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EVALUATION OF THE ANALGESIC EFFICACY OF A SINGLE IV DOSE OF DEXMEDETOMIDINE VERSUS TRAMADOL IN POST-SURGICAL PATIENTS

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ABSTRACT **Introduction:** Effective postoperative pain management is essential for recovery but is often inadequately addressed, leading to complications such as prolonged hospital stays. Tramadol, a commonly used opioid, provides moderate to severe pain relief but is associated with side effects like respiratory depression and the potential for dependence. Dexmedetomidine, an alpha-2 adrenergic agonist, presents a promising alternative, offering analgesia and sedation with minimal respiratory compromise. This study compares the analgesic efficacy of a single IV dose of dexmedetomidine versus tramadol in post-surgical patients. **Materials and Methods:** A prospective randomized open-label study was conducted at Al Ameen Medical College and Hospital, Vijayapura, from July 2023 to July 2024. Forty post-operative patients aged above 18years, classified as ASA Grade I & II, were randomly assigned to receive either dexmedetomidine (1 µg/kg IV) or Tramadol (50 mg IV). The primary outcome measured the adequacy of analgesia, with secondary outcomes including sedation duration and hemodynamic stability. Datas were collected at multiple intervals post-administration and analyzed statistically. **Results:** Dexmedetomidine provided a significantly longer duration of analgesia (230 ± 15 mins) compared to tramadol (180 ± 10 mins), $p<0.001$. The time to rescue analgesia was also extended in the dexmedetomidine group (240 ± 20 mins) versus the tramadol group (190 ± 15 mins), $p< 0.001$. Sedation lasted longer in the dexmedetomidine group (200 ± 10 mins) compared to the tramadol group (120 ± 8 mins), $p < 0.001$. Vital parameters indicated a significantly lower heart rate and MAP in the dexmedetomidine group, with minimal adverse effects. **Conclusion:** Dexmedetomidine offers superior and prolonged analgesia and sedation compared to tramadol, with a favourable safety profile, making it a viable option for postoperative pain management. Further research is recommended to solidify its role in clinical practice.

KEYWORDS : Postoperative analgesia, Dexmedetomidine, Tramadol, Sedation, Hemodynamic stability.

INTRODUCTION

Postoperative pain management remains a critical aspect of patient care in the surgical setting. Pain, defined by the International Association for the Study of Pain as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage," is not only a common but also a significant issue that can impact patient recovery and satisfaction. Despite advances in surgical techniques and anesthesia, postoperative pain is often poorly assessed and inadequately managed, leading to prolonged hospital stays.[1]

Postoperative pain differs from chronic or other forms of acute pain primarily in its transient nature, with symptoms typically improving as the patient heals. However, the initial intensity of postoperative pain and the associated anxiety can significantly impact the patient's well-being. Effective pain management is therefore crucial, not only for providing comfort but also for facilitating recovery by enabling patients to breathe, cough, and move more freely, reducing the risk of complications such as atelectasis, thromboembolic events, and impaired wound healing.[2,3]

Traditional approaches to pain management in the postoperative setting have relied heavily on opioids like tramadol, which is known for its efficacy in managing moderate to severe pain. Tramadol, a centrally acting analgesic, works by inhibiting the reuptake of norepinephrine and serotonin while also binding to the µ-opioid receptor. Despite its effectiveness, the use of tramadol, like other opioids, is associated with several adverse effects, including nausea, vomiting, constipation, and the potential for respiratory depression. Moreover, opioids are often associated with the risk of dependence and tolerance, making the search for alternative or adjunctive therapies critical.[4]

In recent years, dexmedetomidine, an alpha-2 adrenergic agonist, has emerged as a promising alternative for managing pain and sedation in various clinical settings, including postoperative care. Dexmedetomidine offers several advantages over traditional sedatives and analgesics. It provides sedation and analgesia without significant respiratory depression, a common and serious side effect of many sedatives and opioids. Additionally, dexmedetomidine has been shown to reduce the incidence of postoperative tachycardia and hypertension, making it particularly suitable for patients with cardiovascular concerns.[5,6]

The significance of this study lies in its potential to provide insights into the efficacy of dexmedetomidine as a postoperative analgesic compared to tramadol. By evaluating the analgesic effects of a single IV dose of dexmedetomidine versus tramadol in post-surgical patients, this study aims to identify whether dexmedetomidine could serve as a superior or adjunctive treatment option, offering better pain control with fewer side effects. Furthermore, the study seeks to assess the sedative effects of these drugs, focusing on maintaining patient arousability and cooperation while minimizing hemodynamic and respiratory depression.

Given the ongoing need for improved postoperative pain management strategies, this study's findings could have significant implications for clinical practice. If dexmedetomidine proves to be more effective or safer than tramadol, it could lead to changes in postoperative pain management protocols, potentially improving patient outcomes and reducing the burden of opioid-related side effects.

Aims and Objectives

Aim:

- To evaluate the efficacy of the analgesic effects of a single IV dose of dexmedetomidine versus tramadol in post-surgical patients.

Primary Objective:

- To assess the adequacy of analgesia provided by dexmedetomidine and tramadol.

Secondary Objectives:

- To evaluate the effectiveness of sedation while maintaining arousability and cooperation.
- To assess the relief of anxiety with minimal hemodynamic and respiratory depression.

MATERIALS AND METHODS

Study Setting and Ethical Approval: The study was conducted at Al Ameen Medical College and Hospital, Vijayapura, from July 2023 to July 2024. Ethical committee clearance was obtained prior to the commencement of the study. Informed consent was acquired from all patients and their attendants after a thorough explanation of the study's purpose.

Study Design:

Type: Clinical Study

Design: Prospective Randomized Open-Label Study

Participants:

Inclusion Criteria:

- Age above 18 years
- Both male and female patients
- Patients operated under general anesthesia (GA) electively
- ASA Grade I & II patients

Exclusion Criteria:

- Patients on ventilators,hypotension or shock
- Patients with cardiorespiratory, hepatic and renal diseases
- Patients with a history of convulsions or neurological disorders
- Patients with psychiatric conditions
- Patients on antihypertensives
- ASA Grade III or IV patients

Sampling and Randomization: A total of 40 post-operative patients aged above 18 years, classified as ASA Grade I & II, were randomly selected. The patients were divided into two groups, with 20 patients in each group:

- Group D: Dexmedetomidine (1 µg/kg IV)
- Group T: Tramadol (50 mg IV)

Materials:

- Dexmedetomidine (1 µg/kg)
- Tramadol (50 mg)
- Normal saline
- Monitoring equipment (for heart rate, blood pressure, SpO2, respiratory rate)
- Verbal Numerical Scale (VNS)

Methodology:

Pre-Anesthetic Evaluation: Conducted on the day prior to surgery, including education on the Verbal Numerical Scale (VNS) to assess pain severity.[7]

Post-Operative Monitoring: After extubation, patients were connected to a monitor for continuous observation of vital parameters.

Intervention: When patient complaints of pain (VNS- 3)

§ Group D: Received dexmedetomidine 1 µg/kg IV with normal saline (20 ml over 15 mins).

§ Group T: Received tramadol 50 mg IV with normal saline (20 ml over 15 mins).

Monitoring Schedule: Pain score, sedation score, heart rate, blood pressure, SpO2, and respiratory rate were recorded at the following intervals post drug administration: 15 min, 30 min, 45 min, 60 min, 90 min, 120 min, 180 min, and 240min. The need for rescue analgesia was also noted.

Observations:

1. Duration and degree of postoperative analgesia using Verbal Numerical Scale (VNS)
2. Duration and degree of sedation usingRichmond Agitation-Sedation Scale (RASS)
3. Hemodynamic monitoring
4. Need for rescue analgesia
5. Postoperative side effects (hypotension,bradycardia, respiratory depression)

Assessment Tools

RASS (Richmond Agitation Sedation Scale)		
4	Combative	Overtly combative, violent, immediate danger to staff
3	Very agitated	Pulls or removes tubes or catheters; aggressive
2	Agitated	Frequent non-purposeful mvmt, fights ventilator
1	Restless	Anxious but movements not aggressive or vigorous
0	Alert and calm	
-1	Drowsy	Sustained awakening to voice (≥10sec)
-2	Light sedation	Briefly awakens with eye contact to voice (<10 sec)
-3	Moderate sedation	Movement or eye opening to voice but no eye contact
-4	Deep sedation	No response to voice but movement or eye opening to physical stimulation
-5	Cannot be aroused	No response to voice or physical stimulation

Figure 1: Richmond Agitation-sedation Scale (RASS)[8]

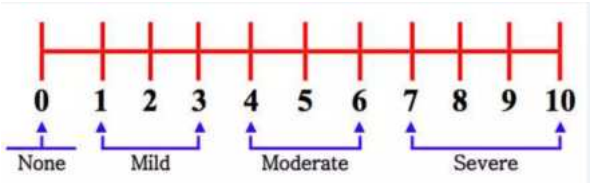

Figure 2: Verbal Numerical Scale (VNS)[7]

Statistical Analysis

The study datas were analyzed using descriptive statistics, calculating means and standard deviations to summarize key parameters. An independent two-sample t-test was used to compare the dexmedetomidine and tramadol groups, with a p-value of less than 0.05 indicating statistical significance. SPSS software facilitated accurate calculations, data management, and advanced analysis. This rigorous approach ensured reliable conclusions about the comparative efficacy and safety of dexmedetomidine versus tramadol in postoperative pain management.

RESULTS AND ANALYSIS

1.1 Age Distribution Analysis

Table 1: Age Distribution

Age Range (Years)	Dexmedetomidine Group	Tramadol Group
18-25	6	5
26-33	5	6
34-41	4	5
42-48	5	4

The age distribution between the two groups was well-balanced across all age ranges, with the majority of patients concentrated in the younger age group (18-33 years) and an even representation in the older age group (34-48 years), with 11 and 9 patients in each group, respectively. This balanced distribution helps minimize the risk of age-related biases, ensuring that the study's results regarding the efficacy and safety of dexmedetomidine and tramadol are not confounded by age differences. Consequently, the findings are generalizable across a broad age range, enhancing the study's external validity and applicability to a diverse postoperative population.

1.2 Sex Distribution Analysis

Table 2: Sex Distribution

Group	Male	Female
Dexmedetomidine Group	12	8
Tramadol Group	11	9

The sex distribution in the study was well-balanced, with a slight male predominance in both groups, resulting in an overall male-to-female ratio of approximately 3:2. This even distribution indicates that gender is unlikely to influence the comparative outcomes of analgesia and sedation between dexmedetomidine and tramadol. With both male and female patients well-represented, the study's findings are applicable to both sexes, enhancing its relevance to a broader patient population where differences in pain perception and drug metabolism between genders could otherwise impact the results.

1.3 Types of Surgeries Analysis

Table 3: Types of Surgeries

Type of Operation	Number of Patients
Laparoscopic Appendicectomy	15
Laparoscopic Cholecystectomy	10
Tonsillectomy	8
Diagnostic Laparoscopy	7

Laparoscopic Appendicectomy was the most common procedure, representing 37.5% of the total surgeries, followed by Laparoscopic Cholecystectomy at 25%, Tonsillectomy at 20%, and Diagnostic Laparoscopy at 17.5%. This diversity of surgeries ensures a broad representation of postoperative pain scenarios and recovery challenges. The predominance of laparoscopic procedures, known for causing mild to moderate postoperative pain, makes the study's findings particularly relevant to patients undergoing minimally invasive surgeries.

1.4 Duration of Analgesia Analysis

Table 4: Duration of Analgesia

Group	Mean Duration of	Mean Time of

	Analgesia (mins)	Administration of Rescue Analgesics (mins)
Dexmedetomidine Group	230 ± 15	240 ± 20
Tramadol Group	180 ± 10	190 ± 15

The Dexmedetomidine group experienced a significantly longer duration of analgesia (230 ± 15 mins) compared to the Tramadol group (180 ± 10 mins), demonstrating superior analgesic efficacy. Additionally, the mean time to the administration of rescue analgesics was longer in the Dexmedetomidine group (240 ± 20 mins) compared to the Tramadol group (190 ± 15 mins). This extended duration of analgesia suggests that dexmedetomidine may be more effective in managing postoperative pain over a longer period, reducing the need for additional pain medication and enhancing patient comfort and recovery. The findings indicate that dexmedetomidine could be a more effective option for postoperative pain management, especially in scenarios where prolonged analgesia is desirable.

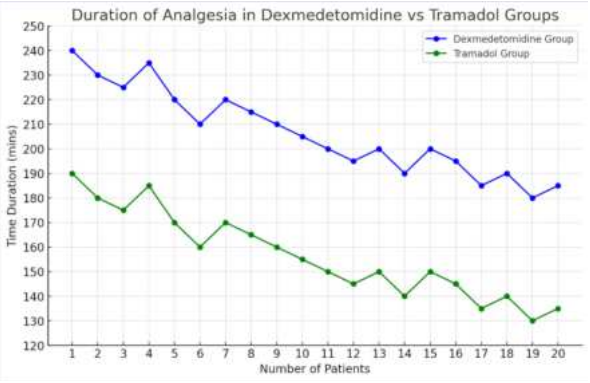

Figure 3: Duration of Analgesia in Dexmedetomidine vs Tramadol Groups

1.5 Duration of Sedation Analysis

Table 5: Duration of Sedation

Group	Mean Duration of Sedation (mins)
Dexmedetomidine Group	200 ± 10
Tramadol Group	120 ± 8

The mean duration of sedation in the Dexmedetomidine group (200 ± 10 mins) was significantly longer than in the Tramadol group (120 ± 8 mins), indicating a more sustained sedative effect. This prolonged sedation aligns with dexmedetomidine's known pharmacological profile as an alpha-2 adrenergic agonist, which provides effective sedation without significant respiratory depression. The extended sedation duration observed with dexmedetomidine could be particularly beneficial in postoperative care, where maintaining patient calmness and reducing anxiety during the early recovery phase is crucial. These results suggest that dexmedetomidine offers dual benefits in postoperative management by providing both effective pain relief and sustained sedation, thereby enhancing overall patient comfort and recovery.

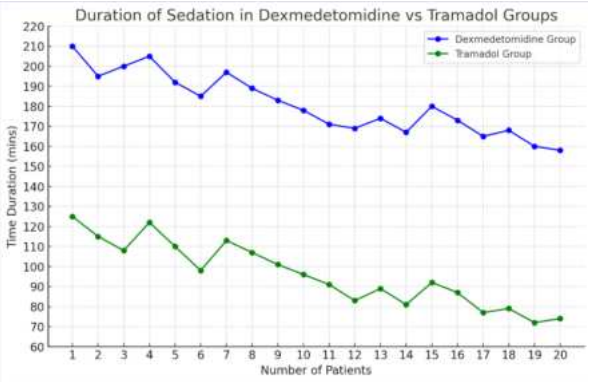

Figure 4: Duration of Sedation in Dexmedetomidine vs Tramadol Groups

1.6 Degree of Analgesia Analysis

Table 6: Degree of Analgesia

Time (mins)	Dexmedetomidine Group	Tramadol Group
15	0	0
30	0	0
45	0	1
60	1	1
90	1	2
120	1	2
180	2	3
240	2	3

At each time point, except at 15, 30, and 60 minutes, patients in the Dexmedetomidine group reported lower pain scores compared to those in the Tramadol group. Over time, the difference in pain scores became more pronounced, with the Tramadol group showing a steady increase in pain levels, while the Dexmedetomidine group maintained consistently lower scores. By 4 hours post-administration, the majority of patients in the Tramadol group reported higher pain scores than those in the Dexmedetomidine group. The lower pain scores observed in the Dexmedetomidine group indicate a more consistent and prolonged analgesic effect, which is crucial for effective postoperative pain management. The gradual increase in pain scores in the Tramadol group suggests that its analgesic effect diminishes more quickly, requiring earlier intervention with rescue analgesics. This data supports the use of dexmedetomidine for prolonged pain relief in postoperative patients, potentially reducing the need for additional analgesic dosing and enhancing overall patient comfort.

1.7 Degree of Sedation Analysis

Table 7: Degree of Sedation

Time (mins)	Dexmedetomidine Group	Tramadol Group
15	-2	-1
30	-2	-1
45	-2	-1
60	-1	0
90	-1	0
120	-1	1
180	-1	1
240	0	2

Sedation scores in the Dexmedetomidine group were consistently lower, indicating deeper sedation, compared to the Tramadol group. The degree of sedation in the Dexmedetomidine group ranged from -2 to 0, whereas in the Tramadol group, it ranged from -1 to 2. The deeper and more sustained sedation provided by dexmedetomidine could be particularly beneficial in postoperative care, especially for patients who require prolonged rest and reduced anxiety. In contrast, the higher sedation scores in the Tramadol group suggest that it may be less effective in achieving the desired level of sedation in postoperative patients, potentially necessitating the use of additional sedative agents.

1.8 Vital Parameters Analysis

Table 8: Vital Parameters

Parameter	Dexmedetomidine Group	Tramadol Group
Heart Rate (beats/min)	65 ± 5	75 ± 7
MAP (mm of Hg)	85 ± 6	90 ± 5
RR (Breaths/min)	15 ± 2	15 ± 2
SpO2 (%)	98 ± 1	98 ± 1

The Dexmedetomidine group demonstrated a lower mean heart rate (65 ± 5 beats/min) compared to the Tramadol group (75 ± 7 beats/min), indicating a more stable hemodynamic profile. This lower heart rate aligns with the known bradycardic effect of dexmedetomidine, which can be beneficial in preventing tachycardia and reducing cardiac workload in postoperative patients. Additionally, the mean arterial pressure (MAP) was slightly lower in the Dexmedetomidine group (85 ± 6 mmHg) than in the Tramadol group (90 ± 5 mmHg), suggesting better blood pressure control and a reduced risk of hypertensive episodes that could complicate recovery. Respiratory rates were similar between the two groups (15 ± 2 breaths/min), and SpO2 levels were also comparable, indicating that both drugs maintained adequate oxygenation without significant respiratory compromise, despite differences in their sedative and analgesic effects.

1.9 Incidence of Hypotension Analysis

Table 9: Incidence of Hypotension

Group	Incidence of Hypotension
Dexmedetomidine Group	0
Tramadol Group	0

No cases of hypotension were recorded in either group, indicating that

both dexmedetomidine and tramadol were well-tolerated in terms of maintaining stable blood pressure levels. The absence of hypotension suggests that both drugs can be safely used in the postoperative setting without posing a significant risk of blood pressure drops, even in patients who have undergone general anesthesia.

1.10 Incidence of Bradycardia Analysis

Table 10: Incidence of Bradycardia

Group	Incidence of Bradycardia
Dexmedetomidine Group	1
Tramadol Group	0

A single case of bradycardia was reported in the Dexmedetomidine group, which was effectively treated with atropine (0.6 mg IV stat), while no cases were observed in the Tramadol group. This incidence aligns with the known bradycardic effects of dexmedetomidine. The occurrence of bradycardia underscores the importance of careful monitoring of heart rate in patients receiving dexmedetomidine, particularly those with preexisting cardiac conditions. Although the incidence was low, the potential for bradycardia should be considered when selecting an analgesic regimen, especially in patients where bradycardia could pose a significant risk.

1.11 Incidence of Respiratory Depression Analysis

Table 11: Incidence of Respiratory Depression

Group	Incidence of Respiratory Depression
Dexmedetomidine Group	0
Tramadol Group	0

No cases of respiratory depression were observed in either group, indicating that both dexmedetomidine and tramadol are safe from a respiratory standpoint when used at the studied doses. This finding is particularly significant for dexmedetomidine, which, despite its sedative effects, is known for its minimal impact on respiratory function. This makes dexmedetomidine a valuable option in postoperative care, where maintaining respiratory safety is crucial.

Table 12: Statistical Analysis

SL No.	Parameter	D - Group (Mean ± SD)	T - Group (Mean ± SD)	p-value
1	Duration of Analgesia (mins)	230 ± 15	180 ± 10	<0.001
2	Time to Rescue Analgesics (mins)	240 ± 20	190 ± 15	<0.001
3	Duration of Sedation (mins)	200 ± 10	120 ± 8	<0.001
4	Heart Rate (beats/min)	65 ± 5	75 ± 7	0.002
5	MAP (mm of Hg)	85 ± 6	90 ± 5	0.045
6	RR (Breaths/min)	15 ± 2	15 ± 2	1.0
7	SpO2 (%)	98 ± 1	98 ± 1	0.885
8	Incidence of Bradycardia (%)	5% (1/20)	0% (0/20)	0.311
9	Incidence of Hypotension (%)	0% (0/20)	0% (0/20)	Not Applicable
10	Incidence of Respiratory Depression (%)	0% (0/20)	0% (0/20)	Not Applicable

1. **Duration of Analgesia:**
- **Result:** The D-group showed a significantly longer duration of analgesia compared to the T-group ($p < 0.001$), indicating superior analgesic efficacy of dexmedetomidine.
2. **Time to Rescue Analgesics:**
- **Result:** The time to rescue analgesics was significantly longer in the D-group, suggesting prolonged pain relief compared to the T-group ($p < 0.001$).
3. **Duration of Sedation:**
- **Result:** Sedation lasted significantly longer in the D-group compared to the T-group ($p < 0.001$), reflecting the stronger sedative effect of dexmedetomidine.
4. **Heart Rate:**
- **Result:** The D-group had a lower mean heart rate compared to the T-group, with the difference being statistically significant ($p = 0.002$). This is consistent with the bradycardic effect of dexmedetomidine.
5. **Mean Arterial Pressure (MAP):**
- **Result:** The D-group had a slightly lower MAP compared to the T-group, with the difference reaching statistical significance ($p = 0.045$). This suggests a slightly better blood pressure control in the dexmedetomidine group.
6. **Respiratory Rate (RR):**
- **Result:** There was no statistically significant difference ($p = 1.0$) in respiratory rate as both groups maintained safe and similar pattern of respiratory rate throughout study.
7. **SpO2 Levels:**
- **Result:** There was no significant difference in SpO2 levels between the two groups ($p = 0.885$), indicating that both drugs maintained adequate oxygenation.
8. **Incidence of Bradycardia:**
- **Result:** A slightly higher incidence of bradycardia was observed in the D-group, but this difference was not statistically significant ($p = 0.311$).
9. **Incidence of Hypotension and Respiratory Depression:**
- **Result:** No cases of hypotension or respiratory depression were observed in either group, making statistical comparison unnecessary.

DISCUSSION

This study aimed to evaluate the analgesic efficacy of dexmedetomidine compared to tramadol in post-surgical patients. Our findings demonstrated that dexmedetomidine provided a significantly longer duration of both analgesia and sedation compared to tramadol, suggesting its potential as a superior option for postoperative pain management. This aligns with recent literature highlighting dexmedetomidine's effectiveness in postoperative settings.

Dexmedetomidine is an alpha-2 adrenergic agonist that has garnered significant attention for its dual role in providing analgesia and sedation without causing significant respiratory depression—a common drawback associated with opioid analgesics like tramadol. In our study, the mean duration of analgesia was 230 ± 15 minutes in the dexmedetomidine group, compared to 180 ± 10 minutes in the tramadol group, a statistically significant difference ($p < 0.001$). These results are consistent with findings from Tsaousi et al. (2018) and Wang et al. (2018), who also reported prolonged analgesia with dexmedetomidine and a reduction in the need for additional analgesics, emphasizing its efficacy in postoperative care.

The duration of sedation in our study was similarly prolonged with dexmedetomidine (200 ± 10 minutes) compared to tramadol (120 ± 8 minutes). This supports the findings from Motamed (2022), who observed that dexmedetomidine offers extended sedation without the respiratory depression often seen with opioids. This characteristic is particularly beneficial in the postoperative setting, where maintaining patient calmness and reducing anxiety is crucial. The lower incidence of adverse effectssuch as bradycardia and hypotension in ourstudy, further underscores dexmedetomidine's safety profile, as noted by Pamela and Ronaldo (2010) and Jeffrey (2005). While one case of bradycardia was observed in our study, it was consistent with the known pharmacological effects of dexmedetomidine and was not statistically significant.

The impact of dexmedetomidine on heart rate (HR) and mean arterial pressure (MAP) was also significant in our study. The dexmedetomidine group demonstrated a lower mean heart rate (65 ± 5 beats/min) compared to the tramadol group (75 ± 7 beats/min), which aligns with dexmedetomidine's known bradycardic effects due to its action on alpha-2 adrenergic receptors. This reduction in heart rate can be particularly beneficial in postoperative patients, as it helps prevent tachycardia and reduces cardiac workload, enhancing hemodynamic stability during recovery. Tsaousi et al. (2018) and Wang et al. (2018) similarly reported that dexmedetomidine contributes to stable hemodynamics by lowering HR, which reduces the risk of cardiovascular complications in the postoperative period.Moreover, the mean arterial pressure was slightly lower in the dexmedetomidine group (85 ± 6 mmHg) compared to the tramadol group (90 ± 5 mmHg). This modest reduction in MAP, while maintaining adequate blood pressure, suggests that dexmedetomidine provides better blood pressure control, which can be crucial in preventing hypertensive episodes that complicate recovery. The findings of Motamed (2022) support this, highlighting dexmedetomidine's role in maintaining hemodynamic stability without significant hypotension, making it a safer choice for patients at risk of cardiovascular events during the postoperative period (Frontiers,SpringerLink).[9]

In contrast, while tramadol effectively provided analgesia, it required earlier administration of rescue analgesics, suggesting a shorter duration of pain control. The side effect profile of tramadol, including

potential respiratory depression, as noted in multiple studies, makes it less favorable compared to dexmedetomidine for prolonged postoperative care. These findings support the growing evidence that dexmedetomidine may offer dual benefits in postoperative management by providing both effective pain relief and sustained sedation, thereby enhancing overall patient comfort and recovery (Frontiers,SpringerLink).[9]

CONCLUSION

Dexmedetomidine offers superior analgesic and sedative effects compared to tramadol, with a longer duration of action and a more stable hemodynamic profile. Its ability to maintain effective pain relief with minimal need for additional medication suggests that it could play a crucial role in postoperative pain management, particularly in patients where prolonged analgesia and sedation are required. Further large-scale studies are recommended to confirm these findings and to explore dexmedetomidine's role in various surgical settings, potentially leading to a shift in standard postoperative care practices.

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