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# **Original Research Article**

# A comparative clinical study between dexmedetomidine and nitroglycerine for controlled hypotensive anaesthesia in spine surgeries

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#### ABSTRACT

**Background and Objective**: To reduces the intraoperative blood loss and to provide better visibility of the surgical field controlled hypotension is used. Aim of this study is to compare dexmedetomidine and nitroglycerine as hypotensive agents for inducing controlled hypotension in patients undergoing elective spine surgeries.

**Materials and Methods:** 60 ASA class I or II adult patients undergoing elective spine surgeries were randomly alloca ted into 2 groups of 30 participant in each group DX and group NG. Group DX received dexmeditomidine bolus 1 microgram/kg over 10 minutes before induction and intraoperative infusion of 0.2 - 0.7 microgram per kg per hour, while group NG received nitroglycerine intraoperative infusion at 0.5 to 10 microgram/kg/ min titrated to a mean arterial pressure (MAP) of 70 - 75 mmHg. In both groups the surgical field quality assessed using Fromme - Boezaart grading. Hemodynamic variable and adverse events were noted. Post operative sedation was also assessed using Ramsay sedation score.

**Results:** The mean heart rate was significantly lower in group DX compared to group NG throughout the procedure. (p<0.001). Mean arterial pressure were found to be significantly lower in group DX than in group NG after induction, after intubation, end of surgery, after extubation, and post operatively (p<0.001), but average intraoperative values were comparable in both groups. Significantly better Fromme - BoezaarT surgical field score was noted in group DX compared to group NG during the intraoperative period.

**Conclusion:** Controlled hypotension using dexmeditomidine as bolus dose 1 microgram per kg intravenous over 10 minutes prior to induction followed by continous intravenous infusion at 0.2 - 0.7 microgram per kg per hour, provided more stable hemodynamics and better surgical field quality compared to nitroglycerine intraoperative infusion at 0.5 to 10 microgram/kg/min.

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## 1. Introduction

Many of the major spine surgeries such as scoliosis correction, posterior lumbar spine fusion surgeries, lumbar dissectomy etc. are assossiated with considerable haemmorhage during and after surgery. So as to reduce blood loss during these major spine surgeries and to improve the operating conditions induced hypotension can be advocated. Maintaining a patients blood pressure within normal limits during surgery using various techniques alone or in combination is a part of skillfull anaesthesia. While achieving controlled hypotension care should be taken in not

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being land up with rare complication including permanant cerebral damage, delayed awakning, cerebral thrombosis and brain ischaemia. 4

There are several pharmacological and non pharmacological techniques for inducing hypotension. The non pharmacological (mechanical) methods include intermittent positive pressure ventilation and positioning the patient and results in hypotesion mainly affecting venous return. The pharmacological agents include directly acting vasodilator drug alpha blockers, beta blockers, combined alpha and beta blockers, calcium channel blockers, alpha 2 agonist, ganglion blocking drug, volatile anaesthetic, propofol, magnesium sulphate, etc. <sup>5,6</sup> Ideally the agents used for

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induced hypotension should be easy to administer, have fast onset of action, have effects that disappear quickly when administration is discontinued, rapid elimination without toxic metabolites, have negligible effects on vital organs and have predictable and dose dependent effects. <sup>6,7</sup>

One of the directly acting vasodilator is Nitroglycerine (NTG); which has been used to achieve controlled hypotension because of the rapid onset, rapid offset and titratibility. It primarily dilates the capacitance vessels, reducing the venous return with results in concomitant reduction in the stroke volume and cardiac output. One of the disadvantage of the nitroglycerine is it causes reflex tachycardia and venous congestion in and around the surgical site causing increased blood loss. <sup>8,9</sup>

Dexmeditomidine is a potent highly selective alpha 2 adrenergic receptor agonist with alpha 2 to alpha 1 receptor affinity ration of 1620:1. Through its central and peripheral sympatholytic action improves the perioperative haemodynamic stability and causes controlled hypotension. In addition to hypotension it also has short term sedation, anxiolysis and analgesic effects. <sup>10,11</sup> The elimination half life of dexmeditomidine is 2 hours and the distribution half life is 6 minutes making it an ideal drug for intravenous titration. <sup>12</sup> Dexmeditomidine had been used both as an adjuant <sup>13</sup> to regional anaesthesia, an intarvenous addition to provide controlled hypotension and to eliminate negative effects of intubation in general anasthesia. <sup>14,15</sup>

Even though dexmedetomidine and nitroglycerine is popularly used as hypotensive agents not many studies have been done on evaluating the efficacy of controlled hypotension in spine surgeries while using the novel alpha 2 agonist dexmedetomidine in comparison with nitrogl ycerine as hypotensive agent. Hence a prospective randomisd double blinded clinical study was done to compare the efficacy of and safety of dexmeditomidine versus nitroglycerine during hypotensive anaesthesia induced by either drug in adult patients posted for elective spine surgeries.

## 2. Materials and Methods

The study was undertaken after obtaining institutional ethical committe clearances as well as in formed consent from all participant. 60 participant belonging to ASA class I or I I between 18 and 60 years of age scheduled for elective spine surgeries were enrolled in the study.

Participant with cerebrovascular diseases, hypertension, asthma, chronic obstructive lung disease, diabetes mellitus, coagulation defects, hepatic or renal failure, psychiatric disease, BMI > 30, known drug allergy or substance abuse were excluded from the study.

A routine pre anaesthaetic examination was conducted on the evening before the surgery assessing the general condition of the participant, including airway assessment and systemic examinations. Routine investigations included CBC, RBS, RFT, coagulation profile, ECG, chest x ray. One PRBC was arranged prior to the surgery after blood grouping and cross matching.

The participant was randomly divided into 2 subgroups of 30 participant each using simple sealed envelope method.

- 1. Group DX : dexmeditomidine group
- 2. Group NG: nitroglycerine group.

The study drug dexmeditomidine was given to group DX in the dose of 1 micro gram/kg body weight in a 600 seconds infusion before induction diluted to 10 ml with normal saline followed by maintenance dose at infusion rate of 0.2 - 0.7 microgm/kg.

The group NG received 10 ml plain normal saline over 600 seconds before induction followed by maintenance dose of nitroglycerine at an infusion rate of 0.5 - 10 microgm/kg/min.

The double blind design of the study was assured by the fact that is a senior anaesthesiologist by the fact that a senior anasthesiologist who was not further involved with the study was assigned to prepare the solution before the administration of drugs. The 50 ml syringe were labelled as LD and MD for laoding dose and maintenanace dose respectively. For patients in group D X, LD syringe contained the bolus dose of dexmedetomidine at 1 microgm /kg diluted to 10 ml with required amount of normal saline and MD had 2 microgm /kg prepared by taking 1 ml (100 microgm) of inj. dexmeditomidine diluted with 49 ml of normal saline. For group N G patients, LD syringe had 10 ml of plain normal saline and MD had 100 microgm/ml of nitroglycerin prepared by taking 1 ml (5 mg) of nitroglycerin diluted with 49 ml of normal saline. The anaesthesiologist responsible for providing anaesthesia and observing the parameters during the surgery and the patient were kept unaware of the content of the syringes.

After arrival in the preanaesthesia room 20 G and 18 Gintravenous cannula were inserted at different anatomical sites for the infusion of the study drug and for the administration of fluids and other drug/ blood respectively.

Standard intraoperative monitoring including Spo2, ECG, NIBP, Et Co2 was performed.

A ll the patients were given 0.02 mg/kg inj midazolam, inj ondensetron 0.05-0.1 mg/ kgand inj fentanyl 1 microgm /kg as premedication. Lignocaine 1.5 mg/kg was given 45 sec before induction in both groups to supress haemodynamic response to laryngoscopy and tracheal intubation. Patients were preoxygenated for 180 seconds and induced with thiopentone 5 mg/ kg iv. inj succinyl choline 1.5 mg/kg iv. after airway was secured by conventional laryngoscopy with appropriate sized tube cuffed flexomettalic endotracheal tube, the patient was put in prone position with chest and pelvic rolls and abdomen hanging. The pressure points were padded. All patients

were operated by the same surgical team. anaesthesia maintained wit O2 + N2O + inj. vecurionium bromide + isoflurane 1%.

The parameters that were compared in both groups included the HR, SBP, DBP, MAP, Spo2, Etco2, visual blood loss estimation as reported by the surgeon in terms of Fromme - Boezaart surgica 1 field grading every 900 seconds, sedation in the post extubation period in terms of Ramsay sedation score (RSS)- post extubation. Adverse events - bradycardia (HR<50 bpm), hypotension (MAP<65 mmhg), tachycardia (HR > 110 bpm).

HR, MAP, SBP, DBP, Spo2, Etco2 recorded at the following periods.

T1- baseline (300 seconds after arriving in the pae room

T 2 - 120 seconds from the start of the bolus infusion

T3- 300 seconds from the start of the bolus infusion

T 4-480 seconds from the start of the bolus infusion

T5-30 seconds post intubation.

T6-300 seconds from intubation.

T7- Start of surgery

T8-900 seconds after start of surgery.

T 9- 1800 seconds from the start of the bolus infusion

T 10-2700 seconds from the start of the bolus infusion

T11 - 3600 seconds from the start of the bolus infusion

T 12 – 4500 seconds from the start of the bolus infusion

T13- 5400 seconds from the start of the bolus infusion

T14 - end of surgery

T 15-30 seconds post extubation.

T 16-300 seconds post extubation.

T17-900 seconds post extubation

Infusion was stopped 300 seconds before the anticipated end of surgery. after patient was put in supine position, any residual neuro muscular block was antagonised with neostigmine 50 microgm /kg and glycopyrrolate 10 microgm /kg and paptient was extubated.

# 2.1. Stastical Analysis

The number of participant enrolled in this study was based on previously conducted in which it was determined based on a desired power of 80% to detect a between- group difference of 20% in the scale use to assess the amount of blood in the surgical field with a significance level of 5 %. 44 participant (22 in each arm of the study would be needed for the study. assuming a dropout rate of 15%, a total of 52 participant would be needed be enrolled. The sample size of 60 patients was selected based on a previous study done by Akkaya a et al (2013).

The descriptives procedure displays unvariable in a single table and standardized value score. The descriptive statistics were employed in the present study were the mean, standard deviation, frequency and percent.

The crosstabs procedure forms two way and multiway table and provides a variety of tests and measures of

assossiation for 2 way tables.

GLM repeated measures analyses group of related dependent variables that represent different measurements of the same attribute.

The independent -samples t test procedure compares man for two group of cases.

All the stastical methods were carried out through the spss for windows (version 16.0)

p<0.001 considered highly significant (HS), p<0.05-significant (S) and p> 0.05 considered not significant (NS)

#### 3. Results

There was no significant diffrences between the two groups with regard to age, mean height, mean weight, BMI, gender of the patients, baseline HR, MAP, mean duration of surgery.(Table 1)

The basal heart rates are comparable between the two groups and the difference is not statistically significant. There is a statistically significant difference between the two groups after starting loading dose infusion and induction, where in statistically significant fall in HR is noted in group DX. But after laryngoscopy and intubation there is increase in heart rate in both groups which more in group NG compared to group DX (p<0.001). The intraoperative mean HR during surgery is significantly lower in group DX compared to group NG(p<0.001). After stopping infusion HR is lower in Group DX compared to Group. Although there is increase in HR after repositioning and extubation, but it is lesser in group DX compared to group N G.

The baseline (MAP) is comparable in both groups and there is no statistical difference in the 2 groups (P=0.240). after starting the loading dose infusion and after induction there is fall in MAP group DX compared to group NG. the MAP increase after laryngoscopy and intubation, but it is significantly low in group D X than group NG. intraoperatively the MAP is significantly low in group D X compared to group N X at T7, T8, T11 but not atT9, T10,T12,T13,T14. The mean MAP values in group S after stopping infusion at the end of surgery, after repositioning and extubation is less compare to group NG.

At 15 min minutes there is no significant difference in the 2 groups with respect to the average surgical field grading of each study population. At 30 min there is significant difference between 2 groups with group DX having average surgical field grade of  $1.90\pm0.48$ , which is less compared to that of group NG,  $2.50\pm0.51$ (p<0.001). The average intraoperative surgical field grade was  $2.08\pm0.48$  in group DX, which was significantly better than  $2.37\pm0.55$  in group NG (p=0.33).

### 4. Discussion

During surgeries it is important to reduce bleeding to allow a better view of the surgical field there by increasing the

Table 1:

Demographic criteria	Group DX	Group NG	p-value	p-value	
Age (years)	36.7+/-7.8	39.5+/-6.8	.219(NS)		
Sex (male/female)	19/11	17/13	.598(NS)		
Mean height (M)	1.644+/-0074	1.647+/076	.886		
Mean weight (kg)	60.0+/-9.16	60.5+/-10.58	.856		
$BMI(kg/m^2)$	22.15+/-2.68	22.19+/-2.85	,960		
Baseline heart rate (HR)	94.1+/-9.24	90.1+/-11.75	.379		
Baseline Mean arterial pressure ( mmhg)	97.93+/-4.85	96.26+/-6.14	.240		
Mean duration of surgery (min)	78.5+/-8.82	79.8+/-10.94	.605		

NS – not significant (p>0.05)

 Table 2: Heart rate changes in the study population

Heart rate (bpm)	Group DX	Group NG	P value	
T1	94.1+/-9.24	$90.1 \pm 11.75$	.379	
T2	$87.03 \pm 8.61$	$91.33 \pm 13.27$	.142	
T3	$69.96 \pm 3.77$	$90.76 \pm 13.33$	.001	
T4	$68.76 \pm 3.40$	$92.33{\pm}12.37$	.001	
T5	$64.3 \pm 2.9$	$91.8 \pm 12.47$	.001	
T6	$102.8 \pm 7.15$	$112.26 \pm 12.2$	.001	
T7	$75.53 \pm 9.66$	$100.8 \pm 12.79$	.001	
T8	$65.83 \pm 2.38$	$98.56{\pm}10.77$	.001	
T9	$62.26 \pm 2.50$	$94.96 \pm 9.15$	.001	
T10	$60.76 \pm 4.41$	$97.1 \pm 10.28$	.001	
T11	$61.53 \pm 3.64$	$94.96 \pm 9.77$	.001	
T12	$63.06\pm2.41$	$95.6 \pm 9.27$	.001	
T13	$66.41 \pm 3.48$	$93.6 {\pm} 10.01$	.001	
T14	$64.25 \pm 1.26$	$92.66{\pm}14.10$	.001	
T15	$66.3\pm3.16$	$105.23 \pm 7.7$	.001	
T16	$80.8{\pm}5.0$	$117.83 \pm 6.64$	.001	
T 17	$74.16\pm3.59$	103.3±7.8	.001	

Table 3: Mean arterial pressure changes in study population

Mean arterial pressure (mmhg)	Group DX	Group NG	p value
T1	$97.93 \pm 4.85$	$96.26\pm6.14$	.240
T2	$95.24 \pm 5.36$	$95.14 \pm 6.02$	.892
T3	$84.67 \pm 5.59$	$95.11 \pm 5.48$	.001
T4	$78.59 \pm 5.08$	$96.29 \pm 5.96$	.001
T5	$71.73 \pm 2.63$	$94.48 \pm 4.91$	.001
T6	$75.95{\pm}2.96$	$113.97 \pm 6.15$	.001
T7	$72.09 \pm 2.66$	$90.74 \pm 4.81$	.001
T8	$69.12 \pm 2.49$	$75.93 \pm 3.54$	.001
T9	$70.53 \pm 2.21$	$69.79 \pm 2.80$	.227
T10	$70.46{\pm}2.98$	$69.40{\pm}2.87$	.208
T11	$70.78 \pm 2.16$	$69.20 \pm 3.23$	.021
T12	$69.86{\pm}2.35$	$69.54{\pm}2.97$	.675
T13	$70.58 \pm 2.13$	$71.75 \pm 4.61$	.519
T14	$70.92{\pm}1.97$	$73.56 \pm 4.61$	.438
T15	$72.9 \pm 1.71$	$77.65 \pm 3.86$	.001
T16	$77.28{\pm}2.45$	$103.82 \pm 12.61$	.001
T17	78.33±2.26	94.02±6.12	.001

Table 4: FrommeBoezaart surgical field grade

	Group DX			Group NG			P value		
	15 min	30 min(	45 min	15 min	30 min	45 min	15 min (	30 min (	45 min (
	(T9)	T10)	(T11)	(T9)	(T10)	(T11)	T9)	T10)	T11)
Grade 0	0	0	0	0	0	0			
Grade I	0	5	2	0	0	0			
Grade II	20	23	26	14	15	22			
Grade III	10	2	2	16	15	5	122	.001	.570
Grade IV	0	0	0	0	0	0			
Grade V	0	0	0	0	0	0			
Average FBG	$2.33 \pm .48$	$1.90 \pm .48$	$2.00\pm$	$2.53{\pm}0.51$	$2.50 {\pm} 0.51$	$2.06 \pm 0.52$			
			0.37						
Average intraoperative FBG	$2.08\pm0.48$			2.37±0.55			.033		

surgeon's control and shortening surgical time which in turn reduces the bleeding. <sup>2,3</sup> By decreasing intraoperative blood pressure bleeding from surgically injured arteries and arterioles can be reduced. Venous dilatation in turn reduces the venous bleeding, especially from cancellous bony sinuses that do not collapse when transected. In various types of surgeries, including spine surgery, for reduction of intraoperative blood loss as well as providing better surgical field for the operating surgeon controlled hypotension is most commonly used technique. <sup>1,2</sup>

Contolled hypotension has been widely advocated to reduce blood loss, but it may be associated with risk of neurological deficit because of reduced spinal cord perfusion. <sup>2,4</sup> The lower limit of human autoregulation can be considered in determing the range of target autoregulation, the target MAP have been derived by various studies. In the studies Ozcan AA et al (2012) <sup>16</sup>, Akkaya et al (2013) and Bhatnagar V et al 2015 <sup>17</sup>, the target MAP used was 65-75mmhg. Therefore in our study MAP of 70 -75mmhg was adopted which was effectively reached in both groups before skin incision.

The ideal hypotensive drug for inducing hypotensive anaesthesia should be easy to administer, with a short onset time, easy titratability; its dose can be meticulously controlled; its effects disappears quickly when its administration is discontinued; it has a rapid elimination and causes no unwanted or adverse effects. <sup>5,6</sup> Many agents can be used to produce hypotensive anaesthesia; out of those in our study the nitroglycerine and dexmedetomidine was used.

The minimum dose of nitroglycerine infusion was  $0.5\mu g/kg/min$  found to be effective dose by many authors,  $^{18,19}$  hence same was used in our study. Khalifa OS et al  $(2015)^{20}$  used  $10\mu g/kg/min$  as maximum dose of nitroglycerin infusion for controlled hypotesion, and the same used in our studies. For the purpose of blinding, 10ml of plain normal saline was infused over 10 min before induction in participants in Group NG in our study;

followed by intraoperative infusion of Nitroglycerin at 0.5- $10\mu g/kg/min$  using syringe pump, titrated to the target MAP.

Many authors <sup>19–21</sup> used loading dose of dexmedetomidine  $1\mu g/kg$  was given over 10 min before induction. The minimum dose of dexmedetomidine infusion intraoperatively is  $0.2\mu g/$  kh/hr<sup>16,20,21</sup> and the maximum dose of dexmedetomidine used was  $0.7\mu g/kg/hr$ . <sup>16,20</sup> Hence the intraoperative infusion of dexmeditomidine in our study was given between 0.2- $0.7\mu g/kg/hr$  in group DX.

The basal heart rates are comparable between the two groups and the difference is not statistically significant. There is a statistically significant difference between the two groups after starting loading dose infusion and induction, where in statistically significant fall in HR is noted in group Dx. But after laryngoscopy and intubation there is increase in heart rate in both groups which more in group NG compared to group DX (p<0.001). So our concurs with the findings of Scheinin H et al  $^{22}$  and Jaakola ML et al.  $^{23}$  The intraoperative mean HR during surgery is significantly lower in group DX compared to group NG(p<0.001). After stopping infusion HR is lower in Group DX compared to Group NG. Although there is increase in HR after repositioning and extubation, but it is lesser in group DX compared to group NG.  $^{24}$ 

The baseline (MAP) is comparable in both groups and there is no statistical difference in the 2 groups (P=0.240). After starting the loading dose infusion and after induction there is fall in MAP group DX compared to group N G. The MAP increase after laryngoscopy and intubation, but it is significantly low in group DX than group N G. <sup>11,25</sup> Intraoperatively the MAP is significantly low in group DX compared to group N G at T7, T8, T11. <sup>20,25</sup> The mean MAP values in group DX after stopping infusion at the end of surgery , after repositioning and extubation is less compare to group NG. <sup>28,22</sup>

Many authors <sup>22,23</sup> used the quality scale proposed by fromme – Boezaart. Fromme – Boezaart surgical field

grading at 15 min minutes was comparable in both group. At 30 min there is significant difference between 2 groups with group DX having average surgical field grade of  $1.90\pm0.48$ , which is less compared to that of group N G,  $2.50\pm0.51$ (p<0.001). The average intraoperative surgical field grade was  $2.08\pm0.48$  in group DX , which was significantly better than  $2.37\pm0.55$  in group NG (p=0.33).

#### 5. Conclusion

Controlled hypotension using dexmeditomidine as bolus dose 1 microgram per kg intravenous over 10 minutes prior to induction followed by continous intravenous infusion at 0.2 - 0.7 microgram per kg per hour, provided more stable hemodynamics and better surgical field quality compared to nitroglycerine intraoperative infusion at 0.5 to 10 microgram/kg/min

## 6. Source of Funding

None.

#### 7. Conflict of Interest

None.

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