Efficacy of Dexmedetomidine Infusion for Procedural Comfort and Intraoperative Sedation in Patients Undergoing Surgeries with Subarachnoid Block: A Randomized Double-blind Clinical Trial

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Abstract

**Introduction:** There is increasing evidence to include sedation as an integral part of regional anesthesia to ensure patient comfort. This may compromise patient cooperation, an important component of regional anesthesia. We decided to determine the efficacy of dexmedetomidine (0.3 μg/kg/h and 0.5 μg/kg/h) for allaying procedural discomfort and ensuring their cooperation in patients undergoing surgery with subarachnoid block. **Setting:** Tertiary care center. **Materials and Methods:** Sixty patients with the American Society of Anesthesiologists physical status Class I and II posted for surgeries under subarachnoid block were randomized into two groups of 30 each to receive dexmedetomidine in a loading dose of 1 μg/kg in both groups followed by continuous infusion of 0.3 μg/kg/h in Group D 0.3 and 0.5 μg/kg/h in Group D 0.5. Observer assessment sedation score, ease of positioning score, response to spinal needle insertion, hemodynamic parameters, patient satisfaction (PS) score, and surgeon satisfaction (SS) score were evaluated. **Results:** Median Observer Assessment Sedation Score ranged between four and three at all times during dexmedetomidine infusion in Group D 0.3. In Group D 0.5, median Observer assessment of alertness/sedation scale ranged between three and two. Ease of positioning (P = 1.000) and response to spinal needle insertion (P = 0.521) were comparable in both groups. PS was higher in Group D 0.5 as compared to Group D 0.3. SS score was comparable in both the groups. **Conclusion:** Intravenous dexmedetomidine infusion 0.3 μg/kg/h produces effective sedation in patients undergoing surgery with spinal anesthesia while ensuring patient cooperation for positioning and without any recall of the procedure in postoperative period.

Keywords: Dexmedetomidine, patient satisfaction, procedural comfort, subarachnoid block

**INTERODUCTION**

A conscious, spontaneously breathing patient, who can maintain a patent airway during the surgical procedure, is definitely an advantage of regional anesthesia. The same “consciousness” during surgery may be one of the factors contributing to patient anxiety and dissatisfaction. Fear of being awake during surgery, fear of needle, and fear of numbness wearing off early were expressed as major factors for refusal of spinal anesthesia by patients. Multiple other reasons such as cold operating environment, new people, awkward positioning, and need to lie down in the supine position for longer periods may increase patient anxiety and reduce patient satisfaction (PS) with anesthesia care.[1] Adequate sedation during spinal anesthesia relieves the patient anxiety, improves physiological and psychological stress, and increases the satisfaction of both the surgeon and patient.[2,3] Dexmedetomidine is a selective α₂ receptor agonist with properties of analgesia, sympatholysis, and flexibility to titrate sedation without causing major respiratory depression. It is well suited for conscious sedation as patients can be quickly aroused and oriented on demand.[4] Various studies have analyzed the dose of dexmedetomidine and its effects on procedural comfort and intraoperative sedation.

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which causes adequate sedation for patients undergoing surgery with spinal anesthesia. However, there is a paucity of studies which analyze the dose of dexmedetomidine which ensures patient cooperation to independently position for subarachnoid block despite being adequately sedated and not being able to perceive stimulus of spinal needle prick. In addition, the patient’s and surgeon’s perspective on satisfaction with the anesthetic care is an important clinical indicator of the quality of perioperative care.\(^5\)

We designed a study to analyze the level of sedation, ease of positioning, response to spinal needle insertion, and recall of the procedure with dexmedetomidine in a dose of 0.3 \(\mu\)g/kg/h and 0.5 \(\mu\)g/kg/h for patients undergoing surgery with subarachnoid block.

**Materials and Methods**

This randomized, double-blind prospective study was conducted at a tertiary care center over a period of 1 year. After approval from the Institutional Ethical Committee, 60 patients aged between 18 and 60 years, of American Society of Anesthesiologist’s (ASA) physical status Class I and II, posted for elective surgeries under subarachnoid block were included in the study. Patients allergic to local anesthetics, with contraindications to central neuraxial blockade, patients with heart blocks, sinus bradycardia or on beta blockers, were excluded from the study.

After obtaining informed consent, all patients were premedicated with oral alprazolam 0.5 mg in the night and 0.5 mg in the morning of surgery. After ensuring 8 h nil per oral status, all patients were preloaded with 10 ml/kg Ringer lactate solution in the preoperative holding area.

On arrival to operating room, baseline hemodynamic parameters were recorded, and the patients were randomized into two groups by a closed envelope technique. Group D 0.3 received dexmedetomidine 1 \(\mu\)g/kg bolus over 10 min followed by 0.3 \(\mu\)g/kg/h intravenous infusion and Group D 0.5 received dexmedetomidine 1 \(\mu\)g/kg bolus over 10 min followed by 0.5 \(\mu\)g/kg/h intravenous infusions [Figure 1]. To ensure blinding, the test solution was given intravenously by an assistant who was not involved in the administration of anesthesia and monitoring. Observer assessment of alertness/sedation scale (OASS): 5 - Responds readily to name spoken in normal tone, 4 - lethargic response to name spoken in normal tone, 3 - responds only after name is called loudly.
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and/or repeatedly, 2 - responds only after mild prodding or shaking, and 1-Does not respond to mild prodding or shaking; was noted 3 min after giving the test drug, and patient was put into the lateral position. Ease of positioning for subarachnoid block (while turning the patient to the lateral position) was assessed by a three-point scale: 1- patient turned on his own, 2 - patient turned with the help of one person, and 3 - patient turned with the help of more than one person. With all strict aseptic precautions, neuraxial block was performed without using local infiltration. Response to spinal needle insertion was noted and graded by 4 - point score: 1- gross patient movement, 2 - back muscle contraction 3 - minimal patient movement, 4 - no patient movement. Then, the patient was placed in the supine position for surgery. Monitored parameters-Heart rate (HR), mean arterial blood pressure (MAP), oxygen saturation (SPO$_2$), and respiratory rate (RR) were recorded every 5 min. OASS was assessed every 5 min. The maintenance infusion was discontinued at the time of the last skin suture. In recovery area when the patient was fully awake, patient recall of the subarachnoid block procedure was quantified as yes or no. The PS and surgeon satisfaction (SS) were assessed on a five-point scale as: 5 - very happy, 4 - somewhat happy, 3 - neutral, 2 - not very happy, and 1 - not at all happy.

Adverse events such as bradycardia (HR <50 beats/min), bradypnea (RR <8 breaths/min), desaturation (SPO$_2$ <92%), hypertension (an increase in systolic blood pressure or MAP >20% of baseline), hypotension (drop in systolic blood pressure >20% of baseline or MAP <60 mmHg), nausea, vomiting, dry mouth, or any other event during or within 2 h of the procedure was noted. Bradycardia was treated with intravenous atropine sulfate 0.01 mg/kg, hypotension with intravenous fluid and if needed, intravenous mephentermine sulfate 3 mg bolus was administered. In case of bradypnea, patient was woken up and was asked to take deep breaths. If patient attains deep sedation or evidence of airway obstruction, the infusion was stopped, airway maintained by chin lift, and supplemental oxygen was administered.

**Statistical analysis**

In our pilot study, OASS of 4 was achieved in 50% of patients in Group D 0.3 and 85% patients in Group D 0.5. Considering alpha 0.05 and beta 80% sample size was calculated as 27 patients in each group. Considering dropouts, a sample size of 30 patients in each group was considered. All data were entered into MS Excel 2011. Data were analyzed by SPSS software version 20.0 (Armonk, New York, IBM corp.). Chi-square test was used to analyze sex distribution, weight, and mallampati class. Age distribution was calculated using t-test. Median OASS was calculated for both groups. Ease of positioning score, response to spinal needle insertion, PS score, and SS score were analyzed using Mann–Whitney test.

**Results**

All 60 patients who were enrolled in the study completed the protocol and were included in data analysis. Demographic data such as age, sex, and ASA physical status were found to be statistically comparable among the two groups [Table 1].

Median OASS ranged between four and three at all times during dexmedetomidine infusion in Group D 0.3. In Group D 0.5, median OASS ranged between 3 and 2, most of the patients with an OASS of 2 beyond 30 min of starting the infusion [Figure 2].

Ease of positioning for subarachnoid block was similar in both groups with no difference in scores ($P = 1.000$) [Figure 3].

There was no response to spinal needle insertion in majority of patients in both groups and the difference among the two groups was also statistically insignificant ($P = 0.521$) [Figure 4].

A decrease in both HR and mean arterial pressure was found in either of the groups but the difference was statistically insignificant [Figure 5].

PS score was significantly better in Group D 0.5 as compared to Group D 0.3 ($P = 0.003$) [Figure 6]. SS score was good and statistically comparable in the two groups ($P = 0.816$) [Figure 6].

**Table 1: Comparison of demographic data between the two groups**

| Parameter          | Group D 0.3 ($n=30$) | Group D 0.5 ($n=30$) | $P$   |
|--------------------|----------------------|----------------------|-------|
| Age, years (CI)    | 42.10 (37.75-46.45)  | 38.53 (35.13-41.94)  | 0.19  |
| Sex (females:males)| 16:14                | 16:14                | 0.02  |
| Weight (kg), mean±SD| 53.19±17.30         | 56.06±10.72         | 0.16  |
| Mallampati class (1/2/3/4) | 13/16/1           | 14/14/2              | 0.77  |

CI=Confidence interval, SD=Standard deviation

**Figure 2: Comparison of observer assessment sedation score between two groups**
Among the reasons for patient dissatisfaction and refusal to spinal anesthesia, the fear of being conscious during surgery has been found to be one of the important factors determining it.\(^6\)\(^-\)\(^8\) It has been, therefore, recommended to sedate patients during surgery. Several drugs such as midazolam, ketamine, propofol, remifentanil, and clonidine have been used for this purpose in the past.\(^1\)\(^-\)\(^3\)\(^,\)\(^9\)\(^-\)\(^11\)

In our study, we have used dexmedetomidine in a loading dose of 1 μg/kg in both the groups followed by continuous infusion of 0.3 μg/kg/h and 0.5 μg/kg/h in each group, respectively, to produce sedation.

In Group D 0.3, median OASS ranged between four and three which implicates that the patients were arousable by their names called out in a normal tone of voice. This indicates appropriate and desirable level of sedation. In Group D 0.5, the median OASS ranged between three and two which means that they were arousable only if the name was called out repeatedly or responded only after mild prodding or shaking.
This indicates a higher level of sedation [Figure 2]. Observer assessment of sedation score measures the level of alertness in subjects who are sedated, and its validity has been tested. A 95% effective single dose of dexmedetomidine was found to be 0.35 μg/kg in elderly and 0.57 μg/kg in young patients undergoing surgical procedures with spinal anesthesia in a prior study. According to the authors, the dose requirement of dexmedetomidine for adequate sedation under spinal anesthesia is relatively less because spinal anesthesia may increase the sensitivity to a sedative agent, explaining the low ED95 for an OAA/S sedation scale.

Recent studies conducted to determine the effective dose of dexmedetomidine for procedural sedation with spinal anesthesia describe and define patient comfort based only on sedation scores with very little emphasis on patient cooperation under sedation and response to spinal needle insertion. The desirable level of sedation would be when the patient can turn for spinal anesthesia on his own or with minimal help and still neither feel the spinal needle prick nor recall the procedure in postoperative period. We studied the patient ability to cooperate for positioning to administer spinal anesthesia through ease of positioning score and found that there was no difference between the two groups. Majority of patients in both the groups (n = 17) turned on their own while some of them (n = 11) in each group had to be turned with the help of one person. Two patients in each group required two persons to turn them to position for spinal anesthesia [Figure 3].

Response to spinal needle insertion was recorded to assess patient comfort during the procedure of spinal anesthesia. Majority of patients in Group D 0.3 (n = 15) and Group D 0.5 (n = 18) had no movement in response to spinal needle insertion. Gross patient movement was noted in three patients in Group D 0.3 and none of the patients in Group D 0.5. The difference was statistically comparable between the two groups [Figure 4]. However, none of the patients had a recall of spinal needle prick in postoperative period. Postspinal backache and needle prick pain were found to be the most common causes of refusal for spinal anesthesia. By achieving adequate sedation before the administration of spinal anesthesia patient comfort was ensured.

Trends in HR and mean arterial pressure show a decrease in both the groups although there was no statistically significant difference found between the two groups [Figure 5]. This could be because both the groups received a loading dose of 1 μg/kg and bradycardia is seen with higher doses of dexmedetomidine (1–4 μg/kg). Subsequent hypotension is also related to the loading dose and is mainly due to blockade of central sympathetic outflow.

RR and SPO2 changes were minimal and statistically insignificant in both the groups. This could be because dexmedetomidine offers a unique ability of providing both sedation and analgesia without respiratory depression.

PS is a major indicator of quality of healthcare provided. Hence, we decided to evaluate overall PS with anesthetic care and found that most of the patient in Group D 0.3 (n = 12) and Group D 0.5 (n = 16) were happy; however, satisfaction score was higher in Group D 0.5 as compared to Group D 0.3 [Figure 6]. This could be because sedation was initiated before performing subarachnoid block and continued throughout the surgery. SS score was found “somewhat happy” and “very happy” in majority of cases in both the groups with no statistically significant difference between the two groups [Figure 6]. This is unique to our study, and it indirectly indicates that patients were well sedated and did not have spontaneous movements which may interfere with surgical procedure.

**Conclusion**

Intravenous dexmedetomidine infusion 0.3 μg/kg/h produces effective sedation in patients undergoing surgery with spinal anesthesia while ensuring patient cooperation for positioning and without any recall of the procedure in postoperative period.

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**Conflicts of interest**

There are no conflicts of interest.

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