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3 **Effect of pre-cooling agent on intensity of pricking pain at intraoral**
4 **injection site in adults: An experimental study**

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12

13 **Abstract**

14 **Objective:** To determine the effect of pre-cooling agent on the intensity of pricking
15 pain at the intraoral injection site in adult patients.

16 **Method:** The in-vivo interventional study was conducted at the Department of
17 Operative Dentistry, Dr. Ishrat-ul-Ebad Khan Institute of Oral Health Sciences, Dow
18 University of Health Sciences, Karachi, from September 2018 to August 2019, and
19 comprised adult patients of either gender. The pricking pain perception during needle
20 administration was assessed using split-mouth technique. Topical anaesthesia
21 benzocaine gel was applied on the left side, which was treated as controls, for 1 min,
22 while on the right side, which was treated as the experimental side, refrigerated
23 cartridge was placed for 2 min. Infiltration anaesthesia was then administered on both
24 sides. Pain perception ratings were measured through visual analogue scale. After
25 profound anaesthesia was achieved, restorative treatment was performed under rubber
26 dam isolation. Data was analysed using SPSS 24.

27 **Results:** Of the 152 subjects, 77(50.65%) were females and 75(49.34%) were males.
28 The overall mean age was 35.97± 8.669 years (range: 21-50 years). The effect of

29 refrigerated cartridge was significant on the intensity of pricking pain at the intraoral
30 injection site in patients aged 41-50 years, and in female patients aged 21-30 years
31 ($p < 0.05$), whereas its effect was non-significant in males aged 21-30 years and
32 patients aged 31-40 years ($p > 0.05$).

33 **Conclusion:** Pre-cooling agent was found to be effective in decreasing pricking pain
34 felt by patients.

35 **Key Words:** Pain, cryoanesthesia, infiltration anaesthesia, Visual analogue scale,
36 VAS, Dental anxiety.

37

38 **Introduction**

39 Pain is considered the fifth vital sign¹ and is an unpleasant emotional and sensory
40 experience associated with likely tissue damage.² There are many factors^{3,4}, out of
41 which major factors are pricking pain and fear caused by the vision of the needle
42 which is known as blenophobia.⁵ Anticipation of pain due to needle prick is most
43 commonly observed in dental procedures. Multiple methods, such as use of topical
44 anaesthetic agent, like benzocaine, buffering the local anaesthetics, distraction
45 methods, warming the local anaesthetic agents and adjusting the pace of the
46 infiltration by lowering the speed of injection, are employed to alleviate such pain.⁵

47 One of the major techniques to relieve pricking pain is to cool the site of injection.⁶
48 There are several ways to do this, such as use of refrigerant spray, like 1,1,1,3,3-
49 pentafluoropropane or 1,1,1,2-tetrafluoroethane, customised form of ice etc. The
50 application of cold to a contained part of the body to obstruct the painful impulses
51 generated by local nerve transmission is called cryoanaesthesia.⁶ Refrigerant sprays or
52 ice in customised form can be used to induce cryoanaesthesia. The major benefit of
53 cryoanaesthesia is that it acts upon every cell compared to topical anaesthesia which
54 acts on nerve cells alone. As such, cryoanaesthesia is regarded to be more efficient
55 than conventional topical anaesthesia.⁷

56 Nearly all dental studies involving pre-cooling agents have been done in paediatric
57 patients.⁵ A study found that cooling the palatal area prior to injection alleviates pain.⁸

58 Another study regarding the comparison between different pre-cooling agents and
59 topical anaesthesia found that ice cone was more effective than refrigerant spray and
60 topical anaesthesia in children aged 5-8 years.⁶

61 Even after the application⁷ of topical anaesthesia, majority of patients still feel some
62 pricking pain at the intraoral injection site. Literature supports the cooling mechanism
63 to overcome pricking pain in paediatric patients. To date, there is only one study
64 conducted in adults⁹ which reported that use of ice had a positive impact. However, it
65 used topical anaesthesia before the application of pre-cooling agents at the infiltration
66 site in adult patients.⁹ There is no need of topical anaesthesia when pre-cooling agent
67 is used because cryoanaesthesia acts upon every cell, including the nerve cells.⁷

68 The current study was planned to determine the response of needle prick by simple use
69 of ice in the form of refrigerated cartridge at the injection site in adult patients.

70

71 **Patients and Methods**

72 The in-vivo, interventional study was conducted at the Department of Operative
73 Dentistry, Dr. Ishrat-ul-Ebad Khan Institute of Oral Health Sciences, Dow University
74 of Health Sciences (DUHS), Karachi, from September 2018 to August 2019. After
75 approval from the institutional ethics review committee, the sample size of 152 was
76 calculated in the light of literature⁵ while using OpenEpi¹⁰ software with 95%
77 confidence interval (CI) and 80% power of test. The sample was raised using non-
78 probability purposive sampling technique. Those included patients of either gender
79 aged 21-50 years coming for restorative treatment of bilateral maxillary premolars
80 with carious lesions and symptoms of reversible pulpitis requiring direct restoration.
81 The diagnosis of reversible pulpitis was established through clinical history,
82 radiographical examination and objective test performed by cold test and electric pulp test
83 (EPT).

84 Patients with systemic diseases, like diabetes, hypertension, human immunodeficiency
85 virus (HIV), and liver or kidney transplant were excluded. Also excluded were
86 patients with intellectual disabilities, psychiatric disorders, dental abscess and intraoral

87 draining sinus or fistula. Patients taking any pain-killer prior to the procedure and
88 those having a tooth with irreversible pulpitis and pulp necrosis were also excluded.
89 To determine the efficacy of pre-cooling agent on reducing the intensity of pricking
90 pain, the split mouth approach was used on bilateral maxillary premolar teeth (Figure
91 1) after taking written informed consent from the subjects. Age was stratified into
92 three groups; 21-30 years, 31-40 years, and 41-50 years. In each group the site of
93 anaesthesia was cleaned with steriled gauze. On the left intraoral side, taken as the
94 control side, topical anaesthesia (Dental Opahl 20% benzocaine), followed by
95 maxillary buccal infiltration anaesthesia (Medicaine-1.8ml inj. [Lidocaine] with
96 1:100,000 epinephrine, using 27G needle) was applied. The area was first dried using
97 triple air syringe and topical anaesthesia was applied using cotton-tipped applicator for
98 1 minute using rubbing motion and left for 30 sec to increase the penetration depth.
99 On the right intraoral side, taken as the experimental side, refrigerated cartridges were
100 used as a pre-cooling agent and were applied for 2 min. Refrigerated cartridges were
101 made by emptying a number of commercially available lidocaine cartridges
102 (Medicaine^R inj.I 1.8ml). These cartridges were chemically disinfected with 70% ethyl
103 alcohol, according to the manufacturers' recommendations.¹¹ They were later were
104 filled with distilled water and placed in the freezer at 0 degree Celsius for a minimum
105 of 48 hours or until usage. Maxillary buccal infiltration anaesthesia was then
106 administered.

107 To indicate the pain perceived on pricking the anaesthetic needle, each participant was
108 asked to indicate the pain of the prick of anaesthetic needle on visual analogue scale
109 (VAS). The pain rating score (PRS) of VAS scale consists of 0-10 readings in which 0
110 = no pain, 1-2 = mild pain, 3-6 = moderate pain, 7-9 = severe pain, and 10 = worst
111 possible pain.⁵ The readings were recorded for each participant by un-blinded
112 principal investigator and was confirmed by the co-investigator who was blinded to
113 the grouping. After profound anaesthesia was achieved, restorative treatment was
114 performed under rubber dam isolation.

115 Data was analysed using SPSS 23. Significance of VAS scores in different age groups
116 was calculated using Fisher Exact test. $P < 0.05$ was considered significant.

117

118 **Result**

119 Of the 152 subjects, 77(50.65%) were females and 75(49.34%) were males. The
120 overall mean age was 35.97 ± 8.669 years (range: 21-50 years). Of the total, 52(34.2%)
121 were aged 21-30 years, 50(32.9%) were aged 31-40 years, and 50(32.9%) were aged
122 41-50 years. Age- and gender-wise analyses of pain scores were done for different age
123 groups (Table 1).

124 Overall comparison of pain rating scores in control and experimental groups was done
125 (Figure 2), and, separately, gender-wise analysis of pain score was done between the
126 two groups (Table 2).

127

128 **Discussion**

129 The present study showed major effect of pain reduction through refrigerated cartridge
130 that were used on the adult patients undergoing dental procedures. Fear associated
131 with the dental treatment is prevalent even in the adults despite advancements in
132 dental care. The fear of the needle is the commonest anxiety-provoking element seen
133 not only in most females during their dental treatment, but also among the males.^{12,13}

134 Anxiety is the fear of staying in a dental office of dental care provider for therapeutic
135 or preventive care.¹⁴ Participants in the present study had received benzocaine gel on
136 the control side, which is the standard procedure and is generally recommended to
137 minimise the sensation of pain.¹⁵⁻¹⁷ This topical anaesthesia is a fast-acting ester-type
138 anaesthetic agent. It has low level of systemic absorption and has a pleasant taste. The
139 major disadvantage of benzocaine gel is its low bio-adhesivity.¹⁸ The major concern of
140 the current study was needle-phobia due to the prick of the needle in the oral mucosa
141 among the participants.¹⁹ Findings suggest that the pain during needle penetration was
142 less felt after the use of pre-cooling agent compared to the use of topical anaesthesia.

143 The finding is in line with an earlier study.²⁰

144 The results of the present study are also in line with a split-mouth interventional study⁹
145 which used pre-cooling agent to distract mind of 33 patients to determine its effect
146 during buccal infiltration. There were significant results ($p=0.02$) among the patients.
147 Similar methodology was conducted as was the case with the present study, but the
148 other study was limited by its small sample size and also there were vast differences in
149 the patient allocation in age-based sub-groups.

150 In the present study, age-based comparison was done with the use of pre-cooling
151 agent. The pain which was moderate to severe or even worst pain in the control group,
152 was reduced to mild to no pain with the use of pre-cooling agent in the intervention
153 group. This reduction of pain was more significantly found in those aged 41-50 years.
154 The reason could be because the pain threshold of the elderly patients is more
155 compared to younger participants, which can decrease the anxiety level, and, hence,
156 reduce pain perception. Another reason of reduction of pain of in all age groups could
157 be cryoanaesthesia. The topical anaesthesia in the control group acted only on the
158 nerve cells, while the mechanism of cooling the tissues produces effect on every cell,
159 including the nerve cells. Thus, there is no need of topical anaesthesia whenever pre-
160 cooling agent is used.²¹

161 For gender-based comparisons, the percentage of effect of mild pain was high in
162 females after the use of pre-cooling agent, while the percentage of 'no pain' was
163 higher in the males after the use of pre-cooling agent. The reason for this could be that
164 females are more anxious than males during dental procedures, thereby feeling mild
165 pain even after the use of pre-cooling agent. The pain was significantly reduced after
166 intervention among females compared to males. The reason for this could be that the
167 females engaged more readily among new gadgets than the males, distracting their
168 mind and the perceived pain was reduced. But due to the anxiety level, females still felt
169 mild pain. The result is similar to a study⁹ which revealed significant reduction in the
170 elderly age groups.

171 The limitation of the current study is the absence of randomisation. The strength of the
172 study is the use of split mouth design which increases the study accuracy, and
173 eliminates inter-subject variability and teeth-specific bias.²²

174

175 **Conclusion**

176 Pre-cooling agent was found to be effective in decreasing pricking pain sensed by the
177 patients of all ages during infiltrate anaesthesia. The score was found significant
178 among the elderly participants as well as younger female participants. Also, pre-
179 cooling agent can be used without topical anaesthesia before administering infiltration
180 because of cryoanaesthesia.

181

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185

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256 **Table 1: Age- and gender-wise analysis of pain scores.**

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Age Group	Gender	Responses of control group		Experimental Pain Rating Score (PRS)			p-values	
		category	'n' count (%)	'n' count (%)				
				No pain	Mild pain	Moderate pain		
21-30 years	female	Mild pain	4(100)	4(100)	0(0)	-	0.03	0.23
		Moderate pain	15(100)	4(26.7)	11(73.3)	-		
		Severe pain	6(100)	2(33.3)	4(66.7)	-		
		Worst pain possible	2(100)	0(0)	2(100)	-		
		Total	27(100)	10(37.0)	17(63.0)	-		
	male	Moderate pain	16(100)	9(56.3)	5(31.3)	2(12.5)	0.86	
		Severe pain	9(100)	4(44.4)	3(33.3)	2(22.2)		
Total		25(100)	13(52.0)	8(32.0)	4(16.0)			
31-40 years	female	Mild pain	10(100)	6(60)	4(40)	-	0.70	0.21
		Moderate pain	16(100)	8(50)	8(50)	-		
		Total	26(100)	14(53.8)	12(46.2)	-		
	male	Mild pain	8(100)	4(50)	4(50)	-	0.22	
		Moderate pain	12(100)	6(50)	6(50)	-		
		Severe pain	4(100)	4(100)	0(0)	-		
		Total	24(100)	14(58.3)	10(41.7)	-		
41-50 years	female	Mild pain	2(100)	2(100)	0(0)	-	0.01	0.00
		Moderate pain	16(100)	10(62.5)	6(37.5)	-		
		Severe pain	6(100)	0(0)	6(100)	-		
		Total	24(100)	12(50)	12(50)	-		
	male	Mild pain	10(100)	10(100)	0(0)	-	0.00	
		Moderate pain	13(100)	9(69.2)	4(30.8)	-		
		Severe pain	3(100)	0(0)	3(100)	-		
Total		26(100)	19(73.1)	7(26.9)	-			

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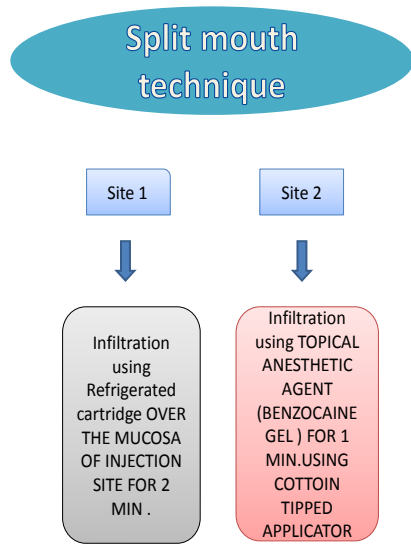
261 **Table 2: Gender-wise analysis of pain scores in control and experimental groups.**

Gender	Responses of control group		Experimental pain rating scores			p-value
	category	'n' count (%)	No pain n (%)	Mild pain n (%)	Moderate Pain n (%)	
Female	Mild pain	16(100)	12(75)	4(25)	-	0.008
	Moderate pain	47(100)	22(46.8)	25(53.2)	-	
	Severe pain	12(100)	2(16.7)	10(83.3)	-	
	Worst pain possible	2(100)	0(0)	2(100)	-	
	Total	77(100)	36(46.8)	41(53.2)	-	
Male	Mild pain	18(100)	14(77.8)	4(22.2)	-	0.346
	Moderate pain	41(100)	24(58.5)	15(36.6)	2(4.9)	
	Severe pain	16(100)	8(50)	6(37.5)	2(12.5)	
	Total	75(100)	46(61.3)	25(33.3)	4(5.3)	

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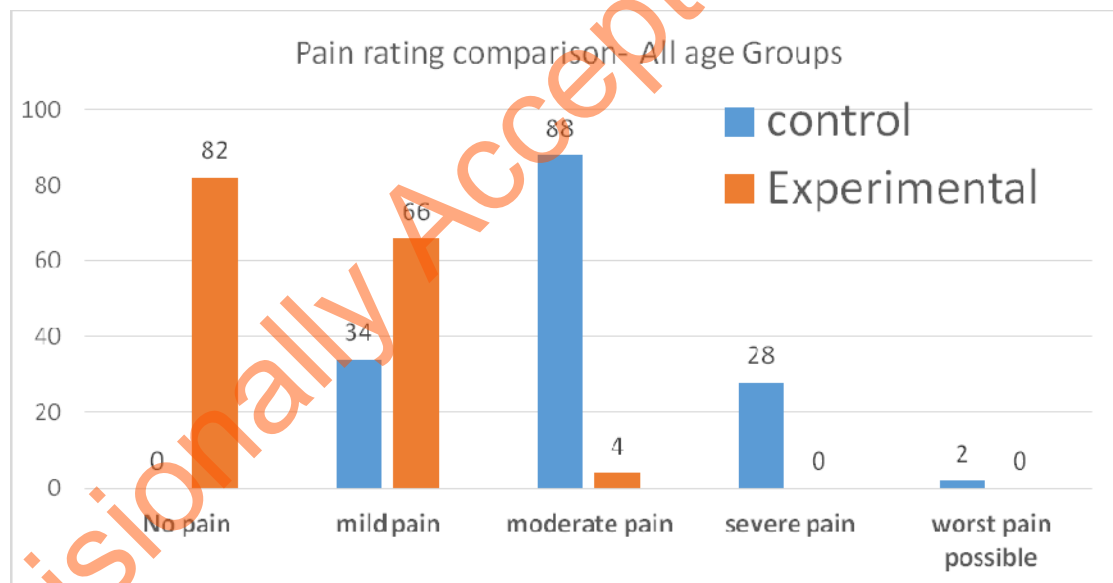
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266 **Figure 1: Split-mouth technique.**

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271 **Figure 2: Overall comparison of pain rating scores (PRSs) in control and**
 272 **experimental groups.**

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