



Comparing the Effect of Aromatherapy and Distraction on the Pain Caused by Venipuncture in Hospitalized Children: Evidence from a Clinical Trial Study

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Abstract

Background: Pain is defined as an unpleasant sensory experience associated with actual or potential damage to body tissues. Therapeutic procedures cause fear in children, which in turn leads to physical and mental stress.

Objectives: This study aimed to investigate and compare the effects of aromatherapy and distraction on the pain caused by venipuncture among hospitalized children.

Methods: In this clinical trial study, 90 children hospitalized in the pediatric ward of Ali-Ebne-Abitaleb Hospital in Zahedan in 2018 were examined. The eligible children were selected using the convenience sampling technique and were divided into three groups (n = 30) using stratified permuted block randomization. In the distraction group, a Kolah Ghermezi (Red Hat) puppet was used to play with the children before and during venipuncture. In the aromatherapy group, lavender essence was used 20 minutes before the beginning of venipuncture. No intervention was provided in the control group. The children's pain intensity was measured using OUCHER standard instrument 10 minutes after the end of venipuncture. Data were analyzed by SPSS version 24 using descriptive statistics, one-way ANOVA, Kruskal-Wallis, and post-hoc tests analyses.

Results: A significant difference was found between the two intervention groups and the control group. Accordingly, both interventions could significantly decrease the pain intensity ($P < 0.001$). However, there was no significant difference between the two intervention groups concerning the impacts of interventions on the pain intensity.

Conclusions: A significant difference was found between the two intervention groups and the control group. Accordingly, both interventions could significantly decrease the pain intensity ($P < 0.001$). However, there was no significant difference between the two intervention groups concerning the impacts of interventions on the pain intensity.

Keywords: Pain, Aromatherapy, Distraction, Pediatrics, Venipuncture

1. Background

The International Association for the study of pain has defined pain as an unpleasant sensory and emotional experience associated with real or potential damage to body tissues (1). Children suffering from chronic diseases experience painful medical procedures through diagnostic, therapeutic, and follow-up processes, some of them are recognized as the most important sources of pain and fear (2-5). Nearly two-thirds of children (63.0%) exhibited needle phobia caused by improper management of pain in the course of a painful procedure (6, 7). Additionally, more than half of the children below eight years old are afraid of needles (6). Ortiz et al. (8) conducted a descriptive, cross-

sectional study on 252 children in the emergency ward and reported that 80.4% of the procedures were painful. Besides, they reported that intravenous catheter insertion was the most painful procedure (46.3%) (8). Since pain is a complex status with physiological, behavioral, psychological, and emotional components (9, 10), lack of timely and effective treatment of pain may cause long-term physical and mental consequences in children (11).

Applying procedures such as local anesthesia, in addition to high costs, results in prolongation of operations due to decreasing the length of vasoconstriction (2). A series of non-pharmacological techniques are developed to reduce needle pain, including environmental techniques

(e.g., cold and heat treatments, skin stimulation, touch, aromatherapy, physical comfort, moving, and being put in parents' arms) and cognitive-behavioral methods (e.g. distraction, verbal assurance, storytelling, and imagination) (12). Distraction is a cognitive-behavioral technique (2) widely used by families and health care providers to decline the pain associated with medical procedures. The effectiveness of distraction is well approved (12-19).

Distraction can be performed either actively (using interactive toys, cards, electronic games, VR, balloons, and ball squeezing) or inactively (by listening to a story or a piece of music, watching TV, and watching a movie) (20-22). In a critical study on 46 investigations, Goldman and Koller (23) reported that distraction could shift children's attention from dangerous stimuli towards substitutions. In the same vein, a meta-analysis on 39 controlled randomized trials including 3939 children aged 2 - 19 years indicated that distraction could effectively reduce pain (5). To achieve success, the distraction technique should be selected in accordance with age. For instance, visual and auditory stimulation might be more effective than abstract or static distraction among children (21). In this context, playing with a puppet can provide a safe environment that leads to emotional discharge and decreased tension (24). While playing with a puppet, children can balance their motivations, evacuate their extra mental energies, and flourish and reshape their physical and mental energies (25).

There has been an increasing trend toward using aromatherapy for pain reduction during the past six decades (14-26). Aromatherapy involves using aromatic oils extracts of flowers and plants for treating various diseases. These oils can be used through inhalation, taking a bath, or massage. Aromatherapy has been used in various fields, such as prenatal health, pain relief, reduction of chemotherapy complications, skin and hair hygiene, wound healing, control of epileptic seizures, reduction of respiratory problems (18), and decreasing stress and depression associated with surgical operations (27).

Lavender belongs to the Lamiaceae family, native to the western Mediterranean region. Its essential oil is one of the most vastly used essential oils for aromatherapy. This plant is a lipophilic monoterpene, which reacts to the cell membrane and changes the activity of ion channels (28). It possesses antibacterial, antifungal, anti-inflammatory, muscle relaxing, and analgesic properties (14). The Lavender essential oil can also be used safely for children (29). A recent study demonstrated that aromatherapy using lavender essence could effectively reduce pain intensity during venipuncture in children (14).

As mentioned above, painful medical procedures like venipuncture, injection, and vaccination have been re-

garded as horrible interventions among children (2, 5, 20). Therefore, using techniques that can effectively reduce injection pain is of crucial importance because children are highly sensitive towards their bodies and show stronger reactions to the venipuncture procedure due to the remaining plastic component of the catheter in their veins (30). Kolah Ghermezi, also known as Red Hat, is one of the favorite puppets of Iranian children. Thus, in the present study, it was employed as the distraction toy to reduce hospitalized children's pain. Few studies have investigated the impact of aromatherapy using lavender on children, and no study has compared the effects of aromatherapy and distraction.

2. Objectives

Hence, the present study aimed to compare the effects of aromatherapy using lavender and distraction using a puppet on the pain caused by venipuncture in a clinical sample of children hospitalized in Ali-Ebne-Abitaleb Hospital, Zahedan, Iran.

3. Methods

In this clinical trial study, patients were selected from 3 to 8-year-old children admitted to the pediatric ward of Ali-Ibn-Abi-Taleb Hospital in Zahedan in 2019 after obtaining permission from the University Ethics Committee (code: IR.ZAUMS.REC.1398.092). Participants were selected using the convenience sampling technique. Then, they were randomly divided into three groups (two intervention groups and one control group). According to the objective of the study, for example, comparing three groups ($k = 3$) in the mean pain associated with venipuncture, the sample size was estimated using the following formula:

$$\Delta = \frac{1}{\sigma^2} \sum_{i=1}^k \left(\mu_i - \bar{\mu} \right)^2, \quad \bar{\mu} = \frac{1}{k} \sum_{j=1}^k \mu_j \quad (1)$$

$$n = \lambda / \Delta$$

Considering $\alpha = 0.05$, power = 90%, $\lambda = 12.66$, and also based on the study conducted by Bikmoradi et al. (14) and Vosoghi et al. (30), the minimum sample size was computed 23 participants in each study group. Considering the 20% probability of loss, 30 participants were enrolled in each study group.

The inclusion criteria were being aged 3 - 8 years, not suffering from asthma, not having an allergy to aromatherapy, not suffering from mental retardation, ability to communicate, being completely conscious, no history of analgesics before venipuncture, and willingness to participate.

In the case of acute pain during venipuncture (severe stomachache or pains associated with fractures or tumors) and lack of success in the first attempt for venipuncture, the subject(s) were excluded from the study (Figure 1).

Data were collected using an author-developed form, which had two sections. The first section contained demographic information, including age, sex, type of disease, catheter insertion site, number of inserted catheters, and history of hospitalization. The second part was about OUCHER standard instrument for assessing pain intensity. This instrument is developed by Beyer to evaluate pain intensity in children aged 3 - 12 years. It can be applied to children who cannot count up to 100. OUCHER consists of six vertical pictures of a child's face showing different pain intensities (Figure 2). In this instrument, scores 0, 20, 40, 60, 80, and 100 are assigned to no pain, mild pain, moderate pain, severe pain, and very severe pain, respectively. The content and structural validity of this instrument are verified. Beyer reported a reliability coefficient of 0.91 for OUCHER (14). Its reliability is also confirmed by Mikaeili et al. (31) and Babaie et al. (32). In the study by Babaie et al. (32), the scale's intra-cluster correlation coefficient (ICC) is calculated as 0.89, which proved its acceptable consistency. Then, participants were allocated to three groups via stratified permuted block randomization. In this way, the three groups were homogeneous with respect to sex and age (33). In total three groups were defined as control, aromatherapy, and puppet. Also, six permutation conditions for numbers 1 - 3 (numbers 1 - 6 for each condition) were defined. Different permutation conditions were selected via lottery up to the achievement of the required sample size, and the subjects were allocated to the study groups on the basis of gender (male and female) and age (< 5 and > 5 years).

The researcher explained the study objectives and procedures to the children's parents and ascertained. Besides, they were informed that they can withdraw from the study at any time. Then, the parents were requested to sign written informed consent forms.

As mentioned before, this study included two intervention groups and a control group. In the first group, distraction was done using Kolah Ghermezi (Red Hat) puppet in the venipuncture room from three minutes before catheter insertion up to the end of the procedure. In doing so, the researcher moved the puppet and talked to and played with the children. In the aromatherapy group, five drops of lavender essence 2% were poured on 10 × 10 napkins that were attached to the children's collars. The children inhaled the lavender essence for 20 minutes and were then transferred to the venipuncture room. In both intervention groups, venipuncture was done by an experienced nurse. In so doing, the nurse prepared an alcoholic

pad, an angiocatheter, and a bandage and, after selecting the proper vessel, fastening the tourniquet and disinfecting the site by an alcoholic pad, performed venipuncture. At the end of the procedure, children were transferred to their beds. After 10 minutes, the pain intensity scale was completed for the children in their rooms (14, 30). To this end, the researcher showed the OUCHER instrument to the children and asked them to point to the picture that showed their pain intensity during venipuncture. Afterward, the researcher marked the pictures selected by the children and recorded the scores in the questionnaires. In the control group, no intervention was conducted, and the pain was assessed 10 minutes after venipuncture. It should be noted that this study was not blinded.

3.1. Data Analysis

Data were analyzed using SPSS version 24. Data were summarized using descriptive statistics, such as frequency distribution tables, graphs, and statistical indices (mean, standard deviation (SD), etc.), and were analyzed using one-way ANOVA and Kruskal-Wallis in case of not following a normal distribution. If the results of one-way ANOVA were significant, the post-hoc test was used for pairwise comparison of the groups. Statistical significance was considered when P-value < 0.05.

4. Results

Each group contained 30 subjects. The results revealed no significant difference between the three groups concerning gender and age. The mean age of participants was [5.17 + 1.8] years, ranging from 3 to 8 years.

We found no significant difference between the three groups concerning demographic features. The results of the chi-square test showed no significant association between pain intensity and demographic characteristics like sex, age, catheter injection site, and catheter size in the three groups ($P > 0.05$). Considering the catheter insertion site, no significant association was found between pain intensity and insertion of the catheter at the back of the hand (68%) and hand cutdown (15%) in the three study groups ($P = 0.51$) (Table 1).

The most common disease was diarrhea ($n = 52$, 27%), followed by pneumonia ($n = 9$, 10%). However, no significant difference was found between the three groups in this regard.

Since the results of the Shapiro-Wilk tests indicated that the three groups were not normally distributed, the Kruskal-Wallis test was employed to compare the pain scores of the study groups. The findings revealed a significant difference between the three groups ($P = 0.001$).

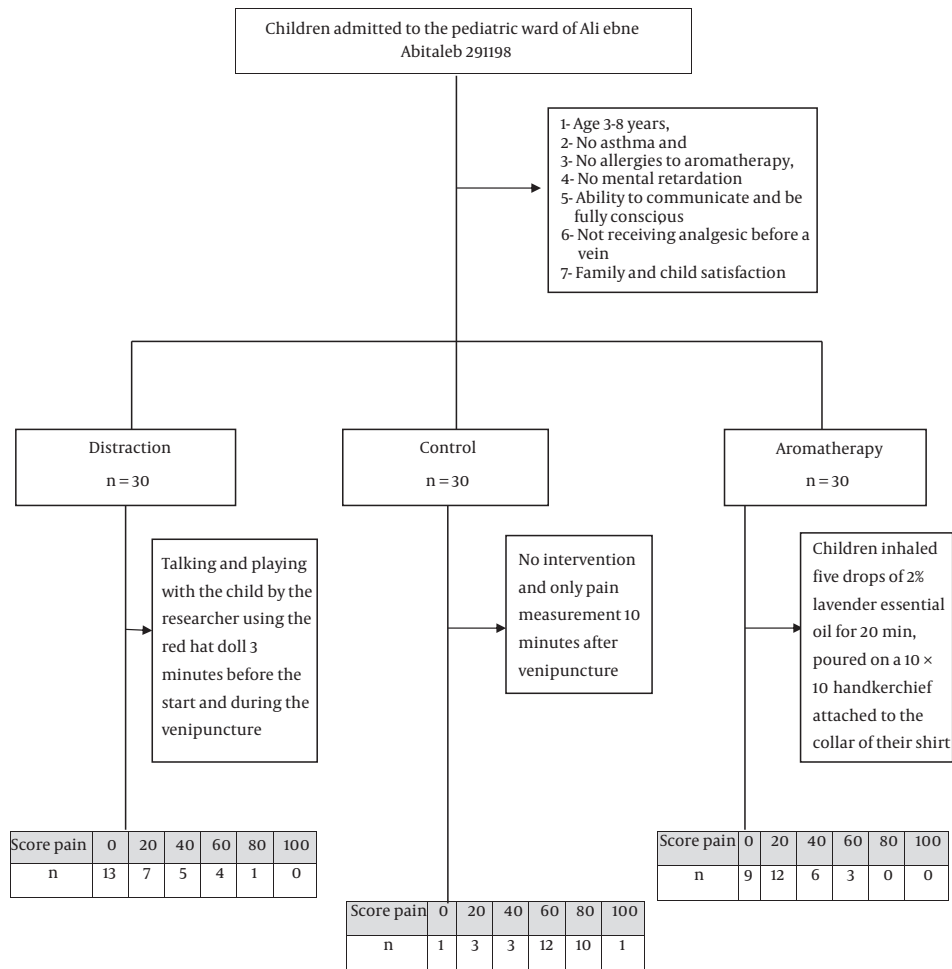


Figure 1. study flowchart

Table 1. Comparing the Catheter Injection Site in Three Groups^a

Injection Site	Groups			Total
	Venipuncture	Aromatherapy	Control	
Back of the hand	19 (63.3)	(76.7) 23	20 (66.7)	62 (68.9)
Hand cutdown	6 (20)	3 (10)	5 (16.7)	14 (15.6)
Forearm	2 (6.7)	0 (0)	1 (3.3)	3 (3.3)
Cubital fossa	3 (10)	4 (13.3)	3 (10)	10 (11.1)
Foot cutdown	0 (0)	0 (0)	1 (3.3)	1 (1.1)
Total	30 (100)	30 (100)	30 (100)	90 (100)

^aP = 0.510, df = 2, $\chi^2 = 1.348$.

According to the results of the Post-Hoc Bonferroni tests, there was significantly lower pain intensity in the two intervention groups compared to the control group (P = 0.001). However, no significant difference was detected

between the two intervention groups in this regard (P > 0.005). In other words, the two interventions had similar effects on the reduction of pain (p = 0.90) (Figure 3).



(Beyer, J., Villarruel, A., and Denyes, M., 2009).

Figure 2. Oucher photographic pain scale: A collection of six pictures representing faces exhibiting increasing degrees of pain (34).

5. Discussion

The present study aimed to compare the effects of aromatherapy and distraction on the pain caused by venipuncture in children hospitalized in the pediatric ward of Ali-Ebne-Abi-Taleb Hospital, Zahedan, in 2019. The results revealed no significant difference between the three groups regarding demographic characteristics. However, the mean score of pain intensity changed in the two intervention groups after the intervention. Accordingly, pain intensity was mild and moderate in the two intervention groups. In the same line, Arjmand et al. (35) disclosed that inhalation aromatherapy using lavender essence had similar effects on acute pains with mild and moderate intensities. Hence, this method was reported to be effective in pain control (35). Aliasgharpour et al. (36) also found a significant difference in the score of pain be-

fore and after inhalation aromatherapy. Yilmaz and Aledar (37) also conducted a clinical trial on the effects of buzzy, jet lidocaine, bubble blowing, and aromatherapy using lavender on pain among the 5-10-year-old children who required blood tests. The results indicated a significant difference between the intervention and control groups regarding pain intensity before and after providing the intervention (37). Similarly, Bikmoradi et al. (14), in a study on preschool children who are normally afraid of harm to their bodies, revealed a significant difference between the aromatherapy and control groups regarding the mean intensity of pain immediately, five minutes, and 10 minutes after catheter insertion. These results reveal the effects of aromatherapy on reducing pain intensity. Moreover, they used catheter sizes of 22 and 24 in their study. However, Bikmoradi's study has only investigated pediatric participants. Furthermore, Soltani et al. (38) referred to the ef-

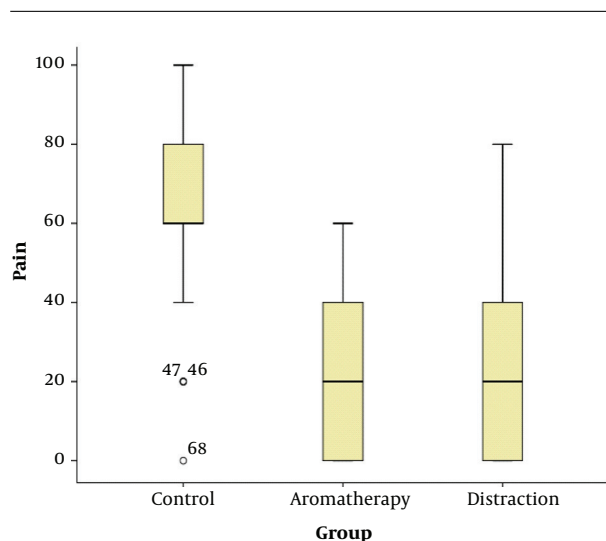


Figure 3. the distribution of pain intensity of patients in three groups

fect of aromatherapy using lavender on post-tonsillectomy pain. The children undergoing this intervention required lower acetaminophen doses, which was in agreement with the current study findings (38).

Preliminary studies have shown that linalool (lavender) has anti-anxiety, anti-inflammatory, and analgesic properties. The findings of the study by Quintans-Junior et al. (39) also revealed the peripheral and central analgesic properties of linalool. Linalool and linalyl acetate in lavender can stimulate the parasympathetic system. Therefore, this plant exerts relaxing, analgesic, and anti-contraction effects. Linalool comprises the most active part of the plant, which shows its spasmolytic and relaxing properties (37). Considering the positive impacts of aromatherapy on managing pain intensity in children in the current study, this non-pharmacological method can effectively reduce the pain associated with venipuncture in children. It worth mentioning that local analgesics are slowly absorbed and their frequent usage can lead to skin rashes or allergic reactions (40).

The findings of the present study indicated that distraction using a puppet resulted in a significant reduction in pain intensity compared to the control group. Distraction can be achieved using various methods. In this study, distraction was performed using Kolah Ghermezi (Red Hat) puppet. Based on the results, distraction using this puppet can be used as a non-pharmacological technique to decrease behavioral reactions while intravenous cannulation. In the same vein, Akgul et al. (41) evaluated the impact of watching a cartoon on the score of pain and length of crying among 3-6-year-old children. The results

revealed a significant difference between the two study groups regarding the intensity of pain and length of crying after blood taking. Fooladi et al. (42), in a clinical trial intended to investigate the effect of distraction on physiological indices and pain intensity caused by the intra-spinal injection of chemotherapy drugs among children with cancer, demonstrated that distraction could effectively reduce the pain intensity. Consistently, Bergomi et al. (43) showed a significantly lower pain intensity among the children in the distraction group compared to the control group. Ballard et al. (13) also stated that distraction using toys is useful to control pain in children. Moreover, Barati et al. (44) indicated that play therapy was effective in the reduction of pain intensity in the intervention group and, as a nursing intervention, had a positive impact on reducing post-operative pain in school-age children. Aydin et al. (20) compared the effects of three distraction methods (i.e. ball squeezing, balloon inflation, and distraction cards) on reducing children's pain and anxiety during venipuncture. The results revealed the relief of pain and anxiety in the three utilized methods, but no significant difference was detected (20). Irani et al. (25) conducted a clinical trial to explore the effect of doll injection display on the intensity of pain resulting from intramuscular injection among preschool children. The results indicated that the mean intensity of pain was significantly lower in the intervention group compared to the control group (25). Similar results are also obtained by Sadeghi et al. (22) and Babaie et al. (32). Playing with a puppet is one of the interactive techniques that is involved with more than one sense, which can further enhance the effect of distraction. On the other hand, this technique can be performed in healthcare centers due to its low costs.

The results of the aforementioned investigations are in agreement with those of the present study. Consistent with our results, Razaghi et al. (17) revealed no significant difference between bubble blowing and touch techniques with regard to the intensity of the pain. On the other hand, Aktas and Alemdar (33) reported a significant difference between distraction and aromatherapy groups concerning pain intensity during and after phlebotomy. According to the findings, pain intensity was lower in the buzzy group ($P < 0.05$). However, Bergomi et al. (43) demonstrated that distraction using cartoons was more effective compared to buzzy and combination of cartoon and buzzy in decreasing pain among children. Mikaeili et al. (31) also found a significant difference between watching a cartoon, bubble blowing, and control groups regarding the decline in pain intensity during chemotherapy in children with cancer. In justifying this contradiction, we can point to reasons such as the type of culture of the society under study, the type of work method, and tools used. The results showed that

the technique of distraction using dolls and aromatherapy with lavender had a positive effect on reducing pain due to venipuncture in children. The disinfectants in the alcoholic pads probably have interfered with the aroma. Positive and negative memories associated with odors could be effective in this area, as well. Moreover, cultural, social, physical, and mental factors and personal conflicts could influence the intensity of pain. Finally, it worth noting that the length of venipuncture was not assessed in this study.

5.1. Conclusions

This study demonstrated that both aromatherapy and distraction could reduce pain in children during venipuncture. Considering these results, nurses are recommended to make use of aromatherapy and distraction, instead of pharmacological methods, for pain relief. In this way, nurses can cooperate more in taking care of children and provide better care services for the promotion of their life quality. Since many children experience fear before performing procedures like venipuncture that intensifies their perception of pain, future studies are suggested to investigate the effects of aromatherapy on pain intensity after operations like appendicitis.

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Footnotes

Authors' Contribution: Fereshteh Ghaljaei, Nasrin Mahmoodi, and Abolfazl Payendeh did study supervision, scientific edition, and final approval. Shiva Karimi Afshar did research implementation, statistical analysis, and manuscript preparation.

Clinical Trial Registration Code: This research registered as a clinical trial (code: IRCT20181214041960N2).

Conflict of Interests: The authors declare no conflict of interest.

Ethical Approval: This study is derived from a research project approved at the Zahedan University of Medical Sciences (code: IR.ZAUMS.REC.1398.092).

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