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Research Article

Quality of MRI pediatric sedation: Comparison between intramuscular and intravenous dexmedetomidine

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Abstract *Objective:* The study was designed to compare the efficacy of dexmedetomidine whether given intramuscular or intravenous for pediatric MRI sedation.
Subjects and methods: Ninety children between the ages of 2 and 8 years with ASA physical status I–II, scheduled for elective MRI, were enrolled in a double blind, comparative randomized study. Patients assigned into two equal groups. Group DV, sedation was performed using IV dexmedetomidine hydrochloride; a loading dose of 1 μg/kg administered over 10 min followed by a continuous infusion at 1 μg/kg/h. Group DM where the patient received IM dexmedetomidine 3 μg/kg. Primary endpoints included incidence of failed sedation and the requirement of midazolam supplementation. Secondary endpoints were time to sedation, duration of sedation, discharge time, and hemodynamic status.
Results: The sedation failure rate was significantly higher in the DV group (40%) in comparison with the DM group (20%) ($P = 0.04$). Also, the use of rescue midazolam was significantly higher in the VD group (0.37 ± 0.47 mg) in comparison to the DM group (0.17 ± 0.35 mg) ($P = 0.025$). The onset of satisfactory sedation was significantly shorter in DV group in comparison to DM group (7.93 ± 0.884 vs. 16.87 ± 4.49). Also, the discharge time was significantly less in the DV group (32.27 ± 3.04 min) in comparison to DM group (41.87 ± 5.80 min). Patients in DV group had significantly lower MBP compared to patients in DM group after receiving dexmedetomidine ($p < 0.05$). Although the HR decreased in both groups during the MRI study, the decrease was statistically significant in the DV group compared to the DM group in the period extended from the 2nd to 35th min ($p < 0.05$).

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Conclusion: In pediatric MRI sedation, although IM dexmedetomidine does have a late sedation onset; it reduces the sedation failure rate, the need for supplement sedation and the incidence of hemodynamic instability associated with IV dexmedetomidine.

1. Introduction

Dexmedetomidine is a potentially effective agent for sedation during non-invasive procedures such as magnetic resonance imaging (MRI) [1,2]. It has several potential beneficial effects over older sedatives including its fast onset of action, minimal respiratory depression, and an option for repeated administration when needed for special procedures [3]. The risks of its sedation are in part related to the inherently unpredictable response to medication and to the route of administration. There is a varied response in sedation to IV dexmedetomidine; it should be titrated for successful sedation [2]. The needs for titration are practically difficult and interfere with the continuity of MRI procedure. The most frequently seen adverse effects of IV dexmedetomidine that has been reported are hypotension and bradycardia [4–7]. The ideal sedative should be administer by a simple and non-sophisticated technique, and produces adequate sedation conditions while minimizing the incidence of adverse events. Intramuscular dexmedetomidine administration might avoid the most serious risks and complications associated with IV dexmedetomidine and might reduce the need for titration which is essential for IV sedation. The study was designed to compare the efficacy of dexmedetomidine whether given Intramuscular or intravenous for pediatric MRI sedation.

2. Patients and methods

After obtaining approval of the hospital's Research Ethics Committee and written informed consent from parents for the sedation, 90 children between the ages of 2 and 7 years with ASA physical status I–II, scheduled for elective MRI were enrolled in a double blind, comparative, randomized study. The study was conducted from June 2009 to March 2012. Patients with a history of cardiovascular, active respiratory tract, hepatic, or renal diseases and by reason of parents' refusal were excluded. Patient demographics, type of MRI study performed and its imaging time, as well as patient's ASA physical status were recorded. Imaging time refers to the duration of imaging study from initiation of scan till the radiologist confirms completion of successful MRI study.

Patients were randomized to one of two groups for sedation: In Group DV ($n = 45$), sedation was performed with dexmedetomidine hydrochloride (Precedex®, Abbott, 200 μg/ml) intravenously, a loading dose of 1 μg/kg administered over 10 min, followed by a continuous infusion at 1 μg/kg/h for the duration of the procedure. In Group DM ($n = 45$), the dexmedetomidine 3 μg/kg was delivered as a single IM injection in the lateral cranial thigh muscle group; using a 25 gauge needle, with the child on the parent's knee or lying on the trolley 20 min before the procedure. Every child had IM injection (dexmedetomidine/saline) and IV infusion (dexmedetomidine/saline) prepared by dedicated nurse, sedation was given by anesthesiologists blinded to the group assignment. The patients were randomly assigned on a one-to-one ratio. Randomization was performed by means of a computer-generated random-numbers table. Parents were instructed to make their children NPO for solids 6 h and to give clear liquids up to 2 h prior to their scheduled appointment. EMLA cream was applied 1 h before the procedure to the places of IM injection and IV cannulation. Before each procedure, an IV access and standard monitoring of electrocardiogram (ECG), non-invasive arterial blood pressure (NIABP), and peripheral oxygen saturation (SpO2), were established. Heart rate (HR) and rhythm were displayed continuously by using a lead II ECG. All values of vital signs (NIABP, HR, SPO2, and RR) were recorded every 2 min during the 1st 10 min and at 5-min intervals throughout the procedure.

The sedation levels were consecutively assessed with Ramsay sedation score (RSS) [8]. Primary endpoints included incidence of failed Sedation and the requirement of midazolam supplementation. Secondary endpoints were time to sedation, duration of sedation, discharge time, and hemodynamic status. The level of radiologist satisfaction regarding the quality of sedation and the incidence of adverse events were also recorded.

The time to sedation is defined as the time in minutes (min) from administration of sedative to achievement of adequate sedation (RSS 4). Duration of sedation is defined as the time from onset to offset of sedation (RSS 2). Time to discharge is the time from giving sedation to point at which patient meets the discharge criteria (Alderete score of 8 or greater) [9]. The sedation was classified as failed if RSS is less than 4 or if unacceptable motion artifacts lead to inability to complete the imaging study. Supplemental sedation was provided by using titrated doses of midazolam IV 0.05 mg/kg every 4 min.

Adverse events, including airway complications, oxygen desaturation less than 92%, emesis, and unplanned admission were recorded. Bradycardia was identified as rates less than 60 beat min^{-1} and was treated with IV atropine 20 μg/kg. Hypotension was identified as a 20% decrease in the mean blood pressure (SBP) and was treated with fluids administration (10 ml/kg) and IV ephedrine 0.1 mg/kg. The need of head repositioning, jaw thrust, and oral airway placement in a state of airway obstruction were recorded. Radiologist satisfaction was evaluated using a 10-cm visual analog scale (VAS) scores (0, not satisfied and 10, totally satisfied) at the end of procedure.

Statistical analyses: EPI-INFO program was used for sample size calculation by using incidence of sedation failure as the primary outcome of this study. The α-error level was fixed at 0.05 and power was set at 80% while the expected change to be detected was 10%. Qualitative data were analyzed with pearson Chi-square test. Quantitative data, expressed as 'mean ± standard deviation (SD)', were analyzed by one way ANOVA test. A probability value of less than 0.05 was considered statistically significant. All analyses were done by using the statistical package for social sciences (SPSS).