

## Comparative Study of Dexmedetomidine and Propofol for Intraoperative Sedation During Surgery Under Regional Anaesthesia

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### ABSTRACT

**Background:** Regional anaesthesia offers several benefits to the patients like staying awake, early family contact, early food intake. This study was done to evaluate cardio-respiratory end points at equi-sedative doses of dexmedetomidine and propofol. Secondary end points for comparison were time to achieve sedation onset and offset, postoperative analgesia requirements and psychomotor test performance.

**Material & Methods:** This study was conducted in 80 adult ASA grade I and II patients undergoing surgeries under regional anaesthesia in the department of Anaesthesiology at Santokba Durlabhji Memorial Hospital cum Research Centre, Jaipur (Rajasthan), after approval from the institutional ethical committee. Patients were randomly allocated to dexmedetomidine (Group I) and propofol (Group II) groups. The objective of the study was to compare the efficacy, side effects, and recovery characteristics of dexmedetomidine versus propofol when used for Intra operative sedation.

**Results:** The mean heart rate decreased significantly in both groups in intraoperative period. At the end of surgery it was  $69.57 \pm 3.48$  in group I and  $72 \pm 5.53$  in group II ( $p$  value = 0.0185, i.e.  $< 0.05$ ). HR changes at different time interval in both group were statistically significant ( $p < 0.05$ ). We did not found any statistically significant difference in respiratory rate at different time intervals compared to baseline value in all groups ( $p > 0.05$ , i.e., not significant). VAS score changes at

different time interval in both groups were statistically significant ( $p < 0.05$ , i.e. significant).

**Conclusion:** On the basis of results derived in our study, it can be concluded that dexmedetomidine achieve similar levels of sedation to propofol, with a slower onset and offset of sedation. Neither dexmedetomidine nor propofol influence respiratory rate, but propofol result in lower MAP during the intraoperative period.

**Key Words:** Regional Anaesthesia, Dexmedetomidine, Propofol, Heart Rate, Respiratory Rate.

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### INTRODUCTION

Regional anaesthesia offers several benefits to the patients like staying awake, early family contact, early food intake.<sup>1</sup> Preservation of protective airway reflexes are the most important advantages however stress of surgery in fully awake state may lead to anxiety and restlessness, so there is always need of sedation preoperatively. Dexmedetomidine may be useful for perioperative sedation. It has a slower onset and offset of sedation compared with propofol. Dexmedetomidine is associated with improved analgesia.<sup>2</sup> This study was done to evaluate cardio-respiratory end points at equi-sedative doses of dexmedetomidine and propofol. Secondary end points for comparison were time to achieve sedation onset and offset, postoperative analgesia requirements and psychomotor test performance.

### MATERIALS AND METHODS

This study was conducted in 80 adult ASA grade I and II patients undergoing surgeries under regional anaesthesia in the department of Anaesthesiology at Santokba Durlabhji Memorial Hospital cum Research Centre, Jaipur (Rajasthan), after approval from the institutional ethical committee duration from August'2014 to November'2015.

Patients were randomly allocated to dexmedetomidine (Group I) and propofol (Group II) groups. After regional anaesthesia, patients in Group I received a loading dose of 1  $\mu\text{g}/\text{kg}$  of dexmedetomidine intravenously by infusion pump over 10 mins followed by a maintenance dose of 0.5-0.7  $\mu\text{g}/\text{kg}/\text{hr}$  till the end of surgery whereas the Group II received intravenous infusion of

injection propofol (75 µg/ kg-1 min-1) for 10 min and maintenance dose (30-60 µg. kg-1. min-1 ) until sedation achieved based on an Observer's Assessment of Alertness / Sedation score 3. After achieving the targeted OAA/S, surgery was begun and infusion doses were adjusted to maintain an Observer's Assessment of Alertness / sedation score <sup>3</sup>.The objective of the study was to compare the efficacy, side effects, and recovery characteristics of dexmedetomidine versus propofol when used for Intra operative sedation.

In this study, the cardio respiratory effects were evaluated by measuring Mean arterial pressure, SPO<sub>2</sub>, heart rate and respiratory rate (recorded preoperatively in OT and intra-operatively at every 5 min intervals up to 60 minute and at the end of surgery, and then postoperatively at 5 min, 20 min, 35 min, 50 min and 65 min). Sedation was assessed by Observer's assessment of alertness/sedation scale (OAA/S). Intra operative sedation levels were targeted to achieve an Observer assessment of alertness/sedation scale score.<sup>3</sup>

Pain was assessed by Visual Analog Scale(VAS score)<sup>4</sup>, which was recorded in preoperative period and then post operatively at 5 min, 20 min, 35 min, 50 min and 65 min. The digital symbol substitution test (DSST)<sup>5</sup>for assessing psychomotor performances

was performed in the preoperative holding area, before the start of the surgical procedure and repeated at 15 and 45 min into recovery room after surgery. Complications and side effects and postoperative analgesic demanded in recovery room were also recorded.

**Exclusion Criteria**

Patient with history of severe cardiovascular disease like left ventricular ejection fraction <30% and 3°heart block are excluded. Psychiatric patient and patient with >50% of ideal body weight are also excluded.

**Statistical Analysis**

All data collected was entered in excel sheet to prepare master chart and was subjected to statistical analysis. Continuous variables were summarized as mean and standard deviation whereas nominal/categorical variables as proportions (%). Unpaired T test was used for analysis of continuous variables. While chi square test was used for nominal / categorical variable as per data yield.

**OBSERVATIONS**

There was no significant difference in demographic data in both the group (Table 1).

**Table 1: Demographic data**

	GROUP I	GROUP II	p-value
Age (Mean ± SD)	44.97 ± 14.95	43.9 ± 14.91	0.74
Weight (Mean ± SD)	64.02 ± 12.45	65.27 ± 11.77	0.64
Sex ( M : F )	1:1	1:1	1:1
Spinal Anesthesia (No.)	31	22	
Spinal + Epidural	3	8	
Nerve Block (No.)	6	10	
Duration of Surgery (Min) (Mean ± SD)	81.87 ± 17.52	86.0 ± 21.42	0.34

We compared both the drugs on following parameters:

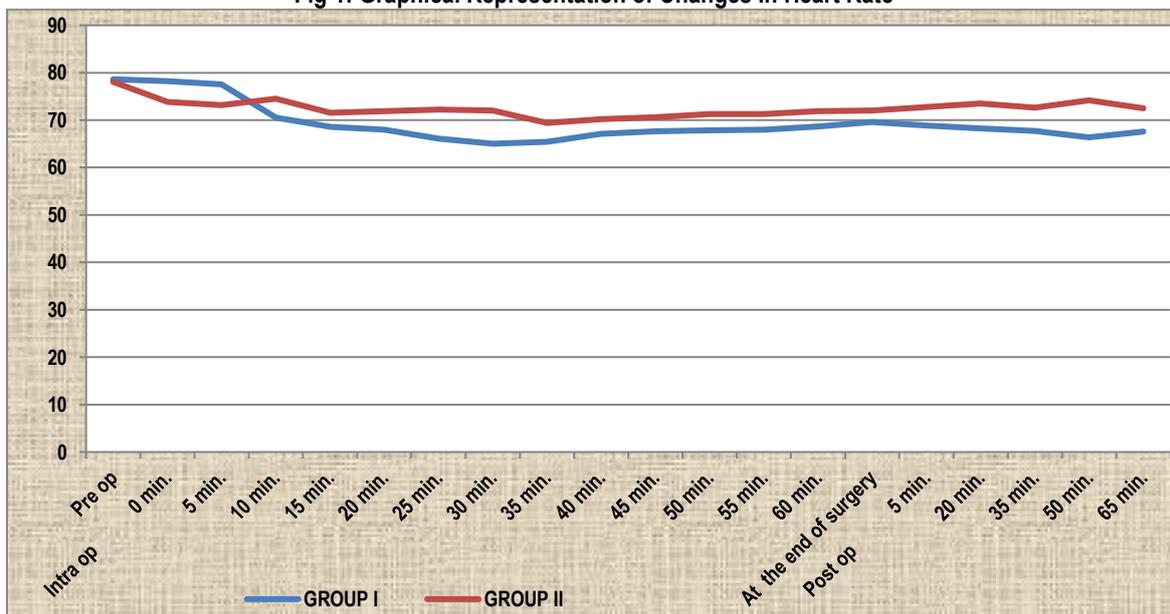
**1. CARDIO-RESPIRATORY VARIABLES**

**Heart Rate**

In our study, the baseline values of heart rate were almost similar in both groups. It was 78.62±11.40 in group I and 78.05±10.86 in group II (p value=0.8195, i.e.,>0.05). The mean heart rate decreased significantly in both groups in intraoperative period. At

the end of surgery it was 69.57±3.48 in group I and 72±5.53 in group II (p value =0.0185, i.e.,<0.05) . In postoperative period heart rate remain lower in group I but in group II heart rate reached near to the base line value. HR changes at different time interval in both group were statistically significant (p<0.05).

**Fig 1: Graphical Representation of Changes In Heart Rate**



**Mean Arterial Pressure**

The baseline values of MAP were similar in both the groups. It was  $99.72 \pm 6.30$  in group I and  $97.77 \pm 6.49$  in group II ( $p$  value =  $0.1766 > 0.05$ ).

After administration of study drug mean blood pressure decreased significantly in both groups and there occur maximum fall (16.38%) in MAP ( $81.75 \pm 5.92$ ) in group II at 10 min ( $p = 0.0001$ , i.e.,  $< 0.05$ ). At the end of surgery it was  $88.15 \pm 4.93$  in group I and  $86.05 \pm 3.57$  in group II ( $p = 0.0321$ , i.e.,  $< 0.05$ ). In postoperative period MAP remain lower in group I but in group II MAP reached near to the base line value.

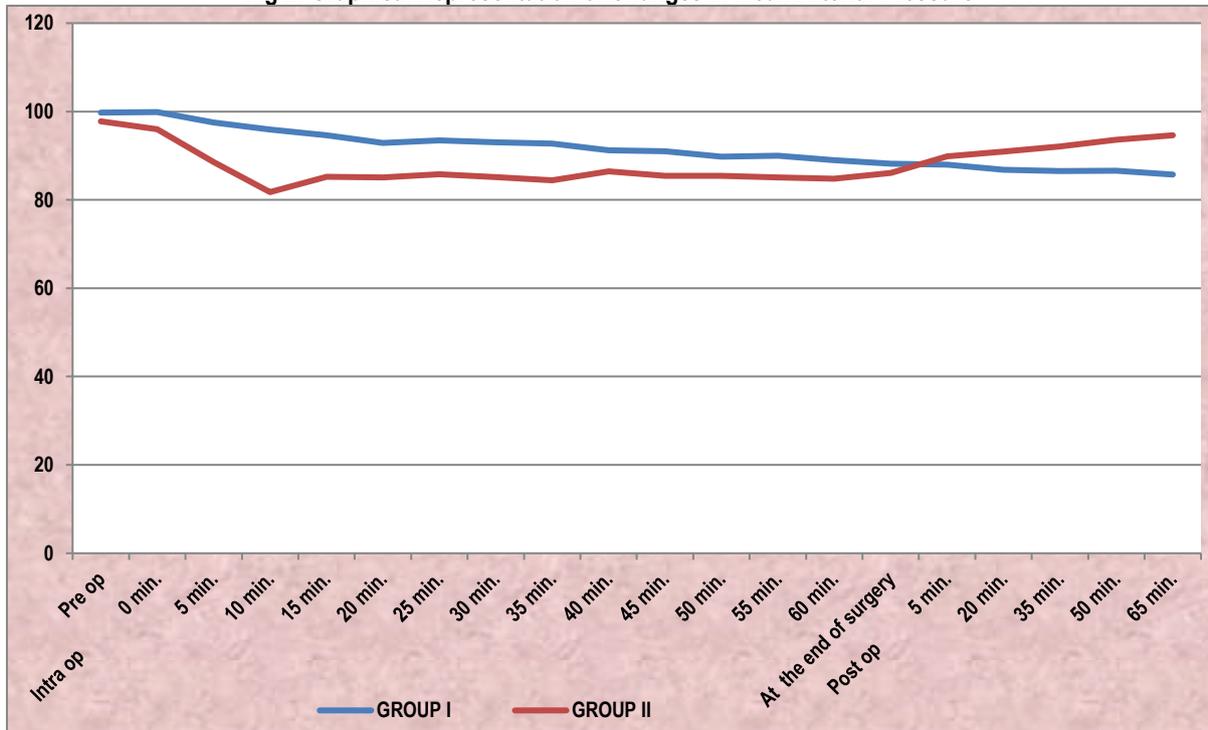
**SPO<sub>2</sub>**

Using student t-test, we were unable to find any consistent pattern of significant difference at different time intervals compared to baseline value in all groups. Mostly all the patients had more than 97% SPO<sub>2</sub> at all-time intervals.

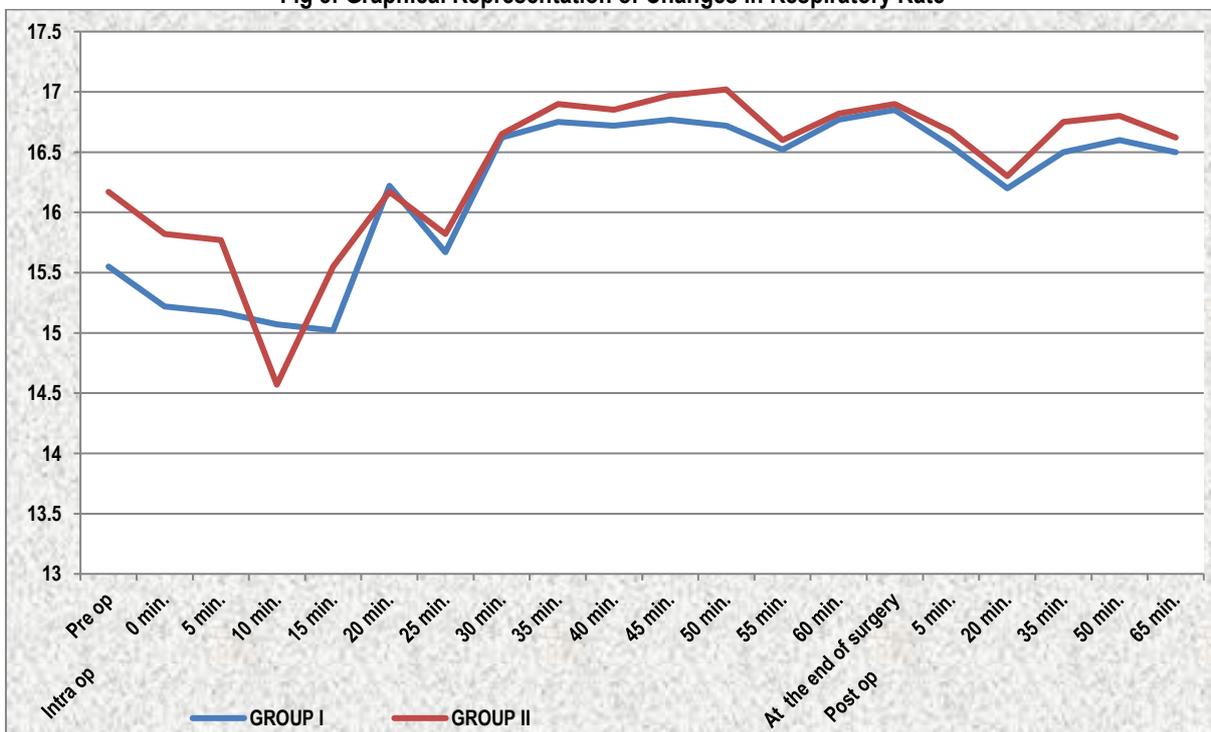
**Respiratory Rate**

The baseline values of Resp. Rate were similar in both the groups. It was  $15.55 \pm 2.18$  in group I and  $16.17 \pm 1.53$  in group II ( $p = 0.1450$ , i.e.,  $> 0.05$ ). We did not found any statistically significant difference at different time intervals compared to baseline value in all groups ( $p > 0.05$ , i.e., not significant).

**Fig 2: Graphical Representation of Changes In Mean Arterial Pressure**



**Fig 3: Graphical Representation of Changes In Respiratory Rate**



**2. SEDATION**

**Observer's assessment of alertness/sedation scale (OAA/S)**

The baseline values of OAA/S were similar in both the groups. It was  $4.85 \pm 0.36$  in group I and  $4.90 \pm 0.30$  in group II ( $p=0.5018$ , i.e.,  $>0.05$ ). The OAA/S decreased significantly in both groups in intraoperative period. Desired OAA/S level close to 3 was achieved in group I at 25 min ( $p=0.0228$ , i.e.,  $<0.05$ , i.e., significant) and in group II at 10 min ( $p$  value  $<0.0001$ , i.e., significant). There occur maximum fall in OAA/S in group I ( $2.70 \pm 0.46$ ) at 30 min ( $p=0.0485 < 0.05$ , i.e., significant) and in group II ( $2.57 \pm 0.60$ ) at 15 min ( $p < 0.0001$ , i.e., significant). In postoperative period OAA/S reached near to the base line value in both groups. In postoperative period the value of OAA/S after 5 min was  $4.22 \pm 0.42$  in group I and  $4.45 \pm 0.50$  in group II ( $p=0.0089 < 0.05$ , i.e., significant). When fall in the values of OAA/S in both groups at

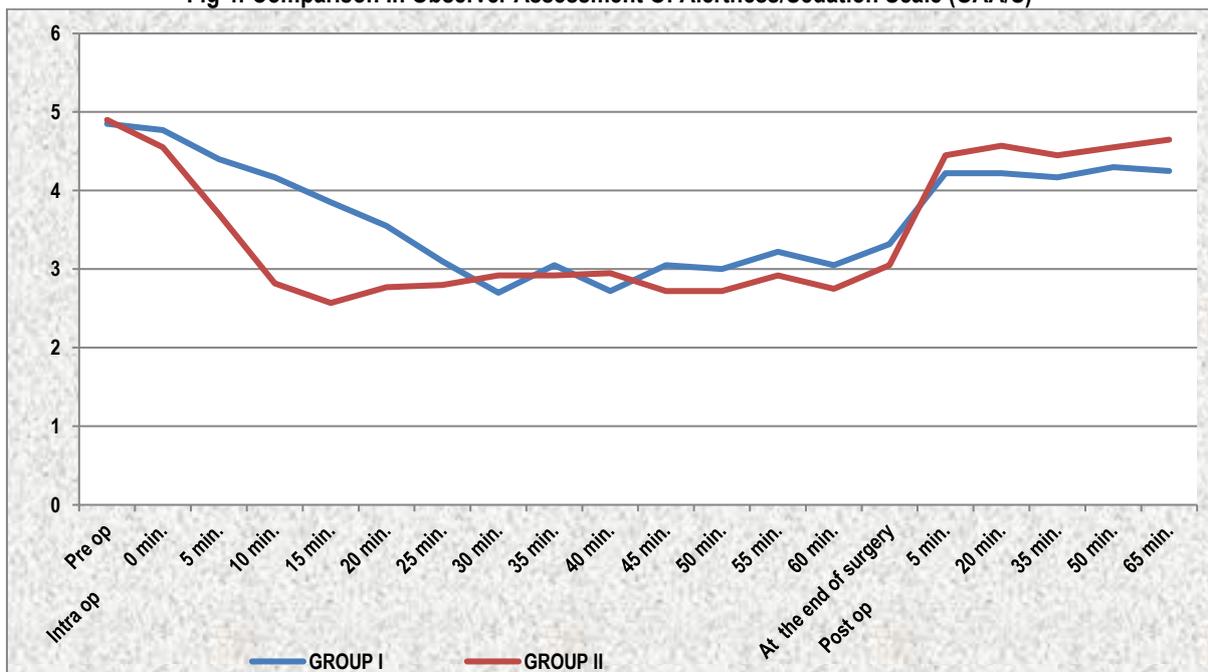
different time interval were analysed statistically it was found significant. Similar results were also found by Arain SR et al.<sup>2</sup>

**3. PAIN**

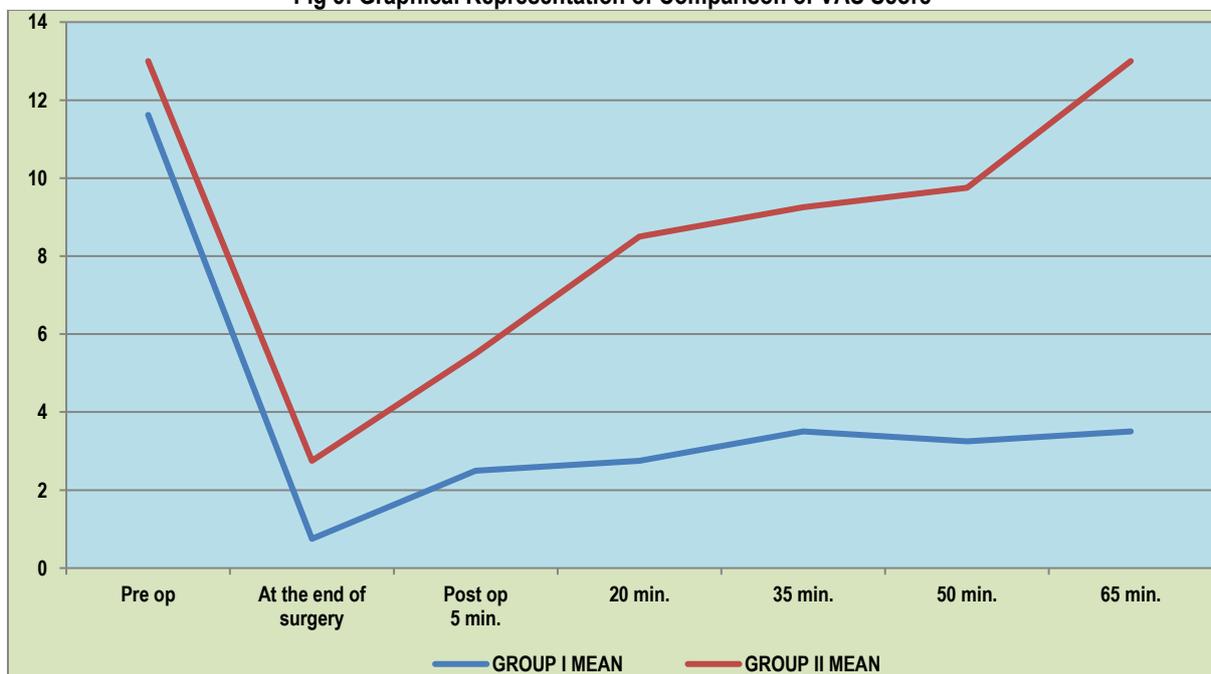
**Visual Analog Scale for pain (VAS score)**

Preoperative value of VAS was similar and statistically insignificant in both groups. It was  $11.62 \pm 11.46$  in group I and  $13.00 \pm 12.18$  in group II ( $p=0.6032 > 0.05$ ). At the end of surgery it was  $0.75 \pm 2.67$  in group I and  $2.75 \pm 5.06$  in group II ( $p=0.0300 < 0.05$ , i.e., significant). In postoperative period VAS score remained lower in group I compared to group II. so, the VAS score changes at different time interval in both groups were statistically significant ( $p < 0.05$ , i.e., significant). In conclusion, our study found that group I (dexmedetomidine) was useful agent for postoperative analgesia.

**Fig 4: Comparison In Observer Assessment Of Alertness/Sedation Scale (OAA/S)**



**Fig 5: Graphical Representation of Comparison of VAS Score**



#### 4. PSYCHO MOTOR PERFORMANCE

##### Digital symbol substitution test (DSST)

By digital symbol substitution test (DSST) psychomotor tests performed before surgery and at 15 min and 45 min after surgery. Both groups had impaired performance on this test 15 min after surgery. After 45 min of surgery both groups had improvement in performance on this test.

#### 5. SIDE EFFECTS AND COMPLICATIONS

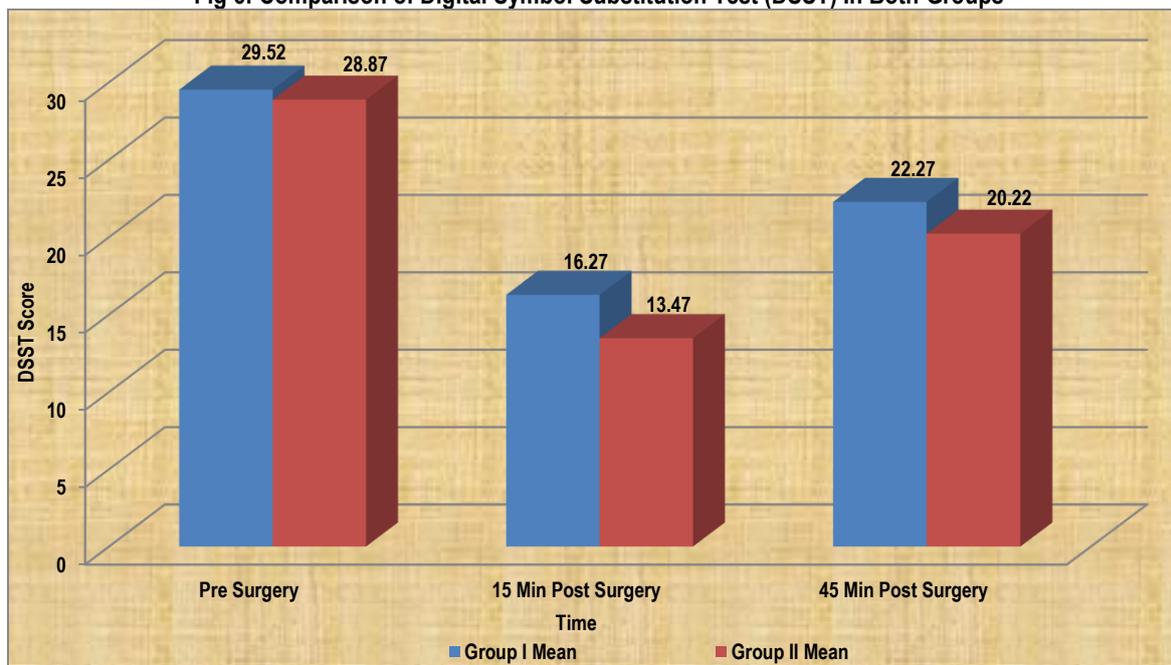
In this study, side effects like nausea and vomiting were noticed. Hypotension was more (24%) in group II compared to 12% in group I (p value = 0.007). Bradycardia was noticed more in group I (25%) compare to group II (7.5 %) (p value =0.033). Complication of respiratory depression and hypertension was not seen in both

the groups. In group I (5%) of patients complain of dry mouth but there was no such complain in group II. Complain of pain was more in group II (20%) compare to group I (5% only) (p value =0.042).

#### 6. REQUIREMENT OF ADDITIONAL ANALGESIA

Requirement of additional analgesia during recovery period was significantly reduced in group I compared with that in group II. In group I, 95% of patients did not require any additional analgesia while in group II, 80% did not require any additional analgesia. (p=0.0425, i.e., <0.05, significant) So dexmedetomidine causes a greater reduction in requirement of additional analgesia than propofol.

Fig 6: Comparison of Digital Symbol Substitution Test (DSST) In Both Groups



#### DISCUSSION

Similar type of study was carried out by Arain SR et al<sup>2</sup>. In this study, forty patients scheduled for elective surgery were randomized equally to receive either dexmedetomidine (1 microg/kg initial loading dose for 10 min; maintenance, 0.4-0.7 microg. kg (-1) h (-1)) or propofol (75 microg. kg (-1). Min (-1) x 10 min; maintenance, 12.5-75 microg. kg (-1). min (-1)). Most of the results obtained in this study were reciprocated in our study too.

##### 1. CARDIO-RESPIRATORY VARIABLES

Aho MS et al<sup>6</sup> observed Both doses of dexmedetomidine decreased heart rate. In the group given 0.4 microgram/kg of dexmedetomidine, 33% of the patients required atropine for bradycardia. Pekka Talke et al<sup>7</sup>, Venn RM et al<sup>8</sup> observed that heart rate was significantly lower in the dexmedetomidine group [mean (SD) 75 (6) vs propofol 90 (4) beats min (-1)]. Similar results were also found by Arain SR et al<sup>9</sup>, Samia Elbaradie et al<sup>10</sup>, Bakhamees HS et al<sup>11</sup>, Olutoye OA et al.<sup>12</sup>

Ebert TJ et al<sup>13</sup> observed in their study that propofol-induced hypotension was mediated by an inhibition of the sympathetic nervous system and impairment of baroreflex regulatory mechanisms. In another study done by Angelini G et al<sup>14</sup>, they observed that Propofol frequently causes hypotension when administered as a bolus or infusion, particularly in patients with

limited cardiac reserve or hypovolemia. Similar results were also found by Arain SR et al<sup>9</sup>, Bakhamees HS et al<sup>11</sup>, Dave J et al.<sup>15</sup> Baseline values of SPO<sub>2</sub> were similar in both the groups in this study. Similar results were also found by Arain SR et al<sup>9</sup> and Yuen VM et al.<sup>16</sup>

Arain SR et al<sup>9</sup> and Yuen VM et al<sup>16</sup> did not found any statistically significant difference in respiratory rate at different time intervals compared to baseline value in both the groupssimilar to this study. Kaygusuz K et al<sup>17</sup>& Dave J et al<sup>15</sup> do not match with our study. Cause may be due to higher doses taken in their studies.

##### 2. SEDATION

##### Observer's assessment of alertness/sedation scale (OAA/S):

The baseline values of OAA/S were similar in both the groups. Fall in the values of OAA/S in both groups at different time interval were analysed statistically it was found significant. Similar results were also found by Arain SR et al<sup>9</sup>. Barr J<sup>18</sup> found that the rapid onset and offset of sedation with propofol. We also found the same result. Arain SR et al<sup>9</sup> evaluated the cardio-respiratory effects of equi-sedative doses of dexmedetomidine and propofol for intraoperative sedation. Sedation was achieved more rapidly with propofol but was similar between groups 25 min after initiating infusions. We also found same result in our study.

### 3. PAIN

**Visual Analog Scale for pain (VAS score):** Venn RM et al<sup>19</sup> studied sedative and analgesic role of dexmedetomidine in the intensive care unit. In conclusion, they found that dexmedetomidine is a useful agent for the provision of postoperative analgesia and sedation.

### 4. PSYCHO MOTOR PERFORMANCE

**Digital symbol substitution test (DSST):** Judith E. Hall et al<sup>20</sup> conducted study on IV infusions of 0.2 or 0.6 µg / kg/ h dexmedetomidine on Seven healthy young volunteers. They found that psychomotor performance in these patients were (28%–41%) of base line at the end of infusion.

### 5. SIDE EFFECTS AND COMPLICATIONS

In a study carried out by Aho MS et al<sup>6</sup>, they observed the effect of dexmedetomidine, 0.2 or 0.4 microgram/kg intravenously. In the group given 0.4 microgram/kg of dexmedetomidine, 33% of the patients required atropine for bradycardia. In our study we found 25% incidence of bradycardia when 0.5 microgram/kg of dexmedetomidine was given. This result favors our study.

### 6. REQUIREMENT OF ADDITIONAL ANALGESIA

Barletta JF et al<sup>21</sup> conducted study on one hundred adults who received either dexmedetomidine (50 patients) or propofol (50 patients) for perioperative sedation. The proportion of patients who did not require opioids during the infusion was significantly higher in the dexmedetomidine group compared with the propofol group (32 [64%] vs 13 [26%],  $p < 0.001$ ). Similar results were also found by Arain SR et al<sup>9</sup>, Olutoye OA et al.<sup>12</sup>

### CONCLUSION

On the basis of results derived in our study, it can be concluded that dexmedetomidine achieve similar levels of sedation to propofol, with a slower onset and offset of sedation. Neither dexmedetomidine nor propofol influence respiratory rate, but propofol result in lower MAP during the intraoperative period. In the recovery room, dexmedetomidine has an analgesic effect, slightly increased sedation, but no compromise of respiratory function or psychomotor responses. Thus, dexmedetomidine may prove to be a useful adjuvant for elective surgery performed under regional anaesthesia, especially when postoperative pain might be predicted to be worse than usual.

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