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Procedural Sedation and Analgesia in Children in Emergency Department—Role of Adjunct Therapies

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Abstract

Objective: To compare sedation efficacy and parent/consultant satisfaction between standard sedation, sedation with music listening, and sedation with Certified Child life Specialists (CCLS) in children undergoing procedural sedation in the Pediatric Emergency Department (PED). **Methods:** Eligible children, aged 3 - 18 years, were randomly allocated to one of 3 groups: 1) standard sedation; 2) sedation with music listening; 3) sedation with CCLS intervention. All 3 groups received intravenous ketamine. The child life group received age appropriate comforting measures, while the music group listened to music of their choice during the procedure. The primary outcome was sedation efficacy, measured by Ramsay Sedation scale, FACES-P scale and need for re-dosing. The secondary outcome was parent/consultant satisfaction. **Results:** Fifty nine patients were analyzed (standard sedation: 20; sedation with music listening: 20; and sedation with CCLS: 19). There was no significant difference in mean initial ketamine dosing (1.58 ± 0.44 vs. 1.68 ± 0.36 vs. 1.42 ± 0.47, p = 0.26). There was no significant difference in median Ramsay Sedation scores [6(IQR:4,6) vs. 6 (IQR:4,6) vs. 6 (IQR:5,6)], FACES-R pain score [0 (IQR:0.0) vs. 0 (IQR:0.0) vs. 0 (IQR:0.0)] and need for re-dosing [9/20 (45%) vs. 4/20 (20%) vs. 8/19 (42.1%)] amongst the 3 groups. Parent and consultant satisfaction was high in all 3 groups. **Conclusion:** Our pilot study did not demonstrate a difference in sedation efficacy or parent/consultant satisfaction when adjunct therapies were used during PSA. Further studies with a large sample size are needed to define the role for such adjunct therapies during procedural sedation in PED.

Keywords

Procedural Sedation, Music Therapy, Certified Child Life Specialists, Emergency

Department, Children

1. Introduction

Providing pain relief associated with diagnostic and therapeutic procedures is an ethical requirement in children. Additionally, it is measured as a quality of care component from the perspective of family for Pediatric Emergency Department (PED) visit. Procedural Sedation and Analgesia (PSA) is increasingly being used in the PED to relieve children of pain, stress and anxiety during painful and unpleasant procedures while maintaining an adequate cardiorespiratory function. While serious adverse events are rare, PSA is associated with adverse events primarily affecting airway and respiratory system, in a small subset of patients [1]. Furthermore, PSA can entail obtaining an intravenous access which by itself is a painful procedure. Hence, it is important to study the role of non-invasive modalities in reduction of pain and anxiety in children undergoing painful procedures in the PED.

Certified Child Life Specialists (CCLS) are formally trained professionals who establish therapeutic relationships with pediatric patients by presenting age appropriate information on procedures, providing play experiences and comforting measures as well as helping children and their families cope with anxiety and the stresses of being in the hospital. They have been shown to reduce behavioral stress during painful procedures in the ED [2] [3], but their role during PSA has not been well defined. Music therapy's capacity to decrease levels of stress, anxiety, and pain in patients is well documented in various health care settings [4] [5] [6]. Furthermore, it has been shown to decrease patient's requirements in sedative and analgesic needs [7] [8]. However, the role of music therapy as an adjunct to PSA in the PED has not been studied.

The objective of our study was to compare the sedation efficacy as well as consultant and parental satisfaction between standard sedation, standard sedation with music listening, and standard sedation with CCLS intervention in children who undergo PSA in the PED for painful (orthopedic, laceration repair, incision and drainage) procedures.

2. Methods

2.1. Study Design and Setting

We conducted a prospective randomized control trial of standard sedation vs. standard sedation with child life intervention vs. standard sedation with music listening in children aged 3 to 18 years of age who required IV ketamine for PSA for orthopedic procedures, laceration repairs and incision and drainage of abscess (I & D) in a PED over a one period from October 2015-2016. Our PED is a level 1 trauma center attached to a free-standing children's hospital with 92,000 patient visits annually. Of these, approximately 1200 children receive PSA for

painful procedures. Written informed consent was obtained from the parents or legal guardian of the patient. In addition, an assent was collected from all children > 7 years of age. This study was approved by the Institutional Review Board (IRB). The study was registered at ClinicalTrials.gov, Identifier: NCT02518919.

2.2. Study Inclusion and Exclusion Criteria

Children between the ages of 3 to 18 years with American Society of Anesthesiologists (ASA) classification I or II [9] who required IV ketamine for PSA for orthopedic procedures, I & D of skin abscess and laceration repair were eligible for participation in the study. We enrolled a convenience sample of eligible patients based on availability of the research assistants and child life personnel. Study participants were identified using an electronic medical tracking board, which lists the presenting complaint and after the need for PSA with IV ketamine was established by the research assistant with the treating physician.

We excluded the following patients from the study:

1) Children with known allergy to or contraindications to use of ketamine;
2) Children who received intramuscular, intranasal or oral sedation or sedation medications other than ketamine;
3) Those who had experienced previous adverse events with ketamine;
4) Those who receive sedation for procedures not listed in the inclusion criteria;
5) Those who are outside the age range listed above;
6) Those whose parent or legal guardian was not available or declined to provide informed consent for the study, or if the child declined to provide assent.

2.3. Study Interventions

Study subjects were randomized into 3 groups: 1) standard sedation; 2) standard sedation with music listening; 3) standard sedation with CCLS intervention. Randomization was performed by a pharmacist from the Investigational Drug Section of the Pharmacy Department via a computer generated random number table. The study research assistant would assign the patient to the randomization group by opening a sealed envelope after informed consent was obtained.

For study subjects assigned to the standard sedation with CCLS intervention group, trained child life personnel introduced the procedure to the child and family. The child life specialist also provided comforting measures appropriate to the age of the patient and according to the patient's and family's preference during the placement of intravenous line and throughout the procedure. The child life specialist also explained the procedure to the child using a teaching doll and real as well pretend medical equipment. There are two child life specialists who work in our PED from 3 pm - midnight during the weekdays.

Those study subjects assigned to the music listening arm were asked to select music of their choice. We felt that the music listening intervention would be more effective if the patient was allowed to listen to the music of their choice rather than to preselected music. The patient listened to the music of their choice

downloaded using icloud via ipad using headphones during the placement of intravenous line as well as during the entire procedure. The study research assistant pre set the volume of music to be the same level for all study patients.

The family was allowed to stay with their child during the procedure and interact with the child for all the three study groups based on their choice.

Children enrolled in the study received sedation after a pre-sedation assessment using current institutional guidelines as applied to all PED sedation patients. Patients were monitored using published sedation guidelines with measurements of vital signs and pulse oximetry at baseline, every 5 minutes during the procedure and post procedure for the entire duration of sedation. The dose of sedation medication administered was left to the discretion of the sedation physician. The research team neither participated nor intervened during the sedation or with the clinical care of the patient. The research assistant however observed the sedation and recorded the sedation depth and pain scores during and after the sedation.

2.4. Study Measurements

The following variables were collected by a trained research assistant: patient demographics, eligible procedure type, NPO status, ASA classification, type and dose of pain medication administered prior to sedation, initial ketamine dosing in mg/kg, need for re-dosing, sedation related adverse events, interventions performed to overcome adverse events and ED disposition. Sedation related adverse events were defined using the standardized definitions provided by the Quebec Guidelines for ED sedation terminology and reporting of adverse events in children [10].

The trained research assistant documented sedation efficacy using the Ramsay Sedation Scale [11] and at the following time points:

- Pre-sedation (three minutes prior to study drug administration);
- During the procedure (after ketamine administration and prior to and after any re-dosing);
- Post sedation (prior to discharge).

Severity of pain was assessed using Faces Pain Scale [12] on a scale of 0 - 10 (0: no pain - 10: most pain, respectively) during three time points mentioned above. During sedation, pain severity was determined by the research assistant using the patient's facial expression and/or response. No facial expression and/or lack of response throughout the sedation were scored as zero. Pre- and post-sedation pain severity were self-assessed using a verbal response from the study subjects.

In addition, a 3-point Likert scale (not satisfied, satisfied, or very satisfied with the sedation) was used to assess sedation efficacy by the parent as well as the physician performing the procedure.

2.5. Outcome Measures

The primary outcome measure for this study was the sedation efficacy as meas-

ured by Ramsay Sedation scale, FACES-P scale during sedation and the number of additional doses of ketamine administered to achieve adequate sedation. The secondary outcome measure was consultant and parent satisfaction using Likert scale.

2.6. Statistical Analysis

A database and coding scheme were created using Excel® to host all data collected for this study. The research assistant performed double data entry to verify accuracy. Categorical data was analyzed and reported using numbers and percentages. The normality of continuous scaled data was tested by Kolmogorov-Smirnov test and reported using mean and standard deviation, whereas non-normally distributed continuous data are reported by median and inter quartile range. Pearson's Chi-squared Test or Fisher's exact test was used to analyze the distribution of categorical data by groups. Comparisons of two or more normal continuous variables is conducted using Student t test and ANOVA respectively, whereas non-normally distributed continuous variables are compared using the Wilcoxon rank sum test and Kruskal-Wallis (ANOVA for ranks) tests. We used SAS (version 9.4, SAS Institute Inc. Cary, North Carolina) to perform statistical analyses. Significance level was set at 0.05. Since this was a pilot study, we did not perform a power analysis or sample size calculation.

3. Results

A total of 419 patients underwent PSA in the PED during the study period. Of these, 356 patients were excluded and 63 patients were randomized for the study as follows: standard sedation (n = 21), standard sedation with music listening (n = 21) and standard sedation with CCLS intervention (n = 21). Protocol violation occurred in 4 patients. Two of these patients were assigned to the CCLS intervention group but the child life personnel were unavailable. In two other patients, the sedation physician and the mother requested the presence of CCLS during sedation though these patients were assigned to standard sedation and standard sedation with music listening respectively. These four patients were excluded from the final study analysis (**Figure 1**).

There was a higher proportion of girls in the child life group but there was no difference in race and ethnicity, ASA classification, indication for PSA, administration of pre procedural pain medication amongst the study three groups (**Table 1**). There was no significant difference in the mean initial dose of IV ketamine (1.58 ± 0.44 vs. 1.68 ± 0.36 vs. 1.42 ± 0.47; p = 0.26) or the proportion of children who required re-dosing amongst the 3 groups [9/20 (45%) vs. 4/20 (20%) vs. 8/19 (42.1%)] (**Figure 2**).

There was no difference in the median Ramsay Sedation scores [6 (IQR:4.6) vs. 6 (IQR:4.6) vs. 6 (IQR:5.6)] and FACES-R score [0 (IQR:0.0) vs. 0 (IQR:0.0) vs. 0 (IQR:0.0)] during sedation between the three groups. A higher proportion of children experienced adverse event secondary to vomiting in the music listening

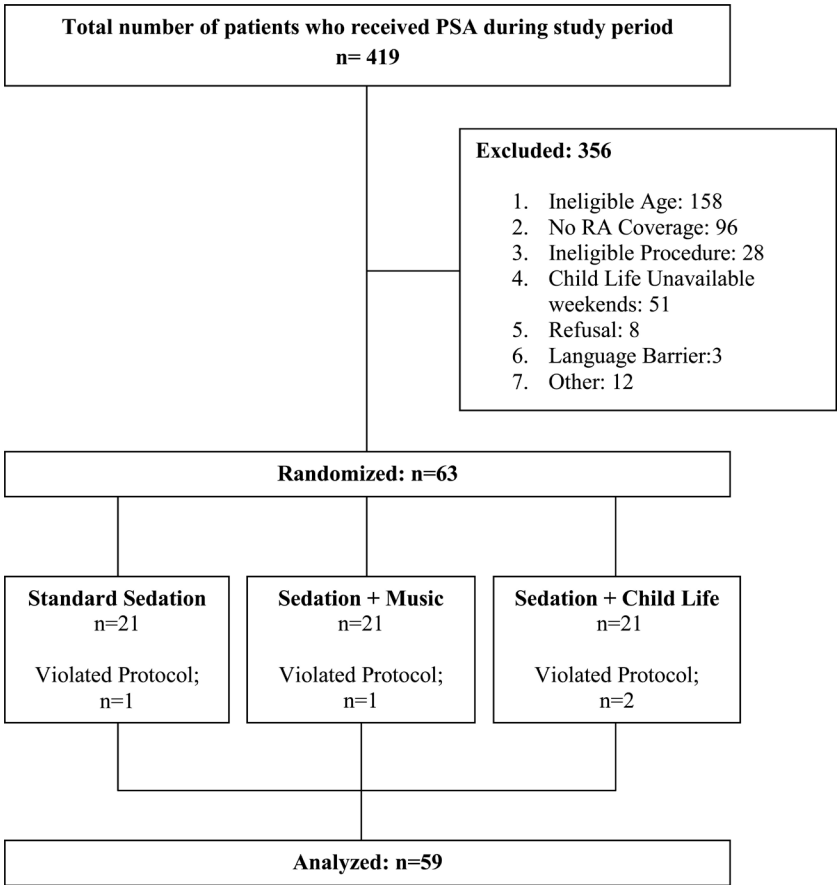

Figure 1. Study flow diagram.

Table 1. Patient demographics of the three study groups.

Variable		Standard sedation n = 20	Standard sedation with music listening = 20	Standard sedation with CCLS n = 19	p value
Age	Median, IQR	5.0 (4.5, 9.5)	8.5 (6.5, 11.0)	9.0 (6.0, 11.0)	0.12
Gender	Male	12	14	6	0.04
	Female	8	6	13	
Race	African American	12	9	10	0.12
	Caucasian	4	9	3	
	Asian	2	1	3	
	Mixed	0	1	0	
	Other	2	0	3	
Ethnicity	Hispanic	2	0	2	0.45
	Non-Hispanic	18	20	17	
ASA	I	16	15	16	0.92
	II	4	5	3	
Procedure type	Fracture/dislocation reduction	12	16	13	0.80
	Incision and drainage	1	1	2	
	Laceration repair	7	3	4	
Pre-sedation pain medications	Yes (Any)	14	10	14	0.25
	No	6	10	5	

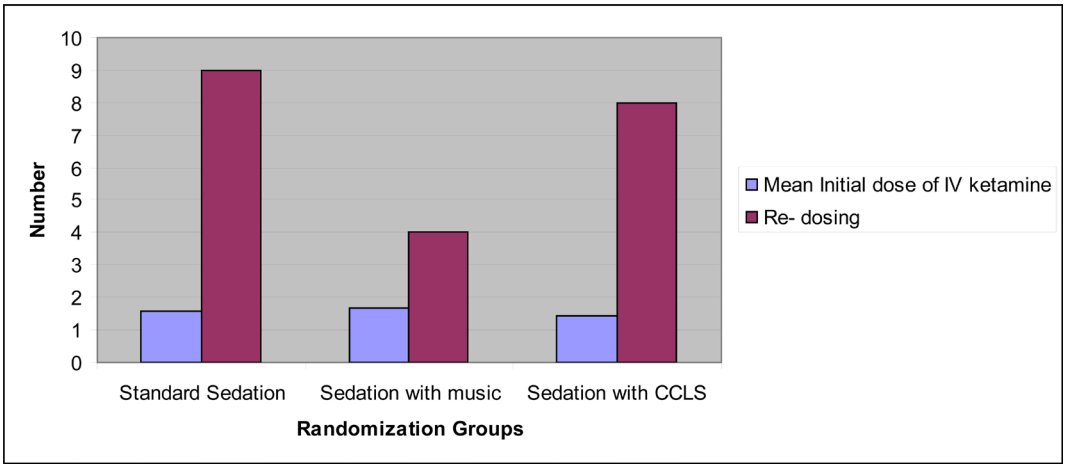

Figure 2. Mean initial dosing of ketamine and need for re-dosing amongst the three study groups.

group but the difference was not statistically significant [3/29 (15%) vs. 8/20 (40%) vs. 3/19 (15.8%), p = 0.12]. The most common adverse event was vomiting in all 3 groups. Three children experienced oxygen desaturation, one in standard sedation group and two in child life group.

Consultants were either "satisfied" [13/20 (65%) vs. 8/20 (40%) vs. 6/19 (31.6%)] or "very satisfied" with the sedation [7/20 (35%) vs. 12/20 (60%) vs. 13/19 (68.4%); p = 0.09]. Parental satisfaction was similarly high (satisfied or very satisfied) in the 3 groups [20/20 (100%) vs. 19/20 (95%) vs. 18/19 (94.7%); p = 0.12].

4. Discussion

Non-pharmacological interventions are an integral part of pain management in the PED along with pain medications. Unlike pharmacological interventions, non-pharmacological interventions have the advantage of lack of adverse events, being able to be tailored to the needs of the particular child as well as providing the patient with a sense of control. Child life intervention and music therapy are two such non-pharmacologic interventions which have been shown to have a positive impact on pain and distress in children. While previous studies have evaluated the efficacy of such interventions in reducing pain and anxiety associated with procedures in children, ours is the first study to our knowledge to evaluate the effects of these interventions on sedation medication requirements and sedation efficacy in a PED.

Scott *et al.* [13] evaluating the effectiveness of CCLS on the frequency of use of daily anesthesia in a pediatric oncology unit showed an absolute reduction of 16% in children aged 3 to 12 years with a significant reduction from 62.3% to 28.8% in children aged 5 to 8 years of age. Another study showed that the institution of mandatory child life consultation in a Magnetic Resonance Imaging suite led to avoidance of general anesthesia in 102 patients during a one year intervention period with the avoidance of sedation being particularly significant in the older age group of children between 5 to 10 years [14]. In a systematic review

of randomized controlled trials on the efficacy of music therapy in children undergoing clinical procedures, Klassen *et al.* [15] showed that music therapy resulted in a significant reduction in pain and anxiety and concluded that it may be considered as an adjunct therapy during painful procedures. Walworth *et al.* [16] examined the cost effectiveness of music therapy as procedural adjunct for computerized tomograms, echocardiograms and other procedures and concluded that music therapy-assisted procedures resulted in successful elimination of sedation, reduction in procedural times and decrease in the number of staff members present for the procedures.

Previous studies have shown higher parent and physician satisfaction scores and a lower perception of child's pain and distress with increased patient cooperation and ease of performance of procedure with CCLS intervention and music therapy compared to standard intervention [6] [17]. While our study did not demonstrate a difference in satisfaction or pain scores amongst the three groups perhaps due to the small sample size, it did show high satisfaction scores in both the intervention groups.

Non-pharmacologic adjuncts play a crucial role in improving the preparation, coping and adjustment of the child to painful procedure and therefore should be offered to families and children along with pharmacologic interventions. Further, passive music therapy which was used in our study is relatively easy to implement and is not limited by availability of trained personnel. Such non-pharmacologic approaches should be integrated into clinical care along with procedural sedation to create a pain-free environment for children in PED.

5. Limitations

Our study has several limitations. We enrolled a convenience sample of eligible patients based on availability of research assistants and child life personnel. The sample size was small as this was a pilot study. There were protocol violations in four study patients who were excluded from the final analysis. Study subjects chose the music of their own choice which meant that there were different forms of music that they listened to during the procedure. We did not control for this difference in our analysis. The study could not be blinded for obvious reasons. We did not randomize study patients by the procedure type, which could have confounded the sedation medication dose. However, the majority of patients enrolled in all three study groups underwent PSA for orthopedic procedures.

6. Conclusion

Our pilot study demonstrates a role for adjunct therapies such as child life therapy and music listening during PSA in children in the ED. Further studies with a larger sample size are needed to evaluate if such adjunct therapies can reduce the sedation medication dose or eliminate the need for intravenous sedation for certain procedures in the ED.

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Conflicts of Interest

The authors have no conflicts of interest to disclose.

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Abbreviations

PED: Pediatric Emergency Department

PSA: Procedural Sedation and Analgesia

CCLS: Certified Child Life Specialists