Original Investigation

# Music to Reduce Pain and Distress in the Pediatric Emergency Department
## A Randomized Clinical Trial

Lisa Hartling, PhD; Amanda S. Newton, PhD; Yuanyuan Liang, PhD; Hsing Jou, MD; Krista Hewson, BMT, MTA; Terry P. Klassen, MD, MSc; Sarah Curtis, MD, MSc

**IMPORTANCE** Many medical procedures aimed at helping children cause them pain and distress, which can have long-lasting negative effects. Music is a form of distraction that may alleviate some of the pain and distress experienced by children while undergoing medical procedures.

**OBJECTIVE** To compare music with standard care to manage pain and distress.

**DESIGN, SETTING, AND PARTICIPANTS** Randomized clinical trial conducted in a pediatric emergency department with appropriate sequence generation and adequate allocation concealment from January 1, 2009, to March 31, 2010. Individuals assessing the primary outcome were blind to treatment allocation. A total of 42 children aged 3 to 11 years undergoing intravenous placement were included.

**INTERVENTIONS** Music (recordings selected by a music therapist via ambient speakers) vs standard care.

**MAIN OUTCOMES AND MEASURES** The primary outcome was behavioral distress assessed blinded using the Observational Scale of Behavioral Distress–Revised. The secondary outcomes included child-reported pain, heart rate, parent and health care provider satisfaction, ease of performing the procedure, and parental anxiety.

**RESULTS** With or without controlling for potential confounders, we found no significant difference in the change in behavioral distress from before the procedure to immediately after the procedure. When children who had no distress during the procedure were removed from the analysis, there was a significantly less increase in distress for the music group (standard care group = 2.2 vs music group = 1.1, $P < .05$). Pain scores among children in the standard care group increased by 2 points, while they remained the same in the music group ($P = .04$); the difference was considered clinically important. The pattern of parent satisfaction with the management of children's pain was different between groups, although not statistically significant ($P = .07$). Health care providers reported that it was easier to perform the procedure for children in the music group (76% very easy) vs the standard care group (38% very easy) ($P = .03$). Health care providers were more satisfied with the intravenous placement in the music group (86% very satisfied) compared with the standard care group (48%) ($P = .02$).

**CONCLUSIONS AND RELEVANCE** Music may have a positive impact on pain and distress for children undergoing intravenous placement. Benefits were also observed for the parents and health care providers.

**TRIAL REGISTRATION** clinicaltrials.gov Identifier: NCT00761033

*JAMA Pediatr*. 2013;167(9):826-835. doi:10.1001/jamapediatrics.2013.200
Published online July 15, 2013.

**Journal Club Slides** at jamapediatrics.com

**CME Quiz** at jamanetworkcme.com and **CME Questions** on page 879

**Author Affiliations:** Alberta Research Centre for Health Evidence, University of Alberta, Edmonton, Canada (Hartling); Department of Pediatrics, University of Alberta, Edmonton, Canada (Hartling, Newton, Jou, Curtis); Department of Epidemiology and Biostatistics, University of Texas Health Science Center at San Antonio, San Antonio, Texas (Liang); Soundaffects Music Therapy, Edmonton, Alberta, Canada (Hewson); Manitoba Institute of Child Health, Department of Pediatrics, University of Manitoba (Klassen).

**Corresponding Author:** Lisa Hartling, PhD, University of Alberta, 4-472 ECHA, 11405-87 Ave, Edmonton, Alberta, Canada T6G 1C9 (hartling@ualberta.ca).

Attending the emergency department (ED) can be distressing for children owing to the unfamiliar people, surroundings, technical equipment, and medical care received.[1] The most frequently performed invasive procedures are venipuncture and intravenous (IV) placement,[2] and these are also the most painful and feared medical experiences by children.[3] Studies have shown that pain assessment and management in the ED setting is inadequate for children[4-7] and this can have long-term detrimental effects.[8,9]

Pharmacotherapy and distraction are the most commonly used approaches to pain control in the pediatric ED.[10] Although there are data to support the use of topical anesthetic creams,[11] vapocoolant cold spray,[12,13] and distraction[14,15] in reducing pain associated with venipuncture and IV placement, their use is not standardized across practitioners and settings.[4,5,16-18] Distraction has received recent attention and involves engaging children in cognitive or behavioral tasks to divert attention from painful stimuli to reduce both pain and distress.[15,19] Numerous distractors with varying complexity have been used either together or in isolation. Audio, videotapes, stories, imagery, and concentrated breathing are some examples.[20,21] The hypothesized mechanism of action is that the child "cannot attend to more than one significant stimulus at a time"[21] and in keeping with the Gate Control Theory of Pain, distraction stimulates the brainstem, which leads to the inhibition of pain perception.[21]

A systematic review of 19 randomized clinical trials involving 1513 children showed that music significantly reduced pain and anxiety during medical procedures.[22] The review concluded that additional research was needed within different clinical settings and for varying painful procedures. The objective of this randomized clinical trial was to compare music with standard care to manage pain and distress among children undergoing IV placement in the ED.

## Methods

### Study Design

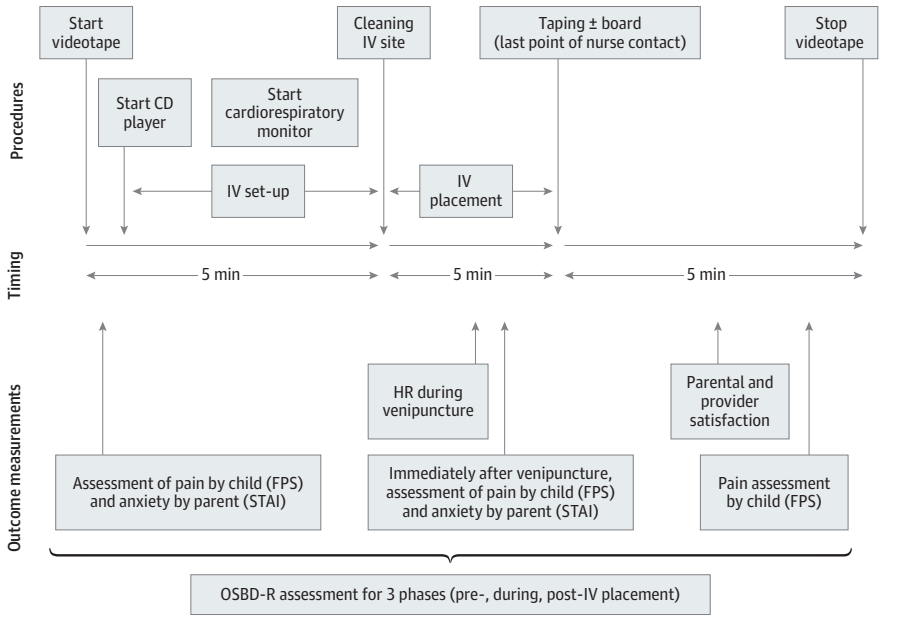
This 2-arm parallel randomized clinical trial with blinded assessment of the primary outcome was conducted at the Stollery Children's Hospital in Edmonton, Canada.

### Participants

The trial was registered prior to patient recruitment (NCT00761033), which occurred from January 1, 2009, to March 31, 2010. Children attending the pediatric ED were eligible if they were aged 3 to 11 years, undergoing an IV placement, conscious, and had sufficient knowledge of English to understand and follow instructions and complete the age-appropriate pain assessment. Children were excluded if they had hearing impairments, developmental disabilities, or sensory impairment to pain (eg, spina bifida). Children were also excluded at the discretion of the attending staff (eg, child in critical condition; requiring urgent IV placement; or in an altered level of consciousness).

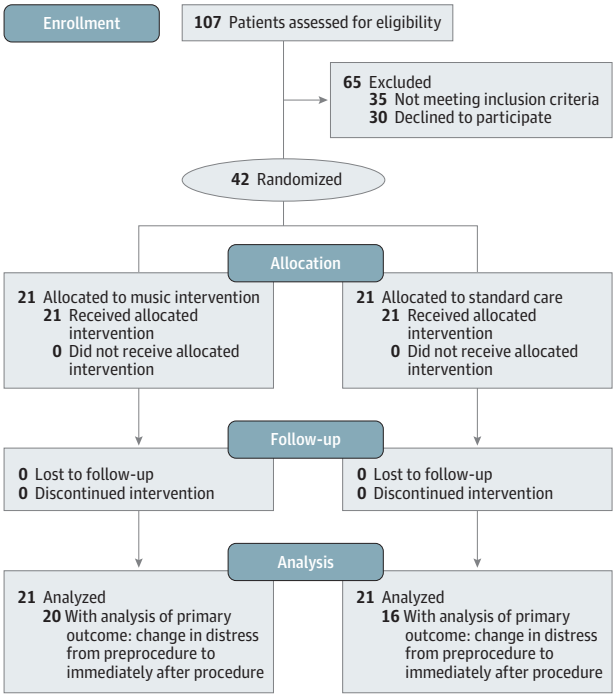
If the patient was eligible, a research nurse explained the study; invited the parent and child to participate; and obtained written, informed consent (parent) and assent (child). The child was then assigned to one of the intervention arms using consecutively labeled, sealed, opaque envelopes that contained the randomization sequence. This sequence was computer generated by a statistician who was not otherwise involved in the study. Allocation was concealed from the research nurse, ED staff, and child and parent until consent was obtained. Given the nature of the intervention, it was not possible to blind the children, parents, researchers, and ED staff. Data were collected using a defined protocol that is depicted in **Figure 1**. Briefly, after informed consent was obtained, the

Figure 1. Flow Diagram




Study procedures and timing of outcome assessments. CD indicates compact disc; FPS, Faces Pain Scale; HR, heart rate; IV, intravenous; OSBD-R, Observational Scale of Behavioral Distress–Revised; STAI, State-Trait Anxiety Inventory.

Figure 2. Participants




Enrollment and randomization of patients in the trial.

research nurse gathered information from the parent on baseline variables, presenting signs and symptoms, and medical history. Within 5 minutes of the start of the procedure, the researcher started the video recorder and immediately collected the child's self-reported pain; at this time, the parent completed the State Trait Anxiety Inventory (STAI), Form Y. For those children assigned to the music group, the researcher then turned on the music. The staff nurse then performed the set up for IV placement. The researcher set up the cardiorespiratory monitor and began the tape at the start of the procedure. The beginning of the procedure was indicated by cleaning of the injection site by the staff nurse. The researcher noted the time of first attempt at IV placement on the rhythm strip from the cardiorespiratory monitor. The researcher collected self-reported pain from the child and the parents completed the STAI immediately after the first attempt at IV placement. The end of the procedure was the last point of contact by the staff nurse (ie, taping cannula in place with or without arm board, wrapping arm with gauze, and taping in place). Shortly after completing the IV placement, the staff nurse performing the procedure and the parents completed the satisfaction questions. While the nurse and parents were completing their questions, the researcher collected postprocedure pain by the child. If the first attempt at IV placement was unsuccessful, additional attempts occurred after the study protocol was completed and all measurements were obtained.

## Ethics

Children received standard medical management (ie, all children received standard care and the music group received music as an additional intervention). The study was approved by the ethics review board at the University of Alberta and received institutional approval at the Stollery Children's Hospital.

## Interventions

Music in the experimental group was chosen by a music therapist (K.H.) and administered through an iPod dock. All participants listened to the same recordings via ambient speakers in the following order: The Planets Op. 32 Jupiter, Storms in Africa, Disco Beat, and Sunny Days. The volume of the music was set in advance and was the same for each child. Children listened to the music until the procedure was completed; in some cases, children did not listen to all 4 selections. Both groups received standard care (including topical anesthetics and techniques that staff would normally use to comfort the child such as talking to the child, explaining what is being done, and saying comforting and supportive things). For both groups, there were no restrictions around whether the parent could be present or how they interacted with their child during the procedure. Multiple health care providers performed the IV placements over the course of the study; the average years of experience for the attending nurse did not differ between groups (10 vs 11 years, $P = .69$).

## Outcomes

The primary outcome was patient distress measured using the Observational Scale of Behavioral Distress-Revised (OSBD-R).[23,24] The scale is reliable and has been validated in our target population.[24] The scale includes 8 behaviors; each behavioral category is weighted according to intensity. An overall score was calculated for each phase (preprocedure, during the procedure, and postprocedure) and for all phases combined using scoring procedures described by the tool developers.[23] This protocol for use of the OSBD-R is standardized[23,24] and has been used in other trials evaluating music in children.[8,25] The primary outcome assessments were completed by pretrained research assistants from viewings of video recordings of the procedure for each individual patient. Using advanced technological dubbing techniques, the same music heard by the intervention group was added to the video recordings of the control group so that the research assistants were blinded to each patient's allocation. Two trained research assistants independently observed the video recording of each child and recorded the frequency of distress-related behaviors every 15 seconds before, during, and after the procedure.

The secondary outcome was change in self-reported pain from baseline prior to the procedure to that recorded immediately following the initial attempt at IV placement. This was measured using the Faces Pain Scale-Revised (range, 0-10), which has been validated and is reliable for young children.[25,26] Assessment of pain scores occurred in a standardized fashion: at each of the 3 stages for pain scoring, the child was shown 6 faces suggesting increasing levels of pain and asked to point to the face that best described how much pain they felt at that moment. Additional outcomes included heart rate (measured with a cardiorespiratory monitor); parent and health care provider satisfaction (measured using Likert scales); and parent state anxiety measured with a validated instrument, the STAI.[27]

Table 1. Demographics by Group

| | Group, No. (%) | | |
|---|---|---|---|
| | Standard Care | Music | Total, No. (%) |
| Age, median (IQR), mo | 78 (50-110) | 64 (47-92) | 75.5 (48-101) |
| No. | 21 | 21 | 42 |
| Sex[a] | | | |
| Boys | 16 (84.2) | 10 (50) | 26 (66.7) |
| Girls | 3 (15.8) | 10 (50) | 13 (33.3) |
| Total, No. | 19 | 20 | 39 |
| Ethnic minority | | | |
| No | 15 (71.4) | 15 (71.4) | 30 (71.4) |
| Yes | 6 (28.6) | 6 (28.6) | 12 (28.6) |
| Total | 21 | 21 | 42 |
| Weight, median (IQR), kg | 27 (17-41.4) | 22 (16.4-29.5) | 24.8 (16.6-31.2) |
| No. | 19 | 21 | 40 |
| Temperature in celsius, median (IQR) | 37 (36.8-37.8) | 37 (36.7-37.7) | 37 (36.7-37.7) |
| No. | 20 | 21 | 41 |
| Systolic blood pressure, median (IQR), mm Hg | 114 (104-118) | 114 (97-121) | 114 (104-120.5) |
| No. | 21 | 19 | 40 |
| Diastolic blood pressure, median (IQR), mm Hg | 66 (61-68) | 67 (59-77) | 66.5 (59.5-73) |
| No. | 21 | 19 | 40 |
| Respiratory rate (breaths/min), median (IQR) | 20 (18.5-23) | 24 (19-26) | 20 (19-26) |
| No. | 20 | 21 | 41 |
| Heart rate (beats/min), median (IQR) | 113 (93-132) | 120 (99-150) | 113.5 (97-134) |
| No. | 21 | 21 | 42 |
| Premature | | | |
| No | 18 (85.7) | 17 (81) | 35 (83.3) |
| Yes | 3 (14.3) | 4 (19) | 7 (16.7) |
| Total | 21 | 21 | 42 |
| Previous ED visit | | | |
| No | 3 (14.3) | 6 (28.6) | 9 (21.4) |
| Yes | 18 (85.7) | 15 (71.4) | 33 (78.6) |
| Total | 21 | 21 | 42 |
| Previous hospitalization | | | |
| No | 15 (71.4) | 15 (71.4) | 30 (71.4) |
| Yes | 6 (28.6) | 6 (28.6) | 12 (28.6) |
| Total | 21 | 21 | 42 |
| Previous needle poke[b] | | | |
| No | 5 (23.8) | 9 (42.9) | 14 (33.3) |
| Yes | 16 (76.2) | 12 (57.1) | 28 (66.7) |
| Total | 21 | 21 | 42 |
| Parent-assessed distress during medical procedures | | | |
| 1 (no distress) | 4 (19) | 1 (5.3) | 5 (11.9) |
| 2 | 3 (14.3) | 0 (0) | 3 (7.1) |
| 3 | 5 (23.8) | 10 (52.6) | 15 (35.7) |
| 4 | 5 (23.8) | 2 (10.5) | 7 (16.7) |
| 5 (as distressed as possible) | 4 (19) | 6 (31.6) | 10 (23.8) |
| Total | 21 | 19 | 40 |

Abbreviations: ED, emergency department; IQR, interquartile range.

[a] Significant difference, $P = .04$.

[b] Parents were asked: Has your child ever had a needle poke in their vein to draw blood or put in an intravenous line?

## Sample Size and Power

Sample size was calculated using a 2-sided, 2-sample *t* test based on the primary outcome of observed behavioral distress. A previous study of children aged 4 to 7 years undergoing IV insertions provided variance data for OSBD-R scores (SD, 2.77).[28] To detect a difference of 2.5 given a type I error rate of 0.05 and 80% power, we required 21 children per group.

Table 2. Child Preferences by Group

| | Group, No. (%) | | |
|---|---|---|---|
| | Standard Care | Music | Total, No. (%) |
| Enjoy watching television | | | |
| Not at all | 0 (0) | 0 (0) | 0 (0) |
| Somewhat | 1 (4.8) | 1 (4.8) | 2 (4.8) |
| Moderately | 2 (9.5) | 4 (19) | 6 (14.3) |
| Very much | 18 (85.7) | 16 (76.2) | 34 (81) |
| Total | 21 | 21 | 42 |
| Enjoy listening to music | | | |
| Not at all | 2 (9.5) | 1 (4.8) | 3 (7.1) |
| Somewhat | 3 (14.3) | 1 (4.8) | 4 (9.5) |
| Moderately | 6 (28.6) | 4 (19) | 10 (23.8) |
| Very much | 10 (47.6) | 15 (71.4) | 25 (59.5) |
| Total | 21 | 21 | 42 |
| Frequency of watching television | | | |
| Never | 0 (0) | 0 (0) | 0 (0) |
| Rarely | 0 (0) | 1 (4.8) | 1 (2.4) |
| Sometimes | 9 (42.9) | 7 (33.3) | 16 (38.1) |
| Often | 12 (57.1) | 13 (61.9) | 25 (59.5) |
| Total | 21 | 21 | 42 |
| Frequency of listening to music | | | |
| Never | 1 (4.8) | 0 (0) | 1 (2.4) |
| Rarely | 3 (14.3) | 1 (4.8) | 4 (9.5) |
| Sometimes | 9 (42.9) | 5 (23.8) | 14 (33.3) |
| Often | 8 (38.1) | 15 (71.4) | 23 (54.8) |
| Total | 21 | 21 | 42 |

### Statistical Methods

Baseline variables were described using appropriate summary statistics. For the primary outcome (observed behavioral distress), a change score (during procedure minus preprocedure) was calculated for each child, and the mean change scores were compared between the study groups using the Mann-Whitney *U* test. Additional model-based analyses (multiple linear regression) were conducted with change in behavioral distress as the response variable and a group indicator as the explanatory variable along with some possible effect modifiers such as sex and age. Our primary analysis was based on an intention-to-treat approach where all children who were randomly assigned to a study group were included.

We considered the following explanatory variables in regression analyses: study group (standard care vs music), age, sex, ethnic minority (based on parent report), child premature (parent report), discharge disposition (discharged home, admitted to hospital, or other), previous ED visit (parent report), previous hospitalization (parent report), and previous IV start (parent report). Backward model selection was used with a probability for removal of 0.1 (ie, how significant the coefficient must be to avoid removal). Additional analyses were performed for a subgroup of children with nonzero OSBD-R scores during the IV placement. All statistical tests were performed at a significance level of .05 (2-sided) using SAS version 9 (SAS Institute).

## Results

We enrolled 42 patients (**Figure 2** and **Table 1**). The average age was 6 years (range, 3-11 years). Ten patients were younger than 4 years of age (6 in the music and 4 in the standard care groups), while 5 patients were between 4 and 5 years (3 in the music and 2 in the standard care groups). Sixty-seven percent of the patients were boys. There were more boys in the standard care group (84% vs 50%, $P = .04$), with no other significant differences between groups at baseline. Approximately 29% identified with an ethnic minority, 17% were premature at birth, 79% had previously been to the ED, 29% had previously been hospitalized, and 67% had previously had a needle poke. Parents provided an assessment of their children's distress levels during medical procedures in general: 36% indicated a moderate amount (distress score = 3 of 5), while 24% suggested a significant amount of distress (distress score = 5 of 5). **Table 2** provides information on children's enjoyment of and experience with music and television, with no differences between groups. The initial attempt at IV placement was not successful for 9 patients (2 in the music and 7 in the standard care groups).

In regard to the primary outcome, without controlling for other potential confounders, we found no difference in the change in behavioral distress from preprocedure to immedi-

Table 3. Scores on the Observational Scale of Behavioral Distress by Group

| | Group | | Total | *P* Value[a] |
|---|---|---|---|---|
| | Standard Care | Music | | |
| Weighted phase 1 score (preprocedure) | | | | |
| No.[b] | 16 | 20 | 36 | .03 |
| Mean (SD) | 0.17 (0.44) | 0.85 (1.07) | 0.55 (0.91) | |
| Median (IQR) | 0 (0 to 0.12) | 0.2 (0 to 2.12) | 0 (0 to 0.43) | |
| Range | 0 to 1.75 | 0 to 2.56 | 0 to 2.56 | |
| Weighted phase 2 score (during procedure) | | | | |
| No. | 21 | 21 | 42 | .27 |
| Mean (SD) | 3.35 (3.66) | 1.74 (2.15) | 2.55 (3.08) | |
| Median (IQR) | 2.21 (0.18 to 3.83) | 0.71 (0.18 to 2.92) | 1.87 (0.18 to 3.57) | |
| Range | 0 to 12.1 | 0 to 7.07 | 0 to 12.1 | |
| Weighted phase 3 score (postprocedure) | | | | |
| No.[c] | 9 | 13 | 22 | .61 |
| Mean (SD) | 1.05 (1.72) | 0.95 (1.86) | 0.99 (1.77) | |
| Median (IQR) | 0 (0 to 1.45) | 0 (0 to 0.21) | 0 (0 to 1.45) | |
| Range | 0 to 5 | 0 to 5.2 | 0 to 5.2 | |
| Total distress score[d] | | | | |
| No. | 8 | 13 | 21 | .54 |
| Mean (SD) | 5.54 (6.24) | 3.87 (4.91) | 4.51 (5.37) | |
| Median (IQR) | 3.49 (0.30 to 9.66) | 1.25 (0.07 to 5.45) | 2.75 (0.18 to 7.41) | |
| Range | 0 to 17.43 | 0 to 14.47 | 0 to 17.43 | |
| Phase 2 − Phase 1 score[e] | | | | |
| No.[b] | 16 | 20 | 36 | .15 |
| Mean (SD) | 2.71 (3.71) | 0.98 (1.63) | 1.75 (2.84) | |
| Median (IQR) | 1.84 (0 to 2.84) | 0.45 (−0.03 to 2.06) | 0.78 (0 to 2.23) | |
| Range | 0 to 11.78 | −2.25 to 4.86 | −2.25 to 11.78 | |

Abbreviation: IQR, interquartile range.

[a] Mann-Whitney *U* test.

[b] Data are missing where video recordings were not started until immediately before the procedure (ie, there was no preprocedure footage).

[c] Data are missing where videos were stopped immediately after the procedure (ie, there was no postprocedure footage).

[d] Summation of 3 weighted phase scores for those with all 3 phase scores.

[e] Weighted phase 2 (during procedure) score minus weighted phase 1 (preprocedure) score.

ately after the procedure (**Table 3**, $P = .15$). However, we conducted regression analyses, including potential explanatory variables, and in the final reduced model, the music intervention was of borderline significance to reduce the increase in distress (**Table 4**, $P = .05$) after adjusting for ethnic minority status. On average, less increase in distress was observed for those identifying with an ethnic minority (Table 4, $P = .06$). None of the other explanatory variables remained in the final model.

We examined the primary outcome, removing from the analysis the children who had no distress during the procedure (5 patients per group) because we rationalized that there was no potential for effect in this subgroup of children. The median changes in distress scores from before to immediately after the procedure were 2.2 (interquartile range [IQR], 1.7-8.7) and 1.1 (IQR, 0.1-2.4) for the standard care and music groups, respectively ($P < .05$). Furthermore, the regression analysis indicated that music significantly reduced the increase in distress (coefficient, −3.19; 95% CI, −5.75 to −0.63; $P = .02$), while none of the other explanatory variables remained in the final model.

Regarding the secondary outcomes, we found a significant difference in the change in pain scores between groups (**Table 5**). The pain score for the standard care group increased (median, 2; IQR, 0-4) but remained the same for the music group (median, 0; IQR, −4.0 to 0.5) from before to immediately after the procedure ($P = .04$). We found no difference between the groups in heart rate during the procedure ($P = .72$) or parent anxiety (Table 5). Parents generally showed moderate levels of anxiety with overall scores of 43 and 45 on the STAI preprocedure and postprocedure, respectively.

Parent satisfaction with management of the child's pain was different between groups, although not statistically significant (Table 5, $P = .07$). Seventy-six percent of parents in the music group were very satisfied compared with 52% in the standard care group ($P = .20$). There were no significant differences between groups in parent satisfaction with the IV start ($P = .49$), although more parents in the music group (62%) were very satisfied compared with the standard care group (48%) ($P = .54$). There was no difference when parents were asked whether they would use the same methods to manage pain for their children in the future.

Health care providers reported that it was easier to perform the procedure for children receiving music (76% very easy) vs standard care alone (38% very easy) ($P = .03$). Health care providers were more satisfied with the IV start in the music compared with the standard care group (86 vs 48% very satisfied, $P = .02$). There was no difference when providers were asked whether they would use the same methods to manage pain for another child undergoing an IV start.

Table 4. Summary of Regression Analyses

| Explanatory Variable[a] | Outcome Models: Full Model Coefficient (95% CI) | Full Model P Value | Reduced Model[b] Coefficient (95% CI) | Reduced Model P Value |
|---|---|---|---|---|
| **Total Patient Distress (OSBD-R) (n = 20)** | | | | |
| Group, music vs control | −5.24 (−11.71 to 1.23) | .10 | | |
| Age, 1 mo | −0.09 (−0.22 to 0.03) | .12 | | |
| Sex, girl vs boy | 1.31 (−6.66 to 9.29) | .72 | | |
| Ethnic minority, yes vs no | −6.21 (−14.45 to 2.03) | .12 | | |
| Premature, yes vs no | 2.38 (−4.62 to 9.38) | .47 | 5.31 (−0.22 to 10.85) | .06 |
| Disposition, admitted vs discharged home | 4.16 (−3.79 to 12.11) | .27 | | |
| ED, yes vs no | 9.13 (−4.76 to 23.03) | .17 | | |
| Hospitalization, yes vs no | −6.19 (−19.12 to 6.74) | .31 | | |
| Poke, yes vs no | 3.21 (−8.58 to 15) | .56 | | |
| **Change in Patient Distress Score (OSBD-R) (during procedure minus preprocedure; n = 33)** | | | | |
| Group, music vs control | −2.15 (−4.55 to 0.24) | .08 | −1.97 (−3.94 to 0) | .05 |
| Age, 1 mo | −0.02 (−0.06 to 0.02) | .31 | | |
| Sex, girl vs boy | −0.51 (−3.06 to 2.03) | .68 | | |
| Ethnic minority, yes vs no | −1.56 (−3.92 to 0.8) | .18 | −1.99 (−4.06 to 0.07) | .06 |
| Premature, yes vs no | 0.62 (−2.05 to 3.28) | .64 | | |
| Disposition, admitted vs discharged home | 1.17 (−1.33 to 3.67) | .34 | | |
| ED, yes vs no | 0.52 (−3.17 to 4.22) | .77 | | |
| Hospitalization, yes vs no | 0.65 (−2.72 to 4.03) | .69 | | |
| Poke, yes vs no | −0.91 (−3.63 to 1.8) | .49 | | |
| **Change in Parental Anxiety Score (STAI) (postprocedure minus preprocedure; n = 30)** | | | | |
| Group, music vs control | −4.63 (−13.7 to 4.44) | .30 | | |
| Age, 1 mo | 0.08 (−0.05 to 0.21) | .22 | 0.1 (−0.01 to 0.21) | .08 |
| Sex, girl vs boy | −3.36 (−13.14 to 6.42) | .48 | | |
| Ethnic minority, yes vs no | −8.89 (−17.57 to −0.22) | .04 | −8.21 (−16.15 to −0.27) | .04 |
| Premature, yes vs no | 4.19 (−4.78 to 13.16) | .34 | | |
| Disposition, admitted vs discharged home | −2.55 (−11.22 to 6.12) | .55 | | |
| ED, yes vs no | −17.4 (−31.64 to −3.16) | .02 | −9.66 (−20.52 to 1.19) | .08 |
| Hospitalization, yes vs no | 5.83 (−4.9 to 16.56) | .27 | | |
| Poke, yes vs no | 4.03 (−5.51 to 13.57) | .39 | | |
| **Change in Patient Pain Score (FPS) (preprocedure minus postprocedure; n = 37)** | | | | |
| Group, music vs control | −0.76 (−2.41 to 0.90) | .36 | | |
| Age, 1 mo | 0.02 (−0.01 to 0.04) | .21 | | |
| Sex, girl vs boy | −0.60 (−2.47 to 1.27) | .52 | | |
| Ethnic minority, yes vs no | −0.34 (−2.06 to 1.38) | .69 | | |
| Premature, yes vs no | 0.93 (−1.10 to 2.96) | .36 | | |
| Disposition, admitted vs discharged home | 2.26 (0.64 to 3.87) | .008 | 2.11 (0.70 to 3.53) | .005 |
| ED, yes vs no | −0.03 (−2.08 to 2.01) | .97 | | |
| Hospitalization, yes vs no | 1.05 (−0.84 to 2.95) | .27 | | |
| Poke, yes vs no | −0.68 (−2.47 to 1.12) | .45 | | |

Abbreviations: ED, emergency department; FPS, Faces Pain Scale; OSBD-R, Observational Scale of Behavioral Distress–Revised; STAI, State-Trait Anxiety Inventory.

[a] For each binary explanatory variable, the latter category is the reference category.

[b] For the first 3 response variables, if the probability for removal was 0.05 (ie, how significant the coefficient must be to avoid removal), none of the explanatory variables remained in the final model.

The results of the regression analysis are summarized in Table 4. For total distress score, prematurity was the only variable that remained in the reduced model, indicating that children who had been born prematurely had greater total distress score ($P = .06$). For change in distress score from before to immediately after the procedure, the study group (ie, music or standard care) and ethnic minority remained in the reduced model, indicating that the standard care group had greater increase in distress ($P = .05$), while those identifying with an ethnic minority had less increase in distress ($P = .06$). For change in parental anxiety, age of the child, ethnic minority, and previous ED visit remained in the final model. That is, parents with older children had a greater increase in anxiety ($P = .08$), while those who identified with an ethnic minority ($P = .04$) and those with a previous ED visit ($P = .08$) had less increase in anxiety. For change in pain score, disposition from the ED was significant ($P = .005$), indicating that those who were admitted from the ED had greater increase in pain.

Table 5. Other Outcomes by Group

| | Group, No. (%) | | Total, No. (%) | *P* Value[a] |
|---|---|---|---|---|
| | Standard Care | Music | | |
| Faces Pain Score (preprocedure), median (IQR) | 2 (0 to 4) | 2 (0 to 7) | 2 (0 to 6) | .71[a] |
| No. | 21 | 20 | 41 | |
| Faces Pain Score (postprocedure), median (IQR) | 4 (0 to 8) | 2 (0 to 6) | 4 (0 to 8) | .20[a] |
| No. | 21 | 21 | 42 | |
| Faces Pain Score change (postprocedure − preprocedure), median (IQR) | 2 (0 to 4) | 0 (−4 to 0.5) | 0 (0 to 4) | .04[a] |
| No. | 21 | 20 | 41 | |
| Heart rate during procedure (beats/min), mean (SD) | 128.7 (28.9) | 126.3 (27.0) | 127.5 (27.6) | .72[a] |
| No. | 21 | 21 | 42 | |
| Parent satisfaction with IV start | | | | |
| 1 (very dissatisfied) | 2 (9.5) | 0 (0) | 2 (4.8) | .49[b] |
| 2 (somewhat dissatisfied) | 2 (9.5) | 0 (0) | 2 (4.8) | |
| 3 (neither satisfied nor dissatisfied) | 3 (14.3) | 3 (14.3) | 6 (14.3) | |
| 4 (somewhat satisfied) | 4 (19) | 5 (23.8) | 9 (21.4) | |
| 5 (very satisfied) | 10 (47.6) | 13 (61.9) | 23 (54.8) | |
| Parent satisfaction with management of child pain | | | | |
| 1 (very dissatisfied) | 1 (4.8) | 0 (0) | 1 (2.4) | .07[b] |
| 2 (somewhat dissatisfied) | 0 (0) | 1 (4.8) | 1 (2.4) | |
| 3 (neither satisfied nor dissatisfied) | 1 (4.8) | 2 (9.5) | 3 (7.1) | |
| 4 (somewhat satisfied) | 8 (38.1) | 2 (9.5) | 10 (23.8) | |
| 5 (very satisfied) | 11 (52.4) | 16 (76.2) | 27 (64.3) | |
| Would you use the same methods to manage pain for your child? | | | | |
| No | 3 (15) | 3 (15) | 6 (15) | >.99[b] |
| Yes | 17 (85) | 17 (85) | 34 (85) | |
| Easy or difficult to perform the IV start | | | | |
| 1 (very difficulty) | 3 (14.3) | 1 (4.8) | 4 (9.5) | .06[b] |
| 2 (somewhat difficulty) | 3 (14.3) | 1 (4.8) | 4 (9.5) | |
| 3 (neither easy nor difficult) | 0 (0) | 1 (4.8) | 1 (2.4) | |
| 4 (somewhat easy) | 7 (33.3) | 2 (9.5) | 9 (21.4) | |
| 5 (very easy) | 8 (38.1) | 16 (76.2) | 24 (57.1) | |
| Provider satisfaction with the child IV start | | | | |
| 1 (very dissatisfied) | 4 (19) | 2 (9.5) | 6 (14.3) | .07[b] |
| 2 (somewhat dissatisfied) | 2 (9.5) | 0 (0) | 2 (4.8) | |
| 3 (neither satisfied nor dissatisfied) | 2 (9.5) | 0 (0) | 2 (4.8) | |
| 4 (somewhat satisfied) | 3 (14.3) | 1 (4.8) | 4 (9.5) | |
| 5 (very satisfied) | 10 (47.6) | 18 (85.7) | 28 (66.7) | |
| Would you use the same methods to manage another child pain? | | | | |
| No | 1 (4.8) | 1 (4.8) | 2 (4.8) | >.99[b] |
| Yes | 20 (95.2) | 20 (95.2) | 40 (95.2) | |
| Parent anxiety score preprocedure, mean (SD) | 41.89 (9.57) | 44.37 (10.18) | 43.16 (9.83) | .53[a] |
| No. | 18 | 19 | 37 | |
| Parent anxiety score postprocedure, mean (SD) | 45.67 (11.17) | 44.1 (14.07) | 44.84 (12.64) | .85[a] |
| No. | 18 | 20 | 37 | |
| Parent anxiety score change (postprocedure − preprocedure), median (IQR) | 1 (−9 to 10) | 0 (−2 to 4) | 0 (−4 to 8) | .76[a] |
| No. | 15 | 18 | 33 | |

Abbreviations: IQR, interquartile range; IV, intravenous.

[a] Mann-Whitney *U* test.

[b] Fisher exact test.

## Discussion

The music group showed numerically smaller average values and lower range extremes in distress scores; however, the difference between groups in our primary outcome of change in behavioral distress was not statistically significant overall. Despite this result, we observed some interesting findings. Regression analyses showed that music was of borderline significance to reduce the increase in distress (Table 4, $P = .05$)

after adjusting for ethnic minority. A subgroup analysis showed that for those children with any level of distress during the procedure, music had a significant distress-reducing effect that may be considered clinically important.[29-31] It is intuitive that an intervention to decrease distress can only be effective in those individuals who actually have distress. This is supported by our earlier systematic review showing that music may be more effective for those children at higher risk for pain and anxiety.[22]

Our secondary outcome measure, change in pain score, was significantly different between groups favoring the music intervention. Furthermore, the difference of 2 points (or 1 face) on the Faces Pain Scale–Revised is considered clinically important.[32] The median baseline pain score preprocedure for both groups was not zero, although the painful stimulus had not been applied yet. This may be because children unwell enough to warrant venipuncture may have been experiencing some discomfort from their underlying illness, or the pain measurement tool may in fact have reflected some distress or apprehension. We found no difference in heart rate between groups, consistent with growing evidence suggesting that heart rate as a proxy measure of pain is not reliable.[33,34]

There were no differences between groups in parental anxiety during the procedure. The fact that parents had moderate anxiety is clinically important in light of emerging evidence that parental anxiety can increase anxiety in the child.[35,36] Health care providers found it easier to perform the procedure and were more satisfied with the procedure for the music group. Any easy-to-implement and low-cost intervention that also contributes to efficiency of care and provider job satisfaction may have some important but as-of-yet largely unmeasured benefits.

We conducted exploratory analyses to examine whether other variables had an effect on outcomes. These findings may provide direction for future research. For instance, prematurity was associated with increased total observed distress, while identifying with an ethnic minority was associated with less increase in distress. Premature babies are well known to exhibit more long-standing anxious behaviors than full-term babies.[37,38] The explanation for reduced anxiety if a member of an ethnic minority may be owing to cultural differences in experience, perceptions, or expectations. With respect to parental anxiety, those with a previous ED visit had decreased anxiety. It is possible that a previous visit lessens anxiety, as a parent is more familiar with the routines and with what to expect. Children admitted to hospital had a greater increase in pain score than those discharged home. It is plausible that children who are sick enough to be admitted to hospital may be more sensitive to pain or less able to deal with pain physiologically or psychologically. Pain thresholds may be lower in unwell individuals and descending inhibitory pathways, which are strongly influenced by neuroendocrine modulators, may be at suboptimal function during times of physiological distress.

### Considerations Regarding the Intervention

The music for this trial was selected by a music therapist. The music was not necessarily familiar to the children, rather it contained a variety of rhythms, instruments, and themes in an effort to serve as a distractor. It is uncertain whether unfamiliar (and possibly more interesting) or familiar (and perhaps more comforting) music is more effective. Recent studies of music and brain physiology suggest that areas of the brain related to emotion regulation and neuroendocrine reward systems are more active for familiar relative to unfamiliar music.[39] Furthermore, exposure to happy vs sad and lyric vs lyric-free music can influence the location and strength of neurological activation.[40] These complex considerations may be highly relevant to the likelihood of effectiveness of a particular musical selection, and many of the intricacies surrounding the most effective approach to a musical intervention remain unanswered including allowing patients to choose their own music.

### Limitations

We were unable to blind the children, parents, and care providers to the study group. However, to our knowledge, this is one of the few studies that has blinded the individuals assessing the primary outcome. This methodological characteristic helps prevent detection bias, which may result in an overestimate of the effectiveness of the intervention. Another methodological challenge was contamination between study groups. As the ED personnel became more aware of the trial, some parents of children in the control group were encouraged to sing to their children. This effect would reduce the ability to detect differences between the groups, which adds strength to our findings. Finally, we did not allow the patients to choose the music they listened to. If the music selected for this study was unappealing to patients, it may have reduced the effectiveness of the intervention.

### Future Directions

Further trials of the effect of music on pain and distress are warranted, particularly in different settings and for different clinical procedures. Larger samples with stratification of subjects based on baseline distress levels is important to consider. A multimodal approach to analgesia may have relevance for anxiety-reducing strategies.[41-44]

## Conclusions

Music may have a positive impact on pain and distress in children undergoing IV placement. Benefits observed for the parents and health care providers have important clinical implications.

ARTICLE INFORMATION

**Accepted for Publication:** January 10, 2013.

**Published Online:** July 15, 2013. doi:10.1001/jamapediatrics.2013.200.

**Author Contributions:** *Study concept and design:* Hartling, Liang, Jou, Hewson, Klassen, Curtis. *Acquisition of data:* Hartling. *Analysis and interpretation of data:* Hartling, Newton, Liang, Curtis. *Drafting of the manuscript:* Hartling, Newton, Klassen, Curtis. *Critical revision of the manuscript for important intellectual content:* Liang, Jou, Hewson, Curtis. *Statistical analysis:* Liang.

*Obtained funding:* Hartling.
*Administrative, technical, and material support:* Hartling, Jou, Hewson.
*Study supervision:* Hartling, Newton, Klassen, Curtis.

**Conflict of Interest Disclosures:** Drs Hartling and Newton are supported by New Investigator Salary Awards from the Canadian Institutes of Health Research.

**Funding/Support:** This trial was supported by a grant from the Women and Children's Health Research Institute in Edmonton, Canada.

**Additional Contributions:** We thank the research coordinators in the emergency department, Erin Logue, RN, MN, and Joyce Chikuma, for their assistance implementing the study protocol, recruiting patients, and managing data. We thank the research assistants who also assisted with patient recruitment and data collection including Chris Bon and Lysiane Knox. We thank Liza Bialy, MPH, and Annabritt Chisholm at the Alberta Research Center for Health Evidence for research support (database development, data entry, and video management). We thank Kyra Klein, BA, and Hansen Zhou, BA, for performing the behavioral distress assessments.

## REFERENCES

**1**. Press J, Gidron Y, Maimon M, Gonen A, Goldman V, Buskila D. Effects of active distraction on pain of children undergoing venipuncture: who benefits from it? *Pain Clin*. 2003;15(3):261-269.

**2**. Singer T, Seymour B, O'Doherty J, Kaube H, Dolan RJ, Frith CD. Empathy for pain involves the affective but not sensory components of pain. *Science*. 2004;303(5661):1157-1162.

**3**. Jacobson S. Common medical pains. *Paediatr Child Health*. 2007;12(2):105-109.

**4**. MacLean S, Obispo J, Young KD. The gap between pediatric emergency department procedural pain management treatments available and actual practice. *Pediatr Emerg Care*. 2007;23(2):87-93.

**5**. Young KD. Pediatric procedural pain. *Ann Emerg Med*. 2005;45(2):160-171.

**6**. Petrack EM, Christopher NC, Kriwinsky J. Pain management in the emergency department: patterns of analgesic utilization. *Pediatrics*. 1997;99(5):711-714.

**7**. Zempsky WT, Cravero JP; American Academy of Pediatrics Committee on Pediatric Emergency Medicine and Section on Anesthesiology and Pain Medicine. Relief of pain and anxiety in pediatric patients in emergency medical systems. *Pediatrics*. 2004;114(5):1348-1356.

**8**. Megel ME, Houser CW, Gleaves LS. Children's responses to immunizations: lullabies as a distraction. *Issues Compr Pediatr Nurs*. 1998;21(3):129-145.

**9**. Curry SL, Russ SW. Identifying coping strategies in children. *J Clin Child Psychol*. 1985;14(1):61-68. doi:10.1207/s15374424jccp1401_10.

**10**. Maclaren JE, Cohen LL. Interventions for paediatric procedure-related pain in primary care. *Paediatr Child Health*. 2007;12(2):111-116.

**11**. Lander JA, Weltman BJ, So SS. EMLA and amethocaine for reduction of children's pain associated with needle insertion. *Cochrane Database Syst Rev*. 2006;3(3):CD004236.

**12**. Ramsook C, Kozinetz CA, Moro-Sutherland D. Efficacy of ethyl chloride as a local anesthetic for venipuncture and intravenous cannula insertion in a pediatric emergency department. *Pediatr Emerg Care*. 2001;17(5):341-343.

**13**. Farion KJ, Splinter KL, Newhook K, Gaboury I, Splinter WM. The effect of vapocoolant spray on pain due to intravenous cannulation in children: a randomized controlled trial. *CMAJ*. 2008;179(1):31-36.

**14**. MacLaren JE, Cohen LL. A comparison of distraction strategies for venipuncture distress in children. *J Pediatr Psychol*. 2005;30(5):387-396.

**15**. Murphy G. Distraction techniques for venepuncture: a review. *Paediatr Nurs*. 2009;21(3):18-20.

**16**. Wilson JE, Pendleton JM. Oligoanalgesia in the emergency department. *Am J Emerg Med*. 1989;7(6):620-623.

**17**. Rupp T, Delaney KA. Inadequate analgesia in emergency medicine. *Ann Emerg Med*. 2004;43(4):494-503.

**18**. Fosnocht DE, Swanson ER, Barton ED. Changing attitudes about pain and pain control in emergency medicine. *Emerg Med Clin North Am*. 2005;23(2):297-306.

**19**. Uman LS, Chambers CT, McGrath PJ, Kisely S. Psychological interventions for needle-related procedural pain and distress in children and adolescents. *Cochrane Database Syst Rev*. 2006;(4):CD005179.

**20**. Kleiber C, Harper DC. Effects of distraction on children's pain and distress during medical procedures: a meta-analysis. *Nurs Res*. 1999;48(1):44-49.

**21**. Aitken J, Wilson S, Coury D, Moursi AM. The effect of music distraction on pain, anxiety and behavior in pediatric dental patients. *Pediatr Dent*. 2002;24(2):114-118.

**22**. Klassen JA, Liang Y, Tjosvold L, Klassen TP, Hartling L. Music for pain and anxiety in children undergoing medical procedures: a systematic review of randomized controlled trials. *Ambul Pediatr*. 2008;8(2):117-128.

**23**. Jay SM, Elliott C. *Observation Scale of Behavioral Distress-Revised: Information Procedures, Definitions of Behaviors, OSBD Interval Coding Form*. Los Angeles, CA: Children's Hospital; 1986.

**24**. Elliott CH, Jay SM, Woody P. An observation scale for measuring children's distress during medical procedures. *J Pediatr Psychol*. 1987;12(4):543-551.

**25**. Noguchi LK. The effect of music versus nonmusic on behavioral signs of distress and self-report of pain in pediatric injection patients. *J Music Ther*. 2006;43(1):16-38.

**26**. Hicks CL, von Baeyer CL, Spafford PA, van Korlaar I, Goodenough B. The Faces Pain Scale–Revised: toward a common metric in pediatric pain measurement. *Pain*. 2001;93(2):173-183.

**27**. Spielberger CD. *State-Trait Anxiety Inventory: A Comprehensive Bibliography*. Palo Alto, CA: Consulting Psychologists Press; 1984.

**28**. Kleiber C, Craft-Rosenberg M, Harper DC. Parents as distraction coaches during i.v. insertion: a randomized study. *J Pain Symptom Manage*. 2001;22(4):851-861.

**29**. Kennedy RM, Porter FL, Miller JP, Jaffe DM. Comparison of fentanyl/midazolam with ketamine/midazolam for pediatric orthopedic emergencies. *Pediatrics*. 1998;102(4, pt 1):956-963.

**30**. Luhmann JD, Kennedy RM, Porter FL, Miller JP, Jaffe DM. A randomized clinical trial of continuous-flow nitrous oxide and midazolam for sedation of young children during laceration repair. *Ann Emerg Med*. 2001;37(1):20-27.

**31**. Stevenson MD, Bivins CM, O'Brien K, Gonzalez del Rey JA. Child life intervention during angiocatheter insertion in the pediatric emergency department. *Pediatr Emerg Care*. 2005;21(11):712-718.

**32**. von Baeyer CL. Children's self-reports of pain intensity: scale selection, limitations and interpretation. *Pain Res Manag*. 2006;11(3):157-162.

**33**. Bossart P, Fosnocht D, Swanson E. Changes in heart rate do not correlate with changes in pain intensity in emergency department patients. *J Emerg Med*. 2007;32(1):19-22.

**34**. Bartfield JM, Janikas JS, Lee RS. Heart rate response to intravenous catheter placement. *Acad Emerg Med*. 2003;10(9):1005-1008.

**35**. McMurtry CM, Chambers CT, McGrath PJ, Asp E. When "don't worry" communicates fear: children's perceptions of parental reassurance and distraction during a painful medical procedure. *Pain*. 2010;150(1):52-58.

**36**. Vervoort T, Goubert L, Vandenbossche H, Van Aken S, Matthys D, Crombez G. Child's and parents' catastrophizing about pain is associated with procedural fear in children: a study in children with diabetes and their mothers. *Psychol Rep*. 2011;109(3):879-895.

**37**. Scher MS, Waisanen H, Loparo K, Johnson MW. Prediction of neonatal state and maturational change using dimensional analysis. *J Clin Neurophysiol*. 2005;22(3):159-165.

**38**. Patural H, Barthelemy JC, Pichot V, et al. Birth prematurity determines prolonged autonomic nervous system immaturity. *Clin Auton Res*. 2004;14(6):391-395.

**39**. Pereira CS, Teixeira J, Figueiredo P, Xavier J, Castro SL, Brattico E. Music and emotions in the brain: familiarity matters. *PLoS One*. 2011;6(11):e27241.

**40**. Brattico E, Alluri V, Bogert B, et al. A functional MRI study of happy and sad emotions in music with and without lyrics. *Front Psychol*. 2011;2:308.

**41**. Mak WY, Yuen V, Irwin M, Hui T. Pharmacotherapy for acute pain in children: current practice and recent advances. *Expert Opin Pharmacother*. 2011;12(6):865-881.

**42**. Yaster M. Multimodal analgesia in children. *Eur J Anaesthesiol*. 2010;27(10):851-857.

**43**. Kraemer FW. Treatment of acute pediatric pain. *Semin Pediatr Neurol*. 2010;17(4):268-274.

**44**. Kraemer FW, Rose JB. Pharmacologic management of acute pediatric pain. *Anesthesiol Clin*. 2009;27(2):241-268.