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A study to observe the effectiveness of administration of intrathecal midazolam as an adjunctive to spinal anesthesia

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Abstract

Aim: The present study was undertaken to observe the efficacy of midazolam as an adjunctive to spinal anesthesia.

Materials and Methods: The study recruited 40 patients with ASA grade 1 and 2, within the age group of 30-60 years. Patients of either sex were recruited in the study. After recruiting the participants, they were randomly divided into two groups. Group 1: (n=15): Control group – received 2.5 ml of 0.5% heavy bupivacaine plus 0.4 ml of 0.9% saline. Group 2: (n=15): Intervention group: received 2.5 ml of 0.5% heavy bupivacaine plus 0.4 ml (2 mg) of preservative free midazolam. All participants underwent thorough physical examination. Demographic data was recorded from the patients. To assess the efficacy, patients stress levels and pain scores were recorded using standard methods in the literature.

Results: Table no 1 presents demographic data of the patients. Majority of the patients belongs to age group of 30-40 years. Table no 2 presents gender-based distribution of participants. Majority of participants were females. Table no 3 presents the STAI and VAS scores. There is a significant less anxiety scores in the group 2 when compared with group 1. VAS scores are significantly less in group 2 when compared with group 1.

Conclusion: The study results support that midazolam is an effective adjunctive with spinal anesthesia. There is a need for further multi center and detailed studies in this area to support adoption of midazolam as an adjunctive with spinal anesthesia.

Keywords: Spinal anesthesia, midazolam, adjunctive

Introduction

Management of pain is much needed area of research till date. Research is going on different drugs and its pain-relieving activity. NSAIDS are most used agents in the management of pain [1]. However, it is associated with certain side effects. Research on adjunctive to spinal anesthesia is topic of interest in recent years [2, 3]. Many clinical research studies are under trials on various drugs to be proposed as adjunctive to spinal anesthesia. One such drug is midazolam [4]. It was reported that midazolam is a less powerful analgesic agent that can be used as an adjunct with spinal anesthesia [5]. Both animal and human research studies support the pain management activity of midazolam. Studies are existing in this topic [6]. Hence, the present study was undertaken to observe the effectiveness of counselling in the recovery of patients after the surgical procedure. AS the studies on midazolam are limited, the present study was undertaken to observe efficacy of midazolam as an adjunctive with spinal anesthesia.

Materials and Methods

Study design: Observational study

Sampling method: Convenient sampling

Study population: The study recruited 40 patients with ASA grade 1 and 2, within the age group of 30-60 years. Patients of either sex were recruited in the study. Informed consent was obtained from all the participants and confidentiality of data was maintained. Patients with severe complications were excluded from the study. Unwilling participants were excluded from the study. After recruiting the participants, they were randomly divided into two groups.

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Group 1: (n=20): Control group – received 2.5 ml of 0.5% heavy bupivacaine plus 0.4 ml of 0.9% saline

Group 2: (n=20): Intervention group: received 2.5 ml of 0.5% heavy bupivacaine plus 0.4 ml (2 mg) of preservative free midazolam.

Data collection: All participants underwent thorough physical examination. Demographic data was recorded from the patients. To assess the efficacy, patients stress levels and pain scores were recorded using standard methods in the literature [4].

Ethical considerations: The study proposal was approved by the institutional ethics committee after satisfying the queries adequately. The study followed all the guidelines as per the ICMR guidelines. Written informed consent was obtained from all the parents of the participants before the commencement of the study. Information related to the patients was kept confidential.

Data analysis: The statistical software SPSS 18.0 version was used to analyze the data. Data was expressed as frequency and percentage. Student t test was applied to test significance of the results. Probability value less than 0.05 was considered significant.

Results: Table no 1 presents demographic data of the patients. Majority of the patients belongs to age group of 30-40 years. Table no 2 presents gender-based distribution of participants. Majority of participants were females. Table no 3 presents the STAI and VAS scores. There is a significant less anxiety scores in the group 2 when compared with group 1. VAS scores are significantly less in group 2 when compared with group 1.

Table 1: Demographic data of participants with respect to age (n=40)

Age (years)	Frequency	Percentage
30-40	20	50
41-50	10	25
51-60	10	25

Data was presented as frequency and percentage

Table 2: Demographic data of participants with respect to gender (n=40)

Gender	Frequency	Percentage
Male	15	37.5
Female	25	62.5

Data was presented as frequency and percentage

Table 3: STAI and VAS score in intervention and control groups (n=40)

	Group 2	Group 1	P value
STAI	40±4.33	52±7.66	0.0001***
VAS	4±0.24	7±0.46	0.0001***

Data was presented as mean and SD (**P<0.001 is significant)

Discussion

As the studies on midazolam are limited, the present study was undertaken to observe efficacy of midazolam as an adjunctive with spinal anesthesia. Table no 1 presents demographic data of the patients. Majority of the patients belongs to age group of 30-40 years. Table no 2 presents gender-based distribution of participants. Majority of

participants were females. Table no 3 presents the STAI and VAS scores. There is a significant less anxiety scores in the group 2 when compared with group 1. VAS scores are significantly less in group 2 when compared with group 1. Earlier studies reported that there is significant anti nociceptive effect was observed followed by administration of midazolam [7]. This was supported by both animal and human studies [8]. It was reported that the use of further analgesics was minimized after administration of midazolam [9]. Few studies reported that there is a chance for neurotoxicity after administration of midazolam. But this was further investigated and reported that only high doses will cause the damage of neurons. Interestingly, low dosage of midazolam has effective results in the management of pain [8, 9]. Hence, in the present study 2 mg of midazolam was administered as an adjunctive and results support the views expressed in earlier studies. AS a single center study, results may not be generalized. But there is a need for multi centre and involving large number of participants to support adoption of midazolam in clinical setting.

Conclusion

The study results support that midazolam is an effective adjunctive with spinal anesthesia. There is a need for further multi center and detailed studies in this area to support adoption of midazolam as an adjunctive with spinal anesthesia.

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Conflicts of interest: None declared

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