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An observational study to compare the pain relief scores of epidural midazolam and buprenorphine for post-operative patients

Shankarappa RV[1], Bharat Kiran[2], Padmanabha BV[3], Sai Sailesh Kumar Goothy[4], Mukkadan JK[5]

[1,2]Assistant Professor, Department of Anaesthesiology, Sambhram Institute of Medical Sciences and Research, Kolar, Karnataka, India, [3]Assistant Professor, Department of Physiology, Northern Border University, Arar, Kingdom of Saudi Arabia, [4]Professor, Department of Physiology, NRI Institute of Medical Sciences, Visakhapatnam, Andhra Pradesh, [5]Research Director, Little Flower Medical Research Centre, Angamaly, Kerala, India

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ABSTRACT

Background: As it was mentioned, the risk of adverse effects and complications is more than what is expected. Hence, the use of epidural analgesia (EA) was decreased in the management of post-operative pain. Hence, there is a need for another pharmacological agent that is more effective. Manly studies reported that buprenorphine transdermal and sublingual both have significant pain relief scores. **Aims and Objectives:** The present study was undertaken to compare the pain relief scores of epidural midazolam and buprenorphine for post-operative patients. **Materials and Methods:** A total of 60 male and female participants, within the age group with the American Society of Anesthesiologists grades I and II were recruited. After recruiting, they were randomly divided into two groups. Soon after the surgery, the pain scores were recorded using the Visual Analog Scale. Soon after recording the pain scores, the corresponding drugs were administered to the participants. Epidural midazolam 30 g/kg and buprenorphine 0.15 mg diluted in normal saline were administered to the corresponding groups for 24 h. **Results:** There is no significant difference in the demographic data of the participants in both groups. There was no significant difference observed between the two groups. Both are equally effective. Nausea and vomiting are the mild side effects observed in the majority of the patients in both groups. **Conclusion:** In the present study, we have observed similar actions by both drugs in the management of post-operative pain. The study not only adds to the literature about the effectiveness of these drugs but also explains the mild side effects. Hence, the study recommends the use of both these drugs in the management of post-operative pain so that patient satisfaction can be improved and the patient stay at the hospital can be minimized. Further, detailed and multi-center studies are recommended to generalize the results.

Key words: Acute pain; Post-operative pain; Analgesia; Opioids

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INTRODUCTION

The management of pain has been the most important topic of discussion for the past many years. It was mentioned that approximately 75% of the patients who underwent surgery experienced acute pain.[1] Hence, it has to be managed properly. If not, it can convert into chronic pain which is difficult to manage and affects the quality of life of the individual. As the pain is an unpleasant sensation and may cause damage to the tissues, it must be treated immediately and effectively. Post-operative pain management is very important to reduce the consequences of post-surgery pain. It helps the patient to recover fast and start a routine lifestyle at the earliest. Hence, it reduces the hospital stay of the patients and also increases patient satisfaction as well. In recent times, it was mentioned that

Address for Correspondence:
Dr. Shankarappa RV, Assistant Professor, Department of Anesthesiology, Sambhram Institute of Medical Sciences and Research, Kolar, Karnataka, India. **Mobile:** +91-9448005851. **E-mail:** shankarapparv@gmail.com

the uses of epidural analgesia (EA) are not very effective. As it was mentioned, the risk of adverse effects and complications is more than what is expected. Hence, the use of EA was decreased in the management of post-operative pain.[2] Hence, there is a need for another pharmacological agent that is more effective. Buprenorphine is a synthetic analgesic agent that can effectively treat pain and opioid use disorder. Many studies reported that buprenorphine transdermal and sublingual both have significant pain relief scores.[3-5] Although previous studies exist in this area, the studies in the Kolar area are sparse. As the results from other areas cannot be directly implemented here, the study was undertaken to observe the pain relief scores of epidural midazolam and buprenorphine for post-operative patients.

Aims and objectives

The present study was undertaken to compare the pain relief scores of epidural midazolam and buprenorphine for post-operative patients.

MATERIALS AND METHODS

The present observational comparative study was conducted at Sambram Hospital and Research Centre. The study protocol was approved by the Institutional Human Ethical Committee (LFMRC/No/EC-49 dated August 03, 2020). The sample size was calculated as 30 per group with a significance level of 0.05, and a power of 80%.[6] The calculation was performed based on the previous studies in this area. A total of 60 male and female participants, within the age group of 20–60 years old, with the American Society of Anesthesiologists grades I and II were recruited from the Department of Surgery after obtaining written informed consent. Participants with serious complications were excluded from the study. All investigations required were conducted under the supervision of senior doctors. After recruiting, they were randomly divided into two groups. All the study procedures including the epidural catheter and Visual Analog Scale were detailed to the participants before obtaining informed consent. All the procedures were performed following the standard protocols. Soon after the surgery, the pain scores were recorded using the Visual Analog Scale. Soon after recording the pain scores, the corresponding drugs were administered to the participants. Epidural midazolam 30 g/kg was administered to group 1 and buprenorphine 0.15 mg diluted in normal saline was administered to the group II participants for 24 h. All vitals were monitored continuously. Participants were advised to report side effects if any were experienced.

Statistical analysis

Data were analyzed using Statistical Package for the Social Sciences 20.0 version software. Student's t-test was used to observe the significance of the difference between the groups. Qualitative data were expressed in frequency and percentage. A probability value <0.05 was considered significant.

RESULTS

Table 1 presents the demographic data of the participants. There is no significant difference in the demographic data of the participants. Table 2 presents the distribution of the duration of analgesia in Group I patients. Table 3 presents the distribution of the duration of analgesia in Group II patients. Table 4 presents the pain scores of participants in the post-operative period. There was no significant difference observed between the two groups. Both are equally effective. Table 5 presents the incidence of side effects in Group I patients. Table 6 presents the incidence

Table 1: Demographic data of the participants

Parameter	Group I (n=30)	Group II (n=30)	P-value
Age (years)	48±1.28	48±1.83	0.3732
Height (cm)	149.86±1.6	154±1.67	0.0801
Weight (kg)	58±1.83	62±2.19	0.1661

Data were expressed in mean and SEM.

Table 2: Distribution of duration of analgesia in Group I patients

Hours	Number of patients (n=30)	Percentage
5–8	4	13.33
9–12	4	13.33
13–16	7	23.33
17–20	6	20
21–24	9	30

Data were expressed in frequency and percentage

Table 3: Distribution of duration of analgesia in Group II patients

Hours	Number of patients (n=30)	Percentage
5–8	8	26.66
9–12	8	26.66
13–16	4	13.33
17–20	2	6.66
21–24	8	26.66

Data were expressed in frequency and percentage

Table 4: Pain scores of participants in the post-operative period

Time (minutes)	Group I	Group II	P-value
0	6±0.37	7±0.55	0.1342
15	4±0.18	4±0.44	1
30	2±0.44	2±0.10	1
60	0	0	

Data were expressed as mean and SEM

Table 5: Incidence of side effects in Group I patients

Side effects	Number of patients (n=30)	Percentage
Nausea	15	50
Vomiting	9	30
Pruritis	0	0
Respiratory depression	1	3.33
Retention of urine	1	3.33
Sedation	4	13.33

Data were expressed in frequency and percentage

Table 6: Incidence of side effects in Group II patients

Side effects	Number of patients (n=30)	Percentage
Nausea	12	40
Vomiting	10	33.33
Pruritis	0	0
Respiratory depression	3	10
Retention of urine	1	3.33
Sedation	4	13.33

Data were expressed in frequency and percentage

of side effects in Group II patients. Nausea and vomiting are the mild side effects observed in the majority of the patients in both groups.

DISCUSSION

Pain is an unpleasant sensation caused by a harmful stimulus. It is of two types that are acute and chronic pain. Globally about 20–40% of patients suffer from post-operative pain which is acute. Although many treatment strategies are available, still management of pain is a herculean task at the bedside. Post-operative pain is a major topic of interest in the clinical scenario as it not only causes a decline in the quality of life but is also related to mortality and morbidity.[6] Hence, it is very much needed to manage the pain immediately after the surgery. Epidural analgesics are well recommended for the management of post-operative pain.[7-9] Midazolam was reported to mediate the analgesic effect spinally. It was reported that administration of single-shot of midazolam provides an efficient analgesic effect.[10] The epidural post-operative pain management was initially applied in the year 1949. Many studies reported that there was a significant decrease in anxiety and pain in the patients soon after surgery.[11]

The opioids usually bind with the receptors located in both the central nervous system and peripheral nervous system. However, the outcome depends on the type of the receptor it binds with. There are three types of receptors for opioids in both the central and peripheral nervous system that are μ, δ, and κ.[11,12] It was mentioned by the earlier studies that the epidural administration of opioids produces better results than when administered intravenously. Buprenorphine is an agonist to the μ-receptor and δ-receptor. However, it is an antagonist to the κ-receptor. It is a more potent drug and about more than 25% of potency than morphine. Further, the most important thing is it has fewer side effects. Sedation and dizziness are possible side effects of this drug.[13-15] Single shot of the midazolam has been reported to have a significant analgesia effect.[16,17]

The present study was undertaken to compare the pain relief scores of epidural midazolam and buprenorphine for post-operative patients. In the present study, there is no significant difference in the demographic data of the participants in both groups. In the present study, we have observed similar actions by both drugs in the management of post-operative pain. Further, nausea and vomiting are the most commonly observed side effects in the majority of the patients. Both these drugs can be preferred in the management of post-operative pain so that patient satisfaction can be improved and the patient stay at the hospital can be minimized.[3,4,17-20] The present study results are in accordance with the earlier studies.

Limitations of the study

The sample size of the study was small. Hence, results cannot be generalized.

CONCLUSION

In the present study, we have observed similar actions by both drugs in the management of post-operative pain. The study not only adds to the literature about the effectiveness of these drugs but also explains the mild side effects. Hence, the study recommends the use of both these drugs in the management of post-operative pain so that patient satisfaction can be improved and the patient stay at the hospital can be minimized. Further, detailed and multi-center studies are recommended to generalize the results.

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SRV- Design of the study, review of literature, analysis, and preparing the manuscript; **BK**- Data collection and preparing the manuscript, **SSKG, PBV, and MJK**- Design of the study, analysis, preparing the manuscript, and proofreading.

Work attributed to:
Sambhram Institute of Medical Sciences and Research, Kolar & Little Flower Medical Research Centre, Kerala.

Orcid ID:
Dr. Shankarappa RV - https://orcid.org/0009-0006-1346-8405
Dr. Bharat Kiran - https://orcid.org/0009-0006-8678-8055
Dr. Padmanabha BV - https://orcid.org/0009-0001-9905-1101
Dr. Sai Sailesh Kumar Goothy - https://orcid.org/0000-0002-2578-6420

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