

To Compare the Effectiveness of Complementary Therapies on Pain Perception to Intra-Oral Needle Insertion in Pediatric Patients – A Randomized Clinical Trial

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ABSTRACT:

Background: Recently, effective control of pain has shifted to other techniques like psychological, complementary, and alternative methods which have gained popularity in the contemporary world. However, the scientific validity of such alternative approaches is often questioned.

Objective: To compare the effectiveness of Complementary therapies on pain perception to intraoral needle insertion in paediatric patients.

Methodology: A Randomized clinical trial was conducted on 78 children aged 8-12 years visiting the department after obtaining informed consent from parents. Children were divided into 3 groups i.e., Group A- acupressure, Group B –aromatherapy, and Group C- control group. Every child was recalled for 3 appointments and in each appointment, any therapy was performed randomly before giving an inferior alveolar nerve block. Pain perception was evaluated using Wong-Baker Faces Scale and the Sound eye motor scale. The intergroup comparison was statistically analyzed using the ANOVA test and distribution using the chi-square test.

Result Synthesis: On intergroup comparison of Wong-Baker and SEM scale between the acupressure and aromatherapy group, a statistically significant difference was seen, whereas when acupressure and aromatherapy were compared with the placebo group highly significant difference was seen ($p=0.00$).

Conclusion: Acupressure and aromatherapy can be used as an adjunct to significantly reduce the pain perception of children undergoing intraoral needle insertion.

KEYWORDS: Acupressure, Aromatherapy, Pain Perception, intraoral needle insertion.

INTRODUCTION

One of the major hindrances in providing necessary intervention for a pediatric patient is dental fear, which complicates the delivery of dental treatment. The administration of local anaesthesia (LA) during dental treatment remains one of the most painful and distressing procedures performed on children, often leading to the development of fear and dental anxiety.^[1] Such fear-related behaviour has long been recognized as the most difficult aspect of patient management and can be a barrier to good dental care.^[2] Therefore, the effective control of pain during dental procedures is an important prerequisite of pediatric dentistry.

Despite continued advances in knowledge of ways to minimize the pain of injection and find a more comfortable and pleasant means of achieving local anaesthesia, intraoral injection is still the most common cause of fear in pediatric patients. Recently, the trend in the use of complementary therapies has shown promising evidence, especially acupuncture and aromatherapy.^[3]

Acupuncture means “to puncture with a needle.” The term acupuncture is derived from Latin: acus means needle and puncture means insertion. (According to Complementary Medicine & the National Health Service, 1996).^[4] Acupressure is like acupuncture in terms of its analysis of the human body, but it uses pressure rather than needles to achieve its effects. Acupressure has been defined as digital pressure performed in a circular motion to treat areas that are typically treated with acupuncture needles and for the same reasons.

Another complementary therapy that has shown a sharp rise in popularity is aromatherapy. The Physiological and psychological effects of essential oils have been acknowledged in folk medicine and aromatherapy for a long time. In 1937, a French Chemist named Rene Gattefosse coined the term “Aromatherapy” in the early 20th century.^[5] Among essential Oils, lavender oil is a well know aromatic essence with mood-enhancing and sedative properties.^[6]

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Studies regarding the effectiveness of acupressure and aromatherapy in dental settings to evaluate pain perception are limited. Hence, this field of study was conducted to compare and evaluate the effectiveness of acupressure and aromatherapy (complementary therapies) on pain perception during intraoral needle insertion in children.

METHOD

Study design: A case-control study

Type of Study: Assessor-blinded Randomized clinical trial.

Sample Selection

A total of 78 healthy children between the age group of 8 to 12 years reported to the department were selected for the study based on the following inclusion criteria: children having a minimum of three teeth requiring treatment (such as vital pulp therapy/ extraction) under inferior alveolar nerve block, children with prior parental consent, no history of systemic disease, no history of allergy to local anaesthesia and exhibiting Frankel's behaviour rating scale grade three/four. Children with Frankel's behaviour rating scale of one/two, a history of systemic disease, and any allergy to local anaesthesia were excluded from the study. All participants were free to withdraw from the study at any time. Parents/guardians were informed about the nature of the study and informed consent was obtained.

Study Procedure

78 sample size was determined (for a confidence level of 95%). The participant was randomly allocated via a 3/3 balanced Latin square design; 6 children were recruited in two blocks and assigned their therapies. Since there was an odd number of visits in the study, an orthogonal Latin square was used in which each column represented the order of complementary therapy (A, B, C) given to each subject to achieve a balance. Thus, we considered the sample size to be a multiple of 6 which inform our decision to enroll 78 patients for this study.

Selected children were given three appointments. Each child was recalled for 3 appointments with a minimum time interval of 1 week. In each appointment, any therapy was performed before the administration of local anaesthesia (inferior alveolar nerve block). The techniques are divided into three groups. Each visit of the individual child was divided as per the combination i.e.

Group A- acupressure + IANB (inferior alveolar nerve block)

Group B- aromatherapy + IANB

Group C – control group+ IANB

The therapies were performed followed by data recording. Statistician was given the coded data to preserve the therapy given. The research was conducted in three dental appointments for the entire subjects.

First appointment- Each patient was placed comfortably in a supine position in the dental chair in a quiet environment and are allowed to relax for 10 minutes. Acupressure points were then marked by using a red marker, which is situated on the dorsal surface of the hand. Acupressure was then started by the operator who is certified to perform this therapy at acupoint LI4 (Hegu point), by the pulp of the right hand in a rotary fashion at 20-25 cycles per minute for three minutes followed by administration of local anaesthesia (inferior alveolar nerve block).

Second appointment - Each patient was placed comfortably in a supine position in the dental chair in a quiet environment and was allowed to relax for 10 minutes. On a sterile cotton ball, five drops of pure lavender (*Lavandula angustifolia*) essential oil (Speaking Tree- premium therapeutic grade, Medizen labs PVT. LTD, Bangalore) was dispensed by the operator and placed on the upper part of the child's cloth for one minute; simultaneously the inferior alveolar nerve block was administered.

Third appointment - After 10 minutes of relaxation any random point will be identified and using the pulp of the right thumb pressure was applied in a rotary fashion for 3 minutes and sterile cotton dipped in water was fixed on child cloth followed by administration of local anaesthesia. Both methods will act as the placebo for acupressure and aromatherapy techniques.

Assessment of Pain perception - In each appointment during the intraoral needle insertion, pain perception will be evaluated by the trained assessor, who will assess the subjective and objective responses standing 60 cm away from the dental chair. The pain perception was evaluated by using Wong-Baker Faces Scale and the sound-eye motor scale. The children were asked to mark the point on Wong-Baker Faces Scale that represented their perceived pain intensity/, while receiving local anaesthesia and the score was recorded by the assessor. The pain perception of each child will be evaluated objectively by using the sound, eye, and motor (SEM) scale. The sounds, eye symptoms, and movement of children will be evaluated by a trained assessor who will be blinded to the therapy given. The level of response for each observation was given a numerical value based on the SEM rating scale and obtained values were averaged to determine the comfort level at a rating interval.

Statistical analysis: Data were analyzed using ANOVA and Post hoc test with $P < 0.05$ considered statistically significant.

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RESULT

The research was initiated with 78 children; however, sixteen children were excluded as five refused to continue after the second visit, and eleven refused due to the pandemic (COVID-19). Hence, the final sample was 62 children who attended all three visits and were considered for analysis.

The mean value score of the Wong-Baker face scale after LA administration for acupressure ($p=0.595$), aromatherapy($p=0.515$), and placebo($p=0.52$) groups showed no significant difference among the visits. (Table 1,2,3) (Graph 1).

There was no significant difference found in sound components of the SEM scale for acupressure($p=0.065$), aromatherapy($p=0.075$), and placebo group($p=0.085$) whereas a significant difference was seen in eye and motor components in the SEM scale among the visits in all the three groups. ($p < 0.05$) (Table 1,2,3) (Graph 2,3,4)

The intergroup comparison was statistically analyzed using the ANOVA test among the group. Post hoc test showed a statistically significant difference among the groups.

The intergroup comparison was statistically significant between the placebo, acupressure, and aromatherapy group. (95% confidence interval, $P < 0.00$)

When the mean value score for the Wong-Baker face scale and eye and motor components of the SEM scale was compared between the acupressure and aromatherapy groups, a statistically significant difference was seen with $p=0.019$, $p=0.029$ and $p=0.041$ respectively, whereas in the sound component of the SEM, scale was compared between the acupressure and aromatherapy groups, no significant difference was seen. When the acupressure and aromatherapy groups were compared with the placebo group highly statistically significant difference was seen with $p=0.00$ (Table 4)

DISCUSSION

The administration of a local anaesthetic (LA) during dental treatment remains one of the most common, painful, and distressing procedures performed on children, often leading to the development of dental anxiety with disruptive behaviour making it difficult to manage patients. (Ram et al 2010) ^[7]. Since control of pain is the most important aspect of guiding a child's behaviour, pediatric dentists are in constant search of tools for painless administration of local anaesthesia. As a result, these days, the trend to reduce fear and dental pain is a shift to non-pharmacologic techniques such as hypnosis, behaviour management, or audio-visual distraction, and psychological, complementary, and alternative methods to overcome anxiety in children. ^[8] Some of the complementary therapies that have received attention in medical and dental settings with promising evidence are acupuncture and aromatherapy. According to the best of our knowledge, there is no clinical study reporting the effect of acupressure complementary therapy on subjective and objective responses to intraoral needle insertion in pediatric patients and on a comparative evaluation of acupressure and aromatherapy (complementary therapies) in the dental field. Young-chang p. Arai et al (2008) ^[6] investigated the effect of acupressure on needle insertion into the skin of a forearm by using a verbal rating scale and heart rate variability (HRV) and they concluded that acupressure significantly reduced needle insertion pain. Also, acupressure significantly reduced the low-frequency/high-frequency ratio of HRV responding to needle insertion, which implies a reduction in sympathetic nervous system activity. Also, a study done by Negin M. Alavi (2007) ^[9] and Seyed Borzoi (2018) ^[10] investigated the effect of acupressure to reduce needle insertion pain in arteriovenous fistulas in hemodialysis patients and the patients receiving intramuscular injection concluded that acupressure is an effective complementary therapy in reducing the pain of needle insertion. The efficacy and analgesic effect of acupressure have already been studied; however, all the studies have been reported in the medical setting.^[9,10] some studies have shown acupuncture as an efficient therapeutic option for managing pain during dental procedures for pain relief during dental procedures.^[11-12] As both acupuncture and acupressure are based on the same fundamental principle of acupoint activation across the meridians, our study chooses acupressure over acupuncture as it is non-invasive and child-friendly therapy.^[13] A pragmatic crossover investigation conducted by Usichenko et al (2015) ^[14] evaluated the effect of acupuncture on pain and autonomic distress during the injection of local anaesthesia in children. His study concluded that stimulation of acupoint L14 significantly reduces pain and autonomic distress in children during LA injection in dental procedures. We have selected LI4 (Hegu) acupoint because of its better analgesic effect. As the inferior alveolar nerve block has been claimed as one of the most painful and stressful procedures of pediatric dentistry ^[15-16], the present study employed this procedure to compare the pain perception and efficacy of complementary therapies. However, because pain is extremely difficult to quantify in children, two different scales were used for pain assessment in our study. The Wong-Baker Faces pain scale was used for subjective measurement, which depends on the child's sensory emotional, and contextual status. It showed good construct validity and is considered one of the reliable measures of self-report pain. ^[17-18] However due to insufficient cognitive development in young children aged under 6 years, these subjective scales are not generally reliable.

Hence, in the present study, subjective evaluations were applied to children aged 8–12 years, i.e., the school-aged children, based on Piaget's classification which is in the stage of concrete operation, therefore, having the ability to evaluate and assess the self-reported pain ^[19,20,21]. As in various studies ^[19,20,21], for an objective assessment SEM scale was used that considers the sound, eye,

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and motor components of patients' response to stimulation and was used because it enables the assessment of the relationship between pain and the reactions which the sensation of pain generates in the patient's eyes, bodily movements, and verbal expressions of discomfort and it can record the degree of intensity of the sensation of pain. Hence in the present study, Wong-Baker Faces pain scale and Sound Eye Motor (SEM Scale) was used for the assessment of pain perception.

The observation from our study indicated that Wong-Baker Faces pain scale and SEM scale gave statistically significant results. The findings showed that patients who received complementary therapies (acupressure and aromatherapy) before LA administration have shown a decrease in pain perception when compared to the placebo (control) group i.e. ($p=0.00$). Our findings agree with the results obtained by Young-chang p. Arai et al (2008) [22] who investigated the effect of acupressure on needle insertion into the skin of a forearm by using a verbal rating scale and heart rate variability (HRV) and he concluded that acupressure significantly reduced needle insertion pain.

Also, a study done by Negin M. Alavi (2007) [9] and Seyed Borzoi (2018) [10] investigated the effect of acupressure to reduce needle insertion pain in arteriovenous fistulas in hemodialysis patients and in the patients receiving intramuscular injection, who stated acupressure is an effective complementary therapy in reducing the pain of needle insertion.

The result of the current study confirmed the similar potential of acupressure complementary therapy as an effective adjunct for pain control to intraoral needle insertion. Acupressure stimulates the nervous system and alters the processing and perception of pain signals and releases natural painkillers, such as endorphins and serotonin in the nervous system, therefore, altering the pain perception of an individual. [23]

For aromatherapy, Lavender oil has been known to have sedative properties for centuries, and it is one of the most effective aromatherapy oils. [24] It is feasible and safe for children who are planning to undergo dental interventions under local anaesthesia. Therefore, we have used lavender oil for aromatherapy which showed a significant reduction in pain perception to intraoral needle insertion in children. The result of the current study is followed the study done by Faezeh Ghaderi et al (2020) [25] on the use of lavender aromatherapy on stress and pain perception in children during dental injection where lavender oil decreased dental anxiety and pain perception during dental injection in a dental setting. Ipek Arslan et al in 2020 [24] studied lavender oil inhalation to overcome dental pain and anxiety in children which had positive and anxiolytic effects on 6–12-year-old children undergoing tooth extraction. Therefore, routine pediatric dentistry can be preferred as a treatment of choice.

Kim et al. recorded minimized pain intensity at the time of needle insertion while patients inhaled lavender oil inhalation. The basic mechanism behind the effectiveness of aromatherapy in pain reduction is that / it stimulates the parasympathetic system and reduces blood pressure and anxiety levels consequently. [24] The result of this study has found no statistically significant difference in the effectiveness of acupressure and aromatherapy complementary therapies when evaluated by the mean score of the Wong-Baker face scale in the first, second and third dental visits when compared.

Similar results were found in the sound component of the SEM scale, as the children in this study were in their cognitive stage of development, and were becoming accustomed to injecting local anaesthetic following their first dentist visit. Hence, this suggests that the pain perception of the individual might get decreased in the subsequent visit because they were able to learn from their previous experience. However, because the eye and motor components are involuntary and not within the control of children, they exhibited statistically significant variations between visits. The strength of the present study may be due to the use of a combination of objective and subjective measurement techniques, which are crucial for the successful assessment of pain perception in children undergoing LA administration.

Our finding suggested that both the complementary therapies evaluated in our study were effective alternative approaches in reducing pain perception to intraoral needle insertion in children receiving local anaesthesia. This is because both therapies stimulate the release of endogenous opioids i.e., endorphin and serotonin which play important role in increasing the pain threshold. [24,11] However the result revealed a statistically significant difference with a pain score lesser in acupressure therapy when compared with aromatherapy when evaluated by Wong-Baker Scale and Sound Eye Motor Scale. This could be because acupressure therapy reduces muscular tension while also increasing blood circulation, resulting in a more soothing and analgesic impact. [11] Therefore, in our study acupressure therapy showed less pain score when compared with aromatherapy This also may be attributed to our inability to control the lavender oil odour; as the lavender scent might have simply masked odours in the dental clinic. Additionally in aromatherapy, precious memories associated with pleasurable odours may be evoked after inhaling resulting in an alteration in pain perception. Therefore, if a child has a negative previous memory of lavender oil, results may be affected by this condition. The Limited number of patients were included in this investigation. As a result, a similar study with a larger sample size is recommended. Furthermore, more research may be done, using different acupoints with various essential oil aromatherapy to lessen pain perception during intraoral needle insertion in pediatric patients.

CONCLUSION

Acupressure on L14 acupoint (Hugo point) can achieve a significant and clinically meaningful reduction in pain perception of children undergoing intraoral needle insertion when compared with aromatherapy. Whereas lavender oil aromatherapy also showed

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effectiveness in reducing the pain of intraoral needle insertion in children. Therefore, both complementary therapies can be used as an adjunct to reduce pain perception and discomfort in children undergoing intra-oral needle insertion. Furthermore, these complementary therapies are safe and inexpensive non-pharmacological alternative therapy to reduce pain and relieve patients in pediatric dentistry.

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Table 1. Mean scores of Wong-Baker scale and SEM scale in Acupressure Group

Visits	Wong-Baker Scale score			SEM Scales								
				Sound component			Eye component			Motor component		
	Mean	SD	P value	Mean	SD	P value	Mean	SD	P value	Mean	SD	P value
First	4.23	1.76	0.595(NS)	1.76	0.86	0.065(NS)	2.46	0.70	0.021(S)	2.23	0.58	0.011 (S)
Second	4.15	1.12		1.50	0.70		1.96	0.44		1.76	0.51	
Third	3.92	1.44		1.65	0.79		2.11	0.65		1.80	0.75	

NS= not significant, S=significant. P value<0.05 is considered statistically significant.

Table 2. Mean scores of Wong-Baker scale and SEM Scale in the Aromatherapy Group

Visits	Wong-Baker Scale score			SEM Scales								
				Sound component			Eye component			Motor component		
	Mean	SD	P value	Mean	SD	P value	Mean	SD	P value	Mean	SD	P value
First	4.53	1.65	0.515 (NS)	1.69	0.67	0.075 (NS)	2.46	0.58	0.022 (S)	2.15	0.67	0.013 (S)
Second	5.15	1.51		1.76	0.51		2.42	0.50		2.11	0.43	
Third	4.38	0.98		1.88	0.76		2.46	0.51		2.15	0.61	

Table 3. Mean scores of Wong-Baker scale and SEM Scale in Placebo Group

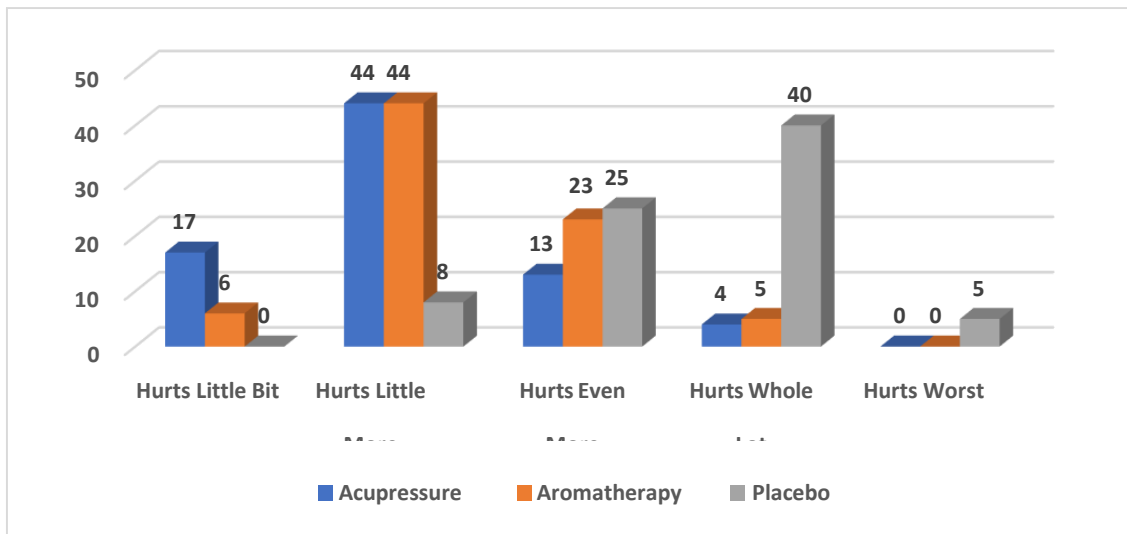
Visits	Wong-Baker Scale score			SEM Scales								
				Sound component			Eye component			Motor component		
	Mean	SD	P value	Mean	SD	P value	Mean	SD	P value	Mean	SD	P value
First	7.67	1.22	0.525 (NS)	2.76	0.51	0.085 (NS)	3.53	0.59	0.021(S)	3.11	0.59	0.014 (S)
Second	6.84	1.28		2.88	0.71		3.30	0.46		2.84	0.46	
Third	6.69	1.87		2.57	0.80		3.03	0.65		2.53	0.65	

Table 4. Mean value of Wong-Baker scale and SEM scale among all groups.

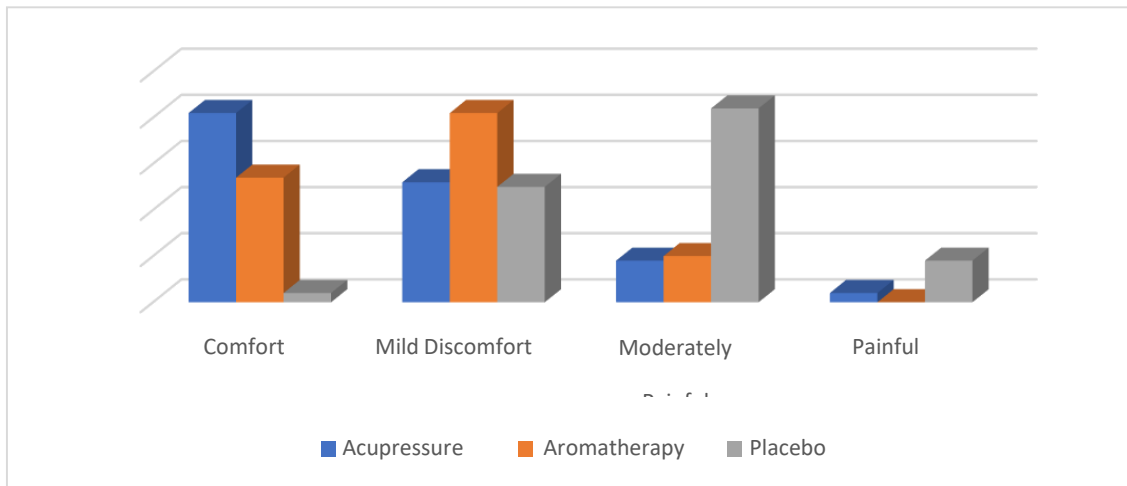
Dependent Variable	(I) Group	(II) Group	Mean difference(I-J)	Std. Error	Sig.
Wong-Baker Scale	Acupressure	Aromatherapy	.69616*	.25546	.019
	Aromatherapy	Placebo	2.59457*	.25175	.000
	Placebo	Acupressure	3.29073*	.25458	.000
Sound Eye Motor (SEM Scale)					
Sound Component	Acupressure	Aromatherapy	.16337*	.12905	.416
	Aromatherapy	Placebo	1.07777*	.12671	0.00
	Placebo	Acupressure	1.24114*	.12816	0.00
Eye Component	Acupressure	Aromatherapy	.28063*	.10916	.029
	Aromatherapy	Placebo	.92978*	.10718	.000
	Placebo	Acupressure	1.21041*	.10841	.000
Motor Component	Acupressure	Aromatherapy	.23518*	.10900	.041
	Aromatherapy	Placebo	.75607*	.10702	0.00
	Placebo	Acupressure	.99125*	.10825	0.00

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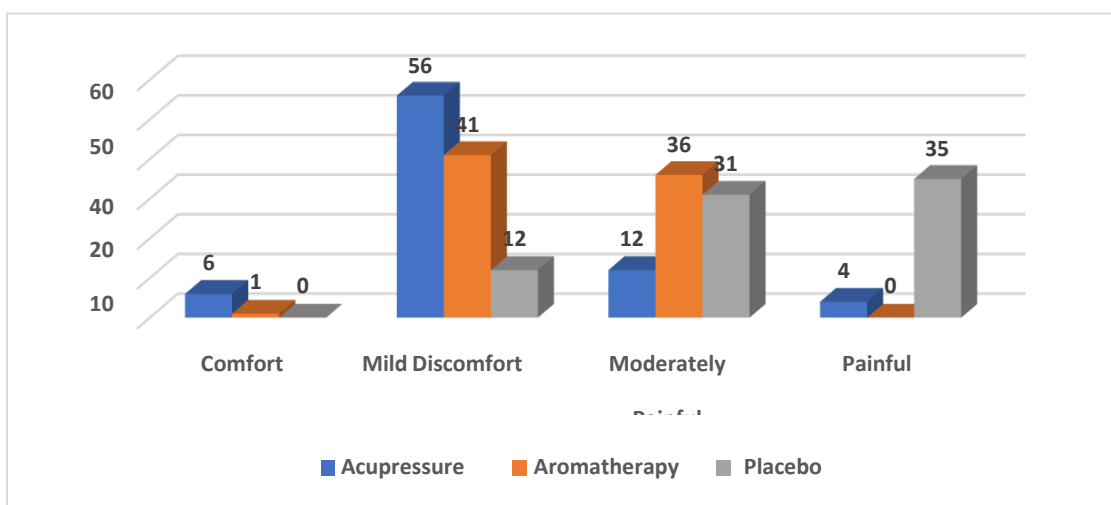
Graph 1: Comparison of Wong-Baker scale among all the groups



Graph 2. Comparison of sound components in SEM scale among all the groups.



Graph 3: Comparison of eye components in SEM scale among all the groups



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Graph 4: Comparison of motor components in SEM scale among all the groups.

