Original Article

A comparative study of oral Dexmedetomidine and oral Midazolam with respect to sedation and mask acceptance as premedication in children

Punita Priya S*, Supriya Saravanan, N Krishnan

Department of Anaesthesiology, Dr B R Ambedkar Medical College and Hospital, Bangalore, Karnataka, INDIA.
Email: punitamd2011@gmail.com

Abstract

Introduction: Anxiety in children undergoing anaesthesia and surgery is characterized by feelings of apprehension, tension, and nervousness. Separation of the child from parents and induction of anaesthesia have been found to be the most stressful period during the surgical/anaesthesia experience **Aims and Objectives:** To Compare Study of Oral Dexmedetomidine and Oral Midazolam With Respect To Sedation and Mask Acceptance as Premedication in Children. **Methodology:** This prospective randomized double blinded, study was conducted in the Department of Anaesthesiology at Government Stanley Medical College and Hospital between April 2013 and November 2013. Chi-square test was used for statistical analysis Patients were divided in the Dexmedetomidine, Midazolam group randomly **Result:** There is no statistical difference between the two groups at 10 and 20 minutes. At the end of 30 minutes, 22 patients achieved a score of 3 in Group D, compared to 56 patients in Group M. Only 4 patients in Group M still had a score of 1. Whereas 20 patients in group D still had a score of 1.This result is statistically significant At the end of 40 min, 100% of the patients achieved a score of 3 in group M whereas only 80% achieved it in Group D this is statistically significant. At 50 min Chi square 5.217, $P < 0.02$. At 60 min Chi square 0.0084, P value - 1, the result is Not Statistically Significant. The mask acceptance score between group M and group D are comparable with a p value of. 093 Group D showed an excellent mask acceptance (score of 1)of 60% with 43.30% acceptance in group M, 53.30% of Group M and 40% of Group D showed a good mask acceptance. **Conclusion:** The Sedation Score at 30, 40 and 50 was better in Midazolam Group as Compared. To Dexmedetomidine while mask acceptance score was comparable to each other.

Keywords: Dexmedetomidine, Midazolam, Sedation Score, Mask Acceptance Score.

***Address for Correspondence:**
Dr. Punita Priya S, No -606, 3rd Stage, 17th Cross, Pillanna Garden Extension, Lingarajapuram, Bangalore - 560084 Karnataka, INDIA.
Email: punitamd2011@gmail.com

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INTRODUCTION

Anxiety in children undergoing anaesthesia and surgery is characterized by feelings of apprehension, tension, and nervousness.[1] Separation of the child from parents and induction of anaesthesia have been found to be the most stressful period during the surgical/anaesthesia experience. Anxiety before surgery is associated with various neuroendocrine changes[2], like increased serum cortisol, epinephrine, growth hormone, and adrenocorticotropic hormone levels. Premedication is administered prior to anaesthesia induction, for anxiolysis, to facilitate separation from parents, and lessen the adverse psychological effects of hospital experiences. In children, premedication is more difficult as intravenous (IV) access is usually not present, and the child may feel placement of an IV cannula or administration of intramuscular (IM) medication as more invasive than the procedure itself. The routine clinical practise frequently makes use of non parenteral routes of administration for the initiation of sedation or for premedication prior to anaesthesia induction[3,4,5]. Oral midazolam is recently the most commonly used sedative drug for premedication in children.[6] Midazolam has many beneficial effects when used as premedication in children produces, sedation, amnesia, reduces vomiting (does not the gastric pH and the gastric volume), has a faster onset

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and limited duration of action[7]. Despite having these beneficial effects, it is not an ideal premedicant, having some of the side effects such as cognitive impairment, long term behavioural disturbances, and respiratory depression[8]. Dexmedetomidine is a highly selective α-2 adrenoceptor agonist that has sedative and analgesic effects[9]. Clinical investigations have demonstrated its sedative, analgesic and anxiolytic effects after IV administration to volunteers and postsurgical patients[10]. Preliminary experience in children has demonstrated its efficacy for the sedation of infants and children during mechanical ventilation. It has also been used to sedate children undergoing radiological imaging studies[11,12]. Dexmedetomidine has limited effects on cardio respiratory function.[13]

AIMS AND OBJECTIVES

To Compare Study of Oral Dexmedetomidine and Oral Midazolam With Respect To Sedation and Mask Acceptance as Premedication in Children.

MATERIAL AND METHODS

This prospective randomized double blinded, study was conducted in the Department of Anaesthesiology at Government Stanley Medical College and Hospital between April 2013 and November 2013. After obtaining approval from the institutional ethical committee, a pilot study was conducted. Based on the results of the pilot study, a sample size of 120 was decided. Patients between 3 years and 10 years, both male and female children. ASA: Physical status 1. Elective Infra-Umbilical surgeries Were included into study while patients with Allergic reaction to dexmedetomidine and midazolam (if previous history is present). Organ dysfunction e.g. : congenital heart disease or cardiac arrhythmias, Mental retardation, Epilepsy, Bronchial asthma and patients with gastrointestinal disease that affects the absorption of the drug were excluded from study. Patients were divided in the Dexmedetomidine, Midazolam group randomly.Chi-square test was used for statistical analysis.

RESULT

Table 1: Sedation Scores at 10 min

	Sedation Score					
Group	1		2		3	
	N	%	N	%	N	%
D	40	66.67	16	26.67	4	6.67
M	32	53.33	20	30.33	8	13.33

40 children in D group and 32 in group M achieved a sedation score of 1 at the end of 10 minutes. Only 4 patients (6.67%) in Group D and 8 patients in Group M achieved a sedation score of 3. There is no statistical difference between the two groups at 10 minutes.

Table 2: Sedation Scores at 20 min

	Sedation Score					
Group	1		2		3	
	N	%	N	%	N	%
D	40	66.67	16	26.67	4	6.67
M	32	53.33	20	30.33	8	13.33

Chi square 2.667, P -0.2636

The sedation scores at the end of 20 minutes were the same as that of 10 minutes. Again, here there is no statistical difference in the time to achieve a score of 3.

Table 3: Sedation Scores at 30 min

	Sedation Score					
Group	1		2		3	
	N	%	N	%	N	%
D	20	33.33	18	30	22	36.6
M	4	6.67	0	0	56	93.33

Chi square 43.48, P <0.0001

At the end of 30 minutes, 22 patients achieved a score of 3 in Group D, compared to 56 patients in Group M. Only 4 patients in Group M still had a score of 1. Whereas 20 patients in group D still had a score of 1.This result is statistically significant

Table 4: Sedation Scores at 40 min

	Sedation Score					
Group	1		2		3	
	N	%	N	%	N	%
D	3	5	9	15	48	80
M	0	0	0	0	60	100

Chi square 13.33, P -0.0013

At the end of 40 min, 100% of the patients achieved a score of 3 in group M whereas only 80% achieved it in Group D. this is statistically significant

Table 5: Sedation Scores at 50 min

	Sedation Score					
Group	1		2		3	
	N	%	N	%	N	%
D	0	0	5	8.33	55	91.67
M	0	0	0	0	60	100

Chi square 5.217, P 0.02, the result is **Statistically Significant**

Table 6: Sedation Scores at 60 min

	Sedation Score					
Group	1		2		3	
	N	%	N	%	N	%
D	0	0	0	0	60	100
M	0	0	0	0	60	100

Chi square 0.0084, P value - 1, the result is **Not Statistically Significant**

Table 7: Mask Acceptance Score (Mas)

	GROUP M		GROUP D	
Excellent	26	43.3%	36	60%
Good	32	53.3%	24	40%

Fair	2	3.3%	0	0%

Chi - square value -4.756., Df -2, P value - 0.093

The mask acceptance score between group M and group D are comparable with a p value of. 093 Group D showed an excellent maskacceptance (score of 1)of 60% with 43.30% acceptance in group M, 53.30% of Group M and 40% of Group D showed a good mask acceptance (score 2)

DISCUSSION

Any child who is brought to the hospital for surgical procedure is under the state of apprehension and anxiousness. These children have a fear of separation from parents and fear of pain caused by needle prick. In view to alleviate psychological stresses due to surgical trauma, needle prick and the various ill effects of anxiety, premedication to children can be given through an oral route which is simpler, and easily acceptable, to both children and their parents. Sedation After 10 Minutes of the administration, 67% of group D and 53 % in Group M were still awake and alert (score 1).only 6.6 % in Group D and 13.3% in Group M achieved a score of 3. Hence there was *no statistical significant difference* with a p value of 0.23 at 10 minutes At The End Of 20 Minutes our study showed that 6.6% of patients in group D and 15 % patients in group M had achieved a score of 3. Thus, there was *no statistically significant difference* between the two groups with a p value of 0.26 at the end of 20 minutes of sedation. At The End Of 30 Minute following the drug administration 93% in group M were relaxed and had achieved the score of 3 compared to 37% in group D. 33 % of patient in group D were still awake and alert at the end of 30 minutes in comparison to only 6 % in group M. The result *showed astatistical significant difference* in between the two groups with the p value of 0. 0001. This result was similar to Karim Kamal38 who showed the early onset of sedation for Midazolam was 28±14.3 minutes when compared to oral Dexmedetomidine. At The End Of 40 Minutes still 20 % in group D were awake and alert (score 1) and none in Group M with a statistical significant difference between the two groups and a p value of. 0013 At The End Of 50 Minutes: 92% in group D were sedated (score 3) which was *statistically significant* and correlates with the study of Karim Kamal *et al*[1], MahamedDaabis[14] and Schmidt *et al* [15] who showed that average onset time of oral Dexmedetomidine was delayed when compared with oral midazolam. At End Of 60 Minutes all the patients in group D were sedated (score 3). One of the reason for giving sedation is for separating the child from the parents this depends on the level of sedation, we used sedation score which is a 5 point scale used by Mohamed daabiss[14] in his study. In our study we found the time required to reach the statistically significant result with the sedation score of 3 in group M was 30minutes and in group D was 40 minutes. These results were similar to the result obtained by Mohamed daabiss study. Our study showed at 30 minutes 75 % patients in group M and at 40 minutes 70 % of patients in group D were easily separable from the parents which is score 1 of the parental separation score, where as the remaining patients had a score of 2 which is whimpers but easily treasurable. These results did *not show any statistical difference* in both the groups. This results correlates with the results of the study conducted by Brian w, Mountain *et al*. *Mask acceptance* **-**Patient was then shifted into the OT where anaesthesia was induced with O2: N_2O,; 40: 60 using a face mask attached to Jackson rees circuit, analgesia was provided with inj fentanyl 2 µg/kg sevoflurane was than reduced in a step-down manner from 8% to maintenance of 2%-3%,. The acceptance of the mask by the child was measured by using mask acceptance scale (likert scale) which is a 4 point scale, this tool was used by both Shukry, Weldon *et al* and Brian[16] wMountain in their study, our study showed no statistical difference in mask acceptance between the two groups which correlates with the results obtained by Brian *et al*[16].

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