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Is a musical intervention effective in the reduction of needle related procedural pain in children?

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A SELECTIVE EVIDENCE BASED MEDICINE REVIEW

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Abstract:

Trypanophobia, or the fear of needles and needle pain is a very common occurrence in children, one that can have significant impacts into adulthood and on an individual's lifelong healthcare. The objective of this systematic review is to determine whether or not a musical intervention is effective in the reduction of needle-related procedural pain in children. The author searched OVID Medline and Cochrane databases for peer-reviewed articles and systematic reviews addressing the topic, published in English after 1996. Three randomized controlled trials were selected on the basis of their being POEM's and not included in previous systematic reviews, the results of which were used to determine the effects of a musical intervention on children's pain, anxiety, and several physiologic markers during needle-related procedures. Each of these three trials measured responses to the musical interventions using visual analog or FACES scales, and results were statistically analyzed, having varying levels of significance in the reduction of pain and distress of the children. Review of these results indicates that when available, a musical intervention is effective in the reduction of needle-related procedural pain in children undergoing medical procedures.

Key words: pain, venipuncture, needle, music, music therapy

Introduction

On average, a child experiences approximately twenty needle sticks by the time he/she is eighteen.¹ These are the basic immunization shots and do not include additional vaccines, or other medically necessary needle-related procedures. Fear of needles and needle pain is a very common occurrence in children, one that can have significant impacts into adulthood, and on their lifelong healthcare. Currently, there are not widely used treatments for procedural needle pain in most medical settings.

Reduction of needle procedural pain, and the fear of it, is of major relevance to both patients and health care providers. Fear of needles and procedures may have a direct effect on a child's behavior in a medical setting. If a child is moving, crying, or attempting escape, there poses a danger of unintentional needle sticks to the provider, the child, or the assistant. There is also an increased risk of injury to the child or assistant if physical restraint is necessary. If the parents play the role of assistant, they too, can be traumatized if they do not perceive the importance of the shots or procedure and must physically restrain their child. The parents may not know the proper safe restraint methods, increasing risk of injury to themselves or the child. Overall, medical procedures of any kind are safer to the provider and patient if the patient remains calm and cooperative.

The extreme irrational fear of medical procedures involving needles is known as trypanophobia.² This needle phobia is a formally defined medical condition in DSM-IV as 300.29.³ There are documented cases of vasovagal syncope occurring in individuals with this condition, and even some rare cases of this resulting in death. Needle procedures cause varying amounts of physical pain, and children can develop emotional and psychological scars that can yield lifelong negative responses to needles and extend into adulthood, directly impacting their

ongoing healthcare.² The implications of lifelong needle avoidance include lack of preventative healthcare measures and noncompliance. They can also lead to increased cost of healthcare when patients present in more severe stages of illness because they have waited to be seen by a healthcare provider due to fear.

Pain during needle procedures is a subjective, multi-factorial reaction that is based on an individual's previous experiences and level of pain tolerance.⁴ It is not feasible to equivocally know the amount of pain a needle causes someone, therefore responses to pain are subjectively measured. There are methods, both pharmacologic and non-pharmacologic, used in attempts to decrease pain. These include topical anesthetic creams, general anesthesia, Nitrous Oxide treatments, distraction techniques, and parental involvement.

These pain reduction methods are not widely used due to the increased time it takes for implementation or their cost and availability in medical offices/hospitals; therefore children typically go without. Some of these methods are quite costly and have increased risks (ie: in the case of general anesthesia). It is because of these costs and risks that a musical intervention during needle procedures is proposed as a simple alternative to the current methods used. Music, as an alternative, or addition to, the usual treatment methods could provide a significant decrease in trauma to the child and parent, as well as improving overall safety and psychological factors.

Objective

The goal of this review is to determine whether or not a musical intervention is effective in the reduction of needle-related procedural pain in children. Three randomized controlled trials are used that compare effectiveness of the addition of a musical intervention during procedures to that of a placebo, or lack of intervention. This review will also attempt to determine if musical intervention is as, or more, effective in pain reduction than anesthetic creams or placebos.

Methods

Three randomized clinical trials were found by the author whose populations included children ranging from 2 to 13 years old who were undergoing needle-related procedures of some kind (either venipuncture or acupuncture). The interventions varied slightly between trials, but all included the addition of music during the needle procedures (either live or recorded music). Comparisons to this intervention included use of a local anesthetic (EMLA cream), or a placebo (the basic standard of care during the procedure and parental involvement). Ovid Medline and the Cochrane Database of Systematic Reviews were used to gather information and to find the clinical trials used for review.

Criteria for selection and inclusion of these studies were: 1) Literature published between 1996 – present. 2) Studies that were randomized controlled trials. 3) Studies that were not previously included in systematic reviews or meta-analysis, or those published after an SR or MA was published. 4) Studies that dealt with outcomes that were POEM's and not DOE's, and therefore important outcomes to the patients. 5) Studies that did not relate to a topic producing a question submitted by a member of a previous PA class. 6) RCT's with statistical significance ($p < 0.05$) for results. Studies not following the above criteria were not included in this review.

In order to narrow the search criteria and find articles for this review, search dates from 1996 to present, “English”, and combinations of keywords were used to search, including: “pain”, “needle”, “venipuncture”, “music”, “music therapy”. From this search, three studies were found that met inclusion criteria and had been published in peer-reviewed journals. These studies included: 1) A prospective RCT comparing placebo, Indian classical instrumental music, and EMLA cream for treatment of pain felt during venipuncture (Balan 2009). 2) A prospective RCT comparing placebo with interactive live music for the treatment of pain and stress during

venipuncture (Caprilli 2007). 3) An RCT comparing placebo with thirty minutes of a child's favorite music for the treatment of anxiety and pain in children with cerebral palsy receiving acupuncture (Yu 2009). Exclusion criteria included: 1) Articles involving other non-musical interventions used to reduce needle procedural pain. 2) Any article involved in a previously published Systematic Review on the Cochrane Database.

Outcomes measured were POEM's and included reduction of pain during the needle procedures. Other POEM's measured were reduction in anxiety levels and physiological markers including mean arterial blood pressure, heart and respiration rates. In order to measure these outcomes, scales were used for members of each study. These included a Visual Analog Scale, FACES, and CHEOPS to measure direct response to pain of the needle procedure, OSBD-A and mYPAS to measure anxiety levels, and measurement of vital signs for physiological markers. In order to determine statistical significance, Kruskal-Wallis and Mann-Whitney U tests, and ANOVA analysis were performed, with $p < 0.05$ indicating statistical significance.

Results

The major characteristics of the trials included in this review are displayed in **Table 1**. While there are minor differences, such as the style of music or method of application, and languages spoken by the children, each of the studies included children of similar ages undergoing needle-related medical procedures of some kind, as well as similar observation and data measurement techniques.

Table 2 shows a comparison of median VAS pain scores in the **Balan 2009** study among the three different intervention groups at 3 different time points via a Kruskal Wallance test. This statistical test illustrates a significant difference among VAS scores of the 3 groups, with the

placebo group significantly distinct from the EMLA cream and music groups, and EMLA cream being the most effective in reduction of median VAS score.

Table 1. Characteristics of Studies Included for Analysis of Musical Intervention in the Reduction of Needle-related Procedural Pain

Study	Type	# Pts	Age yrs	Inclusion Criteria	Exclusion Criteria	W /D	Interventions
Balan, 2009 (1)	Prospective RCT	150	5 - 12	Age 5-12 with parental informed consent, if child >7yo enrolled only if they gave self consent	Children with hx of hypersensitivity to local anesthetics of amide typ of constituents of EMLA, hx of congenital or idiopathic methemoglobinemia, G6pd deficiency, or severe hepatic dz, children with altered sensorium or hearing impairment on clinical exam, and those whose clinical condition warranted urgent drug administration	0	The addition of Hindustani classical music – “raga” during venipuncture procedure, delivered via walkman headphones Vs. Placebo (standard of care) Vs. Local anesth. Cream
Caprilli, 2007 (2)	Randomized Prospective Study	108	4 - 13	Native born, Italian speaking children ages 4-13 undergoing venipuncture with parental consent	Hx of significant hearing or visual impairments, cognitive disorders, or previous experience of hospitalization	0	Addition of live music during venipuncture procedure (along with parental support and standard of care)
Yu, 2009 (3)	RCT	60	2 - 12	Children with CP diagnosis receiving acupuncture	Hx of profound deafness, dysfxn of blood coagulation, or chronic infectious dz, pts suffering from dizziness, vomiting, or who did not want to give consent	0	Addition of 30 minutes of child’s favorite music during acupuncture procedure

Table 2. Comparison of median VAS scores at 3 averaged time points

Observer Category	EMLA	Music	Placebo
Parent	3	6	17
Patient	3	4	17
Investigator	3	6	17
Independent Observer	3	4	16

Table 3 illustrates the statistical significance of a musical intervention on reduction of pain during venipuncture at different time intervals and based upon observations of different observers in the **Balan 2009** study. These results compare Visual Analog scores of EMLA cream and the musical intervention, as analyzed by the Mann-Whitney U test.⁵

Table 3. Mann Whitney Comparison of VAS scores comparing EMLA and music

Observer Category	Time point	Mann Whitney p-value	Inference
Parent	0 min	0.116	Not significant
	1 min	0.033 **	SIGNIFICANT
	5 min	0.221	Not significant
Patient	0 min	0.140	Not significant
	1 min	0.358	Not significant
	5 min	0.827	Not significant
Investigator	0 min	0.030 **	SIGNIFICANT
	1 min	0.003 **	SIGNIFICANT
	5 min	0.003 **	SIGNIFICANT
Independent Observer	0 min	0.115	Not significant
	1 min	0.182	Not significant
	5 min	0.038 **	SIGNIFICANT

As indicated in Table 2 and 3, the VAS pain scores were lower in the local anesthetic (EMLA) group compared to the musical intervention group, however these differences were not always statistically significant with p values < 0.05. There also seems to be considerable observer discrepancy. As shown in the two preceding tables, needle procedures without an intervention resulted in higher VAS pain scores, and EMLA cream seems to have increased efficacy over both musical intervention and placebo.

Table 4 shows results from the **Caprilli 2007** study, in which behavioral distress and pain were measured via observation using OSBD-A . Statistical significance was then determined using the ANCOVA scores with the musical intervention having a significant effect on distress before, during, and after the procedure. Age also affected the child's distress, but gender did not.⁶ An ANOVA score analyzing a FACES scale indicated that a musical intervention also has a statistically significant reduction in self-reported pain.

Table 4. (** indicates statistical significance)

ANCOVA before sampling	ANCOVA during sampling	ANCOVA after sampling	ANOVA music vs. perceived pain (self-reported) P= 0.048 **
Age: p = 0.000 **	Age: p = 0.000 **	Age: p = 0.000 **	
Music: p = 0.000 **	Music: p = 0.000 **	Music: p = 0.000 **	
Gender p = 0.231	Gender p = 0.766	Gender: p = 0.554	

Table 5 shows the results of the **Yu 2009** study in which children with cerebral palsy undergoing acupuncture were evaluated for pain and anxiety during the procedure, with outcomes measured by mYPAS (anxiety), CHEOPS (pain), Wong-Baker FACES, and physiological markers of pain and anxiety including heart and respiration rates, and mean arterial pressure.⁷ Statistical significance was determined using ANOVA, which indicated that the addition of music did not have a statistically significant effect on pain levels in children, but did result in a significant reduction in anxiety. MAP and heart rate were significantly decreased with the addition of music, but the respiration rate was not.

Table 5

ANXIETY	ANOVA – significantly lower mYPAS in music over control (F= 4.270, p=0.043)
	T-test – significant decrease in mYPAS in music at 30 min (t=4.72, p = 0.000)
PAIN	ANOVA – no significant effect in CHEOPS or FACES b/w groups (F=2.343, p=0.131), but significant difference for time (F=87.347, p=0.00)
VITAL SIGNS	MAP – ANOVA – significantly lower in music group (F=4.62, p = 0.04)
	HR – ANOVA – significantly lower in music group (F=6.03, p = 0.02)
	RR – ANOVA – no significant difference (F=0.001, p=0.98)

There were no adverse events reported in any of the trials, and there were no withdrawals of subjects during the studies.

Discussion

These results indicate that musical interventions during needle-related procedures are variable in efficacy at reducing pain, anxiety, and physiologic indicators of the two. In some cases, musical intervention has a statistically significant decrease on pain and/or anxiety, but in

comparison to an anesthetic cream (Balan 2009 study), the cream is more effective in reduction of pain. The results suggest that a musical intervention may affect individuals differently and provide variable reductions in pain and anxiety, but that the addition of music is more efficacious than placebo, or lack of intervention. This suggests that when available, musical interventions may be helpful in the attempt to reduce needle-related pain. Limitations are evident in all three studies, including the individual, subjective nature of pain and anxiety, as well as the subjective nature of measurement of the effects of the interventions and the reliance upon children and observers for measurement of results. The small sample sizes and short lengths of study were also limiting factors. In the Yu 2009 study, the addition of cerebral palsy may have added difficulty to assessment of pain and anxiety due to the disturbances in sensation, perception, cognition, communication, and behavior.⁷ In all trials, bias of the observers is noted since it was impossible to blind observers and study participants to the musical intervention given. With the variable statistical significance shown in each of the three studies, more research needs to be conducted in order to further evaluate the effectiveness of musical interventions. It would also be important to develop measurement techniques that are less subjective and more quantifiable, as well as creating ways to blind the observers in order to decrease bias in the results.

Conclusion

The results of the three studies suggest that the addition of music to needle-related procedures, though variable in efficacy, would be an effective measure in reducing needle-related procedural pain in children. Two of the three studies indicate that the addition of music has a significant reduction in a child's pain over the use of placebo or lack of intervention. The Balan 2009 study furthered investigation by illustrating that EMLA creams were even more effective in pain reduction than both music and placebo. The 3rd trial (Yu 2009) did not show a

statistically significant reduction in pain with a musical intervention, but did indicate a significant reduction in anxiety, as well as a reduction in mean arterial pressure and heart rate, which could potentially indicate reduction in the child's distress and/or pain. Further investigation is warranted to determine the best efficacy in pain reduction during needle-related procedures, but it would seem that as an alternative to no intervention, music would be an effective addition in the attempt to reduce a child's pain and distress during healthcare procedures involving needles.

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