningful pain relief. Mean difference of group A and group B was 1.310 and the comparison was insignificant ($P=0.230$). On the other hand, mean difference of Group B and Group C was 2.719 and the comparison was significant ($P=<0.001$) and mean difference of Group C and Group A was -4.029 and the comparison was significant ($P=0.001$). This shows that 20% benzocaine gel has quick meaningful pain relieving effect followed by 10% benzocaine gel and polyethylene glycol gel. As depicted by table III.

Discussion

Dental treatment demands the co-operation of patients¹⁶. Dental patients come with various oral health issues in LMIC's, for instance, complaint of severe pain, inflammation, and sensitivity, as use of nicotine is also common here.¹⁷⁻²⁰ Media coverage has done a good job to raise the knowledge of the patients but public health measures including awareness should be considered in future as well.^{21,22} Socio-economic position plays a decisive role in determining health consequences, including psychological & physical health.^{23,24} In LMIC settings where access to the definitive care is delayed,

Table III: Pairwise group comparison of achieving meaningful pain relief in terms of time duration.

		Mean Difference (I-J)	Sig.	95% Confidence Interval	
				Lower Bound	Upper Bound
Meaningful Pain Relief	Polyethylene Glycol Gel-10% Benzocaine Gel	1.310	.230	-.500	3.121
	10% Benzocaine Gel-20% Benzocaine Gel	2.719	.000	1.241	4.197
	20% Benzocaine Gel-Polyethylene Glycol Gel	-4.029	.000	-5.840	-2.219

effective topical pain relief becomes more clinically relevant.

One study reported that topical anesthesia provides effective pain relief in dental patients and that its effectiveness is influenced by both pharmacological and psychological factors.¹¹ The authors of another research found that all three topical anesthetics provided effective pain relief on the oral mucosa, with the duration of anesthesia ranging from 5 to 20 minutes depending on the formulation. The authors noted that one of the formulations, which contained benzocaine and tetracaine, was particularly effective in providing deep and long-lasting anesthesia.²⁵

In this study, pairwise group comparison of any pain relief in terms of duration to achieve effect showed that there was a statistically significant difference between 10% Benzocaine gel & 20% Benzocaine gel, where p-value was 0.000. This is in accordance with another research (p-value 0.047).¹⁴ In this research, there was statistically insignificant difference between Polyethylene Glycol Gel and 10% Benzocaine Gel, where p-value was 0.938. This is opposite to another study, where p-value was 0.038.¹⁴

In this study, group comparison of meaningful pain relief in terms of duration to achieve effect showed p-value 0.001, which is comparable to another study.¹⁴ 20% benzocaine gel achieved pain relief significantly faster than 10% gel [$p < 0.001$].¹⁴ This dose-response effect is consistent with pharmacology. For severe toothache, faster onset might improve patient ease before definitive treatment.

The authors of one study concluded that the best topical anesthetic for completely numbing the oral mucosa was benzocaine.²⁶ According to the authors of another research, 5% lignocaine gel is not as efficient in reducing pain in patients with irreversible pulpitis as 20% benzocaine gel is. They recommended using benzocaine

gel to help patients feel more comfortable throughout their endodontic therapy.²⁷ Thompson et al's study looked into the effectiveness and safety of 20% benzocaine gel in treating patients with severe toothaches. The findings demonstrated that 20% benzocaine gel significantly reduced pain in comparison to placebo at all the time points recorded on the VAS. Patients in the 20% benzocaine group reported greater satisfaction levels than those in the placebo group, according to an evaluation of overall patient satisfaction, reporting that 20% benzocaine gel had a favorable safety profile and was effective in significantly reducing pain in patients with acute toothaches.²⁸

Limitations: Limitations of the current study were shorter duration and small sample size. Researcher did not assess the administration of multiple doses of the research gels throughout the day. The data collected did not include information on whether patients in the benzocaine gel groups applied the gel at four different times during each day, which is the maximum dosage specified by the manufacturers of benzocaine tooth relief products. Conducting a study with multiple doses of the product was not feasible or ethically appropriate, as the main purpose of the study was to include participants who needed immediate definitive treatment for their acutely symptomatic tooth on the day of enrollment.

Future implications: Effective topical analgesics like Polyethylene Glycol and Benzocaine gel might help to lessen the need for the opioid prescriptions in dental patients. Study's findings can apprise emergency dental care protocols, possibly leading to more efficient and effective management of acute tooth ache in the emergency settings.

Conclusion

20% benzocaine gel has quick pain relieving effect as compared to 10% benzocaine gel and polyethylene glycol gel. Benzocaine in both concentrations is more effective in achieving clinically meaningful pain relief than Polyethylene Glycol in patients having toothache. 10% Benzocaine Gel-20% Benzocaine Gel and 20% Benzocaine Gel-Polyethylene Glycol Gel were pairwise effective in terms of duration to achieve effect.

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