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Original Research Article

COMPARISON BETWEEN DEXMEDETOMIDINE AND CLONIDINE AS HYPOTENSIVE AGENT IN SPINE SURGERIES: A CLINICAL STUDY

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Abstract:

Background: Spine surgeries are performed most often in prone position. The prone position has been pioneered by spine surgeons from the 1930s and 1940s onwards because of the need for better surgical access. Now a day's spine surgeries are widely performed but excessive blood loss in the field of operation obscures visibility which may lead to increase duration of surgeries and endoscope related complications. In this comparative observational hospital based study, we compare the effect of dexmedetomidine (DEX) and clonidine (CLO) to provide the better surgical field. So, this study was designed to evaluate the effect of dexmedetomidine as hypotensive agent in spine surgeries as compared to clonidine.

Materials and Methods: An observational study was conducted in Gandhi Medical College and associated hamidia hospital, Bhopal (MP). The study included 60 ASA I-II patients, age between 20-50 years of either sex undergoing for spine surgeries in routine operation under general anaesthesia (GA) were included in the study. Group 1 (n=30): was given dexmedetomidine 1 μg/kg over 10 minutes,10 minutes before induction of anaesthesia and Group2 (n=30): was given clonidine 1 μg/kg over 10minutes, 10 minutes before induction of anaesthesia. Heart Rate, SBP, MAP, DBP, and Plethysmography (SPO2) were compared for the 2 groups. Data collected were analyzed using SPSS software. Statistical tests employed for the obtained data were chi-square test and unpaired student t-test. Differences were considered statistically significant if P values were <0.05.

Results: A total of 60 patients fulfilling inclusion criteria were enrolled and were allocated into two groups of 30 in each group. The mean HR was lower in group DEX as compared to group CLO during the whole surgery. A statistically significant difference was seen in mean SBP from 45 minute after intubation in dexmedetomidine group as compared to clonidine group and it was maintained till extubation. The mean sedation score was significantly higher in DEX group as compared to CLO group at 15 min postoperatively, but after 30 minute and 60 minute post operatively there was no significant difference in both groups.

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Conclusion: On the bases of findings of our study, we conclude that a DEX 1 μg/kg before induction is an effective and safe method of producing controlled hypotension in spine surgeries by maintaining better hemodynamics, minimizing blood loss, and providing better field of surgery as compared to CLO 1 μg/kg dose. In addition DEX provides better surgeon's satisfaction score as compared to CLO.

Keywords: Dexmedetomidine, Clonidine, Haemodynamic stability, Spine surgery, GA

1. INTRODUCTION

Spine surgeries are often associated with major blood loss which makes the surgical field visualization difficult and if significant, requires transfusion of blood or blood products. Minimal bleeding in spine surgery is important to keep the patients hemodynamic balance and also allows a better view of surgical field. Induced or controlled hypotension is a method by which the arterial blood pressure is decreased in a predictable and deliberate manner (Cushing in 1917)[1]. The main purpose of deliberate hypotension is to reduce bleeding and thus facilitate surgery and to decrease need of blood transfusion. Use of alpha 2 agonists in anaesthesia has been in vogue since 1970's either as an adjunct intraoperatively or even as premedication. In recent past, the drug clonidine has been widely used in anaesthesia as an adjunct to prevent intubation stress response, sedation, analgesic adjuvant to opioids and to produce hypotensive anaesthesia with inhalational agents. Dexmedetomidine initially used for sedation and analgesia, is now being utilized as an hypotensive agent during anaesthesia. The central and peripheral sympatholytic action of DEX by binding to α2 adrenergic receptors brings about dose-dependent decrease in mean arterial blood pressure and heart rate. Dexmedetomidine can limit rebound hypertension and diminish both sympathetic outflow and reflex tachycardia.[2] so the purpose of the study was to evaluate the effect of dexmedetomidine (DEX) as hypotensive agent in spine surgeries as compared to clonidine.

2. MATERIAL AND METHODS

This study was an observational hospital based study conducted from January 2019 to July 2020 at the department of Anaesthesia, Gandhi Medical College and associated hamidia hospital, Bhopal, MP. After obtaining approval from institutional ethics committee 60 patients aged between 20-50 years, either sex, ASA physical status I and II, routinely scheduled for spine surgeries under general anaesthesia were included in this study. Informed written consent was taken from participants in the study. Exclusion criteria included patients with Age < 20 years and >50 years, pregnant and lactating mothers, patients with anaemia (Hb concentration <10 gm/dl), patients with coagulopathies or receiving drugs influencing blood coagulation, known hypertensive or diabetic, COPD, asthma patients, patients with hypovolemia or hypotension, patients with pre-existing cardiac abnormalities, patients having history of significant neurological , psychiatric, or neuromuscular disorder, deranged renal or hepatic function, and any known hypersensitivity or contraindication to clonidine or dexmedetomidine. The patients were randomly divided into two groups; group 1 (n=30): was given dexmedetomidine 1 μg/kg over 10 minutes,10 minutes before induction of anaesthesia.

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Group2 (n=30): was given clonidine 1 μg/kg over 10minutes, 10 minutes before induction of anaesthesia. After 10 minutes of receiving the study drug , all the patients were preoxygenated with 100 % oxygen for a period of 5 minutes. Injection glycopyrrolate 0.01 mg/ kg IV, injection midazolam 0.05 mg/kg and injection fentanyl 2 μg/kg in both the groups 3-5 minutes before induction were given. Anaesthesia induction was done with injection propofol 2-3 mg/kg. Endotracheal intubation was facilitated by injection atracurium 0.5 mg/kg. Laryngoscopy , intubation , and cuff inflation was completed within 20s in all cases. Controlled ventilation was maintained with 33% oxygen in 66 % nitrous oxide and isoflurane up to 1-2 MAC using Drager Fabius GS premium workstation to maintain end tidal co2 between 32 and 40 mmhg. During hypotension phase, reflex tachycardia was defined as a persistent increase in HR of more than 120 beats per minute (bpm) or more.These patients were given injection esmolol 0.5 mg/kg for control of tachycardia. Patients with HR < 60 bpm will be given injection atropine 0.6 mg for control of bradycardia. Hypotension was defined as MA*P* < 65 mmHg. After stoppage of hypotensive agent , these pt were given injection ephedrine 10 mg intravenously. Intra operative fentanyl requirement in both the groups was noted and compared. Recovery time is noted in both group. Recovery time is the time interval from stopping of the inhalational agent to the time of extubation. At the completion of surgery, the residual neuromuscular blockade was antagonized at the train of four ratio more than 0.7 with neostigmine 0.05 mg/kg IV, and glycopyrrolate 0.01 mg/kg IV and patient were extubated after return of adequate reflexes. After extubation, all the patients were transferred to post operative ICU.

Modified Aldrete Score (0-12) was used to assess post operative recovery and time of achievement of Modified Aldrete Score of 9 or greater will be noted. Patients will be considered ready for discharge from the PACU when the modified aldrete postanaesthesia score was > 9 Postoperative sedation was assessed by Ramsay scale at 15 min, 30 min and 60 minutes after tracheal extubation. The incidence of adverse events (shivering, bradycardia, hypotension, nausea , vomiting was also recorded. Observations were done about HR**,** Systolic Blood Pressure (SBP)**,** Diastolic Blood Pressure (DBP)**,** MAP and Plethysmography (SPO2)

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Modified Aldrete Score Assessment Items[3]

Motoric activity	
▪ Spontaneous movement when addressed	2
▪ Weak spontaneous movements when addressed	1
▪ No movement	0
Breathing	
▪ Coughs on comment or cries	2
▪ Keeps the airway open	1
▪ Obstructed airways	0
Blood pressure compared to reference measurement*	
▪ Δ < 20 mm Hg	2
▪ Δ = 20 – 50 mm Hg	1
▪ Δ > 50 mm Hg	0
Consciousness	
▪ Awake	2
▪ Response to stimulus, reflexes intact	1
▪ No answer, reflexes absent	0
Oxygen saturation	
▪ 100 - 98 %	2
▪ 97 - 95 %	1
▪ < 95 %	0

*Reference measurement was performed 1½ minutes after administration of the spasmolytic agent.

Sedation score [Ramsay, Savage, Simpson et. al.(1947)[4]**:** was measured using the following scale at 15, 30 and 60 minutes after tracheal extubation:

1 = anxious, agitated, or restless;

2 = cooperative, oriented, and tranquil;

3 = responsive to commands

4 = asleep, but with brisk response to light, glabellar tap, or loud auditory stimulus

5 = asleep, sluggish response to glabellar tap, or auditory stimulus

6 = asleep, no response. Patients will also be asked for recalling of intra operative events or any sign of awareness.

Data were entered in Microsoft excel sheet and analyzed by using Statistical Package of Social Science (SPSS Version 20; Chicago Inc., USA). Chi-Square ($\chi 2$) test and Unpaired Student's t-test were used to find out the statistical significance of the comparisons. Significance level was fixed at $P < 0.05$.

Observation and Results:

A total of 60 patients fulfilling inclusion criteria were enrolled and were allocated into two groups of 30 in each group.

Table 1- Demographic profile, Duration of surgery and ASA Grade (n=60)

Parameters	Group DEX	Group CLO	p-value
Age (years)	48.46 ± 4.20	49.83 ± 4.72	0.23
Weight (kg)	58.30 ± 6.73	58.10 ± 5.89	0.90
Male/Female	17/13	19/11	0.59
Duration of surgery (min)	115	120	0.07
ASA Grade I	4	3	0.68
ASA Grade II	26	27	

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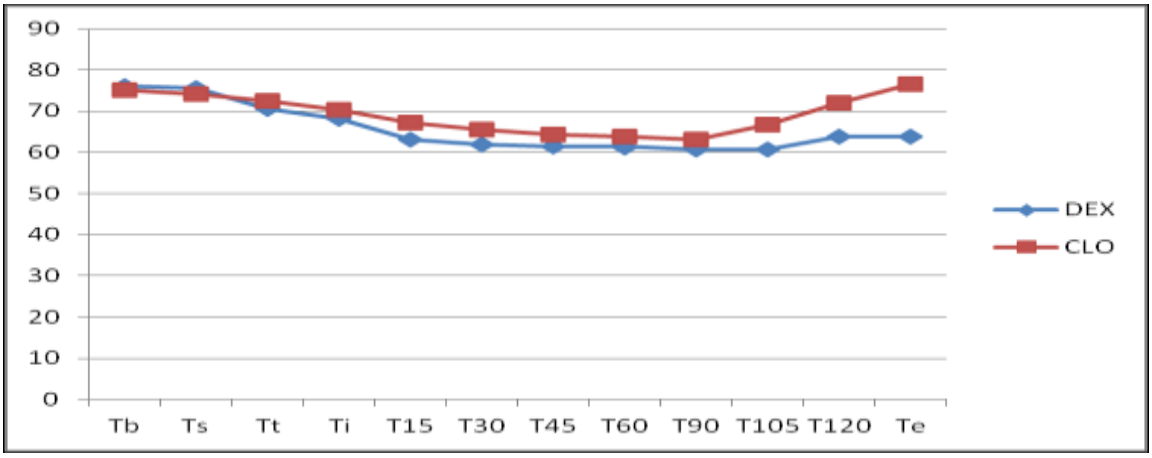
Table 2- Comparison of pre and post-operative mean Haemoglobin [Hb (mg/dl)] and mean Hematocrit value (Hct %)

Groups	Preoperatively		Postoperatively		p- value
	Mean	SD	Mean	SD	
Group DEX Hb (mg/dl)	12.51	1.86	11.67	1.95	0.093
Group CLO Hb (mg/dl)	13.17	1.67	11.58	1.16	0.0001
Group DEX (Hct %)	37.53	5.58	35.01	5.86	0.15
Group CLO (Hct %)	39.53	5.03	35.73	5.00	0.61

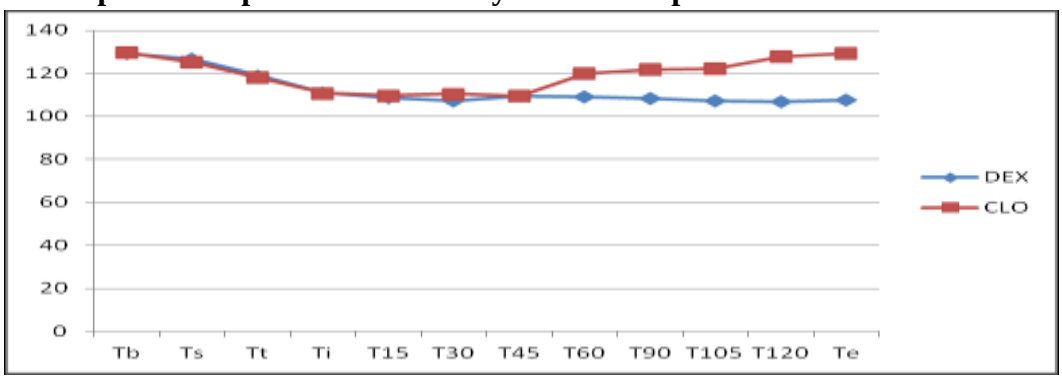
Graph- 1 Comparison of Mean Heart Rate at different time intervals.



Time

Graph 1 shows that there was no significant difference in baseline HR, at start of study drug , after stopping of hypotensive agent and immediate after intubation in both groups. But after that HR was significantly lower in DEX group as compared to CLO group till extubation as P value was <0.005

Graph- 2 Comparison of Mean Systolic blood pressure at different time



Time

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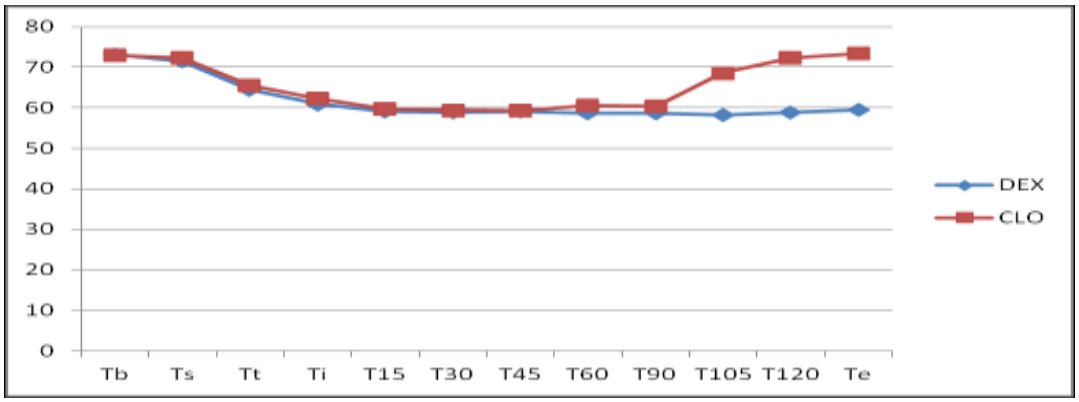
Graph 2 shows that the mean blood pressure was consistently lower at all the time in dexmedetomidine group. There was no statistically significance in mean systolic blood pressure at baseline, at start of study drug, after stoppage of hypotensive agent, immediately after intubation, at 15 minute and at 30 minutes but at 45 minutes and thereafter there was significant difference in mean systolic blood pressure. (P value <0.0001) It was observed that 45 minute after intubation and at the time of extubation, the DEX group maintained a significantly better hemodynamic profile than CLO group $P < 0.05$. (p value<0.05 was considered significant)

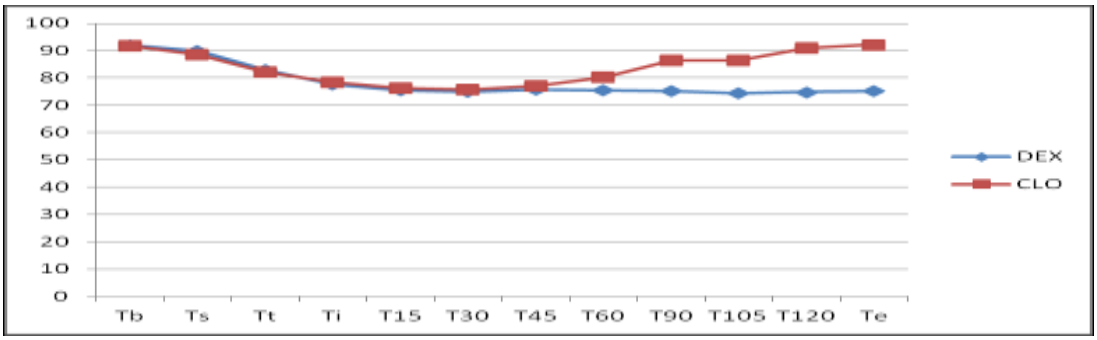
Graph 3 - **Comparison of Mean Diastolic blood pressure at different time intervals**



Time

Graph 3 shows There was significant difference in Mean diastolic blood pressure at 90 minutes , 105 minutes, at 120 minutes and at the time of extubation because P value is < 0.05

Graph 4- Comparison of Mean Arterial pressure at different time intervals.



Time

Graph 4 shows Mean arterial pressure was consistently lower in DEX group till the end of surgery but in CLO group it was lower till 45 minute of surgery and then it increase slowly till the end of surgery . After 45 minutes it become significant between DEX and CLO group. (p value<0.05 was considered significant)

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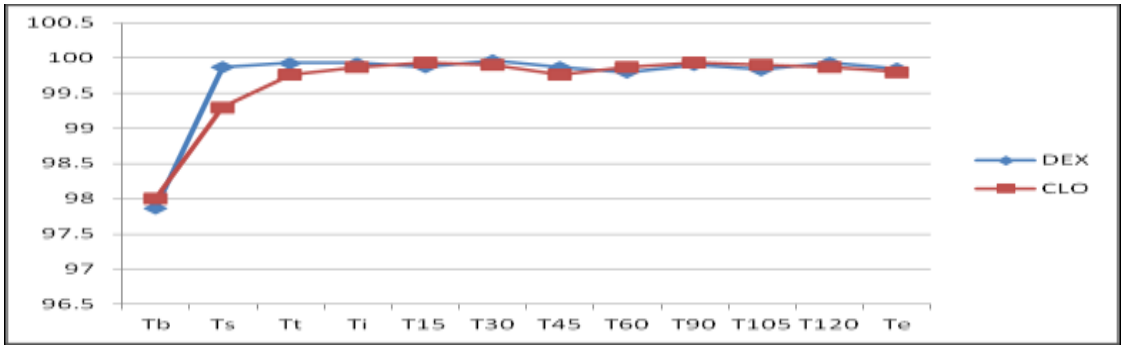
Graph 5- **Comparison of Mean SPO2 at different time intervals.**



Graph 5 shows There was no significant difference noted in mean SPO2 between the two groups at different time intervals($p>0.05$). (p value<0.05 was considered significant)

Table 3: Comparison of mean Ramsay sedation Score

Groups	15 mins		30 mins		60 mins	
	Mean	SD	Mean	SD	Mean	SD
Group 1 DEX	3.73	0.43	2.9	0.40	1.9	0.30
Group 2 CLO	3.33	0.47	3.03	0.18	1.9	0.25
Student 't' test value	3.873		1.62		0	
p- value	0.0002		0.9		0.9	

Table 4: Comparison of modified Aldrete score at Extubation.

Groups	Modified Aldrete score at extubation	
	Mean	SD
Group 1 DEX	7.667	0.80
Group 2 CLO	7.63	0.88
Student 't' test value	0.138	
p- value	0.890	

3. DISCUSSION

Anaesthetizing a patient for spine surgery imposes a lot of challenges for the anaesthesthesiologist. Most patients who come for spine surgeries have chronic pain on multiple medication .Most of the patients are elderly with multiple co-morbidities. Providing an adequate pain relief without any adverse effect is a challenge.

Total 60 patients were selected for the study and were randomly divided into two groups of 30 each. The patients were comparable in relation to the sex distribution ($p=0.598$) as evident from table 1. The patients were comparable to the age ($P= 0.23$), body weight ($p=0.902$) as evident from table 1. Both groups were comparable in relation to ASA grade ($p=0.68$) as evident from table 1.

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Preoperative mean Hb & Hct were comparable in between both the groups. There was no significant difference in both the group with respect to pre op Hb and hct value. But after completion of surgery, Fall in Hb post-operatively in patients receiving DEX (11.67±1.95) was lesser. There was no significant difference in pre op and post op Hb and hct value in DEX group, blood loss was less in DEX group. But in CLO group change in Hb and Hct was more post operatively with respect to pre op value there was statistically significant difference in post op Hb and Hct value in CLO group P value (<0.05) . Blood loss was more in clonidine group as compared to DEX group. Similar results were seen by Tarek Shams et.al.[5] in FESS. DEX, a selective α2 adrenoceptor agonist, causes fall in blood pressure due to inhibition of central sympathetic outflow and also due to stimulation of presynaptic α2 adrenoceptors decreasing norepinephrine release.[6] In our study, we did not found any significant difference in recovery time between DEX and CLO group. The mean wake up time for DEX group was 10.8 (2.56) and for CLO group was 9.97 (2.86). Patients in both the group woke up within 15 minutes of stopping the inhalational agents. It is seen that adding DEX or CLO as an adjuvant to general anaesthesia does not delay recovery time. Gupta et al (2013)[7] in their study on children undergoing spinal surgery found that children in DEX group had a more favourable recovery profile, without adverse perioperative haemodynamics. They also found in their study that post operative nausea and vomiting was also significantly less in patients.

The haemodynamic parametrs compared in our study were HR, SBP, DBP, and MAP. The HR and MAP were attenuated with DEX and CLO and effects compared in both groups. The mean HR was lower in group DEX as compared to group CLO during the whole surgery. In both the groups, immediately after induction and after intubation the mean heart rate was found to be stable in both groups (p >0.05). But after 15 mins till the time of extubation, the HR remain stable in DEX group and there was a rise in heart rate in the clonidine group, and this rise in HR was statistically significant in CLO group as compared to DEX group (p <0.05). In our study we observed that increase in SBP & DBP immediately after intubation was less in DEX group in comparison to CLO group but it was not statistically significant(p>0.05). After 45 minutes till the extubation there was increase in SBP in clonidine group as compared to DEX group which was statistically significant (P value < 0.005). The DBP was less in both the group but after 90 minutes DBP slowly increased in clonidine group and this was statistically significant P value<0.005. The MAP showed a significant reduction in DEX group as compared to CLO group. In our study we found that MAP was lower and non significant in both the group till 45 minute but after 45 minute MAP increased in CLO group and it was stable in dexmedetomidine group and it was statistically significant. Supported by a study conducted by Assem Adel Moharram et al.[8] and they found that DEX infusion without loading dose could be an effective and safe agent in achieving controlled hypotension in adult undergoing elective lumbar spine surgery.

Table and graph shows that the oxygen saturation at all the observation in both the groups was found comparable. Mean SPO2 was comparable throughout the entire period of surgery and was maintained above 98 %. There was no significant difference noted between the two groups at different time intervals (p>0.05). None of the groups showed hypersensitivity.

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The mean modified Aldrete score at extubation was 7.66±0.80 in DEX group and 7.63±0.88 in CLO group. There was no statistically significant difference in both groups. P value = 0.890

Ramsay sedation score Fifteen minute Postoperatively, Mean Ramsay sedation Score was significantly higher in DEX group(3.76±0.43) as compared to CLO group (2.9±0.40)(p=0.0002). but 30 and 60 minute postoperatively, we found no significant difference in mean Ramsay Score (p>0.05) and these findings were similar with Rihong Bai et al.[9] study**.**

4. CONCLUSION

on the basis of findings of our study we conclude that a Dexmedetomidine 1 microgram/kg before induction is an effective and safe method of producing controlled hypotension in spine surgeries by maintaining better hemodynamics, minimizing blood loss, and providing better field of surgery as compared to clonidine 1 microgram/kg dose. In addition Dexmedetomidine provides better surgeon's satisfaction score as compared to clonidine. Dexmedetomidine and clonidine successfully induced deliberate hypotension and were effective in providing better surgical site during spine surgeries, but dexmedetomidine was found to be better as its use showed less fall in hemoglobin and hematocrit (indicating less bleeding at surgical site), greater but acceptable reduction in HR and MAP during surgery and favorable surgeon's satisfaction score (indicating clear surgical field).

Limitations: In our study, we excluded children and with ASA status more than II which is a significant limitation as younger and sicker patients would have more physiological variations than normal patients. Small sample size is another limitation thus we propose larger sample size for future studies for more objective results. In our study, sedation scores could not be measured using sophisticated monitors like bispectral index and electroencephalography due to nonavailability which would have resulted in more objective results.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee GMC Bhopal

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