

Original Research

Efficacy of clonidine & midazolam as premedication agent

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ABSTRACT:

Background: Preoperative preparation of a child undergoing surgery is a major challenge to the anesthesiologists. The present study compared the efficacy of midazolam with clonidine in children. **Materials & methods:** 80 patients with ASA grade I and II of both genders were divided into 2 groups of 40 each. Group I received 4 mcg/kg of oral clonidine and group II received 0.5 mg/kg oral midazolam as a premedication about 1 hour before induction of anaesthesia. Drug acceptance and anxiety score was recorded. Drug acceptance was calculated. **Results:** The mean pulse rate was 87.4 in group I and 86.2 in group II. SBP was 100.2 mm Hg in group I and 104.6 mm Hg in group II, DBP was 68.4 mm Hg in group I and 65.2 mm Hg in group II. Respiratory rate was 20.5 cycles/ minute in group I and 20.8 cycles/ minute in group II. Duration of surgery was 134.2 minutes in group I and 136.4 minute in group II. The difference was non-significant ($P > 0.05$). Drug acceptance score 1 was seen in 24 in group I and 14 in group II, 2 in 10 in group I and 18 in group II. Score 3 was seen in 6 in group I and 8 in group II. The difference was significant ($P < 0.05$). The mean sedation score in group I was 2.9 and in group II was 1.1. The difference was significant ($P < 0.05$). **Conclusion:** Authors found that clonidine offered better sedation and drug acceptance score in children and hence could be used as an alternative to midazolam as pre-anesthetic agent.

Key words: Clonidine, Drug acceptance, Pre-medication

Received: September 22, 2019

Accepted: October 27, 2019

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This article may be cited as: Bajaj V. Efficacy of clonidine & midazolam as premedication agent. J Adv Med Dent Scie Res 2019;7(11):275-278.

INTRODUCTION

Preoperative preparation of a child undergoing surgery is a major challenge to the anesthesiologists.¹ Profound psychological trauma may occur due to a variety of factors like separation from parents, unaccustomed environment of the operating area, and insertion of an intravenous cannula prior to surgery, etc. which can result in negative behavioral changes in later life.²

Premedication should yield a patient who is calm, free of anxiety and pain, sedated, but easily arousable and fully co-operative. Oral premedication is widely used to reduce preoperative anxiety and ensure smooth induction. Anxiety during the perioperative period has been described as a subjective feeling of apprehension, fear, and nervousness. In addition to facilitating the induction of anesthesia and providing a calm perioperative environment, the benefits of effective premedication may be long lasting.³

Midazolam is a benzodiazepine which produces amnestic, hypnotic, anxiolytic and skeletal muscle relaxant effects. The route of administration is

intranasal, sublingual, rectal and the oral routes. It has rapid onset and short half life. Clonidine is another effective agent.⁴ It has significant sedative and analgesic properties. It is another agent used in premedication in children.⁴ It has been shown that oral clonidine effectively produces pre-operative sedation and anxiolysis in children, it acts as an analgesic, it decreases the volatile anaesthetic agent requirement and also improves the peri-operative hemodynamic stability.⁵ The present study compared the efficacy of midazolam with clonidine in children.

MATERIALS & METHODS

This study consisted of 80 patients with ASA grade I and II of both genders. Parental consent was obtained before starting the study.

Data such as name, age, sex etc was recorded. Patients were divided into 2 groups of 40 each. Group I received 4 mcg/kg of oral clonidine and group II received 0.5 mg/kg oral midazolam as a premedication about 1 hour before induction of anaesthesia. Drug acceptance and anxiety score was

recorded. Drug acceptance was calculated as good, indifferent, bitter and unpleasant. Sedation level was calculated as 1 = awake, 2 = drowsy, and 3 = asleep.

Results thus obtained were subjected to statistical analysis. P value less than 0.05 was considered significant.

RESULTS

Table I Distribution of patients

Groups	Group I	Group II
Status	4mcg/kg of oral	0.5mg/kg oral midazolam
M:F	20:20	12:8

Table I shows that group I had 20 males and 20 females and group II had 12 males and 8 females.

Table II Comparison of vital signs

Vital signs	Group I	Group II	P value
Pulse rate (beats/min)	87.4	86.2	0.82
SBP (mm Hg)	100.2	104.6	0.90
DBP (mm Hg)	68.4	65.2	0.72
RR (cycles/min)	20.5	20.8	0.94
Duration of surgery (mins)	134.2	136.4	0.85

Table II, graph I shows that mean pulse rate was 87.4 in group I and 86.2 in group II. SBP was 100.2 mm Hg in group I and 104.6 mm Hg in group II, DBP was 68.4 mm Hg in group I and 65.2 mm Hg in group II. Respiratory rate was 20.5 cycles/ minute in group I and 20.8 cycles/ minute in group II. Duration of surgery was 134.2 minutes in group I and 136.4 minute in group II. The difference was non- significant ($P > 0.05$).

Graph I Comparison of vital signs

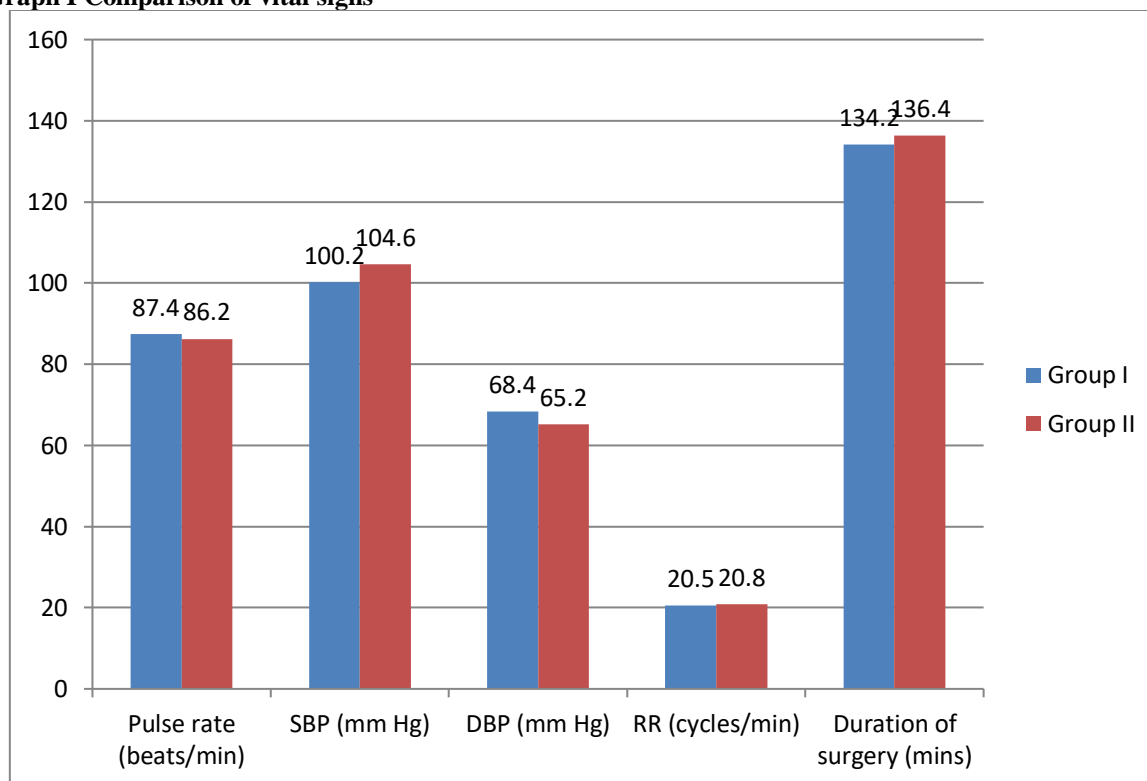
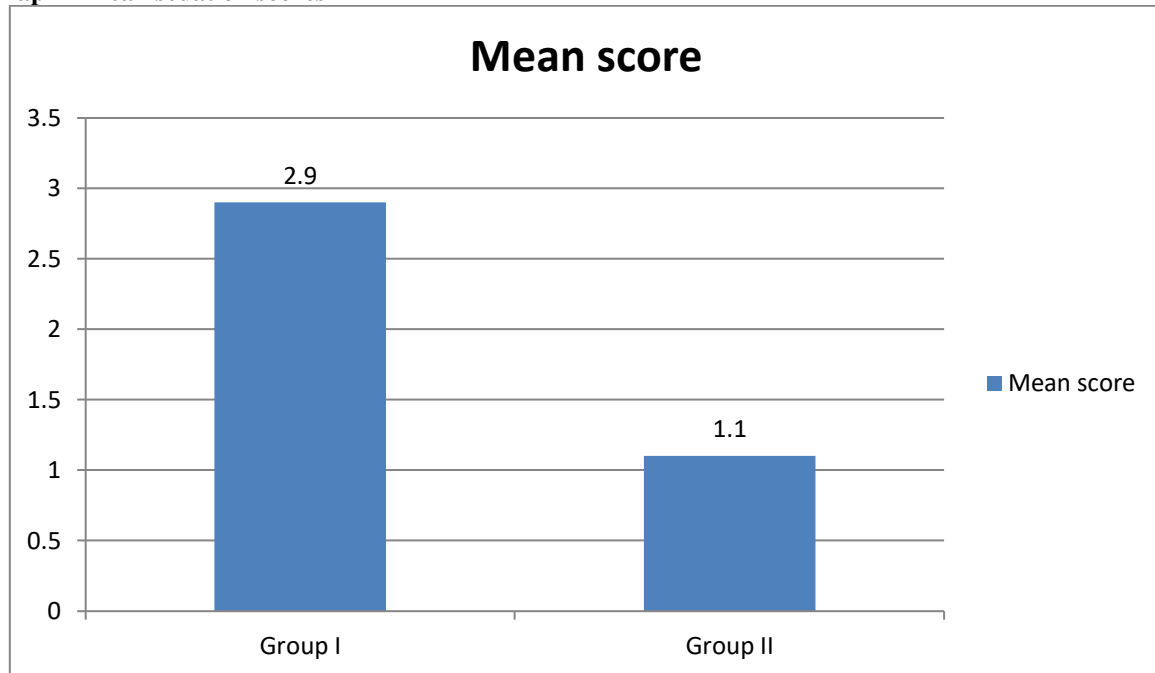


Table III Drug acceptance score

Score	Group I	Group II	P value
1	24	14	0.04
2	10	18	0.05
3	6	8	0.72

Table III shows that drug acceptance score 1 was seen in 24 in group I and 14 in group II, 2 in 10 in group I and 18 in group II. Score 3 was seen in 6 in group I and 8 in group II. The difference was significant ($P < 0.05$).

Graph I Mean sedation scores

Graph I shows that mean sedation score in group I was 2.9 and in group II was 1.1. The difference was significant ($P < 0.05$).

DISCUSSION

Anxiety and fear of operation, injections, physicians, operation theater environment, and parental separation are all traumatizing experiences in patients resulting in postoperative maladaptive behavioral changes. Sedation and anxiolysis are the essential components of anesthesia before surgery in patients.⁶ Currently, the most commonly used sedative premedicants in the preoperative holding area is midazolam (85%), followed by ketamine (4%), fentanyl (3%), and meperidine (2%) with oral route being used most commonly. Clonidine, α_2 -adrenergic agonist is an upcoming preanesthetic agent in patients and hence has been compared with midazolam, the most common premedication used in patients.⁷ Administration of anesthesia in children is a tedious task. A variety of non pharmacological and pharmacological measures have been tried in reducing pre-operative anxiety. Pharmacological agents such as sedatives and non-pharmacological agents such as parental presence, behavioural preparation programs, music, acupuncture, etc are widely used in order to relieve pain and anxiety.⁸ The present study compared the efficacy of midazolam with clonidine as a premedication.

We found that group I had 20 males and 20 females and group II had 12 males and 8 females. Trevor et al⁹ provide additional information comparing clonidine with the commonly used pre-medication oral midazolam. The authors compared premedication with standard doses of oral midazolam (0.5 mg/kg) and clonidine (4 μ g/kg) in a cohort of 60 pediatric patients (ASA I–II) undergoing elective surgery. Additionally, one of the major drawbacks to clonidine

use was noted as the authors administered clonidine 90 min prior to anesthetic induction given its slow onset of action.

We found that drug acceptance score 1 was seen in 24 in group I and 14 in group II, 2 in 10 in group I and 18 in group II. Score 3 was seen in 6 in group I and 8 in group II. Debnath et al¹⁰ selected sixty patients scheduled for elective surgery were randomly allocated to receive either oral midazolam (group I) 30 min before induction or oral clonidine (group II) 90 min before induction of anesthesia. The children were evaluated for levels of sedation and anxiety at the time of separation from the parents, venepuncture, and at the time of mask application for induction of anesthesia. After premedication, the percentage of children who were sedated and calm increased in both the groups. The overall level of sedation was better in the children in the clonidine group, but children in the midazolam group had a greater degree of anxiolysis at times of venepuncture and mask application.

We found that mean sedation score in group I was 2.9 and in group II was 1.1. Sahoo et al¹¹ enrolled sixty children who were scheduled to undergo an elective surgery. They received either oral midazolam (Group M) or oral clonidine (Group C) 60 minutes before induction of anesthesia and were submitted to an evaluation of anxiety and sedation scores. Oral midazolam had better efficacy in the preoperative period as sedative and anxiolytic ($P < 0.001$), allowed better cooperation during venipuncture and facemask application ($P < 0.001$), whereas, oral clonidine provided better palatability ($P < 0.001$), parental satisfaction ($P < 0.001$), stable perioperative hemodynamics ($P < 0.001$), better postoperative

analgesia ($P < 0.001$), and night sleep pattern ($P < 0.05$) without any noticeable side effects ($P > 0.05$). Fazi et al¹² conducted a study and they achieved a significantly better level of sedation with oral clonidine than with oral midazolam, but clonidine needed to be administered at least 45 minutes prior to the induction for an optimum sedation, which could be achieved in 30 minutes with oral midazolam.

CONCLUSION

Authors found that clonidine offered better sedation and drug acceptance score in children and hence could be used as an alternative to midazolam as pre-anesthetic agent.

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