Original Article

The Effect of Entonox, Play Therapy and a Combination on Pain Relief in Children: A Randomized Controlled Trial

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Abstract:

Pediatric pain is often undertreated/neglected due to time constraints, difficulties in timing of oral analgesics, fear of side effects of opioids and anxiolytics, and apprehension of additional pain in the use of local anesthetic injections. In this study, the researcher was prompted to choose rapidly acting interventions that were low dose and allowed the child to stay alert, suitable for a quick discharge. The purpose of this study was to evaluate the effects of Entonox, play therapy, and a combination to relieve procedural pain in children aged 4-15 years. The study was designed as a randomized controlled trial; the subjects were divided into four groups using a sequential allocation plan from 123 total subjects. Group A received Entonox, Group B received play therapy, Group C received both Entonox and play therapy, and Group D received existing standard interventions. The study was vetted by the departmental study review committee. The pain level was assessed using FLACC scale for children aged 4-9 years and the Wong Bakers Faces Pain Scale for children aged 10-15 years; scores ranged from 0 to 10. All the data were analyzed using SPSS 16.0 with descriptive statistics and, inferential statistics. The mean pain scores were as follows: Entonox group, 2.87; Play therapy group, 4; combination group, 3; and control group, 5.87. When statistical testing was applied, a significant reduction in the pain score in all the three experimental groups when compared to the control group was found ($p = .002$), but not in the pain score among the three experimental groups ($p = .350$). The findings of this study indicated that all three interventions were effective in lowering pain scores when compared to the control group. Play therapy is as potent as Entonox in relieving procedural pain, though there was no additive effect on pain relief when play therapy and Entonox were combined. A protocol for age-related choice between play therapy and Entonox administration was introduced as a

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standing order in the Pediatric Surgery department for acute procedural pain relief.

INTRODUCTION

Pain is an intolerable sensation that makes the patient vulnerable (Rao, 2006) and it has been recognized as the fifth vital sign by the Joint Commission on Accreditation of Health Care Organization (JCAHO). Healthcare professionals regard immunizations, injections, dressings, and suturing as routine procedures; for children, however, all these arouse fear and are perceived as stressful. Inadequate relief of pain and distress during childhood procedures may have long-term negative effects on future pain tolerance and pain responses. Infants and children respond to pain with behavioral reactions that depend upon their age and cognitive process: "The inability to communicate in no way negates the possibility that an individual is experiencing pain and is in need of appropriate pain-relieving treatment" (Goddard, 2002, page no. 839).

Pain is defined by the International Association for the Study of Pain as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage" (Fields, 1999). The effects of pain are deleterious. Pain evokes negative physiologic, metabolic, and behavioral responses in children, including increased heart rate; respiratory rate; blood pressure; and secretion of catecholamine, glucagon, and corticosteroids. The catabolic state induced by acute pain is more damaging to infants and young children, who have higher metabolic rates and fewer nutritional reserves than adults (Franck, Greenberg, & Stevens, 2000). The American Society for Pain Management Nursing (ASPMN) believes that individuals who undergo potentially painful procedures have a right to optimal pain management before, during, and after the procedure and a plan should be in place to address potential pain and anxiety before the initiation of any procedure (Czarnecki et al., 2011).

The present study was prompted by the need to address pain in children in the pediatric surgery outpatient clinic, where it was often undertreated/neglected. Acute, short-term painful procedures, such as dressing and suture removal, were common and the limited pharmacological agents available in the outpatient clinic were not being used on a regular basis. Thus, it was necessary to choose rapidly acting interventions that could be applied for procedures done at short notice and not requiring postprocedural observation. The researcher, having observed the use of Entonox (nitrous oxide 50%:oxygen 50%) for burn dressing, felt that the method might be appropriate for pain relief among children for short, planned procedures. When a nonpharmacological intervention is used in association with a medical procedure, either before, during, or after the procedure, the child gets a chance to have a sense of control and experience mastery over procedure, thus reducing anxiety, improving coping and pain relief.

OBJECTIVES

The study was undertaken to assess and compare the pain levels in children undergoing short-term procedures treated with either Entonox, play therapy, both Entonox and play therapy, or standard pain interventions (control group). In addition, the researchers sought to determine the relationship between an observer's pain assessment and the self-reported pain in children aged 10 to 15 years.

Hypothesis

H1: There is a significant difference in the pain level of children in the Entonox group as compared to the control group.
H2: There is a significant difference in the pain level of children in the play therapy group as compared to the control group.
H3: There is a significant difference in the pain level of children in the combination group as compared to the control group.
H4: There is a significant difference in the pain level of children in the combination group as compared to those for whom either Entonox or play therapy alone is used.

METHODS

The aim of the study was to assess the effect of Entonox, play therapy, and a combination of both on pain relief in children in the pediatric surgery outpatient setting of Christian Medical College, Vellore. Children aged 4-15 years who underwent a painful procedure were selected and were divided into four different groups.

Children undergoing painful procedures and those who met the inclusion criteria were identified by the staff nurse in charge of the treatment room and were directed to the researcher. Consent was obtained and the parents were told by the researcher that the child could be in any one of the four groups. The staff in charge randomly allocated the children to one of the experimental groups or the control group

based on the premade computerized randomization chart. All the children who participated in the research were given 20 minutes of preprocedural preparation as a standard mode of care by the researcher in the annex of Outpatient Department (OPD). The pain level during the procedure in all the four groups was assessed by a second researcher, using the standardized pain scale to prevent researcher bias.

For children in Group A (Entonox only), during the period of preprocedural preparation, the child was distracted using cartoons, videogames, and puzzles; at this time, the researcher explained the procedure in simple terms and demonstrated to the subject how to inhale Entonox using a mask. Return demonstration was performed by the child to impart a sense of control. The child was asked to perform the inhalation the same way during the procedure. Pain level was assessed during the procedure by the second researcher using the standardized pain scale.

For children in group B (play therapy only), they were also distracted using cartoons, videogames, and puzzles, and the researcher explained the procedure in simple terms. The children were also told to either play a videogame or watch cartoons during the procedure. The pain level was assessed during the procedure by the second researcher using the standardized scale.

For children in group C (combination Entonox and play therapy), the child was distracted using cartoons, videogames, and puzzles during the preprocedural period. The researcher explained the procedure and demonstrated how to inhale using a mask, with return demonstration provided by the child. The child was asked to inhale as previously demonstrated and was also provided diversion using videogames during the procedure. The pain level was assessed during the procedure by the second researcher using the standardized pain scale.

Children in group D (control group) underwent the standard practice in pediatric surgery without either of the study interventions; their pain level was also assessed by the second researcher using the standardized pain scale. Children in all the groups who were between 10 and 15 years old were asked to provide a self-report of their pain using the Wong Baker Faces Pain Scale. All children were observed for any side effects for a period of 10 minutes after the procedure.

Instrument

The pain level was assessed during the procedure by the second researcher using a standardized pain scale—FLACC scale for ages 4-9 years and Wong Baker Faces Pain Scale for ages 10-15 years—to minimize researcher bias. The Wong Baker Faces Pain Scale was developed by Donna Wong and Connie Baker and the FLACC scale was developed by Sandra Merkel and Shobha Malviya. The FLACC scale was used in this setting because it was difficult to distinguish the child's facial expression of pain with anxiety in the younger age group. Children aged 10-15 years were asked to self-report their pain using the Wong Baker Faces Pain Scale. The pain severity was interpreted on a 10-point scale as follows: worst pain: 10; severe pain: 7-9; moderate pain: 4-6; mild pain: 1-3; no pain: 0.

Due to the difficulty of having a single staff nurse do the pain assessment for all subjects in the busy setting, three staff nurses were assigned for pain assessment. Inter-rater reliability was done between three staff nurses for both scales. The mean interclass correlation coefficient for FLACC scale was $r = .98$, and for Wong Baker Faces Pain Scale was $r = 0.96$; thus, the reliability was judged good.

Ethical Considerations

The study was approved by the Institutional Review Board of Christian Medical College, Vellore. The parents of children scheduled to undergo short-term, painful procedures during their visit to the pediatric surgery outpatient department were approached by the researcher. Informed written consent was obtained from the parents and assent was obtained from children. Confidentiality was maintained throughout the study.

RESULTS

Analysis of the demographic data revealed that majority of the children (65.86%) were in aged 4-9 years, male (64.23%), and the first-born in their families (58.54%). The clinical data revealed that the majority (54.57%) of them underwent invasive procedures and that most had past history of painful procedures (52.85%) and of hospitalization (47.15%).

Since the outcome variable was not normally distributed, nonparametric tests were used to compare the pain levels. Median pain scores were as follows: Group A = 2; Group B = 4; Group C = 4; and Group D = 6. When the experimental groups' pain levels were compared with the control group, there was a statistically significant reduction in the pain ($p = .002$) as presented in Table 1.

When the pain levels in all experimental groups were compared, there was no statistically significant difference of pain level between the combination group as compared to children for whom either Entonox or play therapy alone was used ($p = .350$), as presented in Table 2.

TABLE 1.
Comparison of Pain Level in the Four Groups (N = 123)

Group	Number of Children	Mean Score	Median	Range	Kruskal-Wallis Test	*p* Value
A	31	2.87	2	(1, 5)	14.825	.002*
B	32	4.00	4	(2, 7.25)		
C	30	3.23	4	(0, 5)		
D	30	5.87	6	(2, 8.25)		

*These data suggest that there is a statistically significant difference in the pain level in children in the Entonox group (A), play therapy group (B), and the combination group (C) as compared to the control group (D). $p < .05$.

It was also found that there was a perfect positive correlation between the observer's pain score assessment using the Wong Baker Faces Scale and the self-report by children aged 10-15 years (Spearman's correlation coefficient = .976; see Fig. 1).

DISCUSSION

H1: There is a significant difference in the pain level of children in the Entonox group as compared to the control group (*p* value = .001).

This was congruent with the study findings of Cleary et al. (2002), who evaluated the efficiency of self-administered nitrous oxide oxygen in 55 children with juvenile idiopathic arthritis (median age of 13.54 years) undergoing intra-articular injection and found the median pain score as 1. The median pain score in the group that received Entonox alone in this study was 2.

H2: There is a significant difference in pain level in children in the play therapy group as compared to the control group (*p* value = .027)

The findings are congruent with the study done by Tufekci, Celebioglu, and Kucukoglu (2009), who assessed the effect of distraction technique on pain level in 118 children undergoing phlebotomy. The distraction card group had the lowest pain levels (2.41 ± 2.49) among the groups, and there was a statistically significant reduction in pain levels of the children in the group that received distraction as compared to the control group ($p < .001$). The median pain score in the group that received play therapy alone in this study was 4.

H3: There is a significant difference on pain level of children in the combination of Entonox and play therapy group as compared to the control group (*p* value = .002)

Similar findings are reported by Kazak, Penati, Brophy, and Himelstein (1998), who assessed the effect of the combination of pharmacological and psychological interventions and pharmacological-only interventions in relieving procedural distress. It was found that lower levels of child distress were reported in the combined intervention than the pharmacological-only intervention, especially in the younger age group.

H4: There is no significant difference in the pain level of children in the combination of group as compared to those for whom either Entonox or play therapy alone *was used* ($p = .350$).

We did not find statistically significant additive or synergistic effects from combining the pain-relieving strategies. The combination of pain relief techniques were only as good as each technique applied individually. This leads to the conclusion that these interventions were not independent of one another and that any age-appropriate intervention works well in providing pain relief.

Lautenbacher (2009) investigated 40 young, pain-free individuals' response to mechanically and

TABLE 2.
Comparison of Pain Level in the Three Experimental Groups (N = 93)

Group	Number of Children	Mean Score	Median	Range	Kruskal-Wallis Test	*p* Value
A	31	2.87	2	(1, 5)	2.098	.350
B	32	4.00	4	(2, 7.25)		
C	30	3.23	4	(0, 5)		

These data suggest that there is no statistically significant difference among the pain levels in children between the Entonox group (A), play therapy group (B), and combination group (C).

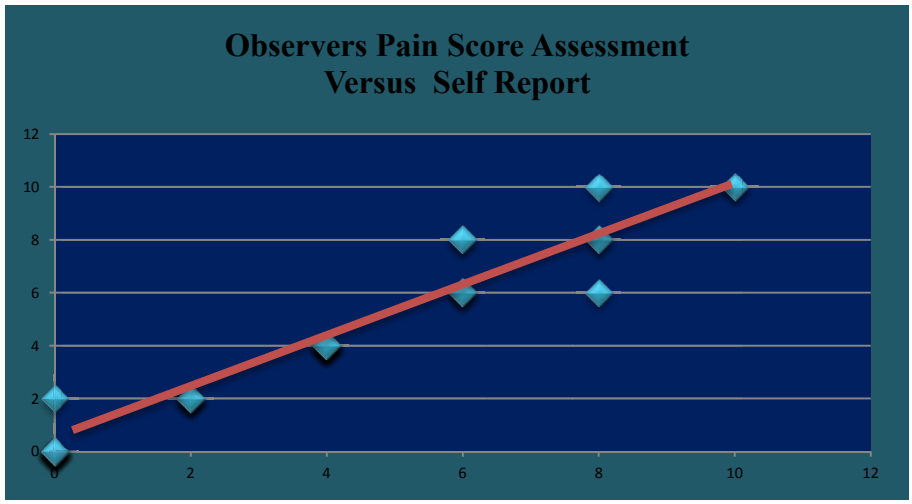

FIGURE 1. ■ Spearman's correlation coefficient = .976. The figure shows that there is perfect positive correlation between the observers pain assessment and self report by children in the age group of 10–15 years. (N = 42).

electrically induced pain to find the relationship between self-report and facial expression of pain. There were significant correlations between the self-report and facial expression in pressure pain and the findings suggest that the facial expression of pain appears to mirror self-report ratings.

Pain management is a major facet of care, especially in children. These findings will help the nurse or play therapist to ensure that each child receives appropriate evidence-based assessment and intervention that effectively treat the child's pain and meet the recognized standard of care. The pain management strategies can be enforced in the inpatient settings in both the medical and surgical departments, thus enhancing the healthcare professionals' primary commitment to the children of promoting health and alleviate suffering.

Staff development programs can be conducted to highlight the knowledge of pain, pain assessment, and standard of care for pain management, thereby focusing on the professionals' ability to advocate for and assure effective pain management for each child. Entonox protocol for the staff emphasizing the importance of play therapy was introduced in the pediatric surgery department for procedural pain relief. The protocol can be utilized in community settings to educate healthcare workers on the effectiveness of Entonox in pain management, as a literature search has identified Entonox's effect in a community setting, thus bridging the gap between theory and practice.

CONCLUSION

Pain management has profound physiological, psychological, ethical, and financial consequences. Age-appropriate, affordable interventions can provide effective pain relief in children even in a busy outpatient clinic. Though pain perception is subjective and unique to each individual, objective assessment of pain is possible to direct to appropriate and timely interventions. An evidence-based nursing practice in pain management, with preprocedural evaluation and preparation of children, educated healthcare professionals, trained personnel, proper equipment, thorough assessment of pain, and appropriate choices of analgesics and sedatives, can be achieved, which thus acts as a platform for further enhancement of the nurse practitioner's role in the field of pain management.

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