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Original Research Article

A Randomized Control Trial of Three Intravenous Dexmedetomidine Doses for Procedural Sedation in Patients Undergoing Minor Gynecological Surgery

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Abstract

Background: Minor surgery, despite its short duration, is associated with significant pain and discomfort. Several anaesthetic techniques and pharmacological agents have been used to reduce patient discomfort and facilitate surgical performance. However, procedural sedation and analgesia (PSA) is still preferred over general anaesthesia during short gynaecological procedures. Most analgesics/sedative drugs, such as midazolam, propofol, and fentanyl, which are commonly used for PSA, can potentially prolong sedation and cause respiratory depression and adverse hemodynamic effects, which may result in increased morbidity and unplanned hospitalization as most cases are done as day-care surgery. Dexmedetomidine, a known sedative and analgesic sparing drug that acts on α2 adrenoceptor, reduces heart rate, blood pressure, and anaesthetic drug requirements in response to any stress. Dexmedetomidine is extensively used as a sedative and analgesic agent in various surgeries, but the optimum dose of dexmedetomidine in these procedures is still unknown.

Aim: The study aims to analyze a randomized control trial of three intravenous dexmedetomidine doses for procedural sedation in patients undergoing minor gynecological surgery.

Method: The study was a randomized control trial conducted at Govt Medical Center & attached Bangur Hospital, Pali, Rajasthan, during the period March 2019 to December 2021. The study population consisted of ASA grade I and II patients aged 18-45 years who were scheduled to undergo short gynecological surgery (20-40 min) under intravenous sedation and analgesia. The study included hysteroscopic copper T removal, dilatation and curettage, hysteroscopic biopsy, and Bartholin cyst excision in the short gynecological surgery. The data was compiled, tabulated, and statistically analyzed using Statistical Product and Service Solutions (SPSS) version 17 (IBM Corp., Armonk, NY). Analysis of variance was used for the analysis of mean difference among groups and Chi-square test for grading of sedation, recovery, and discharge.

Result: all patients had a Ramsay Sedation Score of 3 or more. In half of the patients in group A and in one-fourth of the patients in group B, ketamine was required as a rescue drug. None of the patients in group C required any drug supplementation. Moreover, the Modified Aldrete Score (≥8) was 21.14 ± 9.99 min and was almost doubled in groups B (39.68 ± 18.39 min) and C (45.38 ± 29.90 min). This difference was statistically significant in the A versus B group and the A versus C group (p = 0.000). However, it was comparable between groups

B and C ($p > 0.05$). Patients in group A achieved PADSS score (≥9) earlier (148.64 ± 23.56 min) than in group B (177.10 ± 16.16 min) and group C (200.25 ± 18.47 min).

Conclusion: Dexmedetomidine at a dose of 0.6 µg/kg/hr provides efficient sedation and analgesia but is associated with significant hemodynamic compromise, whereas dexmedetomidine at a dose of 0.4 µg/kg/hr requires ketamine supplementation at 0.3 mg/kg to achieve adequate analgesia and sedation without hemodynamic complications

Keywords: anaesthetic techniques, sedative drugs, procedural sedation and analgesia

Background

Minor surgery, despite its short duration, is associated with significant pain and discomfort [1]. Several anaesthetic techniques and pharmacological agents have been used to reduce patient discomfort and facilitate surgical performance [2]. However, procedural sedation and analgesia (PSA) is still preferred over general anaesthesia during short gynaecological procedures. One of the most important goals of clinicians is patient comfort [3]. When patients present to the emergency department (ED), treating the pain and anxiety that accompany the chief complaint are critical to patient satisfaction and quality of care [4]. Nonetheless, clinicians may underuse sedation, usually from a lack of experience or from unchallenged myths regarding its use [5,6].

Most analgesics/sedative drugs, such as midazolam, propofol, and fentanyl, which are commonly used for PSA, can potentially prolong sedation and cause respiratory depression and adverse hemodynamic effects, which may result in increased morbidity and unplanned hospitalization as most cases are done as day-care surgery [7]. Dexmedetomidine, a known sedative and analgesic sparing drug that acts on α2 adrenoceptor, reduces heart rate, blood pressure, and anaesthetic drug requirements in response to any stress [8]. Unlike other anaesthetics, it also has a sedative response, mimicking natural sleep without significant respiratory depression [9,10] Minor gynecological procedures are usually done in outpatient settings. Early discharge with minimal hemodynamic compromise is an essential requirement of these procedures. Many sedative drugs are being used for outpatient surgeries. Of the sedative agents available, dexmedetomidine, which has sedative and analgesic sparing effects, has the best safety profile in the cardiorespiratory system [11]. Therefore, we evaluated the optimum dexmedetomidine dose for providing better procedural sedation.

Dexmedetomidine is extensively used as a sedative and analgesic agent in various surgeries, but the optimum dose of dexmedetomidine in these procedures is still unknown [12]. Thus, the study will evaluate the optimum dexmedetomidine dose for short gynaecological surgery. Moreover, the study will observe perioperative hemodynamic changes and any additional intraoperative adjuvant drug requirements, as well as to evaluate postoperative parameters using the Modified Aldrete Score.

Aim

The study aims to analyze a randomized control trial of three intravenous dexmedetomidine doses for procedural sedation in patients undergoing minor gynecological surgery.

Method and material

The study was a randomized control trial conducted at Govt Medical Center & attached Bangur Hospital, Pali, Rajasthan,

during the period March 2019 to December 2021. The study population consisted of ASA grade I and II patients aged 18-45 years who were scheduled to undergo short gynecological surgery (20-40 min) under intravenous sedation and analgesia. The study included hysteroscopic copper T removal, dilatation and curettage, hysteroscopic biopsy, and Bartholin cyst excision in the short gynecological surgery. The study excluded patients with hypertension, cardiopulmonary diseases, hepatic disease, or who were allergic to any drug from the study. Assuming a 30 min difference in sedative effect between the two groups based on the pilot study with $\alpha = 0.05$ and an 80% power, the minimum number of cases required under each group was 40, making it a total of 120 patients in three group.

The different doses of dexmedetomidine infusion were prepared by medical personnel not involved in the study. We prepared infusion drugs in a 50-ml syringe, and concentration varied in other groups. In groups A, B, and C, 100 µg, 200 µg, and 300 µg of dexmedetomidine were added in a 50-ml syringe, respectively. Moreover, Heart rate, systolic blood pressure, diastolic blood pressure, mean blood pressure, peripheral oxygen saturation, and respiratory rate were monitored at the baseline, every 5 min thereafter until surgery was completed, and every 15 min for the first hour followed by every 30 min until the patient was discharged.

Statistical analysis

The data was compiled, tabulated, and statistically analyzed using Statistical Product and Service Solutions (SPSS) version 17 (IBM Corp., Armonk, NY). Analysis of variance was used for the analysis of mean difference among groups and Chi-square test for grading of sedation, recovery, and discharge. Results were presented as mean ± SD. Probability values less than 0.05 were considered significant.

Results

Table 1: Age and weight

	Group A (N=40)	Group B (N=40)	Group C (N=40)	P value		
				A vs B	A vs C	B vs C
Age (years)	35.78 ± 7.54	35.50 ± 7.39	35.28 ± 7.14	0.435	0.381	0.445
Weight (kg)	57.78 ± 7.97	57.00 ± 6.51	56.8 ± 6.68	0.318	0.278	0.448

The table has provided the information related to the age and weight and all variables has shown no significant association as p value is higher than 0.05.

Table 2: Sedation score

Parameters	Group A		Group B		Group C	
	Frequency	%	Frequency	%	Frequency	%
Sedation score						
3	17	42.5	18	45	13	32.50
4	23	57.5	22	55	27	67.50
Ketamine supplementation	18	45	9	22.5	0	0

According to analysis of table 2 all patients had a Ramsay Sedation Score of 3 or more. In half of the patients in group A and in one-fourth of the patients in group B, ketamine was required as a rescue drug. None of the patients in group C required any drug supplementation

Table 3: Time

	Group A	Group B	Group C	P value		
				A vs B	A vs C	B vs C
Time to achieve Modified Aldrete Score	21.14 ± 9.99	39.68 ± 18.39	45.38 ± 29.90	0.000*	0.000*	0.177
Time to achieve PADSS Score	148.64 ± 23.56	177.10 ± 16.16	200.25 ± 18.47	0.000*	0.000*	0.000*

As per the table 3 in group A, the time taken to achieve the Modified Aldrete Score (≥8) was 21.14 ± 9.99 min and was almost doubled in groups B (39.68 ± 18.39 min) and C (45.38 ± 29.90 min). This difference was statistically significant in the A versus B group and the A versus C group ($p = 0.000$). However, it was comparable between groups B and C ($p > 0.05$). Patients in group A achieved PADSS score (≥9) earlier (148.64 ± 23.56 min) than in group B (177.10 ± 16.16 min) and group C (200.25 ± 18.47 min). This time, the difference in the achievement of the PADSS score was statistically significant among all three groups ($p < 0.001$).

Discussion

Procedural sedation and analgesia (PSA) is still preferred over general anaesthesia during short gynaecological procedures. Dexmedetomidine, a known sedative and analgesic sparing drug that acts on α2 adrenoceptor, reduces heart rate, blood pressure, and anaesthetic drug requirements in response to any stress. Unlike other anaesthetics, it also has a sedative response, mimicking natural sleep without significant respiratory depression. Dexmedetomidine is extensively used as a sedative and analgesic agent in various surgeries, but the optimum dose of dexmedetomidine in these procedures is still unknown. The use of general anesthesia or central neuraxial blocks during short gynecological procedures is inappropriate. These techniques not only delay the discharge but also increase morbidity. PSA, which combines the use of local anesthesia with intravenous sedation, can be the technique of choice during such short procedures.

As per the outcome of the study, all patients had a Ramsay Sedation Score of 3 or more. In half of the patients in group A and in one-fourth of the patients in group B, ketamine was required as a rescue drug. None of the patients in group C required any drug supplementation. Moreover, Modified Aldrete Score (≥8) was 21.14 ± 9.99 min and was almost doubled in groups B (39.68 ± 18.39 min) and C (45.38 ± 29.90 min). This difference was statistically significant in the A versus B group and the A versus C group ($p = 0.000$). However, it was comparable between groups B and C ($p > 0.05$). Patients in group A achieved PADSS score (≥9) earlier (148.64 ± 23.56 min) than in group B (177.10 ± 16.16 min) and group C (200.25 ± 18.47 min). This time, the difference in the achievement of the PADSS score was statistically significant among all three groups ($p < 0.001$). As per the study of Sharma et al., (2022) [13] the time taken to achieve a Modified Aldrete Score ≥8 and a Postanesthetic Discharge Scoring system (PADSS) >9 dose-dependently increased and reached its maximum with higher doses of dexmedetomidine infusion. A similar recovery time was observed in other studies [14]. However, recovery time similar to group C was observed with a dose of 0.2 µg/kg/hr in a study. This may be due to the fact that their recovery criteria were different, and the procedure was less painful [15,16].

Conclusion

This study was a prospective, randomized, double-blinded control trial conducted in patients undergoing minor gynecological surgeries to determine the optimum dose of dexmedetomidine infusion for procedural sedation in such surgeries. Moreover, Dexmedetomidine at a dose of 0.6 µg/kg/hr provides efficient sedation and analgesia but is associated with significant hemodynamic compromise, whereas dexmedetomidine at a dose of 0.4 µg/kg/hr requires ketamine supplementation at 0.3 mg/kg to achieve adequate analgesia and sedation without hemodynamic complications.

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