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**ORIGINAL RESEARCH**

# Comparative assessment of effects of nitroglycerin and dexmedetomidine on cerebral oxygen saturation utilizing near-infrared spectroscopy in subjects undergoing controlled hypotensive anesthesia

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## ABSTRACT

**Background:** Existing literature data is scarce concerning comparing hypotensive drugs to assess cerebral effects by evaluating rSvO2 (regional cerebral oxygen saturation). **Aim:** The present study aimed to comparatively assess the effects of nitroglycerin and dexmedetomidine on cerebral oxygen saturation utilizing near-infrared spectroscopy in subjects undergoing controlled hypotensive anesthesia. **Methods:** The present study assessed adult subjects undergoing head and neck surgeries at the Institute under general anesthesia. Subjects were randomly divided into two groups where one group of subjects was given dexmedetomidine and the other group of subjects was given nitroglycerine infusion for controlled hypotensive anesthesia. The data gathered included perioperative hemodynamics, bilateral rScO2, CDEs (cerebral desaturation events), and NIRS for cerebral oximetry in both groups. **Results:** Among 164 study subjects assessed in both groups, cerebral desaturation events were seen in 30 subjects each from both groups. A reduction from baseline by 20% was seen in six subjects with two from the nitroglycerine and four in the dexmedetomidine group. The risk of getting cerebral desaturation events was equal among the two groups. The time to cerebral desaturation events was comparable in the two groups with $p>0.05$. Differences in heart rate showed statistical significance in the two groups with $p<0.001$. **Conclusion:** The present study concludes that dexmedetomidine is not inferior to nitroglycerin concerning the occurrence of cerebral desaturation events when used for controlled hypotensive anesthesia in subjects undergoing head and neck surgeries.

**Keywords:** cerebral desaturation events, controlled hypotensive anesthesia, dexmedetomidine, nitroglycerin, regional cerebral oxygen saturation



## INTRODUCTION

Hypotensive anesthesia is a process of achieving a state of hypotension in a controlled and deliberate manner to decrease the bleeding and improve the visualization of the surgical site. Existing literature data holds substantial evidence to achieve hypotensive anesthesia including a 30% decrease in mean arterial pressure (MAP) in previous hypertensive subjects, a reduction in MAP by 50-60 mmHg in normotensive subjects, and a reduction of systolic blood pressure to 80-90 mmHg.[1]

Different pharmacological agents have been assessed to get the ideal agent that achieves hypotensive anesthesia where the advantages of hypotensive anesthesia have been reported and documented, however, there is a need for caution along with

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benefits as there is an associated risk of hypoperfusion in the vital organs with controlled hypotensive anesthesia.[2] The hepatic, renal, pulmonary, cardiovascular, and cerebral effects of hypotensive anesthesia are studied in the previous literature. Specific attention is needed for the cerebral effects as monitoring of adequate cerebral oxygenation is not done routinely during the anesthesia. The cerebral effects of controlled hypotensive anesthesia are assessed by observation of POCD (postoperative cognitive dysfunction) as a surrogate biomarker of intra-operative cerebral hypoperfusion.[3]

Cerebral oxygenation can be assessed using jugular venous oximetry, NIRS (near-infrared spectroscopy), and brain tissue partial pressure of oxygen. NIRS assesses the regional cerebral oxygen saturation (rScO2) and provides real-time values with the non-invasive method. However, following NIRS, there is no defined ischemic threshold based on the values of rScO2 values, and there is high variability in normal baseline values in the subjects.[4] Hence, NIRS is taken as a trend monitor where a decrease or increase in values is more vital than absolute value. It is a promising tool for cerebral oximetry and is used for the diagnosis of cerebral desaturation in major surgeries or surgeries utilizing hypotensive anesthesia. Existing literature data is scarce concerning comparing hypotensive drugs to know the cerebral effects of monitoring rScO2 using NIRS.[5]

The present study hypothesizes that dexmedetomidine is not inferior to nitroglycerin for rScO2 values in subjects undergoing surgery under controlled hypotensive anesthesia. The present study aimed to comparatively assess the effects of nitroglycerin and dexmedetomidine on cerebral oxygen saturation utilizing near-infrared spectroscopy in subjects undergoing controlled hypotensive anesthesia. The study also aimed to compare the effects of nitroglycerin and dexmedetomidine on hemodynamics including heart rate and blood pressure and right and left rScO2.

## MATERIALS AND METHOD

The present randomized controlled clinical study was aimed to comparatively assess the effects of nitroglycerin and dexmedetomidine on cerebral oxygen saturation utilizing near-infrared spectroscopy in subjects undergoing controlled hypotensive anesthesia. The study also aimed to compare the effects of nitroglycerin and dexmedetomidine on hemodynamics including heart rate and blood pressure and right and left rScO2. The study subjects were from the Department of Surgery of the Institute. Verbal and written informed consent were taken from all the subjects before study participation.

The study included 164 subjects from both genders within the age range of 18-45 years and in the ASA (American Society of Anesthesiologists) physical status I and II and were undergoing head and neck surgery in neutral head and supine position under general anesthesia with controlled hypotension. The exclusion criteria for the study were subjects with sensitivity to study drugs, orthostatic hypotension, cardiac disease, carotid artery stenosis, cognitive disability, cerebral pathology, and subjects who were not willing to participate in the study.

The subjects were then randomly divided into two groups where Group I subjects were given nitroglycerin and Group II subjects were given dexmedetomidine as IV (intravenous) infusion to attaincontrolled hypotension. Loading dose as 10 mL normal saline was given in Group I (nitroglycerin) with maintenance nitroglycerin dose made by diluting 25mg (5mL) with 45 mL normal saline to a concentration of 500 µg/mL. In Group II (dexmedetomidine), the loading dose comprised 1 µg/kg of dexmedetomidine diluted in NS in a 10 mL syringe. The maintenance dose was made by dilution of 2mL (200 µg) with 48 mL NS to a 4 µg/mL concentration. Recommended doses of dexmedetomidine and nitroglycerin were 0.2–0.7 µg/kg/h and 0.5–2 µg/kg/min respectively.

Subjects were fasted for 2 hours for clear liquids and 6 hours for the solids. In the operation room, monitors were attached to assess bilateral rScO2, bispectral index (BIS),peripheral oxygen saturation (SpO2), non-invasive blood pressure, and heart rate (HR). Premedication was done with IV midazolam at 0.03mg/kg and preoxygenation. General anesthesia induction was done with IV fentanyl 2 µg/kg, propofol 2 mg/kg, and rocuronium 0.6 mg/kg followed by endotracheal tube securing and mechanical ventilation to achieve target end-tidal carbon dioxide (EtCO2) of 35–40 mmHg. Anesthesia maintenance was done using sevoflurane in an oxygen/ air mixture (fraction of inspired oxygen to attain BIS as 45-60. 1 µg/kg fentanyl bolus (IV) was given hourly and repeated rocuronium bolus was given to maintain a train-of-four count of 1—2. The head of the subjects was maintained in a neutral position.

The arterial cannula was transduced and secured for monitoring continuous invasive blood pressure. Loading was started during surgical site preparation followed by maintenance infusion. Study drug infusion was titrated to achieve MAP in the range of 55–65 mmHg. Continuous vital monitoring for HR, invasive MAP, SpO2, BIS, and bilateral rScO2 was recorded and done before pre-oxygenation and induction (T0); 10 minutes after induction with FiO2 0.4 (T1) to be considered as baseline value; 10 minutes after starting study drug maintenance infusion (T2); 30, 60, 90, 120 minutes after start of study drug infusion (T3, T4, T5, and T6, respectively); 5 minutes after stopping study drug infusion (T7); and after tracheal extubation when patient was breathing room air (T8).

The number of CDEs with cerebral desaturation was taken as 10%, 20%, and 30% reduction in rScO2 from the baseline value (T1) for at least 15 seconds. The

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intervention was needed and done when the reduction was >20% for a minimum of 15 seconds by assessing the head position, increasing FiO2 and fluid administration, maintaining MAP within 55–65 mmHg, and ventilation (to achieve an EtCO2 of 35–40 mmHg). The number and types of interventions needed were also noted along with CDE time after study drug administration.

After the surgical procedure completion, infusion of study drugs was stopped and 1g IV paracetamol was administered, reversal of residual neuromuscular blockade was done with glycopyrrolate 0.01 mg/kg and IV neostigmine 0.05 mg/kg. Following extubation, subjects were shifted to PACU (post-anesthesia care unit) and then were discharged after the criteria were met.

The data gathered were analyzed statistically using SPSS (Statistical Package for the Social Sciences) software version 24.0 (IBM Corp., Armonk. NY, USA) for assessment of descriptive measures, one-way ANOVA (analysis of variance),and chi-square test.Kaplan–Meier survival analysis with log-rank test was used for comparison of CDEs. The results were expressed as mean and standard deviation and frequency and percentages. The p-value of <0.05 was considered statistically significant.

## RESULTS

The present randomized controlled clinical study was aimed to comparatively assess the effects of nitroglycerin and dexmedetomidine on cerebral oxygen saturation utilizing near-infrared spectroscopy in subjects undergoing controlled hypotensive anesthesia. The study also aimed to compare the effects of nitroglycerin and dexmedetomidine on hemodynamics including heart rate and blood pressure and right and left rScO2. The study assessed 164 subjects that were randomly divided into two groups where Group I subjects were given nitroglycerin and Group II subjects were given dexmedetomidine as IV (intravenous) infusion to attaincontrolled hypotension. The mean age of the study subjects was 28.76±6.4 and 28.76±6.4 years in Groups I and II respectively which was non-significant with p=0.07. There were 78 males and 4 females in Group I and 72 males and 10 females in Group II showing non-significance with p=0.22. Mean BMI, height, and weight were statistically comparable in Groups I and II with p=0.26, 0.85, and 0.09 respectively. Mean surgery duration was comparable in Groups I and II with 124.76±20.95 and 125.63±35.63 minutes respectively (Table 1).

Concerning the assessment of CDEs (cerebral desaturation events) by 10% and 20% in two groups of study subjects, it was seen that in Group I CDE by 10% was seen in 30 subjects and not seen in 52 subjects. Similar results were seen in Group II where CDEs were seen in 30 subjects and not seen in 52 subjects with Odd's ratio of 1 and 95% CI of 0.43 and 2.44 in Groups I and II respectively. For CDEs by 20%, they were seen in 2 subjects from Group I and 4 subjects from Group II with Odd's ratio of 2.03 and 95% CI of 0.16 and 23.53 (Table 2). No subject showed more than a 30% decline in baseline values from either group.

On Kaplan–Meier survival analysis for comparison of CDE time with a 10% decline from baseline in two groups, mean time to CDEs was 104.62 (94.24-115.04) minutes in Group I and was 10.5.36 (95.42-115.34) minutes in Group II. Time to CDEs was statistically comparable with p=0.67. Analysis was not performed for time to CDEs by 20% owing to smaller subjects showing a decrease from baseline rScO2. Two study groups were comparable concerning left and right rScO2 at all the assessment times.

The study results showed that for comparison of heart rates in two study groups at different time intervals, non-significant differences in baseline heart rates were seen at T0 and T1 with p=0.743 and 0.08 respectively. However, significantly higher heart rates were seen in Group I (nitroglycerin) compared to Group II (dexmedetomidine) at T2, T3, T4, T5, T6, T7, and T8 with p<0.001 at all the assessment times (Table 3).

**Table 1: Demographic and disease data in study subjects**

| Characteristics | Group I (n=82) | Group II (n=82) | p-value |
|---|---|---|---|
| **Mean age (years)** | 28.76±6.4 | 30.03±8.92 | 0.07 |
| **Gender n (%)** | | | 0.22 |
| Males | 78 | 72 | |
| Females | 4 | 10 | |
| **Mean BMI (kg/m2)** | 20.73±1.84 | 21.34±2.67 | 0.26 |
| **Mean height (cm)** | 169.7±3.47 | 169.71±3.87 | 0.85 |
| **Mean weight (kg)** | 60.13±7.04 | 61.66±8.53 | 0.09 |
| **Surgery duration (mins)** | 124.76±20.95 | 125.63±35.63 | 0.87 |

**Table 2: CDEs by 10% and 20% in two groups of study subjects**

| Groups | CDE by 10% | | Odd's ratio | 95% CI | CDE by 20% | | Odd's ratio | 95% CI |
|---|---|---|---|---|---|---|---|---|
| | Yes | No | | | Yes | No | | |
| **I** | 30 | 52 | 1 | 0.43 | 2 | 80 | 2.03 | 0.16 |
| **II** | 30 | 52 | | 2.44 | 4 | 78 | | 23.53 |

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**Table 3: Heart rate comparison in two study groups at different time intervals**

| Times | Heart rate (beats/min) | | p-value |
|---|---|---|---|
| | Group I | Group II | |
| **T0** | 83.4±11.3 | 82.3±9.6 | 0.743 |
| **T1** | 79.7±8.7 | 75.7±8.6 | 0.08 |
| **T2** | 84.6±8.3 | 70.7±6.2 | <0.001 |
| **T3** | 87.2±8.8 | 68.6±5.7 | <0.001 |
| **T4** | 88.3±9.4 | 66.7±4.8 | <0.001 |
| **T5** | 89.5±8.2 | 65.6±6.4 | <0.001 |
| **T6** | 90.1±6.7 | 67.4±8.6 | <0.001 |
| **T7** | 89.3±9.4 | 70.3±10.6 | <0.001 |
| **T8** | 92.1±9.3 | 76.3±13.4 | <0.001 |

## DISCUSSION

The present study assessed 164 subjects that were randomly divided into two groups where Group I subjects were given nitroglycerin and Group II subjects were given dexmedetomidine as IV (intravenous) infusion to attaincontrolled hypotension. The mean age of the study subjects was 28.76±6.4 and 28.76±6.4 years in Groups I and II respectively which was non-significant with p=0.07. There were 78 males and 4 females in Group I and 72 males and 10 females in Group II showing non-significance with p=0.22. Mean BMI, height, and weight were statistically comparable in Groups I and II with p=0.26, 0.85, and 0.09 respectively. Mean surgery duration was comparable in Groups I and II with 124.76±20.95 and 125.63±35.63 minutes respectively. These data correlated with the previous studies of Denault A et al[6] in 2007 and Heller JA et al[7] in 2015 where authors assessed subjects with disease and demographic data comparable to the present study.

The study results showed that concerning the assessment of CDEs (cerebral desaturation events) by 10% and 20% in two groups of study subjects, it was seen that in Group I CDE by 10% was seen in 30 subjects and not seen in 52 subjects. Similar results were seen in Group II where CDEs were seen in 30 subjects and not seen in 52 subjects with Odd's ratio of 1 and 95% CI of 0.43 and 2.44 in Groups I and II respectively. For CDEs by 20%, they were seen in 2 subjects from Group I and 4 subjects from Group II with Odd's ratio of 2.03 and 95% CI of 0.16 and 23.53 (Table 2). No subject showed more than a 30% decline in baseline values from either group. These results were consistent with the findings of Rigamonti A et al[8] in 2005 and Samra SK et al[9] in 2000 where cerebral desaturation events at 10% and 20% reduction were comparable to the present study reported by the authors in their respective studies.

It was seen that on Kaplan–Meier survival analysis for comparison of CDE time with a 10% decline from baseline in two groups, mean time to CDEs was 104.62 (94.24-115.04) minutes in Group I and was 10.5.36 (95.42-115.34) minutes in Group II. Time to CDEs was statistically comparable with p=0.67. Analysis was not performed for time to CDEs by 20% owing to smaller subjects showing a decrease from baseline rScO2. Two study groups were comparable concerning left and right rScO2 at all the assessment times. These findings were in agreement with the results ofMurkin JM et al[10] in 2009 and Tobias JD et al[11] in 2006 where authors reported no significant difference in CDEs with different anesthetic agents which was similar to the results of the present study.

It was also seen that for comparison of heart rates in two study groups at different time intervals, non-significant differences in baseline heart rates were seen at T0 and T1 with p=0.743 and 0.08 respectively. However, significantly higher heart rates were seen in Group I (nitroglycerin) compared to Group II (dexmedetomidine) at T2, T3, T4, T5, T6, T7, and T8 with p<0.001 at all the assessment times. These results were in line with the studies ofMaghawry KM et al[12] in 2015 and Farzanegan B et al[13] in 2018 where authors also reported lower heart rates with dexmedetomidine in their studies as seen in the present study.

## CONCLUSIONS

Within its limitations, the present study concludes that dexmedetomidine is not inferior to nitroglycerin concerning the occurrence of cerebral desaturation events when used for controlled hypotensive anesthesia in subjects undergoing head and neck surgeries. However, future studies with longer follow-up and a larger number of subjects are warranted to reach a definitive conclusion.

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