Original Article

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Effectiveness of Various Concentrations of Benzocaine and Polyethylene Glycol Gel in Patients with Acute Tooth ache

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Author`s Contribution

[1,3]Substantial contributions to the conception or design of the work; or the acquisition, [1,5]Drafting the work or revising it critically for important intellectual content [4,5]Supervision and Final approval. [2,6,7]Active participation in active methodology, analysis, or interpretation of data for the work,

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ABSTRACT

Objective: To find out the reduction in pain in one hour, upon application of topical Benzocaine gels, with 10% and 20% concentrations, for toothache due to irreversible pulpitis.

Methodology: This comparative study was conducted in Department of Operative Dentistry, Pakistan Institute of Medical Sciences Islamabad from Dec 2018 to Feb 2020. Sample of 200 in each group, 10% Benzocaine group, 20% Benzocaine group and polyethylene glycol gel group was achieved via stratified random sampling. Patients without any systemic disease, 15 years or older reported with toothache due to irreversible pulpitis in one permanent maxillary or mandibular tooth with an open cavity were included. The intensity of endodontic pain was evaluated by the Visual Analogue Scale (VAS). The ethical committee of PIMS/SZABMU approved the study and the informed consent was taken from participants after a diagnosis of irreversible pulpitis was made with cold test.

Results: Out of 600 patients, males were 254 and females were 346. Patients with moderate severity of pain upon arrival for dental treatment were 404, while 196 had severe pain. Chi-square test revealed that there was a significant difference between the levels of pain after one hour among the three groups (P=< 0.001). Similarly, chi-square revealed that there was a significant difference between the levels of pain relief among the three groups after one hour (P=<0.001).

Conclusion: Benzocaine gel (20%) showed more effective results as compared to the 10% benzocaine gel in patients with tooth ache. Benzocaine, in both concentrations, is more effective than Polyethylene Glycol.

Keywords: Benzocaine, Irreversible pulpitis, Polyethylene Glycol, toothache, Visual Analogue Scale.

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Introduction

Oral health is tremendously imperative for over-all physical health, as health is thought as supreme assets of human life.[1,2] Outcomes of certain procedures has been always a matter of concern for both the clinician and patient.[3] Dental patients may complaint of severe pain, sensitivity, and swelling. [4-6] Toothache or dental pain is defined as "pain that originated from a tooth and its support structures, and it is often labeled as most frequent sort of oro-facial pain.[7,8] There are different causes for dental pain but the most frequent ones include pulpitis and acute apical periodontitis. [9].

In low-income nations, many individuals face significant barriers to accessing treatment due to financial constraints.[10,11] Most individuals under-take dental treatment to get relief from pain and reinstate oral functions [12-14], whereas some prefer self-medication with analgesics and antibiotics [15]. Ideally, various decisions & factors should be taken into account preceding their prescription. [16,17]

The most common form of self-medication for relief of acute toothache includes topical anesthetic agents. These anesthetics are available in different potencies and formulations, containing various and diverse agents to bring about the anesthetic or analgesic effect. Such topical agents not only have a pharmacological advantage but also a psychological one. Newer topical anesthetic agents claim improved efficacy [18]. One of the most commonly used topical anesthetic agents these days is benzocaine (ester type). Benzocaine (Ethyl para-aminobenzoate) itself is used either topically or in different nonprescription dosage forms such as creams, gels, lotions, ointments, lozenges and aerosols to bring about pain relief in several conditions including toothache [19]. Kincheloe et al concluded that the use of a topical anesthetic (20% benzocaine gel) can significantly reduce pain during dental treatment. [20]

The objective of this study was to find out the reduction in pain in one hour, upon application of topical Benzocaine gels, with 10% and20% concentrations, for toothache due to irreversible pulpitis.

Methodology

This comparative study was conducted in Department of Operative Dentistry, Pakistan Institute of Medical Sciences Islamabad from Dec 2018 to Feb 2020. Sample size was calculated using the Epi-info software according to the parameters mentioned below:

Confidence interval 95%, margin of error 5%, design effect 1, Anticipated population proportion (P1) =81.00%, Anticipated population proportion (P2) =87.00%, Anticipated population proportion (P3) 21 =70.00%. Final sample size came out to be 600, 200 each for 10% Benzocaine group, 20% Benzocaine group and polyethylene glycol gel group.

Stratified random sampling was done. All three gels were available commercially. Group A: Polyethylene glycol gel group, Group B: 10% Benzocaine Gel, Group C: 20% Benzocaine Gel. Inclusion criteria was: Patients aged 15 years or more and without any systemic disease, toothache due to irreversible pulpitis in one permanent maxillary or mandibular tooth with an open cavity, patients with toothache of at least moderate intensity according to Visual Analogue Scale (VAS). The intensity of endodontic pain was evaluated by the Visual Analogue Scale (VAS) as: "Yes (VAS ranging from 1 to 10) and No (VAS=0), and the intensity of pain considered was the highest score recorded (1-3=mild, 4-6=moderate, 7 10=severe)14. While exclusion criteria were: Patients whose pain originated from multiple soft-tissue or hard-tissue regions, having periodontal abscess, having any allergy or contraindication to any local anesthetics, including benzocaine, patients having used any topical or systemic analgesic within 4 hours prior to the visit.

The ethical committee of PIMS/SZABMU approved the study and the informed consent was taken from participants after a diagnosis of irreversible pulpitis was made with cold test using endo Ice. The patients were asked to evaluate their pain and rate it on an Ordinal Dental Pain Scale (DPS) according to the following criteria;

No pain: 0, mild pain: 1, moderate pain: 2, severe pain: 3

The patients having at least ‘Moderate Pain’ according to the Ordinal Dental Pain Scale were selected for the study and were then allocated to either Group A, B or C, stratified in a ratio of 1:1:1 using a software (randomizer.org). The primary investigator as well as the assistant investigator supervised the application of gel by every participant. A standardized (pea sized) amount of polyethylene glycol gel, 10% Benzocaine gel or 20% Benzocaine gel of even thickness was placed on a glass slab. The participants were given the gel who then applied it to the tooth and surrounding area properly with their finger, under the supervision of the primary investigator. To ensure all the participants used the same standardized amount of gel, the primary investigator used a marked instrument to measure the thickness of the gel given to the participant.

Patients were given instructions by the primary investigator for application of the gel according to standardized dosage (pea size). The gel was applied to the soft tissue surrounding the tooth and also in the open tooth cavity. Upon application of the gel, two stop watches were started by an assistant, who was not informed of the type of gel applied to the tooth cavity. A rescue analgesic (Ibuprofen) was provided to participants who opted to retire from the study due to excessive pain.

Patients were asked to assess the intensity of their pain and pain relief after 60 minutes of application of the gel using the Ordinal Dental Pain Scale and an Ordinal Pain Relief Scale according to the following criteria.

No relief: 0, little relief: 1, some relief: 2, A lot of relief: 3, complete relief: 4

Patients were instructed to notify the assistant investigator when and if they feel any pain relieving effect and the first stop watch was stopped. The onset time of meaningful pain relief was also noted by the assistant investigator with the help of the second stopwatch, if it occurs. The patients were instructed regarding meaningful pain relief occurring if their pain intensity improved at least one point on the Ordinal Dental Pain Scale. Patients were also asked to notify the primary and/or assistant investigator of any adverse effects, if they felt any. The participants were referred for definitive dental treatment after completion of data collection.

Variables measured were pain intensity after 1 hour, pain relief after 1 hour, time taken measured in minutes and seconds in decimal points, for any pain relieving effect (Stopwatch 1), time taken measured in minutes and seconds in decimal points, for meaningful pain relief (Stopwatch 2).

All the data collected was entered and analyzed using Statistical Package for Social Sciences (SPSS version 25). Percentages were calculated of participants with an improvement in pain intensity. The data obtained was assessed with a chi-square test for difference in pain relief for the three groups. P-value ≤0.05 was considered significant.

Results

Out of 600 patients, males were 254 (42.40%) and females were 346 (57.60%). The mean age was 35.91±1.18.

In the Polyethylene Glycol Gel group (Group A), 200 patients were inducted among which 140 presented with moderate pain and 60 presented with severe pain. In the 10% Benzocaine Gel group (Group B), 200 patients were inducted among which 134 presented with moderate pain and 66 patients presented with severe pain. In the 20% Benzocaine Gel group (Group C), 200 patients were inducted among which 130 presented with moderate pain and 70 patients presented with severe pain. As shown in table I.

Table I: Severity of pain upon arrival for dental treatment.

		Pain upon arrival	
		Moderate Pain	Severe Pain
Groups	Polyethylene Glycol Gel	140(70%)	60(30%)
	10% Benzocaine Gel	134 (67%)	66 (33%)
	20% Benzocaine Gel	130 (65%)	70 (35%)

Results of chi-square revealed that there was a significant difference between the levels of pain after one hour among the three groups (P=< 0.001). Patients with mild pain were 40(20%), with moderate pain were 140(70%) and with severe pain were 20(10%) in group A, according to the Ordinal Dental Pain Scale. In group B, patients with no pain were 44(22%), with mild pain were 120(60%), with moderate pain were 28(14%) and with severe pain were 8(4%). In group C, patients with no pain were 84(42%), with mild pain were 96(48%), with moderate pain were 20(10%) and with severe pain were 0(0.0%). The results showed that effect of 20% Benzocaine gel has a better effect in terms of pain control as compared to 10% Benzocaine gel whereas Polyethylene Glycol Gel has a very minor effect. This group wise comparison in terms of pain after 1 hour is shown in table II.

Results of chi-square revealed that there is a significant difference between the levels of pain relief among the

Table II: Group wise comparison in terms of pain after 1 hour.

		Pain after one hour				P-value
		No Pain	Mild Pain	Moderate Pain	Severe Pain	
Groups	Polyethylene Glycol Gel	0(0.0%)	40(20%)	140(70%)	20(10%)	<0.001
	10% Benzocaine Gel	44(22%)	120(60%)	28(14%)	8(4%)	
	20% Benzocaine Gel	84(42%)	96(48%)	20(10%)	0(0.0%)	

Table III: Comparison of three groups in terms of pain relief after 1 hour.

		Pain relief after one hour					P-value
		No Relief	Little Relief	Some Relief	A lot of Relief	Complete Relief	
Groups	Polyethylene Glycol Gel	60(30%)	100(50%)	20(10%)	20(10%)	0(0.0%)	< 0.001
	10% Benzocaine Gel	8(4%)	32(16%)	60(30%)	72(36%)	28(14%)	
	20% Benzocaine Gel	2(1%)	10(5%)	46(23%)	58(29%)	84(42%)	

three groups after one hour (P=<0.001). Patients with no relief in group A were 60(30%), with little relief were 100(50%), with some relief were 20(10%), with a lot of relief were 20(10%), and with complete relief 0(0.0%). Patients with no relief in Group B were 8(4%), with little relief were 32(16%), with some relief were 60(30%), with a lot of relief were 72(36%), and with complete relief 28(14%). Patients with no relief in Group C were 2(1%), with little relief were 10(5%), with some relief were 46(23%), with a lot of relief were 58(29%), and with complete relief 84(42%). As depicted in table III

Discussion

Application of local anesthesia is required for a pain-free dental procedures. But, the perception of patients that association of pain with injection which leads to mucosal puncture or the local anesthesia deposition pressure will be painful can aggravate the feeling of pain and causes even more anxiety. So to deal with such issues and also to control the pain of patients with acute dental pain before definite dental treatment is provided, various methods have been introduced in dentistry. Among such techniques, topical anesthesia application and also use of needle technique to deposit anesthesia with sharp and narrow needle, low-pressure injection, and slow rate of injecting drug are of significance. [22,23] Patients come with different issues of oral health in LMIC's as use of nicotine is also common here. [24]

The results of this research showed that effect of 20% Benzocaine gel has a better effect in terms of pain control as compared to 10% Benzocaine gel, whereas Polyethylene Glycol Gel has a very minor effect. A study conducted by Hersh et al reported similar results that 10% benzocaine gel is less effective in treatment of acute pain as compared to the 20% benzocaine gel. [21]

This research showed that there was a significant difference between the levels of pain relief among the three groups after one hour. The results of the study showed that benzocaine gel provided significant pain relief in patients with acute dental pain. Of those patients included in 20% Benzocaine group 71% patients felt 'A lot of relief' or 'Complete relief" according to the Ordinal Pain Relief Scale, while 50% of the 10% Benzocaine group and 10% of placebo group felt comparable relief. Similar results were reported in different studies with similar objectives. The study by Janković et al reported that the difference in pain relief between the two groups (Group A – benzocaine gel and Group B – placebo gel) was statistically significant (p<0.05) with Benzocaine gel producing favorable results.[25] The results of other studies showed that 20% benzocaine gel [26] and 10% benzocaine gel [27] significantly reduced pain in patients as compared to placebo (P<0.001) as measured on a Visual Analog Scale (VAS).

Limitations: limitations of the current study were shorter duration and small sample size

Future implications: This study's findings can contribute towards development of effective topical analgesics used for managing patients with acute tooth ache, potentially leading to improved patient outcomes. Based on this research, future studies can compare the effectiveness of various topical analgesics, including Polyethylene glycol and benzocaine gel in various formulations and concentrations.

Conclusion

Benzocaine gel (20%) showed more effective results as compared to the 10% benzocaine gel in patients with tooth ache. Benzocaine, in both concentrations, is more effective than Polyethylene Glycol. Overall, Benzocaine gel, in both 10% and 20% concentrations, can be used for acute toothache effectively, especially in anxious patients.

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