

EFFICACY OF MUSIC THERAPY IN THE REDUCTION OF REQUIREMENT OF SEDATIVE AGENTS, IN SURGERIES PERFORMED UNDER CAUDAL ANAESTHESIA: A ONE YEAR DOUBLE BLINDED RANDOMIZED CONTROLLED TRIAL

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ABSTRACT: CONTEXT: Paediatric patients undergoing surgeries under regional anaesthesia require adequate sedation. Various intravenous agents and inhalational anaesthetics have been used for this purpose. The purpose of this study is to establish a relationship between music and intra operative requirement of sedative agents (inhalational and intravenous agents) in pediatric patients undergoing surgeries under caudal epidural anaesthesia. **AIM:** The aim of this study is to establish a relationship between music and reduction in intra operative requirement of sedative agents (inhalational and intravenous agents) in pediatric patients undergoing surgeries under caudal epidural anaesthesia. **SETTINGS AND DESIGN:** One year hospital based double blinded randomized clinical controlled trial. **MATERIALS AND METHODS:** 50 ASA grade I and II children in the age group of 1 to 6 years who were scheduled for herniotomy were included in this study. Children were randomly divided into two groups A and B. All the children received 1 ml/kg body weight of 0.25% bupivacaine in caudal epidural space, in addition all the a head phone was applied in all the children, the children in Group A were played a classical Indian music via head phone whereas children in Group B were devoid of any music in the intra operative period. SpO₂, ECG, NIBP were monitored intra operatively. Level of sedation using "Ramsay Sedation Scale". If the sedation scale was < 3, Inj.midazolam-0.03 mg/kg was administered i.v. as and when required, so that the maximum dose did not cross 0.6mg/kg⁴. If the midazolam requirement exceeded the maximum dose then adequate sedation scores were achieved using sevoflurane. The total number of doses of sedatives required and the total dose required were noted. **STASTICAL ANALYSIS:** The data was analyzed using the Mann Whitney test and Student's t test comparing the sedation scores of between the two groups. **RESULTS:** The demographic parameters, duration of surgery were comparable. 18 out of 25 children in Group A had no further requirement of sedative agents. Whereas only 5 out of 25 children in Group B did not require additional sedative agents. None of patients required inhalational agents. **CONCLUSION:** Music therapy is associated with reduced requirements of sedative agents in the form of inhalational or intravenous agents in children undergoing surgical procedures under caudal epidural anaesthesia.

KEYWORDS: Caudal Epidural, Music Therapy, Intra operative sedation.

INTRODUCTION: Music has been used for the treatment of depressive and behavioral disorders,¹ from the studies it is evident that it reduces the stress levels in the patients. It also increases the acceptance of procedure by the patient² along with reduction in pain intensity levels.³

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The aim of this study is to establish a relationship between music and reduction in intra operative requirement of sedative agents (inhalational and intravenous agents) in pediatric patients undergoing surgeries under caudal epidural anaesthesia.

METHODS: Patient Selection: The study protocol was approved by Institutional Ethics Committee. This prospective randomized double blind clinical trial was conducted in K.L.E.S. Dr. Prabhakar Kore Hospital and M.R.C. over a period of one year and included 50 ASA grade I and II children in the age group of 1 to 6 years who were scheduled for herniotomy after obtaining written informed consent from the parent/guardian. Exclusion criteria were children with ASA physical status grade II& IV, history of allergy to any of the study drugs, hearing loss, infection at the site of block, bleeding diathesis, pre-existing neurological problems and abnormalities of sacrum.

GENERAL PROCEDURE: Children were kept nil by mouth for 6 hours pre-operatively, on the day of surgery, children were shifted to the operation theatre after pre medicating with Inj. Glycopyrolate-18 micrograms/kg and Inj. Ketamine-2mg/kg body weight administered intramuscularly.

Monitors were attached which included SpO₂, ECG, NIBP. Intravenous access was secured in right hand using 26G cannula, while oxygen was delivered using a paediatric venti mask. Inj. midazolam-0.05mg/kg was given i.v. and induction was done using Ketamine-2mg/kg. Caudal anaesthesia was administered in a dose of-1ml/kg body weight of 0.25% Bupivacaine.

Children in Group A would listen to Indian classical instrumental song played repeatedly via head phone and those in Group B would listen to a blank soundtrack, headphones were applied and secured with tissue plasters and the attending anesthesiologist without knowing which soundtrack is being played, assessed the level of sedation using "Ramsay Sedation Scale" as mentioned below:

Grade I: Anxious and agitated or restless, or both.

Grade II: Co-operative, oriented, and calm.

Grade III: Responsive to commands only.

Grade IV: Exhibiting brisk response to light glabellar tap or loud auditory stimulus.

Grade V: Exhibiting a sluggish response to light glabellar tap or loud auditory stimulus.

Grade VI: Unresponsive.

If the sedation scale was < 3, Inj. midazolam-0.03 mg/kg was administered i.v. as and when required, so that the maximum dose did not cross 0.6mg/kg⁴. If the midazolam requirement exceeded the maximum dose then adequate sedation scores were achieved using sevoflurane. The total number of doses of sedatives required and the total dose required were noted.

The data was analyzed using the student's t test comparing the sedation scores of between the two groups. Null hypothesis was framed which stated that there was no difference between the two groups and this would be rejected if P was found <0.05.

STATISTICAL ANALYSIS: The statistical analysis was done using SPSS for Windows version 15.0 software. Data were presented as median, mean (SD) or frequency as appropriate. The requirement of additional doses of sedation was compared using Mann-Whitney test and Student "T" test for the two groups. p value of <0.05 was considered to be significant.

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RESULTS:

Demographics and statistical Data:

	Group A	Group B
Age (years)	3.8 ± 1.30	3.6 ± 1.24
Sex (Male/Female)	12/13	15/10
Duration (Minutes)	61 ± 12.67	66.9 ± 14.9

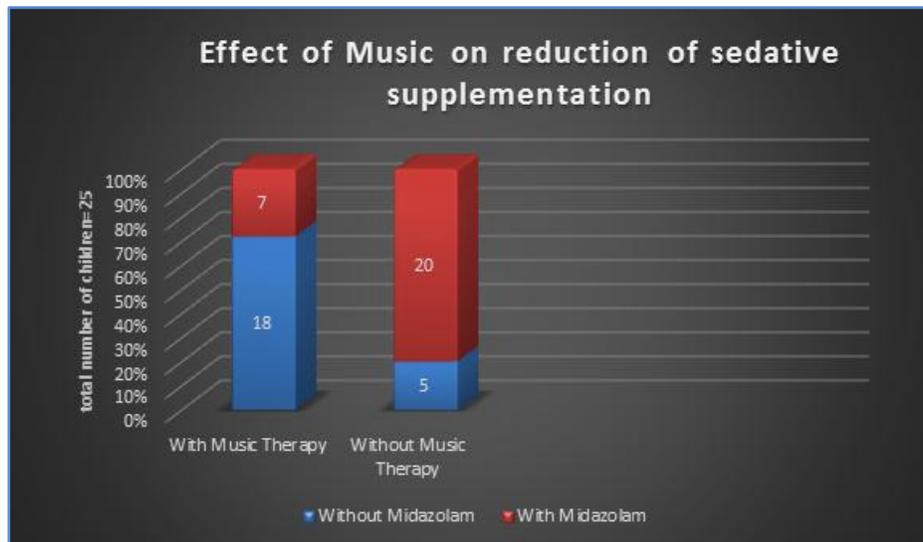
TABLE 1

In our study, the two groups are comparable in terms of age, sex and duration of surgery.

	Group A	Group B
Total no. of patients who required further sedation	7	20
Average no of additional doses of sedation required	0.28	2.1
Maximum additional doses of sedation required	1	6

TABLE 2

In our study, we found that 18 out of 25 children in Group A had no further requirement of sedative agents. Whereas only 5 out of 25 children in Group B did not require additional sedative agents. None of patients required inhalational agents.



The P value was obtained using the above data which was found to be 0.0012, which rejected the null hypothesis and the difference between the two groups was found to be statistically significant.

DISCUSSION: Sedation is always necessary in a pediatric population for various procedures like MRI, foreign body removal and as an adjuvant in the intra operative period. Benzodiazepines can cause respiratory depression in a dose dependent manner, and ketamine causes emergence delirium.

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According to recent studies, Ketamine has been found to cause behavior and memory abnormalities especially in children <3 years, even though reflexes are intact risk of aspiration is present⁵ and these commonly used drugs have upper limit. For these reasons a non-pharmacologic approach of music therapy will be advantageous as its adverse effects are not evident and it reduces pain anxiety and stress.

Music therapy has been used to reduce the requirement of sedatives in procedures under spinal anaesthesia in adults.⁶ Yilmaz E, et. al concluded that extra corporeal shock wave lithotripsy could be performed safely with music therapy as it had adequate anxiolytic effects.⁷ Camara J G et, al. found that the vital signs of the patients undergoing ophthalmic surgery under local anaesthesia were lower in the set of those who patients who listened to live classical piano music compared to the control group. This was attributed to the anxiolytic effects of music therapy.⁸

In our study, we found that this form of therapy reduced the additional doses of sedatives required in paediatric patients. Based on these results we hope that music can also be useful in other age groups and a variety of surgeries as an adjuvant to regional anaesthesia.

CONCLUSION: Use of Music therapy is associated with reduced requirements of sedative agents in the form of inhalational or intravenous agents in children undergoing surgical procedures under caudal epidural anaesthesia.

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