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Comparison of Dexmedetomidine and Midazolam for Preoperative Sedation in Patient Under Going Surgeries Under Spinal Anaesthesia

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Abstract

Preoperative anxiety is a frequent condition. Generally, it starts two days before the operation and reaches its peak just prior to induction of anesthesia. Anxiety, stress, and fear that arise just before the operation and anesthesia may lead to psychological trauma and increase the levels of stress hormones, resulting in undesirable metabolic responses before anesthesia. In our study primary objective was to compare the effectiveness of dexmedetomidine and midazolam with control group in preoperative sedation prior to surgical procedures. Considering the sample size and methodology of the seed article a sample size of 207 was obtained This prospective, hospital based, comparative study was conducted in Department of Anesthesia, Mahatma Gandhi Medical College & Hospital, Jaipur over a period from March 2023 to august 2024. Group C was control, Group D was dexmedetomidine, and Group M was the midazolam group. Patients of Group C were given 100 ml of physiological saline over 10 min. patients of Group D were given 0.25 µg/kg dexmedetomidine in 100 ml physiological saline over 10 min. Group M were given 0.03 mg/kg midazolam in 100 ml physiological saline over 10 min. Group D (dexmedetomidine group) has significantly lower bromage score, Anxiety, and VAS scores, demonstrating better overall recovery, reduced anxiety, and less pain as compare to other two group. Also group D patient show better stabilization of vital parameter.

Introduction

Preoperative anxiety is a frequent condition. Generally, it starts two days before the operation and reaches its peak just prior to induction of anaesthesia.[1]

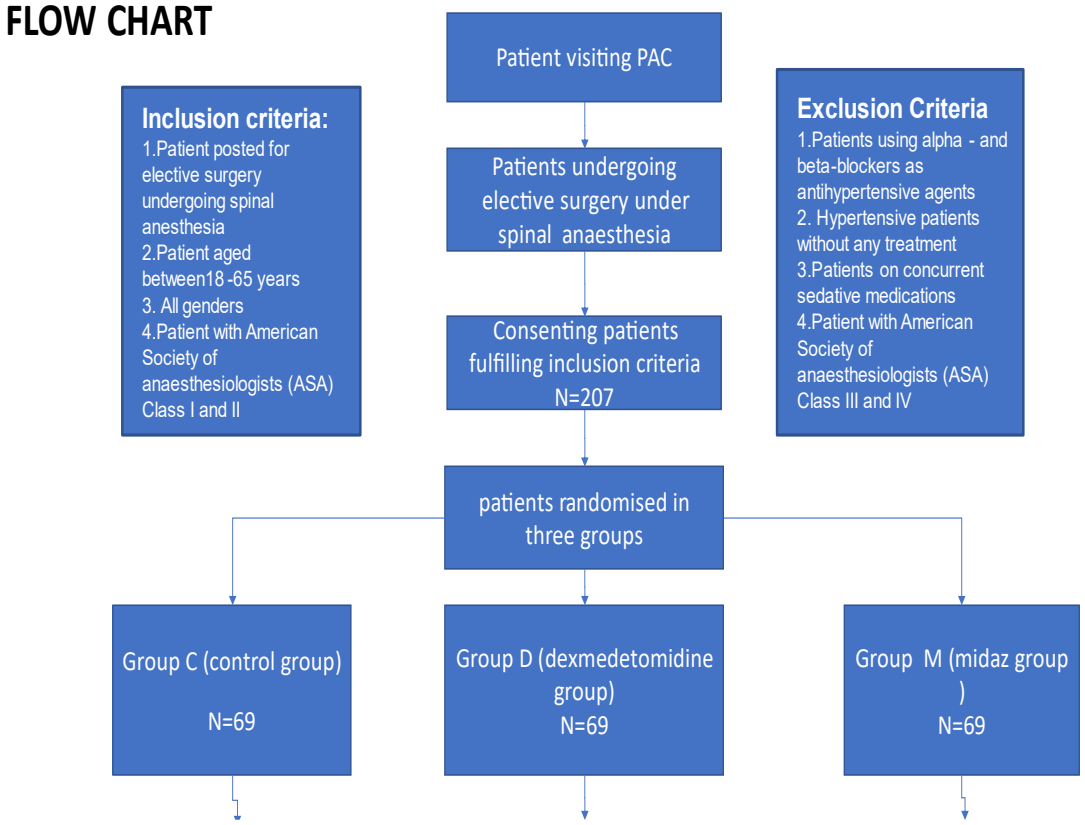
Anxiety is more common in younger patients, women, and people with negative experience of anaesthesia or fear of death[2]. Anxiety, stress, and fear that arise just before the operation and anaesthesia may lead to psychological trauma and increase the levels of stress hormones, resulting in undesirable metabolic responses before anaesthesia. High catecholamine levels increase arterial blood pressure, heart rate, and oxygen consumption.[3 ,4] Controlling these metabolic reactions is a necessity for modern anaesthesia.[5] Comfortable anaesthesia induction and maintenance can be achieved by controlling anxiety. Various agents such as phenothiazines, benzodiazepines, barbiturates, opioids, and antihistamines are have been used to relieve anxiety and provide sedation. Now days, the most frequently used drugs are benzodiazepines.[6] Midazolam has rapid onset and short lasting effect. [7-12] Its

sedative effect has been shown in many studies.Dexmedetomidine is a selective, specific, and highly potent alpha-2 adrenoceptor agonist.[13-15] The affinity of alpha-2/ alpha-1 receptors, only alpha-2 effects are observed in low-moderate doses and slow administrations. It has anxiolytic, hypnotic, sedative, and analgesic effects. It affects alpha-2 receptors in the central nervous system, peripheral nerves, and autonomic ganglions. It is widely used in intensive care units due to these characteristics. in our study primary objective was to compare the effectiveness of dexmedetomidine and midazolam with control group in preoperative sedation prior to surgical procedures.

Methodology

Considering the sample size and methodology of the seed article a sample size of 207 was obtained This prospective, hospital based, comparative study was conducted in Department of Anaesthesia, Mahatma Gandhi Medical College & Hospital, Jaipur over a period from march 2023 to august 2024 . After ethical committee's approval, informed written consent was obtained from all patient .During a preanesthetic visit, the patients Were informed about the procedure and written informed consents of all participants were obtained, a day before surgery.

The participants were randomized into three groups with computer generated radomized table. Group C was control, Group D was dexmedetomidine, and Group M was the midazolam group. Patients of Group C were given 100 ml of physiological saline over 10 min. patients of Group D were given 0.25 µg/kg dexmedetomidine in 100 ml physiological saline over 10 min. Group M were given 0.03 mg/kg midazolam in 100 ml physiological saline over 10 min. These drugs were given by independent anaesthesiologist thus investigator will be blinded to group allocation of patient. The agents used in sedation were administered by an intravenous slow infusion in the preparation room in order to provide better control and stop them in case of any complication.



Type of study design:-

Hospital based, Prospective, Comparative, Randomized Study, single blind type.

Types of data collection: Quantitative and qualitative Data

Inclusion criteria:

1. Patient posted for elective surgery undergoing spinal anaesthesia
2. Patient aged between18-65 years
3. All genders
4. Patient with American Society of anaesthesiologists (ASA) Class I and II

Exclusion Criteria

1. Patients using alpha- and beta-blockers as antihypertensive agents
2. Hypertensive patients without any treatment
3. Patients on concurrent sedative medications
4. Patient with American Society of anaesthesiologists (ASA) Class III and IV

The patients Were transferred to preparation room 30 minutes prior to anaesthesia induction. They were reminded about the procedure and on how to use the visual analog score (VAS) ,Non-invasive blood pressure measurement, electrocardiography, and peripheral oxygen saturation monitoring. Peripheral venous routes were accessed via 20-G catheters. The infusions of the medications will be started 15 minutes before anesthesia induction and infusions will be completed in 10 minutes .All patients were given spinal anesthesia in sitting position with standard technique, 25 G. Quinks spinal needle and 3.5 ml of 0.5 % bupivacaine heavy at L3- L4 or L2- L3 levels after adopting sterile technique.

Vitals were recorded base line , and every 5 th minute till 30 minute after induction and after that every 15 min till effect of spinal anaesthesia . Perioperative Hemodynamic monitoring, Ramsay sedation score, Modified Bromage scale, Post op nausea vomiting, pruritis ,headache etc. were recorded

Plan for statistical analysis of the study .

1. The sample size was calculated using the formula for one way ANNOVA by anticipating effect size of 0.25 between the 3 groups (group C, D,M).
2. The final sample size was estimated to be 69 in each group with 5% level of significant and 90 % power.

Analysis plan

1. All the category variables weresummarized as frequency with % all the continuous variable B.P., HR ,MAP etc
2. As mean with std. deviation or median with interquartile range depending upon the distribution of data . The normality assumption would be checked by KOLMOGOROV SMIRNOV test. The mean difference in the RAMSAY score , modified bromage scale etc in between 3 groups were assesed by one way ANOVA .
3. All the statistical test were done at 5% level of significance and p value <0.05 will be considered as statistically significant .

Modified Bromage Scale	
Activity	**Score**
Able to lift legs against gravity	0
Able to flex knee but unable to flex legs	1
Able to move feet but unable to flex knee	2
Unable to move any joints	3

RAMSAY SEDATION SCORE

Sedation Level	Score
Patient is anxious and agitated or restless, or both	1
Patient is co-operative, oriented, and tranquil	2
Patient responds to commands only	3
Patient exhibits brisk response to light glabellar tap or loud auditory stimulus	4
Patient exhibits a sluggish response to light glabellar tap or loud auditory stimulus	5
Patient exhibits no response	6

Amsterdam pre operative anxiety and information scale

Questions	The Amsterdam preoperative anxiety and information scale				
	1	2	3	4	5
1. I am worried about the anesthetic	□	□	□	□	□
2. The anesthetic is on my mind continually	□	□	□	□	□
3. I would like to know as much as possible about the anesthetic	□	□	□	□	□
4. I am worried about the procedure	□	□	□	□	□
5. The procedure is on my mind continually	□	□	□	□	□
6. I would like to know as much as possible about the procedure	□	□	□	□	□

1: Not at all, 2: Somewhat, 3: Moderate, 4: Moderately high, 5: Extremely

RAMSAY SEDATION SCORE

Sedation Level	Score
Patient is anxious and agitated or restless, or both	1
Patient is co-operative, oriented, and tranquil	2
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Patient exhibits no response	6

Result

	Group C N=69	Group M N=69	Group D N=69
Genders			
Male	37 (53.60%)	47 (68.10%)	43 (62.30%)
Female	32 (46.40%)	22 (31.90%)	26 (37.70%)
Age	39.4±11.2	41.7±13.7	42.8±13.2
Height	164.5±9.8	168.7±10.7	166.4±8.6
Weight	69.3±7.9	72.4±9.2	74.1±8.8

Table 1- Demographic details in each group

POST-OP and INTRA-OP COMPLICATIONS	Group C N=69	Group M N=69	Group D N=69	P value
NAUSEA/VOMITTING	5 (7.2%)	9 (13 %)	1 (1.4%)	**0.03**
SPINAL HEADACHE	8 (11.6%)	4 (5.8 %)	1 (1.4%)	**0.04**
BRADYCARDIA	4 (5.8 %)	7 (10.1%)	1 (1.4%)	**0.04**
SHIVERING	8 (11.6%)	6 (8.7%)	-	0.5
HYPOTENSION	5 (7.2%)	6 (8.7%)	-	0.7

Table 2- Distribution of side effects in each group

BASE LINE AND INTRA-OP VITALS AT 25-30 MIN	Group C N=69	Group M N=69	Group D N=69	P value
DBPBaseline	105.5±3.1	104.7±3	105.9±3.6	0.6
DBP At 25 MIN	80.73±6.3	74.8±8.3	73.2±8.7	**0.03**
DBP At30 MIN	79.8±5.2	74.2±7.5	72.9±8.1	**0.02**
SBP Baseline	139.7±3.1	139.6±2.5	140.9±3.3	0.4
SBP At 25 MIN	92.4±9.8	90.8±5.7	83.2±10.5	**0.01**
SBP At 30 MIN	91.9±9.5	90.6±5.5	82.8±10	**0.01**
SPo2 Baseline	98.9±0.7	99±0.8	98.8±0.7	0.7
SPo2 At 25 MIN	98.7±0.96	98.6±0.9	99±0.9	0.5
SPo2 At 30 MIN	98.8±1	98.6±0.96	98.4±1	0.5
PR Baseline	84.3±8.4	84.5±8.4	84.1±9.4	0.9
PR At 25 MIN	88±7.7	87.6±7	88±6.4	0.8
PR At 30 MIN	88.2±7.7	88±6.9	88.5±6.8	0.8
Baseline MAP	39.24±4.8	40.6±4	38.73±4.9	0.6
MAP At 25 MIN	34.91±0.2	35±0.3	34.8±0.2	0.7
MAP At 30 MIN	34.89±0.3	34.82±0.4	34±0.2	0.6
Baseline RR	17±2.3	17.2±1.6	16.9±1.8	0.4
RR At 25 MIN	16.8±2.7	16.6±1.4	17±1.5	0.4
RR At 30 MIN	16.6±2.9	16.7±1.5	16.6±1.5	0.4

Table 3- Vital comparison at baseline vs intra-op at 25min and 30min

*Mean±SD

*Level of significance = 0.05

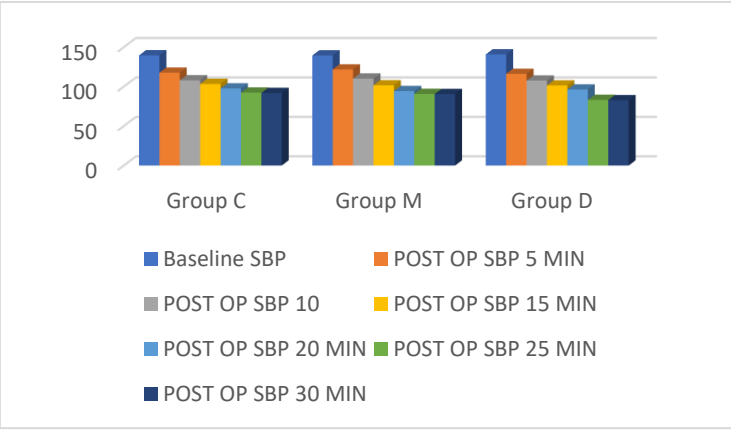

Fig 1 SBP visual representation across all timeline

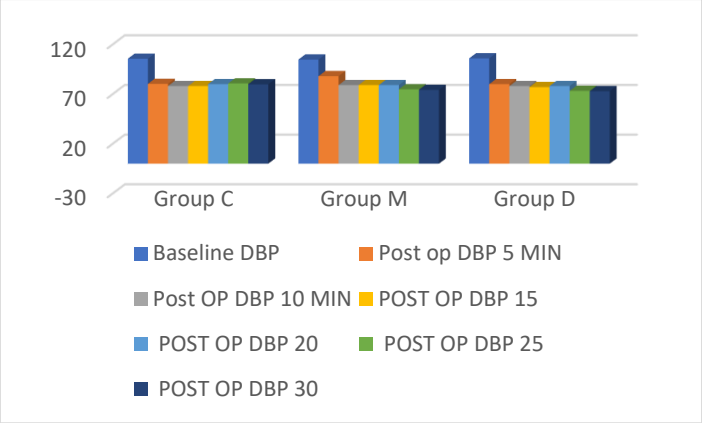

Fig 2 DBP visual representation across all timeline

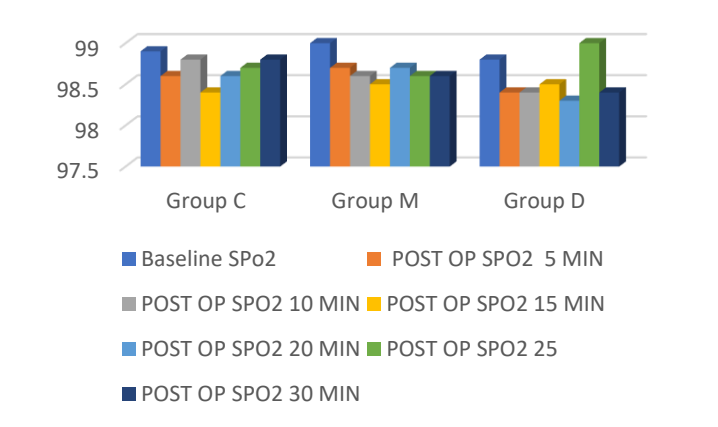

Fig 3 SPo2 visual representation across all timeline

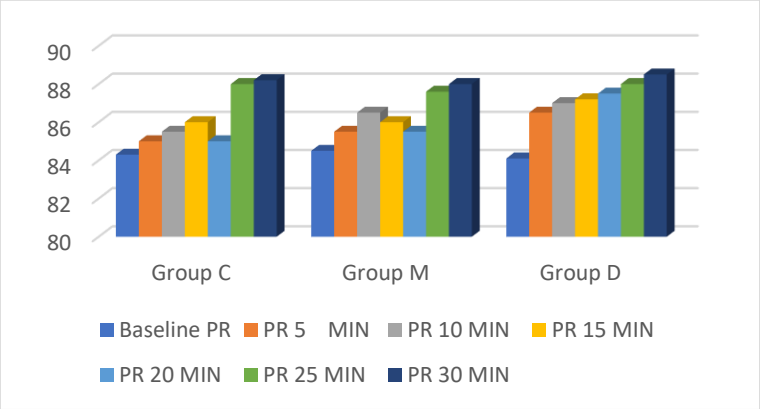

Fig 4 PR visual representation across all timeline

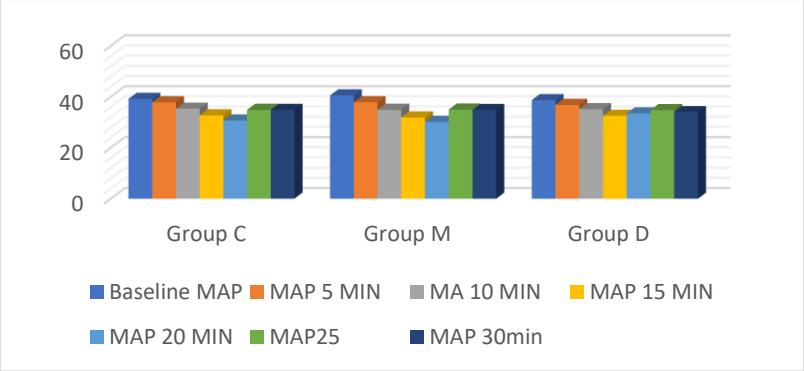

Fig 5 MAP visual representation across all timeline

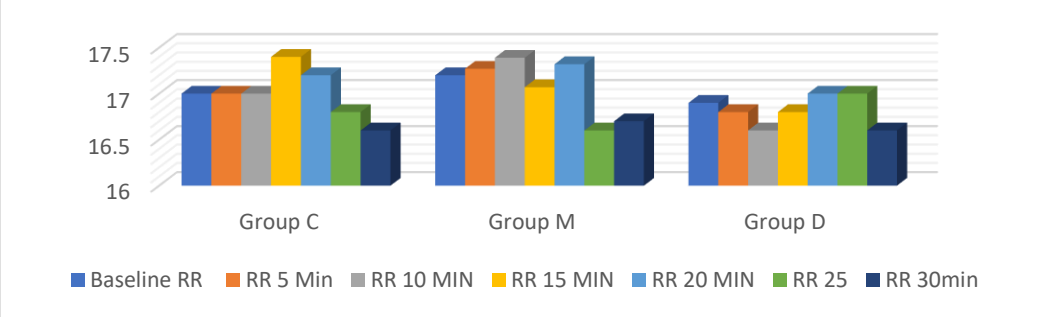

Fig 6 RR visual representation across all timeline

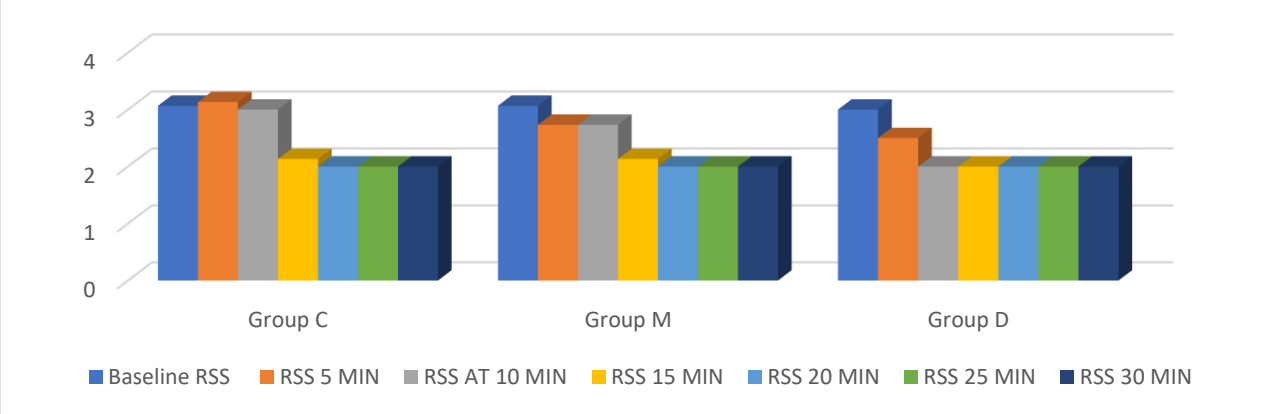

Fig 7- RSS scores visual representation across all timeline

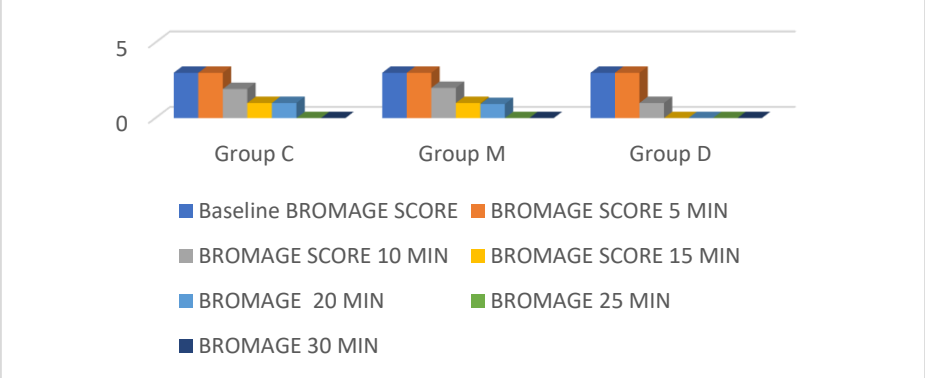

Fig 8- BROMAGEscores visual representation across all timeline

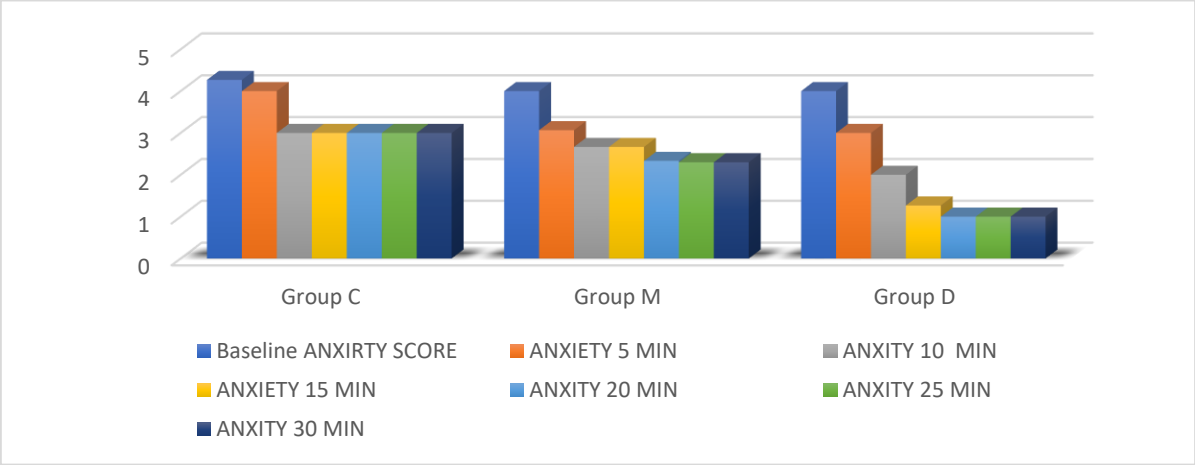

Fig 9- Anxity scores visual representation across all timeline

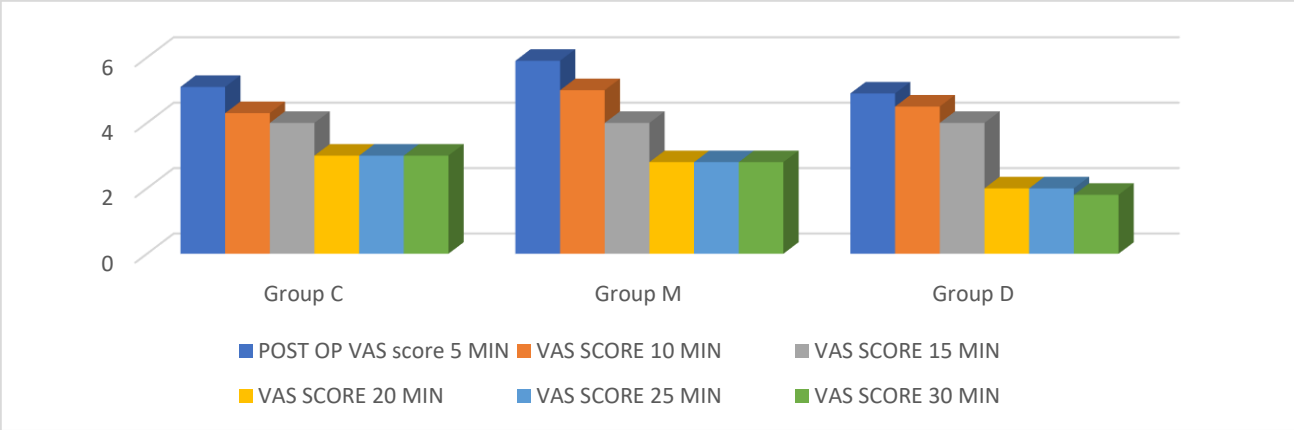

Fig 10- VAS scores visual representation across all timeline

Results Summary:

POST-OP and INTRA-OP COMPLICATIONS:

- A Chi-Square test was performed to compare the proportion of patients experiencing the side effects**Nausea/Vomiting**, **Spinal Headache**,**Bradycardia** and **Shivering**across the three treatment groups (Group C, Group M and Group D).
- The results showed **statistically significant difference** in the proportion of side effects between the groups ($p < 0.05$).
- This indicates that the incidence of **Nausea/Vomiting**, **Spinal Headache**,**Bradycardia** and **Shivering**is different among patients treated with all three drugs.

Baseline and Intra-Operative Vitals (25-30 min):

- An **ANOVA test** was conducted to compare baseline and intra-operative vitals at the 25-30minute mark across the three drug groups.
- The analysis revealed a **statistically significant difference** ($p < 0.05$) in vitals between the groups at both baseline and during intra-operative monitoring.
  - This suggests that the drugs had different impacts on vital signs (SBP and DBP), with one or more drugs (likely Group D) showing significantly better stabilization of vital parameters compared to the others.

Data Visualization Summary:

- The visualized data (Fig) highlights that **Group D** (dexmed group)has significantly **lower bromage score , Anxiety, and VAS scores**, demonstrating better overall recovery, reduced anxiety, and less pain as compare to other two group . also group D patient show better stabilization of vital parameter.

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