Indian Journal of
Applied Radiology

Open Science Publications

Volume 9, Issue 1 - 2023

www.opensciencepublications.com

MRI Scanning in Young Children: Child-Focused Play Intervention Reduces Sedation and Improves Parental Satisfaction

Research Article

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Article Information: **Submission: 14/09/2021; Accepted: 16/01/2023; Published: 19/01/2023**

Abstract

Objective: To examine the impact of a non-invasive strategy, such as a customized play activity, in reducing the need for sedation in young children undergoing diagnostic magnetic resonance imaging (MRI).

Methodology: A randomized controlled trial design was used. All children (4-7 yrs) undergoing diagnostic MRI at the department of paediatrics of a tertiary care hospital were eligible for enrolment. The exclusion criteria included history of development delay, previous MRI scan, and acute traumatic or painful condition. A total of 164 children (83 in control and 81 in intervention arm) were recruited. The intervention involved familiarization with MRI procedure and scanner using a mock scanner, training the child to stay motion free in the machine, and providing the child multiple trial-runs of the MRI imaging with a favoured toy.

Results: The two groups of children were matched on age, gender, and education level of the mother. The percentage of children receiving sedation in the intervention group was 49.4% and this was lower than the control group (63.8%), however, the difference did not approach statistical significance (χ^2=3.5, P=0.06). Comparison of the groups on the secondary outcome measure of ease of performing scan by the ratings of a radiologist, blinded to group status, revealed that a significantly higher proportion of the intervention group scans were reported to be easy or extremely easy, relative to the control group (χ^2=10.83, P= 0.013).

Conclusion: The study underscores the need for using a child-centric approach in diagnostic testing as this considerably improves family satisfaction and reduces need for sedation.

Keywords: MRI; Child-Focused Play Intervention; Sedation, Parental Satisfaction

Introduction

Magnetic resonance imaging (MRI) is a commonly used procedure in children to get the structural details of the organs. The procedure itself is painless and non-invasive but the MRI scanner environment for children is anxiety-provoking. The scanning procedure requires children to remain motionless for a prolonged duration of time in an enclosed and unfamiliar equipment, be exposed to loud noises, and sometimes also involves needle insertion for intravenous administration of contrast agents [1]. The distress

ISSN: 2581-3919

children experience during the procedure can lead to restlessness, excessive crying, and refusals contributing to poor quality imaging and delays in diagnosis and treatment. Excessive distress can also have a profound effect on the physical and psychological well-being of children [2]. In order to circumvent some of these adverse effects, the current clinical practice uses sedation in children to guarantee good quality MRI scans. Some of the associated medical risks of sedation include cardio- respiratory depression, airway obstruction, motor imbalance, hypoxia, and hypotension [3]. Since anaesthesia is detrimental to the child's safety, several ethical concerns for its use in diagnostic testing have been raised [4].

Several behavioral interventions have been developed to reduce head motions during neuro-imaging sessions, increase relaxation, and promote procedural understanding as alternatives to sedation among children [5]. Some of these interventions include the creation of a child and family-friendly MRI environment [6], use of play and guided imagery [7], mock scanner training educational training using toy scanners, videos, play tunnels, and audio simulations [8], virtual reality [9], video-based education [10], relaxation and distraction techniques [11], and psychological interventions (clown shows, music, pets) [12]. All these interventions have been reported to be advantageous in reducing anxiety before and during an MRI procedure.

Using child-friendly techniques to reduce distress before medical procedures and surgery is routinely used in the West; however, their use in India is relatively recent. Indeed, in India, clinicians spend little time for preparing children or their families for the radiological investigations. Some of the reasons cited include constraints of time, an excessive rush of patients, and lack of awareness of alternative techniques. One drawback of the research on alternatives to sedation among children is that most studies have focused on older patients. The present study redresses this imbalance by extending previous literature on a much larger sample of younger children using a wider range of outcome measures. Specifically, the present study aimed to study the impact of an MRI customized play activity on the need for sedation in young children aged 4-7 years undergoing diagnostic MRI using a randomized control trial study design.

Methodology

The study was designed as a prospective randomized controlled trial and all children undergoing Diagnostic MRI at the department of pediatrics of a tertiary care hospital in the age group of 4 to 7 were eligible for enrolment. The exclusion criteria included a history of development delay, previous MRI scan, and acute traumatic or painful condition. A total of 164 children (83 in the control arm and 81 in the intervention condition) were recruited. The flow chart of the study is presented in Figure 1. Group allocations were done based on computer-generated varying block randomization procedure wherein allocations were sequentially numbered and hidden in opaque sealed envelopes. Written informed consent was obtained from parents before randomization and ethical approval was obtained by the Institute's ethics committee.

Sample Size Calculation: The size of the sample was calculated assuming the fraction requiring sedation in the control group as

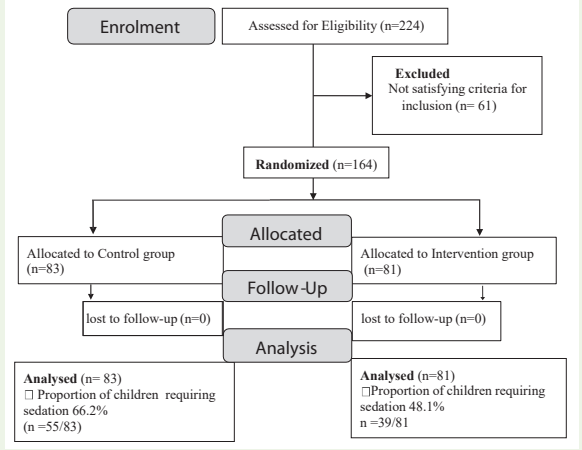

Figure 1: Study flow chart.

40% and the ability to bring an absolute reduction of 20% in the intervention group, with the power of 80% and an alpha error of 5%. These assumptions were based on our previous research study.

Procedure: The detailed MRI customized play activity intervention used in the present study has been standardized and described in our previous study [7]. Briefly, the intervention involved three phases of training. In the first phase of the training, children were familiarized with the procedure and the MRI scanner using a mock scanner machine. During this phase, the child was repeatedly exposed to the loud acoustic noise in the scanner. The child was also asked to select his/her favorite doll/toy and this was placed in the MRI model and the child was allowed free play. In the second phase, the child was trained to stay motion free in the machine by playing games like 'turning to stone.' In the final phase of the training, the child was asked to carry out multiple trial-runs of the MRI imaging with the favorite doll/toy. On the day of the imaging, one of the training team members accompanied the child and the parent/caregiver for the procedure. Twenty minutes was allowed before imaging, and in case the radiologist, who was blinded to the study, felt that the child would not cooperate during the MRI procedure, the child was sedated as per the standard protocol.

The primary outcome measure was the percentage of children requiring sedation by group status. In addition, two secondary outcomes were selected. The first was the ease of conducting the procedure rating by the radiologist, who was masked to the group allocation, on a 4-point Likert scale ranging from very difficult to very easy. The second secondary outcome was the rating of the parent/caregiver on the satisfaction with the procedure (dissatisfied or satisfied).

Results

The mean age of the sample was 5.61 years (SD=1.01) and the study population was primarily from urban areas (81%). The randomized intervention and control groups were well matched and did not differ on age (t=.11, P=0.701) and gender of the child (χ^2=1.39, P=0.239), and education level of the mother (χ^2=3.75, P=0.154.) However, nearly twice as many children from the upper socio-economic status

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group in the intervention group as compared to the control group (χ^2=10.31, P= 0.006) (Table 1).

Table 2 presents the comparison of the two groups on primary and secondary outcomes. The percentage of children receiving sedation in the intervention group was 49.4% and this was lower than the percent receiving sedation in the control group (63.8%). The absolute risk difference in being sedated during the MRI procedure was 14.4% lower in the intervention group (with 95% CI of 29.5% lower to 0.5% higher risk in the intervention group). The risk ratio (RR) of receiving sedation during MRI was 23% lower in the intervention relative to the control group (RR 0.77, 95% CI: 0.59-1.02; P= 0.06). Although more than half (56%) of the children in the intervention group did not require any sedation during MRI scan as compared to a lower proportion of control subjects, the difference showed a trend although it did not approach statistical significance (χ^2=3.50, P= 0.061).

Comparison of the groups on the secondary outcome measure of ease of performing scan by the ratings of a radiologist, blinded to the group status, revealed that a significantly higher proportion of the intervention group scans were reported to be easy or extremely easy, relative to the control group (χ^2=10.83, P= 0.013). In fact, the relative risk of an MRI being reported as "very easy" increased by 1.77 times in the intervention as compared to the control group (RR 1.77; 95% CI: 1.33-2.35) and this effect size was significant (P= 0.0035). In addition, a higher percentage of the parents of children in the intervention group (74.1%) were satisfied with the procedure as compared to a much lower percentage of parents from the control group (22.7%) (χ^2=26.82, P=0.001). The risk of parents reporting as 'not satisfied' with the MRI procedure decreased by nearly 60% in children who underwent the play-based intervention as compared to the control group (RR 0.39; 95% CI: 0.26-0.58) and this result was also significant (P=0.001). These results demonstrate that play-based intervention was useful in reducing the dose of sedatives and parental dissatisfaction with the procedure.

Discussion

The primary objective of the study was to examine the impact of a non-invasive strategy, such as a customized play activity, in reducing the need for sedation in young children (4-7 yrs) undergoing diagnostic MRI, using a randomized control trial study design. The findings indicate that the use of a play-based technique substantially reduced the need for general anesthesia relative to controls. These results extend previous findings and add to the literature by demonstrating that young children too can benefit significantly from a play-based structured intervention in the Indian setting. Previous studies have documented the positive benefits of interventions with older children [7,13] and demonstration of effectiveness in young cognitively immature children is limited, especially in low-resource settings. The combination of the MRI scanner model and play activity intervention is a cost-effective, safe, engaging, and fun way to reduce the frequency of sedation in young children. There are several other advantages as well such as increase in consumer safety, parental satisfaction, easing the flow of patients in the radiologic

Table 1: Demographic and Socio-economic Characteristics by Groups

Variable	Control (n = 83) Percent (n)	Intervention (n = 81) Percent (n)	t ratio/ χ^2	P value
Age (yrs) Mean (SD)	5.62 (1.00)	5.60 (1.03)	.11	.912
Age groups (yrs) 4 to 5 5 to 6 6 to 7	 30.1 (25) 27.7 (23) 42.2 (35)	 35.8 (29) 23.5 (19) 40.7 (33)	.71	.701
Gender Boys Girls	 59.0 (49) 41.0 (34)	 67.9 (55) 32.1 (26)	1.39	.239
Education (mother) < 10 10-12 Graduate	 56.2 (41) 35.6 (26) 8.2 (6)	 56.1 (37) 25.8 (17) 18.2 (12)	3.75	.154
Socioeconomic categories Lower middle Upper lower Upper middle	 60.2 (50) 15.7 (13) 24.1 (20)	 40.7 (33) 11.1 (9) 48.1 (39)	10.31	.006

Table 2: Comparison of Groups on the Primary and Secondary Outcome Measures

Outcomes	Control (n =83) Percent (n)	Intervention (n = 81) Percent (n)	χ^2	P value
Need for Sedation No Yes	 36.1 (30) 63.9 (53)	 50.6 (41) 49.4 (40)	3.50	.061
Ease of doing procedure (Radiologist rating) Very easy Easy Difficult Very difficult	 4.8 (4) 33.7 (28) 32.5 (27) 28.9 (24)	 19.8 (16) 30.9 (25) 18.5 (15) 30.9 (25)	10.83	.013
Procedure Duration < 30 mins > 30 mins	 22.9 (19) 77.1 (64)	 40.0 (32) 60.0 (48)	5.55	.019
Satisfaction (caregiver rating) Dissatisfied Satisfied	 66.7 (55) 22.7 (28)	 25.9 (21) 74.1 (60)	26.82	.001

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units, and substantially lowering the burden of management during the procedure. Notably, for younger children, the benefits of learning from a live three-dimensional demonstration far exceed the benefits of viewing it on a two-dimensional video screen [14-15].

Previous studies conducted in the developing countries have demonstrated the use of play- based techniques with younger children and with children with neurodevelopmental disorders. For example, in a retrospective audit study, Carter et al found that the need for general anesthesia in the mock MRI group was 17% lower relative to the non-mock MRI group for 3 to 8 yr olds [16]. Barnea-Goraly et al in a multi-site study used a commercial MRI scan simulator or an inexpensive mock scanner for imparting behavioral training to 222 type 1 diabetic patients and age-matched healthy controls (4-10 yrs). The success rates of behavioral desensitization for obtaining a non-sedated high-quality MRI scan reported were very high (93% for inexpensive mock scanner and 95% for the commercial mock scanner) [8]. Variable success rates have been reported ranging from 30 to 94% depending on the age of the children and the procedure used [7,16-17]. Indeed, familiarizing children regarding the MRI procedure in child-friendly settings and educational training before the actual scan reduces distress and apprehension in children and their families and makes the actual scanning easier [6,8].

Two secondary outcome measures also demonstrated the usefulness of the play intervention. Blind ratings by the radiologist indicated that the ease of diagnostic procedure was significantly facilitated and the chances of MRI procedure being rated 'very easy' increased more than 4 times in children who underwent the play intervention activity. In addition, the caregiver level of satisfaction with the MRI procedure was significantly enhanced for the intervention group. Previous research has reported a decline in anxiety among children and parents after a preparation trial with children [18]. For example, Rothman et al. found that parental anxiety significantly dropped after a pre-MRI intervention which comprised of multiple interactive preparation resources (instructional booklet, movie, and simulator practice) used with children aged 5-16 yrs [18].

Children have many unmet informational needs when they attend hospitals and undergo clinical and diagnostic procedures. Addressing these needs can further enhance cooperation and allay anxiety [19]. It is important to recognize that practice with mock MRI scanners combined with play-based activity, like the one we have used; although useful are costly in terms of time and manpower resources. Keeping some of these constraints in mind, newer research has now shifted to designing internet-based tools with some measure of success [9,20- 21]. For example, Ashmore et al. have developed the virtual reality app which via videos presents the child with a panoramic view of the entire MRI procedure [9]. Such technologies, which are freely accessible, provide immense opportunities to further improve the quality and outreach of the pediatric neuroimaging services. Culturally relevant educational materials or internet based preparatory videos can be another option for wider applicability of use across ages. Clearly, there is a need to develop innovative, cost-effective, non-invasive, and accessible strategies to reduce sedation and distress in children undergoing pediatric radiology procedures.

The study has several strengths including a strong design, rigorous implementation of random allocation, and concealment thereby significantly reducing the confounding and selection bias. Even though blinding the intervention from the treating team and the investigator was not feasible, the radiologist team was blinded to the group allocation. Secondly, the sample size was adequate with a nearly balanced distribution of children in the two groups. Finally, children included in the study represented a relatively homogenous age group with an easily documentable and objective outcome of sedation. Indeed, there are several indirect benefits of having such an ongoing educational and training program for children undergoing radiological diagnostic investigations as it increases awareness about the risks associated with use of general anesthesia on a regular basis to the pediatric and radiological staff who are associated with this program [16,22]. The main limitation of the study is the baseline imbalance in the distribution of children from different socioeconomic strata in the two groups. Possibly, this may have underestimated the benefits of the intervention as most children from the intervention arm were from the higher socioeconomic groups.

In conclusion, the study underscores the need for using a child-centric approach in diagnostic testing as this considerably improves family satisfaction and quality of neuro-imaging in the pediatric population. Future extensions of this work should investigate the positive impact of having an ongoing educational program regarding the risks associated with general anesthesia in pediatric centres, and the feasibility of using play-based strategies for imaging across different clinical populations including children with neurodevelopmental disorders.

Key Messages

What is Already Known?

1. The distress that children experience during the MRI procedure can lead to restlessness and excessive crying contributing to poor quality imaging and delays in diagnosis and treatment.
2. Using child-friendly techniques to reduce distress before medical procedures and surgery is routinely used in the West; however, their use in India is limited.

What this Study Adds?

1. Child-centric play techniques improve quality of neuro-imaging in young children undergoing diagnostic radiological investigations.
2. Using child-friendly techniques to reduce distress among young children before medical procedures is possible even in busy pediatric centres.

Contributions of the Authors: BB, PM, and AKS conceived and designed the study. BB and PM trained PPK to conduct the study. BB and PM analyzed and interpreted the data. PM drafted the manuscript. All the authors critically reviewed the manuscript and are responsible for the final approval of the manuscript.

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