

Effect of Deep Breathing Exercise using Smartwatch on Behaviour, Anxiety and Pain in Children during Buccal Infiltration Anaesthesia-A Randomised Clinical Trial

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ABSTRACT

Introduction: Despite the newer innovation and recent technological advances in modern dentistry, fear and anxiety constitute an important theme in dentistry. They are a usual reaction to stressful conditions that help children while staying alert in situations of an impending threat.

Aim: To evaluate the effect of deep breathing exercise in reducing dental anxiety, behaviour and pain using smartwatch during maxillary buccal infiltration in children aged 7-11 years.

Materials and Methods: A prospective interventional and single-blinded randomised clinical trial conducted in the Department of Paediatric and Preventive Dentistry, NDCH, Nellore, Andhra Pradesh, India, from November 2019 to October 2020. A total of 70 children of age between 7-11 years. They were randomly allocated into two groups, 35 in each. Children in group I were trained for deep breathing exercise using smartwatch and group II (control group) was traditional tell show do technique. The reaction of children during maxillary buccal infiltration anaesthesia was recorded in terms of behaviour

(Frankl's behaviour rating scale), anxiety (Facial Image Scale (FIS) and pulse rate), and pain perception (Wong-Baker FACES pain rating scale and face, leg, activity, cry and consolability scale). Data was tabulated using Kolmogorov-Smirnov test and Kruskal-Wallis for data distribution. Independent Student's t-test or Mann-Whitney test (Quantitative variables) and Chi-square test or Mann-Whitney test (Qualitative variables) were used to test statistical significance using Statistical Package for Social Sciences (SPSS) version 25.0.

Results: The mean age of children in smartwatch group was 8.9±1.4 years and in control group was 8.9±1.6 years with no statistical significant difference. Statistically significant decrease in pulse rate was observed in smartwatch group (p=0.003), subjective anxiety and pain was lowered in intervention group. Objective pain was decreased significantly in smartwatch group (p=0.007).

Conclusion: Children performing deep breathing exercise using smartwatch had efficiency to reduce dental anxiety and pain perceived during maxillary buccal infiltration anaesthesia.

Keywords: Distraction, Local anaesthesia, Pain control, Relaxation technique

INTRODUCTION

Children's dental anxiety is a common problem that develops primarily in childhood and adolescence and sometimes distresses the parents, and dental practitioners. Despite the newer innovation and recent technological advances in modern dentistry, dental anxiety continues to be a widespread problem affecting the child population. Several researchers have described a "dynamic vicious cycle" relating dental anxiety to bad oral health [1-3]. The sight and sensation of the injection needle was considered as the most fear elucidating stimulus in children undergoing dental treatment [4]. The buccal infiltration is most commonly used to anaesthetise individual teeth [5]. Traditionally, this technique is used to anaesthetise both the anterior and posterior maxilla and the anterior mandible. Infiltration anaesthesia may be successful in up to 100% of cases in the maxilla regardless of whether articaine or lidocaine is administered. Increased level of anxiety is associated with intensified levels of pain perception, which can be due to the inborn tendency to focus on the pain [6]. Hence, behaviour guidance is a core component of paediatric dental practice.

Distraction which is one of the behaviour guidance techniques is defined as a non aversive approach that is used to modify children's discomfort by disrupting the attention off from the main task to accomplish successful treatment with high quality [7]. Various behaviour management techniques are there, like communication, voice control, tell show do, distraction, modelling, guided imagery and reinforcement are there, which can be implied to different

children [8]. Moreover, breathing exercises as distraction can be considered as a behavioural coping technique because of physical involvement of the body and it has been more effective in reducing pain [9].

The first applied relaxation method was "Breathing Control Technique". This technique is meant to induce the relaxation of the whole body and to bring normal values. During the breathing control technique, the patient is instructed to breathe slow, deep, or diaphragmatic, with a constant rate and without interruptions for several minutes. This kind of breathing allows oxygen exchange leading to lowered pulse rate and blood pressure [10]. There are many benefits of deep breathing exercises. It makes the child calm, helps to detoxify the body, relieves pain, improves the child's posture, regulates the major organs of the body such as lungs and the heart, and lowers blood pressure. Therefore, breathing exercises are excellent for reversing the stress response [11]. Off late, breathing applications and wearables are configured to promote mindfulness practice by measuring breathing in a bid to improve mental and physical health [12]. Fitbit smartwatch introduce relax application in 2018, which provides users the chance to engage in two or five minute breathing exercises to create and customise daily breathing exercises designed to 'calm the mind'. These sessions guide users through deep breathing via feedback, gentle vibrations, graphic animations, and heart rate tracking. These wrist watches provide mindfulness from just a few minutes of inhales and exhales each day' [13]. Therefore, using technology as a distraction can

obstruct the dental environment and allow the child to adapt to the dental operator, and allow good communication of the child and clinician.

So far, no studies have been reported on using tools like smartwatch for deep breathing exercises to reduce dental anxiety, behaviour, and pain among children. Thus, the present study aimed to evaluate the effect of deep breathing exercises in reducing dental anxiety, behaviour and pain using smartwatch during buccal infiltration in children between 7-11 years.

MATERIALS AND METHODS

The present study was a prospective interventional and single-blinded (outcome assessor) randomised clinical trial with a parallel design of a balanced allocation ratio of 1:1. Study was carried out in Department of Paediatric and Preventive Dentistry, NDCH, Andhra Pradesh, India, from November 2019 to October 2020. Study protocol had Institutional Ethical Clearance (n.IEC/NDCH/2019/P-47) and approval from Dr.NTR University of health sciences. The parent or legal guardian was explained about the clinical procedure, informed consent from the parents and assent from children were obtained.

Sample size calculation: Based on the sample size calculation for the randomised trial, the minimum sample size required to conduct the present study was 35 at 80% of power and 5% error. Thus, the authors have taken 35 as the desired sample size for the present study. The formula used for sample size calculation was [14]:

$$\text{Sample size} = \frac{z_{1-\alpha/2}^2 SD^2}{d^2}$$

The present randomised clinical trial included 70 children (33 boys and 37 girls) between 7-11 years of age. Children were selected irrespective of race or socio-economic status by block randomisation.

Inclusion criteria:

- Healthy children with an age range of 7-11 years irrespective of their behaviour and gender
- Children who require maxillary buccal infiltration
- Children who had no prior experience of Local Anaesthesia (LA) administration
- Parents who have given written informed consent and assent from their children

Exclusion criteria:

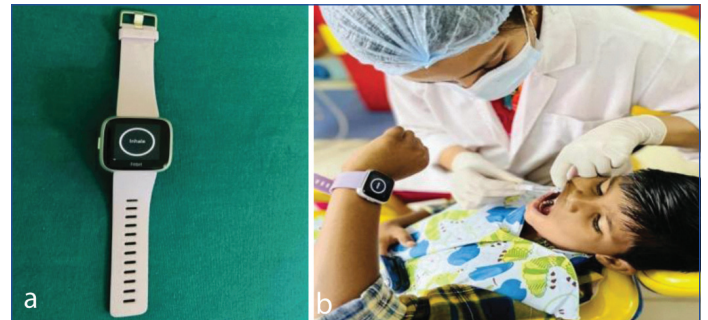
- Children with any hearing and speech impairment
- Systemic diseases and mental illness
- Any previous dental pain or problems entailing emergency dental treatment
- Children who were allergic to lignocaine.

Study Procedure

After meeting the inclusion criteria, a total of 70 children were recruited into two groups (n=35 in each group).

Interventions: Group I (smartwatch group): A total of 35 children were recruited in this group. Prior to the procedure, the principal investigator explained deep breathing exercise to the child using smartwatch fitbit versa lite relax application on how the inhalations and exhalations was done by following the circle and vibrations. Child was asked to perform inhalation from start of appearing the circle on the screen, proceeding deeply along with vibrations and exhalation after completion of vibrations in front of the investigator by pressing and holding the button to begin the session and was asked to be still during calibration

period that had lasted for 30-40 seconds and the phrase called "sensing your breathing". If needed demonstration was repeated again by the principal investigator. Subsequently, child was asked to perform deep breathing exercise during maxillary buccal infiltration anaesthesia using smartwatch which was held by the child [Table/Fig-1a,b].



[Table/Fig-1]: a) Smartwatch for deep breathing exercise. b) Local Anaesthesia (LA) administration while performing deep breathing with smartwatch.

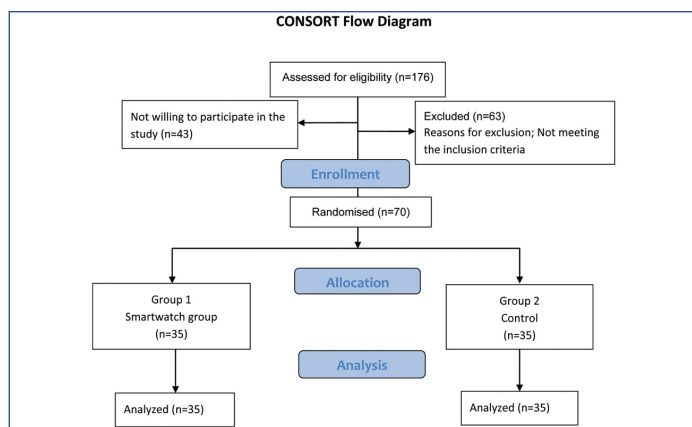
Group II (control group): A total of 35 children were recruited in this group. Traditional technique of tell show do was intervened for the children during the LA administration.

Initially, anxiety levels were recorded 5 minutes prior to LA administration by using pulse oximeter, FIS [15] in both the groups. The needle prick site was dried, then topical anaesthetic gel (MUCOPAIN® gel (Benzocaine-20% Jelly, ICPA Health Products Ltd., Ankleshwar, India) was applied for 30 seconds. Buccal infiltration technique was used to administer LA by using 23 gauge short needle syringe (0.6×25 mm; 23GX1[®]. BD Discardit II™ Syringe, Becton Dickinson India (P) Ltd., Haryana, India). Anaesthetic solution was injected at the rate of 0.8 mL/min as standard technique for buccal infiltration and 1 mL of 2% lignocaine along with 1:80000 adrenaline as vasoconstrictor was injected (Lignox® 2% A, Warren, Navi Mumbai, India). Slow speed continuous injection was given to decrease the pain perception. To standardise the technique only single investigator carried out the treatment procedures. During the procedure, the children were given a standard set of appropriate euphemisms and verbal reinforcement.

The children in smartwatch group were asked to perform deep breathing by inhaling and slowly exhaling. As a physiological indicator pulse oximeter was used to record the pulse. Variations in the pulse was recorded five minutes before, during and five minutes after the injection by the coinvestigator. Procedures like pulp therapy and extractions were carried out after achieving profound anaesthesia. During LA administration behaviour was assessed using Frankl's behaviour rating scale (1 is definitely negative, 2 is slightly negative, 3 is slightly positive and score 4 is definitely positive) [16]. Immediately after LA administration child was made to quantify their pain perception during the injection using the Wong-Baker Faces Pain Rating Scale (WBFPRS) [17]. In association with WBFPRS, an observation pain rating scale that is Faces Legs Activity Cry and Consolability (FLACC) scale was used. This scale consists of five categories of behaviour. Each category was scored on a 0-2 scale that results in a total score between 0 and 10 [Table/Fig-2] [17].

STATISTICAL ANALYSIS

Data was collected on predefined case record forms and transcribed into MS Excel spreadsheets. Data distribution was assessed using Kolmogorov-Smirnov test. Reliability analysis was performed, and also Cronbach's Alpha value was calculated. Quantitative variables in between the groups were tested for significance using either Independent Student's t-test or Mann-Whitney test. Qualitative variables in between the groups were



[Table/Fig-2]: Consolidated Standards Of Reporting Trials (CONSORT) flowchart.

tested for the significance using either Chi-square test or Mann-Whitney test. Kruskal-Wallis test was utilised to compare the mean age among three groups. All the statistical analysis was performed utilising SPSS version 25.0 (IBM Corp, Somers, NY, USA). The p-value ≤ 0.05 was considered as statistically significant.

RESULTS

A total number of 70 children considered for eligibility, recruitment, randomisation, allocation and analysed was provided in a flowchart [Table/Fig-2] with a mean age of 8.9 ± 1.4 years in smartwatch group and the mean age of 8.9 ± 1.6 years in control group with no statistical significant difference ($p=0.968$) were included in the study. Overall, 30 (27%) children belonged to seven years age. The smartwatch group had 18 (51.4%) males and 17 (48.6%) females whereas, control group had 14 (40%) males and 21 (60%) females. Significant difference was not found in gender distribution among two groups ($p=0.63$). Intragroup comparison of pulse rate between different time intervals, revealed that there was a significant difference observed in smartwatch group ($p=0.03$) [Table/Fig-3]. When intergroup comparison was done on pulse rate between smartwatch and control groups using Independent Student's t-test implied that, there was a significant difference during LA administration ($p<0.0001$) [Table/Fig-4].

Group	Intervals	Mean	Std. deviation	F value	p-value
Smartwatch group	Before LA	99.1143	16.37389	2.34	0.03*
	During LA	95.9143	17.81997		
	After LA	101.0000	20.47093		
Control group	Before LA	98.5714	15.27452	1.85	0.09 (NS)
	During LA	109.0857	17.72398		
	After LA	103.8286	18.81877		

[Table/Fig-3]: Intragroup comparison of pulse rate at various intervals. Repeated measures for Analysis of Variance (ANOVA) $p<0.05^*$ significant

Intervals	Groups	Mean	SD	T-value	p-value
Before	Control	98.57	15.27	0.143	0.886 (NS)
	Smartwatch group	99.11	16.37		
During	Control	109.08	17.7	3.10	0.003*
	Smartwatch group	95.91	17.8		
After	Control	103.82	18.8	0.602	0.549 (NS)
	Smartwatch group	101.0	20.4		

[Table/Fig-4]: Intergroup comparison of pulse rate at various intervals. Independent t-test $p<0.05^*$ significant

On comparison of anxiety by using FIS, Mann-Whitney test, showed no significant difference between the groups ($p=0.56$) [Table/Fig-5]. Regarding behaviour assessment by using Frankl's behaviour rating scale, Chi-square test, revealed that, there was insignificant difference between the groups ($p=1.00$) [Table/Fig-6]. Mean values of pain by using WBFP RS, Mann-Whitney test showed that, there

Groups	Outcome measures-FIS			
	Mean \pm SD	Median	Mean Difference	p-value
Smartwatch group (I)	2.06 \pm 0.93	2.0	34.16	0.56
Control group (II)	2.31 \pm 1.30	2.0	36.84	

[Table/Fig-5]: Intergroup Comparisons of anxiety using FIS among two different study groups. Mann-Whitney test

Groups	Outcome measures-Frankl Behaviour				
	Negative (2)	Positive (3)	Definitely Positive (4)	χ^2 statistics	p-value
Smartwatch group (I)	12 (34.3%)	12 (34.3%)	11 (31.4%)	0.001	1.00
Control group (II)	12 (34.3%)	12 (34.3%)	11 (31.4%)		

[Table/Fig-6]: Intergroup comparisons of Frankl Behaviour among two different study groups. Chi-square test

was a significant decrease in smartwatch group ($p=0.007$) [Table/Fig-7]. Pain perceived as measured by the FLACC scale disclosed that, there was a statistical significant decrease in discomfort found in smartwatch group ($p=0.0063$) [Table/Fig-8].

Groups	Outcome measures- WBFP RS			
	Mean \pm SD	Median	Mean Difference	p-value
Smartwatch group (I)	2.26 \pm 2.54	2.0	29.18	0.007*
Control group (II)	4.34 \pm 3.45	4.0	41.81	

[Table/Fig-7]: Intergroup comparisons of pain assessed using Wong-Baker Faces Pain Rating Scale (WBFP RS) among two different study groups.

DISCUSSION

In the current study, mean pulse rate was used as a reflection of the physiological changes that occur in the body in response to stress and anxiety. Pulse rate was observed to be significantly lowered during the LA administration in the smartwatch group (95.91 ± 17.8). This is attributed to the smartwatch feature which provides personalised breathing patterns for individuals based on their heart rate. The results of the present study were similar to other studies done by Bahrololoomi Z et al., and Azher U et al., where they found mean pulse rate was reduced in the bubble blower group compared to their control group [18,19]. Levi M et al., reported that there was a significant decrease in anxiety in the diaphragmatic breathing group [20]. This could be attributed to the stimulation of parasympathetic nerve impulses during relaxation, which leads to a slower heart rate, more regular respiration, and general relaxation [21]. When pulse rate was compared between the two groups in the present study significant decrease was observed in smartwatch than the control group. This is because of the fact that, smartwatches are technologically advanced and that kids are spending more time with electronic media as a result of the arrival of digital change in the society [22]. These results were consistent with other studies Mori H et al., reported that there was a significant reduction in pulse rate after deep breathing exercise [22]. Additionally, Zeitoun S et al., concluded that there was a decreased heart rate and dental anxiety on intervening in the respiratory biofeedback [23]. Furthermore, Bucur SM and Pacurar M reported that both Jacobson's progressive relaxation technique and breathing control technique had great effectiveness in reducing the pulse rate [24]. Large inhalations result in suppressed sympathetic activity, arterial dilation, decreased in blood pressure, and pulse rate.

In the present study, more than one technique of measurement was used to record anxiety and pain, considering that the children have lesser cognitive or linguistic skills when compared to adults [15]. In order to quantify the anxiety, FIS was utilised as a self-reported measuring tool. FIS has shown to have good validity

Groups	Outcome measures-FLACC					χ^2 statistics	p-value
	Relaxed/comfortable	Mild discomfort	Moderate discomfort	Severe discomfort			
Smartwatch group (I)	16 (45.7%)	14 (40%)	03 (8.6.3%)	02 (5.7%)		12.35	0.0063*
Control group (II)	05 (14.3%)	13 (37.1%)	10 (28.6%)	07 (20.0%)			

[Table/Fig-8]: Intergroup comparisons of pain assessed using FLACC among two different study groups.
Chi-square test

and also gives immediate feedback of the child's state of anxiety [25]. In the present study, intervention group showed decreased FIS score when compares to control group. Similar results were reported by Bahrololoomi Z et al., Sridhar S et al., Bargale S et al., where children's anxiety scores were decreased on performing bubble breathing exercises [18,26,27]. Pain management has witnessed an inclusion of newer drugs and technologically driven delivery systems. These are quite engaging and also effective [28]. Quantifying pain is difficult for a clinician, as it relies on each individual internal experience with a great amount of variation especially among children.

In the present study, the Wong-Baker Faces Scale (WBFS) as self reporting and FLACC scale as an observational tools were used for measuring pain, as developmental, cognitive and situational issues might affect the child's reporting of pain, both the self-reporting and observational tool were used. Regarding the pain assessment, smartwatch group has showed decreased pain scores than the control group on both WBFPRS and FLACC scales. These results were similar to Bahrololoomi Z et al., Sridhar S et al., studies where they found significant decrease in pain scores in the bubble blower group [18,26]. Furthermore, Levi M et al., stated that there was a significant decrease in pain among children who performed diaphragmatic breathing [20]. Omidpanah N et al., found insignificant reductions of pain after breathing exercise during buccal infiltration [29]. This may be ascribed to deep breathing exercises potential to provide children with an opportunity to engage in a proactive and child friendly activity, which gives them a sense of control during painful treatment.

Assessment of the paediatric patient's behaviour in a dental setting helps to facilitate the dental team for planning the proper behaviour management. In the present study, the behaviour observed using Frankl's behaviour rating scale, showed no improvement in dental behaviour among children in smartwatch group similar to Sridhar S et al., study, where deep breathing exercises did not improved dental behaviour [27]. This may be because dental behaviour, whilst firstly influenced by dental anxiety, is also influenced by temperament, parental factors, coping abilities, sociodemographics, family socialisation, siblings, and the environment related to dental settings [30]. Study was conducted in a real clinical setting rather than an experimental setting ecological validity. Deep breathing exercises are simple and easy to teach with no harmful side effects.

Limitation(s)

Psychological pain perception which varies by culture, personal history, emotional development, and personality of the individual, were not considered in the present study. Also, blinding was not possible due to the nature of the intervention.

CONCLUSION(S)

Smartwatch reduced dental anxiety, pain, and pulse rate during maxillary buccal infiltration. There was a significant decrease in pulse rate, pain and insignificant decrease in anxiety levels in children in the smartwatch group. Smartwatch was effective in reducing the anxiety and pain but not for improving the dental behaviour of the child. Comparison of smartwatch with other smart devices, which decrease child's dental anxiety can be done in future.

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