

Children Anxiety and Pain while Performing Interim Therapeutic Restorations with Hand Instruments compared to Rotary Instruments: A Randomised Clinical Trial

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ABSTRACT

Introduction: Children with dental anxiety may avoid visiting the dentist until a more serious and painful condition develops. Dentists could use less stressful techniques, like Interim Therapeutic Restorations (ITR), to treat dental cavities in difficult or young patients. ITR performed with hand tools may be preferred due to the absence of handpiece vibration, sound, or smell.

Aim: To assess the anxiety and pain levels experienced by children during ITR procedures performed with hand instruments compared to rotary instruments.

Materials and Methods: The present randomised clinical trial was conducted in the Department of Pediatric Dentistry at King Abdulaziz University Dental Hospital in Jeddah, Saudi Arabia. The inclusion criteria consisted of children aged 3-12 years visiting the dental clinic for the first time and having a carious primary anterior (incisor or canine) tooth. Patients were recruited from the paediatric screening clinic and randomly assigned to either the "Hand instrument group" or the "Rotary instrument group." Caries excavation was performed using a hand instrument in

the former group, while a low-speed handpiece was used in the latter group. Anxiety levels were assessed using Venham's anxiety rating scale before and after the procedure. Heart rate was measured using pulse oximetry every two minutes. Pain levels were evaluated using the Wong-Baker Faces Pain Rating Scale after completing the procedure.

Results: The study included 60 patients, with a mean age of 5.87 ± 2.09 years. The anxiety score after the procedure was significantly lower in the hand instrument group compared to the rotary instrument group ($p=0.007$). Although the heart rate was lower in the hand instrument group compared to the rotary instrument group, the difference was not statistically significant. The subjects in the hand instrument group reported lower pain levels compared to those in the rotary instrument group ($p=0.029$).

Conclusion: Performing ITR using hand instruments resulted in reduced anxiety and pain levels among young children compared to ITR performed using rotary handpieces.

Keywords: Dental anxiety, Dental atraumatic restorative treatment, Randomised controlled trials, Toothache

INTRODUCTION

Children's behaviour at the dental office is greatly influenced by dental anxiety [1], which is defined as a feeling of anxiety related to dental care that is not always triggered by specific external stimuli [2]. A child with dental anxiety may avoid visiting the dentist or put off attending until a more serious and painful condition develops. Dental anxiety can negatively impact both the dentist and the dental staff, potentially leading to more stressful procedures or lower-quality care [3]. To ensure patient safety and quality of care, dentists may resort to more advanced techniques such as sedation or general anaesthesia for dental treatment [4]. This, in turn, can increase expenses for parents and workload for dentists [5]. Various factors in the dental clinic have been observed to cause dental anxiety, including the sound of drilling, vibrations from the rotary handpiece, and previous unfavourable dental experiences [6]. High levels of dental anxiety have also been linked to increased pain sensitivity [3]. Previous research has shown that patients with dental anxiety and heightened pain sensitivity may experience amplified pain reactions during challenging dental treatments [7].

In the dental office, dentists are encouraged to use ITR procedures to treat dental caries in challenging or young patients [8]. These procedures involve the removal of gross dental caries using hand instruments such as a spoon excavator or a round carbide bur mounted on a low-speed handpiece. The cavities are then restored with fluoride-releasing materials such as glass ionomer cement. ITR strives to enhance remineralisation by facilitating fluoride release

and reducing cariogenic bacteria after caries excavation. These restorations are temporary and will be replaced with permanent restorations in the future [9]. It has been suggested that ITR using hand instruments is less intimidating due to the absence of handpiece vibration, sound, or smell [10]. However, discomfort is frequently reported during restorative treatments, particularly when the technique is invasive or not performed under local anaesthesia [11]. Additionally, fear of invasive dental procedures can significantly distress anxious children, especially considering their typically low pain thresholds [12,13]. On the other hand, ITR has been researched as a technique for managing anxious children by combining the benefits of minimal trauma and conservative treatment without the need for local anaesthesia [11,14].

Research findings regarding anxiety and pain when comparing ITR performed with hand instruments versus rotary equipment have yielded inconsistent results [11,14-17]. Therefore, the present study aimed to compare the anxiety and pain levels experienced by children undergoing dental treatment using the ITR approach with hand instruments versus the ITR approach with rotary instruments. The present research aimed to address the inconclusive findings in the literature and fill the knowledge gap in this area.

MATERIALS AND METHODS

The parallel randomised clinical trial was conducted in the Department of Pediatric Dentistry between January to June 2020 at the Dental Hospital of King Abdulaziz University in Jeddah, Saudi Arabia. Ethical approval was obtained from the Research

Ethics Committee at King Abdulaziz University's Faculty of Dentistry (No.: 100-10-18).

Inclusion and Exclusion criteria: Patients were recruited from the new patients screening clinic. Healthy paediatric patients aged 3 to 12 years who were visiting the dentist for the first time and had at least one primary anterior (incisor or canine) tooth with caries affecting multiple surfaces but not reaching the pulp or indicating extraction were included. Patients with negative or definitely negative behaviour according to the Frankl Behaviour Rating Scale, emotional or psychological disorders, allergies to glass ionomer filling material, or those requiring emergency care for pain, trauma, or facial swelling were excluded. Written informed consent was obtained from the parents.

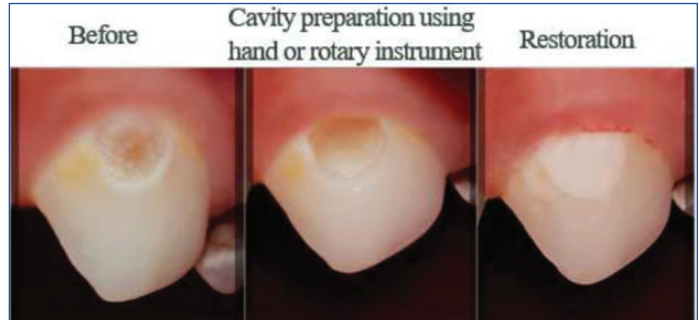
Sample size calculation: The sample size was determined using G*power software. A total of 60 patients (30 in each group) were required to detect a statistical difference between the groups with a significance level of 0.05 and 80% power. Patients were randomly assigned to either the hand instrument group or the rotary instrument group using computer-generated sequence randomisation. The randomisation sequence was maintained by a dental assistant not involved in the trial, who oversaw the random allocation. If the subject had multiple carious anterior teeth, one anterior tooth was chosen randomly using the bowl method. The recruitment process and the breakdown of study participants into the study groups are presented in [Table/Fig-1].

Score	Description
	Relaxed, smiling, willing and able to converse.
1	Uneasy, concerned. During stressful procedure may protest briefly and quietly to indicate discomfort. Hands remain down or partially raised to signal discomfort. Child willing and able to interpret experience as requested. Tense facial expression, may have tears in eyes.
2	Child appears scared. Tone of voice, questions and answers reflect anxiety. During stressful procedure, verbal protest, (quiet) crying, hands tense and raised, (not interfering much- may touch dentist's hand or instrument, but not pull at it). Child interprets situation with reasonable accuracy and continues to work to cope with his/her anxiety.
3	Shows reluctance to enter situation, difficulty in correctly assessing situational threat. Pronounced verbal protest, crying. Using hands to try to stop procedure. Protest out of proportion to threat. Copes with situation with great reluctance.
4	Anxiety interferes with ability to assess situation. General crying not related to treatment. More prominent body movement. Child can be reached through verbal communication, and eventually with reluctance and great effort he or she begins the work of coping with the threat.
5	Child out of contact with the reality of the threat. General loud crying, unable to listen to verbal communication, makes no effort to cope with threat. Actively involved in escape behaviour. Physical restraint required.

[Table/Fig-1]: The Venham's anxiety rating scale [18].

Two researchers independently assessed the degree of anxiety in the subjects using Venham's anxiety rating scale before the start of treatment [18]. The scale consists of six points, with the lowest point designating a relaxed subject and the highest point indicating an out-of-touch subject [Table/Fig-1][18]. Before the study began, the evaluators were trained on how to apply the Venham's anxiety scale, and interexaminer reliability showed a high degree of similarity among evaluators (kappa=0.82). No rubber dam or local anaesthesia was used in either group. Isolation was achieved using cotton rolls and high suction managed by an assistant. Blinding of subjects or operators was not possible due to the nature of the study. The hand instrument group underwent ITR using a hand instrument (spoon excavator #13 or #12, depending on cavity size), while the rotary instrument group received ITR with a rotary instrument (low speed without water coolant, round bur size 8). After cavity removal in both groups, glass ionomer restoration (Fuji IX, GC) was placed. An example of selected cases and the restorative procedure is shown in [Table/Fig-2]. Behaviour management was accomplished by consistent communication and the tell-show-do method. The dental assistant used a pulse oximeter to measure the patient's

heart rate every two minutes as an objective measure of anxiety during the procedure. The excavation time was two minutes, whereas restoration time was four minutes. After completing the treatment, Venham's anxiety rating scale was used again to assess the patient's level of anxiety. Pain was evaluated using the Wong-Baker FACES Pain rating scale. The child underwent an assessment of their level of discomfort using the Wong-Baker FACES pain rating scale without parental involvement. The scale consists of six points, with zero denoting "no hurt" and ten denoting "worst hurt," and the respondents select a picture that best represents how they feel about the therapy they received [19].



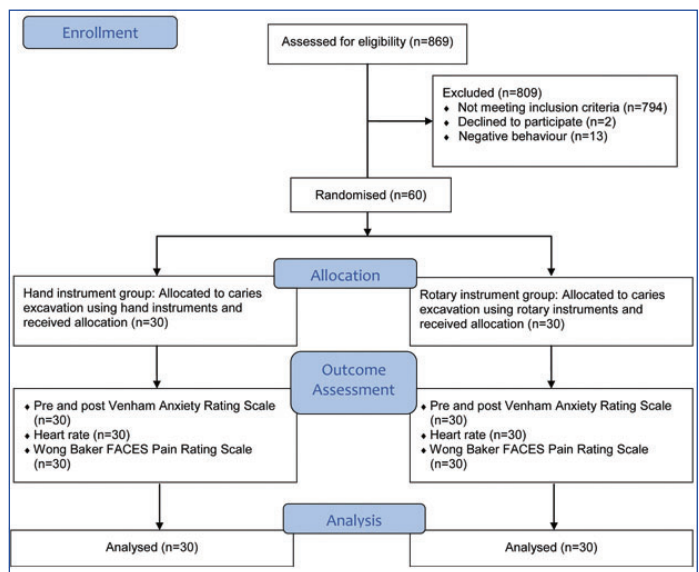
[Table/Fig-2]: An example of the case selection, cavity preparation and restorative procedure.

STATISTICAL ANALYSIS

Statistical analysis was performed using the Statistical Package for the Social Sciences (SPSS) version 22.0 (SPSS, Chicago, Illinois, USA). Interexaminer reliability was calculated using Kappa statistics. Independent sample t-tests were conducted to analyse the differences in Venham's scores, heart rate measurements, and Wong-Baker FACES Pain rating scale between the two groups, with a significance level set at p<0.05.

RESULTS

A total of 869 patients were assessed for eligibility at the screening clinic, and only 75 met the inclusion criteria. Two patients refused to participate, and 13 were excluded due to extremely negative behaviour. Consequently, 60 patients were included in the study, as demonstrated in [Table/Fig-3]. The mean age of the patients was 5.87±2.09 years, ranging from 3 to 12 years. There were no significant differences in age and gender between the study groups (p=0.808 and p=0.605, respectively), as shown in [Table/Fig-4].



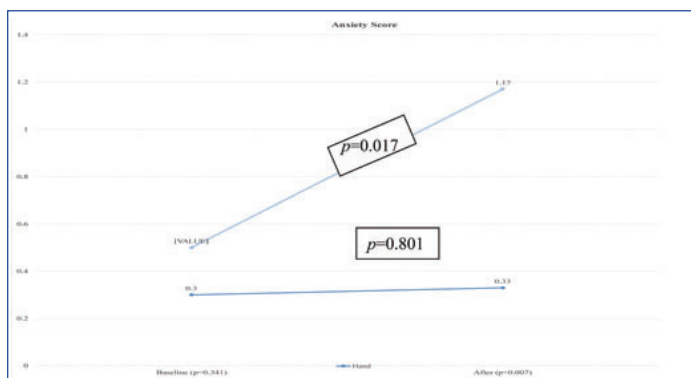
[Table/Fig-3]: Study flow diagram.

The mean anxiety score for the rotary instrument group was 0.50±1.01, while for the hand instrument group, it was 0.30±0.54. However, this difference was not statistically significant (p=0.341).

Variables	Category	Hand instruments group n (30)	Rotary instruments group n (30)	p-value
Mean age	In years	5.93±2.39	5.8±1.79	0.808
Gender	Male	13 (43.3%)	15 (50.0%)	0.605
	Female	17 (56.7%)	15 (50.0%)	

[Table/Fig-4]: Comparison of demographic data for the hand instrument group and the rotary instrument group.

After the treatment, the rotary instruments group had a significantly higher mean anxiety score (1.17 ± 1.51) compared to the hand instruments group (0.33 ± 0.55) ($p=0.007$). The results indicate a statistically significant increase in anxiety scores in the rotary group ($p=0.017$) from baseline to post-procedure. However, there was no significant change in anxiety values in the hand instrument group ($p=0.801$), as shown in [Table/Fig-5].



[Table/Fig-5]: Difference in Venham's anxiety rating scale score between the hand instrument group and rotary instrument group.

The mean heart rate reading at baseline was not significantly different between the hand instruments group (96.43 ± 16.84) and the rotary instruments group (93.67 ± 16.72) ($p=0.526$). Two minutes after starting the treatment, the mean heart rate was lower in the hand instruments group (102.60 ± 13.47) compared to the rotary group (110.43 ± 19.59), but the difference was not statistically significant ($p=0.076$). The mean heart rate readings after four minutes were slightly lower in the hand instrument group (100.83 ± 13.02) compared to the rotary instrument group (104.80 ± 20.64), but the difference was not statistically significant ($p=0.382$), as shown in [Table/Fig-6].

Parameters	Hand instruments group n (30)	Rotary instruments group n (30)	p-value
Heart rate baseline	96.43±16.84	93.67±16.72	0.526
Heart rate 2 minutes	102.60±13.47	110.43±19.59	0.076
Heart rate 4 minutes	100.83±13.02	104.80±20.64	0.382

[Table/Fig-6]: Comparison of heart rate between the hand instrument group and the rotary instrument group at baseline, after two minutes, and after four minutes.

Regarding the pain level at the end of the treatment, the mean pain levels were significantly lower in the hand instruments group (0.27 ± 0.69) compared to the rotary instruments group (1.73 ± 3.43) ($p=0.029$) based on the Wong-Baker FACES Pain rating scale, as shown in [Table/Fig-7].

Variables	Hand instruments group n (30)	Rotary instruments group n (30)	p-value
Wong-Baker FACES Pain Rating Scale	0.27±0.69	1.73±3.43	0.029*

[Table/Fig-7]: Comparison of Wong-Baker FACES Pain rating scale for the hand instrument group and the rotary instrument group.

*Statistically significant ($p < 0.05$)

DISCUSSION

The primary objective of the present study was to examine the levels of pain and anxiety experienced by paediatric patients during

caries excavation in their initial visit, specifically comparing the use of hand instruments versus rotary instruments. The present findings indicate that the utilisation of hand instruments during restorative procedures resulted in reduced levels of dental pain and anxiety among paediatric dental patients compared to the use of rotary instruments.

The use of hand instruments in the ITR technique eliminates anxiety and fear-inducing elements like noise, vibration, and local anaesthesia injections that are present when excavating caries with rotary devices [9]. Previous studies have shown a link between dental anxiety, injections, and drilling burs [12,13]. To foster a positive perception of dental clinics, it is recommended to use ITR as an introduction to the dental environment during the initial visit [20]. In present study, author included children who had never visited a dentist to eliminate any effects from prior exposures that might have influenced dental fear and discomfort. Author did not adopt a split-mouth crossover design because we believed that the initial visit experience would impact the subjects' anxiety during subsequent visits. This was supported by a study by De Menezes Abreu DM et al., which examined anxiety levels before each dental appointment for three different treatment approaches for the same subject. Regardless of the type of treatment given at the initial session, anxiety levels remained high in subsequent visits [21].

In present study, author used the Venham's scale to measure participants' anxiety levels before and after receiving dental care. The results revealed a significantly greater anxiety score in the group using rotary devices compared to the baseline score after completing the procedure. The present findings regarding differences in dental anxiety between hand and rotary ITR are consistent with previous research [17,22]. Schriks MC and van Amerongen WE conducted a study in Indonesia using the Venham's scale and concluded that more subjects in the rotary group had higher levels of anxiety than those in the hand group [11]. Another study found that preschoolers' anxiety around dental care decreased following ART treatment. Children experienced more anxiety before receiving ART than during or after the procedure [23]. Other studies demonstrated comparable levels of dental anxiety between conventional treatment strategies and interim therapeutic treatment-based approaches to caries control [15,24,25]. However, direct comparisons between present study and these studies were not feasible. Some of these studies compared multiple groups from various investigations conducted at different times and locations. Additionally, they did not record baseline data for comparison and used the Venham's Picture Test (VPT) after administering the treatment [24]. Another study used a modified version of the Venham's scale that incorporated movement during treatment as an indicator of discomfort [25].

Heart rate was used as an objective measure of anxiety in present study. During cavity preparation, when most of the instrumentation took place, the hand instrument group displayed lower heart rates compared to the rotary instrument group at two minutes into the dental treatment. Previous studies have consistently shown similar results [11,17,22]. Goud RS et al., also found that rotational instruments induced more anxiety in the younger age group, while there was no significant difference in anxiety caused by hand instruments between younger and older children [17].

Previous studies mostly measured either anxiety or pain, but the inclusion of both pain and anxiety as outcomes in this study sheds light on the distinct meanings of the two emotions. Evidence suggests that children feel less pain when caries are excavated using hand techniques rather than rotary devices [26-28]. In public health settings, where hand instruments are commonly used for caries excavation, children typically report little pain [29]. Studies by van Amerongen et al., and Rahimtoola et al., found that hand instrument ITR caused less pain compared to rotary ITR, as reported by the patients themselves without prior explanation [28,30]. In present study, authors used the Wong-Baker FACES Pain rating

scale, which has been established to be reliable, valid, simple to use, and appropriate for children aged 3 and above [31]. Based on the findings of present study, it is recommended to employ the ITR technique with the use of hand instruments rather than rotary instruments to reduce pain and anxiety levels in children during dental procedures.

Limitation(s)

One of the limitations of present study is that the sample was obtained from a single institution, which restricts the generalisability of the findings. Although a sample size calculation was performed a priori, it is possible that larger differences in heart rate measurements could be observed with a larger sample. Additionally, the inclusion of a broad age range (3-12 years) facilitated the recruitment of participants but may have weakened the impact of the interventions on the study's results.

CONCLUSION(S)

The findings of present study suggest that hand instruments cause less pain and anxiety than rotary devices during restorative dental procedures on children. Utilising hand instruments in initial dental visits may help children have a favourable dental experience and be more accepting of additional therapy. Further research involving a larger number of subjects from multiple centers may provide additional evidence to support the precision of these findings.

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