Sedative Regimens for Pediatric patients undergoing Diagnostic Magnetic Resonance Imaging (MRI)

Roshan Radhakrishnan, Shubhada Aphale, Manjula Shantaram

Abstract

**Background:** Neonates, infants and children frequently require sedation for diagnostic imaging procedures such as MRI or Computed Tomography (CT) to minimize motion artifacts. Pediatric patients who undergo radiologic procedures usually need both sedation and analgesia to endure the procedure and aid optimal conditions.

**Objectives:** The aim of this work was to study the two sedative regimens currently used for diagnostic MRI in our setup and devise a near effective protocol. This would aim at optimal sedation and simultaneously minimize the rate of complications in pediatric age group.

**Methods and Materials:** In this study, 60 pediatric patients up to the age group of five years with American Society of Anesthesiologists (ASA) Class I – III undergoing MRI studies were assessed. Our study was carried out with two sedative regimens routinely used in our setup. All the children in our study were supervised by anesthesia personnel, with appropriate monitoring and resuscitation equipment available at hand. They were observed following the procedure for a minimum of 2 hours in the recovery room and discharged only after ensuring that there were no post sedation complications.

**Results:** Both the groups showed no incidence of adverse events both during the procedure and in the recovery room. This suggests that in addition to having comparable efficacy and success rate with each other, both the multi-drug combinations are safe for sedation in pediatric age groups undergoing diagnostic MRI.

**Conclusion:** Different setups will have various regimens of sedation for MRI studies in pediatric patients. This study emphasizes the importance of forming a fixed protocol for sedative regimens by testing these regimens and modifying them to suit individual setups.

**Keywords:** MRI, sedative regimen, pediatric patients, anesthesia, diagnosis
INTRODUCTION:
Magnetic Resonance Imaging (MRI), or nuclear magnetic resonance imaging (NMRI), is primarily a medical imaging technique commonly used in radiology to envisage the internal structure of the body as it offers much greater contrast between the different soft tissues of the body than Computed Tomography (CT). Many techniques in radiology such as CT scanning and MRI require the pediatric patient to lie absolutely still for the acquisition of the images which may take from a few minutes up to an hour. For the procedure to be undertaken successfully, often there is a need for adequate sedation which in children is different from adults.

The set up in the radiology department may be remote from the main operative set ups, which makes giving sedation in these locations more risky due to inadequate facilities, lack of immediate help or trained personnel. There is a presence of a wide variety of formulations for pediatric sedation and they vary greatly. These regimens are usually influenced by a spectrum of factors including the practitioner’s preferences, cost effectiveness, the presence of co-morbid conditions in the child and the hospital set up. Often the requirement of a diagnostic facility like MRI indicates an underlying high risk pathology which may have anesthetic implications. These may include delayed milestones, congenital anomalies, convulsions or systemic infections. As a result of these pathologies, various drawbacks are encountered in the form of inadequate sedation, a longer recovery time, associated cardiovascular and respiratory complications besides a host of drug-related side effects.

A perfect sedation regimen should produce a rapid and expected response, with an appropriate degree and duration of sedation for the procedure carried out. In practice, this may be extremely difficult to attain and many sedative regimens are inadequate. There is significant unpredictability in the pharmacokinetics and pharmaco-dynamics of sedative drugs in children such that responses to sedation may change from slight depression of conscious level to anesthesia. Considering all these aspects, it was decided to study two sedative regimens currently used for diagnostic MRI in our setup and devise a near effective protocol which would aim at optimal sedation and simultaneously minimize the rate of complications in pediatric age group.

MATERIALS AND METHODS

Selection of patients:
In this study, 60 patients up to the age group of five years with American Society of Anesthesiologists (ASA) Class I – III undergoing MRI studies were assessed.
Children who were excluded from the study in whom sedation was contraindicated such as
- The presence of abnormal airway
- Respiratory failure
- Cardiac failure
- Active respiratory tract infection
- Informed refusal from parents / guardian.

Children who did not fall under the above categories were included in the study. Patients were randomly assigned in 2 groups of 30 each (Table 1) after taking appropriate consent from their parents and guardians.
Rescue sedation was provided if movement was anticipated during the procedure to allow the procedure to continue smoothly.
Table 1: Details of medication for two groups

| Medication               | **Group A**                                                                 | **Group B**                                                                                                |
|--------------------------|------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------|
| Pre-medication           | Chlora Hydrate 30-50 mg/Kg orally, 30 minutes prior to onset of procedure. | Chlora Hydrate 30-50 mg/Kg orally, 30 minutes prior to onset of procedure.                                 |
| Induction / Sedation:    | Midazolam 0.05 – 0.1 mg/Kg + Fentanyl 0.5 – 1mg/Kg, i.v.                    | Pentazocine 0.3 – 0.7 mg/Kg + Promethazine 0.5 – 0.7 mg/Kg, i.v.                                          |
| [ Main medication ]      |                                                                              |                                                                                                          |
| Rescue sedation:         | Ketamine 0.5 – 1.0 mg/Kg, i.v.                                                | Ketamine 0.5 – 1.0 mg/Kg, i.v.                                                                            |

(i.v. = intravenous)

Consent:

Written, informed consent was obtained and documented prior to the procedure. Informed consent included an explanation of the procedure, the risks associated with the procedure, the need for sedation and any queries that the parents or guardians had.

Ethical clearance was obtained from the institution ethics committee before commencing the study.

Dietary precautions:

Agents used for sedation have the possibility to damage protective airway reflexes, particularly during deep sedation. Because the complete threat of aspiration during procedural sedation is not yet known, guidelines for fasting periods as used for elective general anaesthesia were followed.

Environment and personnel:

The response of an individual to the administration of sedatives is unpredictable. Hence, sedation in children was only executed in a situation where the facilities, personnel and equipment to manage pediatric emergencies were immediately available.

Sedation Scale:

Wisconsin Sedation Scale of the children’s hospital was followed for evaluating the level of sedation for the selected patients. This was modified from the Ramsay scale to provide additional behavioral anchors in the useful range of moderate sedation. It was aimed to attain a score of 2 - 4 throughout the procedure (Table 2).
Table 2: Wisconsin Sedation Scale of the Children’s Hospital

| Sedation Classification | Sedation Score | Description                                           |
|-------------------------|----------------|-------------------------------------------------------|
| Inadequate sedation     | 6              | Anxious, agitated, or in pain                          |
| Minimal-conscious sedation | 5           | Spontaneously awake without stimulus                   |
| Moderate – conscious sedation | 4       | Drowsy, eyes open or closed, but easily arouses to consciousness with verbal stimulus |
| Moderate-deep sedation  | 3              | Arouses to consciousness with moderate tactile or loud verbal stimulus |
| Deep sedation           | 2              | Arouses slowly to consciousness with sustained painful stimulus |
|                         | 1              | Arouses, but not to consciousness, with painful stimulus |
| Anesthesia              | 0              | Unresponsive to painful stimulus                       |

Student’s unpaired ‘t’ test and Chi square test were applied in the study for comparing different variables in the 2 groups.

RESULTS

Mean age, sex, American Society of Anesthesiologists physical status classification, procedure wise distribution of cases, and pre-existing pathology were similarly distributed between the two study groups (Table 3 & 4). The average age of patients in group A was 24.53±16.74 months compared to 16.66±15.89 months in group B. The majority of cases done in both groups (26/30) were a study of MRI brain (Table 5).
Table 3: Average age and comparison of gender in study groups

|         | Age (Mean ± SD) | Male | Female | Total |
|---------|-----------------|------|--------|-------|
| Group A | 24.53±16.74     | 22   | 8      | 30    |
| Percentage | -               | 55   | 40     | 50    |
| Group B | 16.66±15.89     | 18   | 12     | 30    |
| Percentage | -               | 45   | 60     | 50    |
| Total number | -             | 40   | 20     | 60    |

Table 4: Procedure-wise distribution of cases in study groups

| Procedure          | Group A | Group B |
|-------------------|---------|---------|
| MRI Brain         | 26      | 26      |
| MRI Brain + Angio | 1       | 1       |
| MRI Brain + Contrast | 2     | 3       |
| MRI Brain + Spine | 1       | 0       |

The mean time from onset of sedation to initiation of procedure was 5.76±2.51 minutes with Group A and 6.33±2.13 minutes with Group B which was not statistically significant (Table 7). In our study, the overall incidence of inadequate sedation, requiring rescue sedation was found to be 13.3% (Table 8) with 8 out of 60 patients requiring rescue sedation following movement during the procedure. Of the 8 patients who required rescue sedation, 6 were from Group A as compared to 2 from Group B which was found to be statistically insignificant. This incidence was similar to that reported by Malviya et al who noted a rate of 13.2% of cases out of a total of 1140 cases done requiring additional sedation².

In our study, there was no incidence of sedation failure amongst the 60 patients (Table 9). All 60 imaging studies were completed successfully. More significantly, there was no episode of complications noted during or after the procedure in either groups (Table 10).
### Table 5: Incidence of important preoperative pathologies

|       | Infections |                     | Delayed milestones |                      | Convulsions |                     |
|-------|------------|---------------------|--------------------|---------------------|-------------|---------------------|
|       | Yes | No | Yes | No | Yes | No |
| Group A | 4  | 26 | 19 | 11 | 19 | 11 |
|         | 40% | 52% | 48.7% | 52.4% | 47.5% | 55.0% |
| Group B | 6  | 24 | 20 | 10 | 21 | 9 |
|         | 60% | 48% | 51.3% | 47.6% | 52.5% | 45.0% |
| Total   | 10 | 50 | 39 | 21 | 40 | 20 |
| P value | 0.488 | 0.787 | 0.584 |

Chi square test is applied. P value is significant if <0.05

### Table 6: Comparison of time from primary sedation to initiation and duration of procedure

| Parameters | Mean ± SD | P value |  |
|------------|-----------|---------|---|
|            | Group A   | Group B |   |
| N = 30     | 5.76±2.514 | 6.33±2.13 | 0.35 |
| Sedation to initiation of procedure (minutes) |  |  | 1 |
| Duration (minutes) | 73.03±15.59 | 70.50±17.23 | 0.55 |

Unpaired ‘t’ test is applied. P value is significant if <0.05.

### Table 7: Comparison of need for additional sedation during procedure

| Group | Additional sedation | Total | P value |
|-------|---------------------|-------|---------|
|       | Yes | No |      |       |
| A     | 12  | 18 | 30   | 0.165 |
|       | 40% | 60% | 100.0% |
| B     | 7  | 23 | 30   |       |
|       | 23.3% | 76.7% | 100.0% |
| Total | 19 | 41 | 60   |       |
Table 8: Comparison of need for rescue sedation during procedure

| Group | Rescue sedation | Total | P value |
|-------|-----------------|-------|---------|
|       | Yes  | No   |       |
| A     | 6    | 24   | 30     | 0.129  |
|       | 20 % | 80 % | 100 %  |
| B     | 2    | 28   | 30     |
|       | 6.6 %| 93.4 %| 100.0 %|
| Total | 8    | 52   | 60     |

Chi square test is applied. P value is significant if <0.05.

Unpaired ‘t’ test is applied. P value is significant if <0.05.

Table 9: Incidence of completed procedures and adverse effects

| Procedures                  | Group A | Group B |
|-----------------------------|---------|---------|
| Procedures abandoned        | 0       | 0       |
| Procedures completed        | 30      | 30      |

Adverse effects

| Adverse event | Group A | Group B |
|---------------|---------|---------|
| Intraoperative| 0       | 0       |
| Recovery      | 0       | 0       |

Table 10: Recovery time

| Parameter | Mean ± SD | Group A | Group B | P value |
|-----------|-----------|---------|---------|---------|
| Recovery time (minutes) | 10.83±2.67 | N = 30  | 11.10±2.26 | N = 30  | 0.679 |

DISCUSSION

Sedating a pediatric patient for MRI study is like a tight-rope walk for the anesthesiologist. On the one hand, the need to provide an adequate depth of anesthesia so that the child remains motionless during the entire noisy procedure is paramount to the success of the scan. Yet, there exists the constant risk that, in aiming to attain this, the child may easily reach a deeper level of anesthesia.

This was associated with an increased vulnerability to hypoxemia, hypoventilation,
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Apnea, airway obstruction; laryngospasm and cardiopulmonary impairment are the other serious associated risks. It was noted how the need for deep sedation should be anticipated in younger age groups while also acknowledging the ease with which children tend to pass from the intended level of sedation to a deeper, unintended plane of sedation\(^4\). Cote and Wilson noted how it was essential that practitioners of sedation must have the skill to rescue the patient from a deeper level of sedation than intended for the procedure\(^4\). An in-depth knowledge of the agents that will be used, their potential complications and emergency airway management procedures is necessary.

Onset times for both our regimens were similar to the onset times as noted by Mason \textit{et al} for their comparative study (pentobarbital group, 6.5 ± 4.4 min; pentobarbital—midazolam group, 8.0 ± 4.4 min) in 2001 and Dalal \textit{et al} for their study using propofol (9.1 ± 6.7 min) in 2006\(^5,6\). Cravero \textit{et al} in their extensive review of pediatric sedation noted how the rate of sedation failure had been reported by various investigators\(^7\) to be as infrequent as 1\%–3\% and by others to be as frequent as 10\%–20\%.

Hollman \textit{et al} in 1995 reported a pediatric MRI scan success rate of 98.1\% as compared to the earlier success rate of 85.1\% following implementation of an organized pediatric sedation program\(^8\). Their failure rate of 1.9\% was comparable to Karian \textit{et al}’s 9sedation failure rate (1\%) in 1665 patients, Mason \textit{et al}’s review of 1070 patients (1\%) and Ruess \textit{et al}’s study of 388 patients\(^9,10\)(1.5\%). However, a higher failure rate of 8\% by Malviya \textit{et al} in a study of 376 patients and 17.5\% by D’Agostino was also noted\(^11,12\). The results of our study showed no incidence of sedation failure and were comparable with the results noted by Gozal \textit{et al}\(^13\).

While providing sedation for MRI scans in pediatrics, constant vigilance is needed to detect and prevent adverse events from further compromising the health of the child in addition to the primary pathology. The most common adverse events observed were excessive sedation, agitation, vomiting, hypoxemia, allergic reactions and major airway compromise. McDowall \textit{et al}\(^14\) pointed out that sedation with ketamine was associated with a high incidence of vomiting (14.6\%), agitation (15.0\%) and tachycardia (19.5\%). Mason \textit{et al}’s study revealed an adverse event rate of 3.3\% with 17 out of 1070 cases (1.58\%) having an allergic or paradoxical reaction to pentobarbital\(^5\).

Significant respiratory depression can occur at any time during the procedure and hence constant monitoring is essential during the procedure. All patients in our study were constantly monitored using an MRI compatible pulse oximeter. There was no incidence of hypoxemia or respiratory depression noted in our study in either group. This was comparable with the findings published by Hollman \textit{et al}, Merola and O’Driscoll \textit{et al}\(^8,15,16\) and superior to the rates noted in studies.
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conducted by Mc Dowall et al\textsuperscript{14} among children sedated using propofol (15.7 %), Malviya et al (5.5 %), Gozal et al (2.37 %) and Sanborn et al\textsuperscript{13,17,18} (1.2 %).

It is believed that the reason for our sedation success rate was multifactorial - that is, a combination of the use of a fixed sedation protocol, the close supervision by the anesthesiologist staff providing sedation, the priority to safety of the patient and the expertise and cooperation of the radiologists and nursing staff. Having sedatives administered by personnel who are experienced in pediatric sedation and endorsed in pediatric advanced life support ensures safe and effective intravenous sedation in children.

All the children in this study were supervised by anesthesia personnel, with appropriate monitoring and resuscitation equipment available at hand. They were observed following the procedure for a minimum of 2 hours in the recovery room and discharged only after ensuring that there were no post sedation complications. Both groups showed no incidence of adverse events both during the procedure and in the recovery room. This suggests that in addition to having comparable efficacy and success rate with each other, both multi-drug combinations are safe for sedation in pediatric age groups undergoing diagnostic MRI.

**CONCLUSION**

Our study was carried out with two sedative regimens routinely used in our setup. Their safety and efficacy were tested and the results were noted. Similarly, different setups will have various regimens of sedation for MRI studies in pediatric patients. This study emphasizes the importance of forming a fixed protocol for sedative regimens by testing these regimens and modifying them to suit individual setups.

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