Original Research Article

Prospective randomised control study of dexmedetomidine for controlled hypotension in functional endoscopic sinus surgery

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ABSTRACT

Background: Functional endoscopic sinus surgery is one of the commonly performed Surgeries. Induced hypotension is a method employed in functional endoscopic sinus surgery to reduce blood loss and to improve the visibility of the surgical field. This study aimed to evaluate the effect of dexmedetomidine infusion on the requirement of Isoflurane to produce controlled hypotension (mean arterial pressure of 60-70 mmHg), quality of the bloodless surgical field, duration of surgery, and the awakening time in patients undergoing Functional endoscopic sinus surgery (FESS).

Methods: 50 patients were divided into Group D, Group C Group D. After successful tracheal intubation, anesthesia was maintained with 66% nitrous oxide + 33% oxygen + isoflurane titrated to achieve a mean arterial pressure (MAP) of 60-70 mmHg. Isoflurane and dexmedetomidine/saline infusion was stopped 10-15 minutes before the end of surgery. The intraoperative surgical field was assessed by using a 6 points Fromme-Boezaart scale.

Results: A statistically significant (p<0.001) reduction in intraoperative isoflurane requirement in patients receiving dexmedetomidine infusion (0.387±0.102) in comparison to those receiving placebo (1.7±0.211). Both the group provided better visualization of the surgical field. The duration of surgery was statistically (p=0.004) low in Group D (76.84±14.174) compared to group C (94.1±25.083). The awakening time in min was statistically (p=0.001) low in group D (5.12±1.691) compared to group C (9.72±1.100).

Conclusions: Dexmedetomidine infusion helps in achieving a targeted reduction in MAP reduced intraoperative Isoflurane requirement, better bloodless field, and faster awakening in patients undergoing Functional endoscopic sinus surgery.

Keywords: Dexmedetomidine, FESS, Controlled hypotension

INTRODUCTION

Impairment of intraoperative visibility due to bleeding is a problem during otorhinolaryngologic surgeries especially in endoscopic surgeries like FESS.1 Bleeding in the surgical field can lead to incomplete surgical procedures which increase further bleeding and increased the risk of complications due to the nonvisualization of important structures.2 During these surgeries, the slightest bleeding at the surgical area would look larger due to the magnifying effect of the microscope which could upset surgical comfort.3 Controlled hypotension is one of the anesthetic techniques used to reduce bleeding during endoscopic surgeries. There are varieties of methods and medications used to obtained deliberate hypotension.4 The ideal hypotensive agent should be nontoxic, maintain cerebrovascular autoregulation, no change in cardiac function, have short-term effects, and be easily titrated.
Alpha 2 agonists like clonidine augment hypotensive action and therefore reduce bleeding. Dexmedetomidine, another highly selective Alpha 2 agonist acts by a central mechanism and reduces bleeding. This study chosen this study to evaluate the effect of dexmedetomidine on the intraoperative isoflurane requirement to maintain mean arterial pressure of 60-70 mmHg, quality of the surgical field, and awakening time in patients undergoing FESS. Hypotensive anesthesia is a technique, used intraoperatively to help to minimize surgical blood loss, thereby decreasing the need for blood transfusion. By providing a clear surgical field they also decrease the duration of surgery.

**METHODS**

This prospective randomized controlled study was done in 2019 July to 2019 December over six months in 50 ASA I Patients age 18-60 years diagnosed having chronic sinusitis scheduled for FESS under general anesthesia were divided into two groups. Group D: received 10-20 min before induction of anesthesia 1 µg/kg IV bolus of Dexmedetomidine followed by an infusion of 0.3-0.6 µg/kg/hr. Group C: received 10-15 min before induction of anesthesia a normal saline rate similar to group D. Following a uniform premedication all patients were induced with injection propofol and relaxed with injection vecuronium bromide. After successful tracheal intubation, anesthesia was maintained with 66% nitrous oxide + 33% oxygen + isoflurane titrated to achieve a mean arterial pressure [MAP] of 60-70 mmHg.

**Exclusion criteria**

Hypertensive patients. History of cerebrovascular accident/Transient ischemic attack. IHD. Poor respiratory reserve. Significant hepatic or renal disease. Hypersensitivity to study drugs. Patients who are not willing to participate in the study.

**Methodology**

50 patients with the above criteria were divided into two equal groups. Group D: received bolus dose of Dexmedetomidine 1 µg/kg over ten min before induction followed by infusion of 0.3-0.6 µg/kg/hr. (2 ml of dexmedetomidine was diluted with 48 ml of NS making a solution of 4 µg/ml) Group C: received an equal amount of normal saline. Preoperative investigations reports like Hb%, blood urea, serum creatinine, platelets, clotting time, bleeding time were recorded. On arriving at the operating room monitors were connected and baseline vital parameters were noted. Two peripheral intravenous lines with 18 G IV Cannula one for IV infusion another for study drug was started. Preloading was done with 10 ml/kg of balanced salt solutions. Premedicated with Injection Midazolam (0.05 mg/kg), injection Glycopyrrolate 10 mcg/kg + Injection Fentanyl 12 mcg/kg. The study drugs were started according to the group. Then anesthesia was induced with Injection Propofol 2 mg/kg + Injection Vecuronium 0.1 mg/kg and intubated with appropriate size endotracheal tube. Throat packed with saline-soaked gauze. Anesthesia was maintained with 66% N2O + 33% O2 + IPPV with a titrated dose of isoflurane and Vecuronium. The mean arterial pressure was maintained around 60-70 mmHg by titrating the intraoperative isoflurane percentage. The isoflurane concentration was recorded every five min and averaged for analysis. Intraoperative Tachycardia (HR>150 bpm) controlled by IV Metoprolol 1-5 mg. Intra-operative bradycardia (HR <50 bpm) managed by, 0.6 mg atropine in both study drugs and isoflurane were stopped 20 min before the end of surgery. Injection Ondansetron 4 mg was given intraoperatively. The residual neuromuscular blockade was reversed with injection neostigmine 50 mcg/kg+ injection Glycopyrrolate 10 mcg/kg and was extubated. The awakening time in min (clearly telling their name) from the time of extubation was recorded. Patients were observed in the recovery room for nausea and vomiting, sedation score, and then monitored in the postoperative ward. Both groups were hemodynamically stable and none showed any adverse reactions like reflex hypertension, nausea, and vomiting.

**Statistical analysis**

The variables were entered into Statistical package for social sciences (SPSS), version 15, statistical software for analysis. Statistical analysis was done by using descriptive statistics and cross-tabulation. Mean and standard deviation was used to assess changes within and between the two groups. The difference in proportions is tested for statistical significance using the nonparametric chi-square test for variables measured on a nominal scale. For variables measured on a continuous scale, the student “t” test was used. A p<0.05 was considered to be statistically significant.

**RESULTS**

The mean age between the comparison groups was almost similar (Table 1). The minimum age taken for the study was 18 and the maximum was 55. Not statistically significant. The male preponderance was forthcoming in all the study groups. However, the distribution of sex among the groups was not statistically significant. The mean distribution of cases by weight was observed to be not statistically significant between the two groups.

### Table 1: Age distribution.

|          | Group D | Group C | P value |
|----------|---------|---------|---------|
| No. of cases | 25      | 25      | 0.611   |
| Mean      | 33.20   | 31.76   |         |
| S.D.      | 9.574   | 10.325  |         |
| Range     | 18-53   | 18-55   |         |
Pre induction heart rate was almost similar. No statistical difference (p=0.119) (Table 2). But the heart rate after induction, after intubation, and during the intraoperative period was statistically significant which was lower in group D compared to group C.

Regarding the systolic blood pressure both groups showed almost equal results in the pre-induction period. But the systolic blood pressure after induction, after intubation, and during the intraoperative period was lower in group D which was statistically significant.

The diastolic blood pressure was lower in group D after intubation and during the intraoperative period which was statistically significant. Regarding the mean arterial pressure, post-intubation and average intraoperative values were low in group D which was statistically significant. Other value like pre-induction, post-induction and post-extubation were comparable in both and was not statistically significant.

The average intraoperative isoflurane requirement was low in group D (0.387) Compared to group C (1.783) (Table 3). This was statistically significant (p<0.001).

Intraoperative problems such as hypertension, hypotension, arrhythmia, tachycardia, ischemia were not seen in any groups (Table 4). Bradycardia was seen in two cases in group D and three cases in group C. This was not statistically significant. All patients underwent the same type of surgery. The duration of surgery was less with group D when compared to group C which is statistically significant (p=0.004).

| Table 2: Intra-operative parameters. |
|--------------------------------------|
| Parameter          | Group D       | Group C       | P value |
| Heart rate         |               |               |         |
| Pre induction      | 75.92±5.787   | 79.24±8.695   | 0.119   |
| Post induction     | 71.68±6.830   | 76.48±9.417   | 0.045*  |
| Post intubation    | 75.12±5.761   | 88.04±7.618   | 0.001*  |
| Avg. Intraop       | 58.44±2.873   | 75.84±6.472   | 0.001*  |
| Post extubation    | 72.88±5.231   | 79.04±11.681  | 0.020*  |
| SBP                |               |               |         |
| Pre induction      | 122.28±8.532  | 121.28±8.824  | 0.639   |
| Post induction     | 105.96±10.5   | 114.88±13.48  | 0.012*  |
| Post intubation    | 100.84±12.7   | 117.56±12.14  | 0.001*  |
| Avg. intraop       | 91.16±1.864   | 93.40±3.44    | 0.006*  |
| Post extubation    | 116.88±9.52   | 124.00±10.19  | 0.014*  |
| DBP                |               |               |         |
| Pre induction      | 81.36±6.376   | 78.72±7.22    | 0.177   |
| Post induction     | 69.44±7.896   | 71.60±11.36   | 0.439   |
| Post intubation    | 65.04±8.039   | 78.40±11.23   | 0.001*  |
| Avg. intraop       | 58.80±1.581   | 61.08±2.499   | 0.001*  |
| Post extubation    | 77.24±8.686   | 80.76±9.701   | 0.183   |
| MAP                |               |               |         |
| Pre induction      | 95.00±6.333   | 92.85±7.27    | 0.271   |
| Post induction     | 81.61±8.058   | 86.03±11.06   | 0.113   |
| Post intubation    | 76.97±9.217   | 91.45±11.066  | 0.001*  |
| Avg. intraop       | 69.72±1.400   | 71.80±2.566   | 0.001*  |
| Post Extubation    | 90.45±8.654   | 95.17±9.385   | 0.071   |

*statistically significant

| Table 3: Intraoperative isoflurane requirement. |
|-----------------------------------------------|
| No. of cases | Group D | Group C | P value |
|---------------|---------|---------|---------|
| Mean          | 0.387   | 1.783   | <0.001* |
| S.D.          | 0.102   | 0.211   |         |
| Range         | 0.2-1.4 | 1-2.5   |         |

*Statistically significant

The average intraoperative isoflurane requirement was low in group D (0.387) Compared to group C (1.783) (Table 3). This was statistically significant (p<0.001).

| Table 4: Intraoperative adverse events. |
|----------------------------------------|
| Intraoperative problems | Group D | Group C | P value |
|-------------------------|---------|---------|---------|
| Hypertension            | N       | %       | N       | %       |         |
| Yes                     | 0       | 0       | 0       | 0       | -       |
| No                      | 25      | 100     | 25      | 100     | -       |
| Hypotension             | N       | %       | N       | %       |         |
| Yes                     | 0       | 0       | 0       | 0       | -       |
| No                      | 25      | 100     | 25      | 100     | -       |
| Arrhythmia              | N       | %       | N       | %       |         |
| Yes                     | 0       | 0       | 0       | 0       | -       |
| No                      | 25      | 100     | 25      | 100     | -       |
| Tachycardia             | N       | %       | N       | %       |         |
| Yes                     | 0       | 0       | 0       | 0       | -       |
| No                      | 25      | 100     | 25      | 100     | -       |
| Bradycardia             | N       | %       | N       | %       |         |
| Yes                     | 2       | 8       | 3       | 12      | -       |

Continued.
Table 5: Evaluation of the surgical field by surgeon.

| Fromme Boezzart Scale | Group D | Group C | P value |
|------------------------|---------|---------|---------|
| No. of cases           | 25      | 25      | 0.333   |
| Grade I                | 14      | 14      |         |
| Grade II               | 11      | 09      |         |
| Grade III              | 00      | 02      |         |

Table 6: Ramsay sedation scale.

| Time in min | Score 2 | Score 3 |
|-------------|---------|---------|
| Group D     |         |         |
| 15 min      | 15      | 10      |
| 30 min      | 19      | 06      |
| 45 min      | 25      | 00      |
| 60 min      | 25      | 00      |
| Group C     |         |         |
| 15 min      | 10      | 15      |
| 30 min      | 18      | 07      |
| 45 min      | 24      | 01      |
| 60 min      | 25      | 00      |

The surgical field grading was almost equal in the two groups (Table 5). Two patients in group C showed Grade III, none in group D. But this was not statistically significant. (p=0.333). The awakening time was low in group D compared to the C group which was statistically significant. (p=0.001)

There was no significant difference in the sedation score.

DISCUSSION

Dexmedetomidine offers beneficial pharmacological properties, providing dose-dependent sedation, analgesia, sympatholysis, and anxiolysis without relevant respiratory depression.8 The dominant action of adrenoceptor-2 agonists with low and clinically recommended concentrations is hypotension.9 Nowadays Dexmedetomidine has been used for controlled hypotension in the middle ear as well as nasal endoscopic surgeries.10 The advantage of dexmedetomidine over nitroglycerine will not cause reflex tachycardia. To achieve controlled hypotension in functional endoscopic sinus surgeries either inhalation technique or intravenous technique are used routinely. If inhalational agents were used to providing hypotensive anesthetica large inspired concentration of the anesthetics was used than that required to produce surgical anesthesia.11 By stimulating the presynaptic alpha 2-adrenoceptors dexmedetomidine decreases the norepinephrine release and causes a fall in blood pressure and heart rate.12 Because of this property, Dexmedetomidine is nowadays used as a hypotensive agent in endoscopic surgeries. It also has an added advantage of the analgesic property thus reducing perioperative analgesic requirement. Hence this study was designed to evaluate the effect of dexmedetomidine on isoflurane requirement in achieving a MAP of 60-70 mmHg. Both groups were comparable in demographic distribution, resting heart rate, and blood pressure.13 Even though both the group received the same mode of induction, the intubation response was less in the dexmedetomidine group compared to the control. This was comparable with the result of Newman et al intraoperative means arterial pressure was maintained around 60-70 mmHg by titrating isoflurane percentage.14 The group C needed more isoflurane (1.7±0.211) than group D (0.387±0.102). This was statistically significant (p<0.001). This finding concurred with the results of the study by Richa et al, in their study on 'Dexmedetomidine, is a useful hypotensive adjunct during middle ear surgery under general anaesthesia', in their study, the mean isoflurane requirement in the DEX group was 1.3±0.4 and in the saline group was 3.1±0.3.15 The same result was observed by Robert et al but they used halothane.16 The intraoperative heart rate was found to be lower in group D. This finding concurred with the results of the study by Ronald et al They found that the heart rate was lower in the DEX group. This finding also concurred with the results of showed DEX will not cause reflex tachycardia perioperatively. The average intraoperative systolic blood pressure, diastolic blood pressure, mean arterial pressure was significantly lower in the Dexmedetomidine group compared to the control group. Regarding the intraoperative adverse reaction, 2 patients in group D (8%) and 3 patients in group C (12%) developed bradycardia. It was easily reversed by atropine 0.6 mg IV single dose in both the groups. This was not statistically significant (p=1.000).17 Other intraoperative problems like hypertension, arrhythmias, tachycardia, ischemia were not encountered in either of the groups. There was a statistically significant difference in duration of surgery (p=0.004) The mean duration of surgery in group D was (76.84±14.174) In group C was (94.1±25.083). The evaluation of the surgical field was done by a surgeon blinded to the study drugs using the Fromme Boezzaart scale. All patients in group D belonged to grade 2 and below and in group C to grade 3 and below, which denotes a highly acceptable surgical field as far as the surgeon was
concerned. The awakening time in min (time required to tell their name from the end of tracheal extubation) was lower in group D (5.12±1.691) compared to group C (9.72±1.100). It was statistical significance (p=0.001). It concurred with the result of Scheinin et al they found that the mean awakening time index group was 9.1±2.7 min and in the NS group was 12.8±0.2 min. The intraoperative isoflurane consumption was comparatively more than our study (in group D 1.3 versus 0.38, in group C (3.1 versus 1.7). This may be the reason the awakening time was prolonged in both the group in their study. Regarding the hemodynamic stability after extubation, both groups returned to their baseline values. In our study, however, none of the patients in both groups had nausea and vomiting in the post-operative period. This could be due to the prophylactic administration of injection Ondansetron. There was no significant difference in the postoperative sedation score in both groups.19,20

CONCLUSION

Dexmedetomidine infusion helps in achieving a targeted reduction in MAP, reduced intraoperative Isoflurane requirement, better bloodless field, and faster awakening in patients undergoing Functional Endoscopic Sinus Surgery. Group D lowered intra operative blood pressure better than group C. Group D produced a lower intraoperative heart rate than group C. Intra-operative isoflurane requirement was low in group D compared to group C. Both the group provided better visualization of the surgical field assessed by the surgeon using the Fromme Boezzaart scale.

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

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