Original Article

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Anaesthesia Section

Anaesthetic and Haemodynamic Effects of Dexmedetomidine vs Midazolam used as Premedication in Minor Obstetrics and Gynaecological Procedures- A Prospective Interventional Study

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ABSTRACT

Introduction: Preoperative anxiety for any surgery is a frequent condition. It may lead to high catecholamine levels which increases blood pressure, heart rate and oxygen consumption. Various agents have been used for anxiolysis and sedation as premedicants.

Aim: To compare the anaesthetic and haemodynamic effects of injection Dexmedetomidine and injection Midazolam used as premedication in minor Obstetrics and Gynaecological procedures.

Materials and Methods: This was a prospective interventional study conducted from July 2016 to September 2017, on total number of 60 patients of American Society of Anaesthesiologist Physical Status (ASA PS I and II) enrolled for the study. They were randomised in two groups: Group A (n=30) for Injection (Inj.) Midazolam 0.04 mg/kg and Group B (n=30) for injection Dexmedetomidine 1mcg /kg injected over a period of 10 minutes prior to General Anaesthesia. After appropriate monitoring like, Heart Rate (HR), Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP), Mean arterial Pressure (MAP), Peripheral oxygen saturation (SpO_2), Respiratory Rate (RR) were noted during the procedure at interval of 5 minutes till 30 minutes and, Ramsay Sedation Score (RSS) and Visual Analogue Scale (VAS) in postoperative period for 1 hour at interval of 15 minutes. The significance between all variables and amongst the two groups was calculated by Chi-square test, Repeated measure Analysis of Variance (ANOVA) test and Independent sample t-test.

Results: It was observed that mean HR, SBP ($p<0.05$), DBP ($p<0.05$) and MAP ($p<0.05$) decreased significantly in group B. The RR ($p<0.05$) was significantly decreased in group B. There was no significant difference in SpO_2 ($p=0.4$) value in both the groups. VAS ($p<0.05$) of group B patients was significantly reduced in the postoperative period but there was no significant difference in RSS score ($p=0.1$) at 45 and 60 minutes in both the groups.

Conclusion: Dexmedetomidine is more effective as a sedative agent than injection Midazolam when used in minor gynaecological procedures. Though Dexmedetomidine caused significant reduction in SBP, DBP and HR, it maintained haemodynamic stability well without causing any adverse effects.

Keywords: Analogue, Anaesthesia, Postoperative, Ramsay sedation, Visual analog scale

INTRODUCTION

Prompt and street fit recovery after a day care surgery has become necessity in modern anaesthesia practice. Preoperative anxiety is a frequent medical condition. Generally it starts two days before the operation and reaches its peak just prior to the induction of anaesthesia [1]. Anxiety is more common among younger patients and females. Anxiety, stress and fear that arise just before the operation, may lead to psychological trauma and increase the release of stress hormones resulting in undesirable metabolic responses before anaesthesia [1-3]. High catecholamine levels in blood increase arterial blood pressure, heart rate and oxygen consumption. Comfortable anaesthesia induction and maintenance can be achieved by controlling preoperative anxiety. Various agents such as Phenothiazines, Benzodiazepines, Barbiturates, and Opioids and Antihistamines have traditionally been used to relieve anxiety and provide sedation. Today the most frequently used drugs are Benzodiazepines [4]. Midazolam is the medication from this group with rapid onset and short lasting effect. Its sedative effect has been shown in many studies [5-7].

It has been evident that alpha 2 adrenoceptor agonist may also work in conjunction with anaesthesia [8,9]. Dexmedetomidine is an imidazole derivative. It has sedative, analgesic, sympatholytic and anxiolytic effect that blunt many of the cardiovascular responses in the perioperative period. Dexmedetomidine exerts a sympatholytic effect by activating inhibitory alpha 2 receptors, both in the Central Nervous System (CNS) and peripheral sympathetic nerve endings [9-12].

Number of minor obstetrics and gynaecological procedures are performed as day care procedures. The objectives of the present study were-

- To compare the anaesthetic and haemodynamic properties of inj. Dexmedetomidine and inj. Midazolam used as a premedication in minor obstetrics and gynaecological procedures.
- To observe any side effects of these drugs.

MATERIALS AND METHODS

The present study was a prospective interventional study, conducted from July 2016 to September 2017, on 60 patients who came to Department of Obstetrics and Gynaecology, MIMER Medical College, Talegaon Dabhade, Pune, India, after obtaining approval of the Institutional Ethical Committee (IEC/157). A written informed consent was obtained from all participants after informing about the procedure.

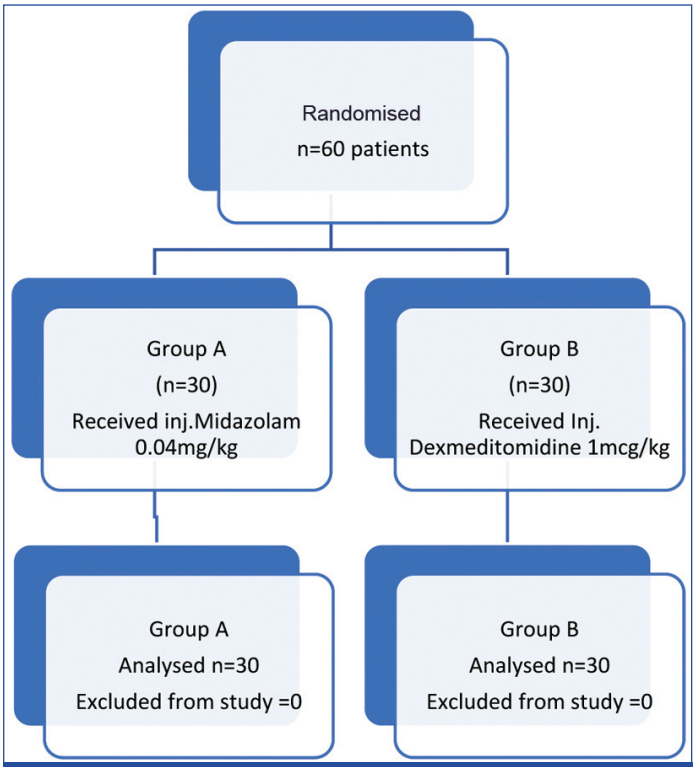
Inclusion criteria: Those patients aged 18-60 years of American Society of Anaesthesiologist Physical Status (ASA PS) grade I and II

[13], admitted in Gynaecology Department, planned to undergo a minor obstetrics and gynaecological procedures like Dialatation and Currettage, Medical Termination of Pregnancy (MTP), copper T-insertion etc. under general anaesthesia were included in the study.

Exclusion criteria: Those patients on alpha and beta blockers as antihypertensive, hypertensive patients without any medication (uncontrolled hypertension), patients with psychiatric illness and those on concurrent sedative medications were excluded from the study.

Sample size calculation: With pilot study of 20 patients done earlier and considering power >80%, confidence interval of 95% and alpha error of 5%, the appropriate sample of the present study was calculated to 60 patients.

Hence, a total of 60 patients satisfying the inclusion and exclusion criteria were enrolled in the study and were divided into group A (n=30) and group B (n=30) according to the treatment planned as depicted in the flow diagram [Table/Fig-1].



[Table/Fig-1]: Flowchart for all participants of the study.

Study Procedure

The patients were randomly allocated in two groups, group A (n=30) Midazolam group and group B (n=30) Dexmedetomidine group. The group A received Inj. Midazolam 0.4 mg/kg in 100 mL normal saline and group B received inj. Dexmedetomidine, 1 microgram/kg in 100 mL normal saline over the period of 10 minutes. These agents used for premedication were administered by slow intravenous (i.v.) infusion to provide better haemodynamic control and stop them if needed in case of complication.

The patients were transferred to the preoperative room 40 minutes prior to anaesthesia induction. Peripheral venous routes were accessed via 20-G catheters and infusion of ringer lactate solution was started. They were reminded about the procedure and about how to mark the VAS [14]. Non invasive blood pressure measurement, electrocardiography and peripheral oxygen saturation monitoring was performed. The infusions of the medications were given before induction and completed within 10 minutes. Both groups received injection Fentanyl citrate 1 microgram/kg and injection Glycopyrrolate 0.02 mg/kg before induction. Anaesthesia was induced with injection Propofol 2 mg/kg and maintained with Nitrous oxide/Oxygen (70%:30%) by face mask and with top up doses of injection Propofol.

Onset time of sedative infusion was taken as 0 minute and the following parameters were measured at the interval of five minutes. The HR, SBP, DBP, MAP, RR and SpO_2 were recorded. After the procedure and recovery from anaesthesia, the patients were observed for one hour. The anxiety threshold was assessed with the VAS, preoperatively as well as postoperatively at 15 minutes interval.

The patients were asked to self evaluate their feelings of anxiety with the scores of 0-10 with (0=absent and 10=worst). The level of sedation was assessed by using RSS [15], preoperatively as well as postoperatively at 15 minutes interval, RSS, 1=agitated, restless, 2=cooperative, tranquil, 3=responds to verbal commands while sleeping 4=brisk response to glabellar tap or loud voice while sleeping, 5=sluggish response to glabellar tap or loud voice, 6=no response to glabellar tap or loud voice). Drug related side effects like bradycardia (HR<50 beats/minute), hypotension (MAP <60 mm of Hg), nausea, vomiting were recorded and treated accordingly.

STATISTICAL ANALYSIS

Statistical analysis was performed by using Statistical Package for Social Sciences (SPSS) software version 21.0 . Comparison of qualitative data was performed with Chi-square test and expressed in terms of median, frequency and percentage. The statistical analysis of the changes in pulse, mean arterial pressure, SBP, DBP, RR and SpO_2 were performed with Repeated measure ANOVA test. Statistical analysis of the VAS and Ramsay score was done over two period of time, from start of study till the time of induction and from recovery till the patient is shifted to the wards, with independent sample t-test. Mean and standard deviation were calculated for quantitative variables. Analysis of variance test was used to compare the parameters with normal distribution between the groups. The p-value <0.05 was considered to be significant.

RESULTS

Total of 60 patients aged 18-60 years were enrolled in the present study. Mean age of 30 patients included in group A was 28.5 years while those of 30 patients in group B was 29.1 years. The demographic data of both the groups was comparable [Table/Fig-2].

Demographic parameters	Group A (Midazolam group) n=60	Group B (Dexmedetomidine group) n=60
Mean age (years)	28.5	29.1
Mean weight (Kg)	52.4	51.83

[Table/Fig-2]: Demographic data of both the groups.
Total N=60; Kg: Kilogram unit

Mean HR measured, analysed and compared for all study subjects amongst the two groups are tabulated [Table/Fig-3]. It was observed that mean HR differed significantly between Group A and Group B at all time intervals. There was significant reduction in the HR in group B as compared to group A. Further analysis showed that there was significant difference within group A and (p-value=0.01). Mean SBP differed significantly between group A and group B 15 min onwards intra-operatively and at 15 min postoperatively. There was significant reduction in the systolic blood pressure in group B as compared to group A [Table/Fig-3].

The mean DBP differed significantly between Group A and Group B from 15 min onwards intra-operatively, and at all points of time postoperatively. There was significant reduction in the diastolic

Variables	Baseline	Intra operative					Postoperative					F-value
		5 min	10 min	15 min	20 min	25 min	30 min	15 min	30 min	45 min	60 min	
Heart rate (Beats/min)												
Group A (Midazolam) (mean±SD)	79±4	75±3	75±4	77±4	76±3	75±3	76±3	76±3	74±3	74±3	75±4	5.067
Group B (Dexmede-tomidine) (mean±SD)	74±2	71±2	69±3	66±3	65±3	64±3	63±3	64±2	66±2	67±2	68±2	52.47
t	6.282	6.037	8.053	12.84	12.75	13.21	16.38	15.01	11.22	9.412	7.76	
p-value	0.08	0.07	**0.011**	**0.018**	**0.018**	**0.019**	**0.023**	**0.021**	**0.016**	**0.013**	**0.010**	
SBP (mmHg)												
Group A (Midazolam) (mean±SD)	110.4± 5.8	105.8± 5.9	105.6± 5.3	107.7± 5.2	106.1± 4.9	105.5± 4.7	106.8± 4.7	107.5± 4.6	105.3± 3.8	105.2± 3.9	106.0± 4.1	2.901
Group B (Dexmede-tomidine) (mean±SD)	110.9± 3.5	108.0± 2.8	106.1± 2.6	103.9± 2.7	102.1± 2.3	100.7± 2.0	101.0± 2.3	102.9± 2.2	104.3± 2.4	105.7± 2.0	107.3± 1.8	47.73
t	0.4	1.8	0.4	3.4	4.0	4.8	5.7	4.6	1.2	0.7	1.5	
p-value	0.7	0.1	0.7	**<0.001**	**<0.001**	**<0.001**	**<0.001**	**<0.001**	0.2	0.5	0.1	
DBP												
Group A (Midazolam) (mean±SD)	71.7±4.7	68.9±4.8	68.9±4.8	71.3±4.5	71.4±3.5	72.2±3.8	72.6±3.6	73.4±3.7	71.8±3.1	71.7±3.0	72.3±3.5	3.591
Group B (Dexmede-tomidine) (mean±SD)	72.3±1.9	70.2±2.0	68.4±2.7	66.3±2.5	64.8±2.6	63.7±2.3	63.3±2.1	64.9±2.0	66.5±1.9	67.6±2.0	68.8±1.4	48.74
t	0.6	1.3	0.5	5.0	8.0	9.7	11.1	10.08	7.572	6.101	4.836	
p-value	0.5	0.2	0.6	**<0.001**	**<0.001**	**<0.001**	**<0.001**	**0.014**	**0.01**	**0.018**	-0.05	
MAP (mmHg)												
Group A (Midazolam) (mean±SD)	84.6±4.7	81.2±4.6	81.2±4.5	83.4±4.2	83.0±3.5	83.3±3.4	84.0±3.3	84.8±3.5	83.0±2.9	82.9±2.8	83.6±3.3	2.817
Group B (Dexmede-tomidine) (mean±SD)	85.2±2.0	82.8±1.9	81.0±2.4	78.9±2.3	77.2±2.1	76.0±1.8	75.9±1.8	77.6±1.9	76.6±1.7	80.3±1.8	81.6±1.3	66.95
	0.6	1.7	0.2	5.0	7.3	9.3	10.5	9.0	6.0	4.2	2.9	
p-value	0.5	0.1	0.8	**<0.001**	**<0.001**	**<0.001**	**<0.001**	**<0.001**	**<0.001**	**<0.001**	0	
RR (Breaths/min)												
Group A (Midazolam) (mean±SD)	13.0±1.0	13.0±0.9	12.9±0.8	12.8±0.8	12.4±0.5	12.3±0.5	12.5±0.6	12.8±0.5	12.2±0.4	12.1±0.3	12.1	8.544
Group B (Dexmede-tomidine) (mean±SD)	12.8±0.8	12.2±0.4	12.2±0.4	12.3±0.5	12.3±0.4	12.3±0.5	12.2±0.4	12.1±0.3	12.3±0.4	12.3±0.4	12.1	4.29
t	1.1	3.8	4.2	2.9	1.1	0.3	2.7	5.6	0.6	1.3	0.0	
p-value	0.3	**<0.001**	**<0.001**	**<0.001**	0.3	0.8	**<0.001**	**<0.001**	0.5	0.2	1.0	
SpO_2 (%)												
Group A (Midazolam) (mean±SD)	99.2±0.7	99.1±0.8	99.4±0.6	99.4±0.6	99.7±0.5	99.8±0.4	99.9±0.2	99.9±0.3	99.8±0.4	100.0	100.0	13.25
Group B (Dexmede-tomidine) (mean±SD)	99.7±0.5	99.8±0.4	99.5±0.5	99.6±0.5	99.6±0.5	99.5±0.5	99.8±0.4	99.8±0.4	99.6±0.5	99.8	99.7	1.627
t	3.1	3.9	0.2	1.5	0.8	1.9	1.8	1.4	2.0	2.0	3.6	
p-value	**<0.001**	**<0.001**	0.8	0.1	0.4	0.1	0.1	0.2	**<0.001**	0	0	

[Table/Fig-3]: Heart Rate (HR), Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP), Mean Arterial Pressure (MAP), Respiratory Rate (RR) and Peripheral Oxygen Saturation (SpO_2) of all study participants.
p-values calculated by Repeated measure ANOVA test; SD: Standard deviation; Group A: Midazolam group; Group B: Dexmedetomidine group

blood pressure in group B as compared to group A [Table/Fig-3]. Mean MAP differed significantly between group A and group B from 15 min onwards intra-operatively and all time points postoperatively. There was significant reduction in the MAP in group B as compared to group A [Table/Fig-3].

Mean RR reduced significantly in Group B as compared to Group A at 5 min, 10 min, 15 min and 30 min during the operation and at 15 min postoperatively. Mean SPO_2 differed significantly between Group A and Group B at base line time and at 5 minutes time only. There was no significant difference at other point of intraoperative time. Further analysis showed that there was significant difference within Group A but not in Group B [Table/Fig-3].

Mean VAS differed significantly between Group A and Group B at all time points after the operation. The VAS score was less in Group B as compared to Group A in the post operative period. Ramsay sedation score differed in group A and group B at 15 min and 30 min postoperatively only. Ramsay sedation score is more in Group B as compared to Group A at 15 and 30 minutes postoperatively [Table/Fig-4].

No prevalence of side effects such as nausea, vomiting and hypoxia were observed. Only one patient of group B (Dexmedetomidine group) developed bradycardia (Heart rate <50 beats/minute) which was treated with injection Atropine 0.6 mg i.v.

ParemVisual Analog Scale (VAS)	Baseline	Postoperative			
		15 min	30 min	45 min	60 min
Group A (mean±SD)	3.4±0.5	2.1±0.3	2.3±0.5	2.2±0.4	2.2±0.4
Group B (mean±SD)	3.4±0.5	2.0±0.0	1.9±0.2	1.1±0.2	1.1±0.3
t	0.5	2.1	3.7	11.7	11.8
p-value	0.6	<0.001	<0.001	<0.001	<0.001
Ramsay Sedation Score (RSS)	**Baseline**	**Postoperative**			
		15 min	30 min	45 min	60 min
Group A (mean±SD)	1.6±0.5	3.4±0.5	3.3±0.5	3.0±0.4	3.0±0.3
Group B (mean±SD)	1.8±0.4	4.0±0.0	3.9±0.2	3.0±0.2	3.0±0.0
t	1.4	5.8	6.3	1.7	1.8
p-value	0.2	<0.001	<0.001	0.1	0.1

[Table/Fig-4]: Mean VAS and RSS score of all participants and their comparative analysis.
p-values calculated by Independent t-test; VAS analysis

DISCUSSION

Preoperative anxiety is a frequent medical condition. It may lead to psychological trauma and increase the release of stress hormones [1,2]. Various agents have been used to relieve the anxiety and provide sedation. Benzodiazepines are most frequently used drugs. Midazolam is the medication from this group having rapid onset and short lasting effect and can be used for sedation [5-7]. Dexmedetomidine which is α-2 adrenoceptor agonist having sedative, anxiolytic and sympatholytic effect and can be used in conjunction with anaesthesia for premedication [8,9,12].

In this study we have compared the anaesthetic and haemodynamic effects of Injection Dexmeditomidine and Injection Midazolam used as premedication in short gynaecological procedures. In this study, we enrolled 60 patients of ASA grade one and two with 30 patients in each group.In the present study there was significant reduction in HR, SBP, DBP and MAP in the Dexmedetomidine group (Group B) as compared to Midazolam group (Group A). But this decrease was within limits. Dexmedetomidine induced bradycardia was not found to be clinically challenging and can be treatable. Hypotension and bradycardia caused by Dexmedetomidine could be explained by its agonist action on central α–2 receptors which decreased the release of Noradrenalin from sympathetic nervous system [8,16].Similar results were found in the study conducted by Eren G et al., where they have done the comparison of Dexmedetomidine and three different doses of Midazolam as preoperative sedation [16]. Results of the present study are also comparable to those of study done by Erkola O et al., [10], who compared the effects of Dexmedetomidine and Midazolam in elective abdominal surgery. The similar results were also found in the study conducted by Kumari A et al., [17]. Here they have compared the sedative and Propofol sparing effect of Dexmedetomidine and Midazolam as premedicants in minor gynecological surgeries.

When respiratory rate and SpO_2 values were evaluated, Dexmedetomidine caused reduction in the respiratory rate as compared to Midazolam but without compromising the SpO_2 values in both the groups. Similar results were obtained in the studies done to see the effects of Dexmedetomidine on respiratory parameters like in the study done by Hall JE and colleagues [18]. Venn RM et al., studied the respiratory effects of Dexmedetomidine in postoperative intensive care unit patients and found similar results [19].

Sedative and anxiolytic effects of both the drugs were studied with the help of Ramsay sedation score and VAS, respectively. Both Midazolam and Dexmedetomidine caused satisfactory sedation and anxiolysis in the pre and postoperative period as compared to the base line values. But Dexmedetomidine caused more intense sedation and anxiolysis as compared to Midazolam. Similar results were observed in the study conducted by Eren G et al., [16] and also in the study conducted by Anita Kumari and colleagues [17].

Side effects like hypotension and bradycardia were treated accordingly. Only one patient from Dexmedetomidine group developed bradycardia (pulse <50 beats per minute), which was treated by giving injection Atropine 0.6 mg intravenously. None of the patient from both the groups developed apnoea or desaturation. None of the patient had nausea or vomiting either.

Limitation(s)

Study was done for gynaecological procedures only and it can be used for other short procedures.

CONCLUSION(S)

Dexmedetomidine is more effective as a sedative agent than Midazolam when used for minor gynaecological procedures. Although Dexmedetomidine caused significant reduction in SBP, DBP, MAP and HR, it maintained haemodynamic stability well within limits without causing any adverse effects.

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