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Comparison of infusion of dexmedetomedine and magnesium sulfate on the stability of hemodynamic status during emergency orthopedic surgery: a randomized double-blind clinical trial

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Abstract: **Objective:** Preparing patients for emergency surgeries requires accurate consideration of their clinical condition and medical history to avoid potential hemodynamic instability and compromise the immune system. This study aims to compare the effects of dexmedetomidine and magnesium sulfate infusions in maintaining stable hemodynamics during emergency orthopedic surgery.

Methods: The present study was conducted as a randomized and double-blind clinical trial with the participation of 80 patients who were candidates for an emergency orthopedic surgery during 2021. Magnesium sulfate was administered as an intravenous bolus at a loading dose of 50 mg/kg over 10 minutes, followed by a continuous infusion at a rate of 15-20 mg/kg/hour. Dexmedetomidine was administered as an intravenous bolus at a loading dose of 1 mcg/kg over 10 minutes, followed by a continuous infusion at a rate of 0.2-0.7 mcg/kg/hour, depending on patient response. These infusions were initiated 15 minutes before induction of anesthesia and continued until the end of surgery. All drugs (dexmedetomidine and magnesium sulfate) were diluted in a 50-cc syringe and infused. The hemodynamic status (diastolic blood pressure (DBP), systolic blood pressure (SBP) mean arterial pressure (MAP) and heart rate (HR)) of the patients between the two groups was recorded and finally compared with each other.

Results: The hemodynamic status (DBP, SBP, MAP and HR) between the two groups at all (perioperative time) times were without significant statistical differences (P>0.05).

Conclusion: Both dexmedetomidine and magnesium sulfate are effective and safe options for achieving hemodynamic stability during emergency orthopedic surgery.

Keywords: Dexmedetomedine; Hemodynamic Status; Magnesium Sulfate; Orthopedic Surgery; Stability

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1. Introduction

Orthopedic surgeries, particularly those involving joint replacement or spinal procedures, often require deep sedation or general anesthesia due to the need for immobility and the potential significant intraoperative pain. Achieving the delicate balance between adequate anesthesia, patient comfort, and hemodynamic stability can be challenging. Hemodynamic fluctuations, such as hypertension and tachycardia, can lead to increased bleeding, surgical complications, and postoperative discomfort (1-6).

Dexmedetomidine, with its unique pharmacological profile, offers a promising solution. By selectively targeting central alpha-2 adrenergic receptors, it reduces sympathetic outflow, leading to lowered blood pressure and heart rate. Furthermore, dexmedetomidine provides a controlled and tranquil sedation without causing respiratory depression, making it an attractive option for maintaining hemodynamic stability during surgery (7-11).

On the other hand, magnesium sulfate, primarily known for its role as a muscle relaxant and anticonvulsant, has shown potential in modulating cardiovascular function. Magnesium exerts vasodilatory effects by blocking calcium influx into vascular smooth muscle cells, leading to peripheral vasodilation and reduced systemic vascular resistance. Additionally, magnesium's influence on myocardial contractility

and excitability may contribute to improved hemodynamic stability during surgery (12-17).

While both dexmedetomidine and magnesium sulfate have shown promise individually, their direct comparison in the context of orthopedic surgery remains scarce. Thus, this study aims to fill this gap by rigorously evaluating the effects of these agents on hemodynamic stability. We hypothesize that dexmedetomidine and magnesium sulfate, when administered as perioperative infusions, will provide comparable hemodynamic stability during emergency orthopedic surgery (18-21).

Understanding the comparative effects of dexmedetomidine and magnesium sulfate on hemodynamic stability during emergency orthopedic surgery holds significant clinical relevance. The findings of this study have the potential to inform anesthesia and surgical practices, providing evidence-based guidance for selecting the most appropriate pharmacological agent to maintain hemodynamic stability in this patient population.

Additionally, this research contributes to the broader knowledge of perioperative management and may lead to improved patient outcomes, reduced complications, and enhanced postoperative recovery in orthopedic surgery (22-24). Patients aged 45 years and older frequently grapple with an array of underlying health conditions, precipitating instability in their hemodynamic status. Moreover, the urgency surrounding the need for surgery often leads to negligence regarding the disclosure of pertinent medical history by both patients and their companions. This negligence compounds the risk of hemodynamic instability during surgery, necessitating proactive measures for those slated for emergency surgery. Thus, the present study was undertaken to address this critical gap in knowledge by comparing the efficacy of dexmedetomidine and magnesium sulfate infusions in stabilizing hemodynamic status during emergency orthopedic procedures.

2. Methods

2.1. Study design

This randomized and double-blind clinical trial was conducted to compare the effects of the infusion of dexmedetomidine and magnesium sulfate on the stability of hemodynamic status during emergency orthopedic surgery. The study received approval from the Institutional Review Board (IRB), and all participants provided written informed consent.

2.2. Sample size and method

A total of 80 adult patients aged 45-70 years, scheduled for emergency orthopedic surgery, were enrolled in this study. The sample size was calculated based on the primary outcome variable, mean arterial pressure (MAP) during surgery. Assuming a clinically significant difference of 10 mmHg in MAP between the two groups, a standard deviation of 12 mmHg, a power of 0.80, and a significance level of 0.05, a minimum sample size of 34 patients in each group was required. To account for potential dropouts and enhance statistical power, a total of 80 patients were enrolled. Patients were selected through consecutive sampling, where every eligible patient scheduled for emergency orthopedic surgery during the study period was invited to participate.

2.3. Inclusion/exclusion criteria

The inclusion criteria for this study encompass individuals aged between 45 and 70 years, deemed suitable for emergency orthopedic surgery with a trauma-to-surgery interval ranging from 24 to 48 hours, conducting surgeries on the lower limbs encompasses procedures with blood loss less than 750 ml and surgeries where a tourniquet is applied to mitigate bleeding during the surgical intervention. Additionally, candidates should fall under American society of anesthesiologists (ASA) physical status classifications I or II, have a surgery duration of less than 120 minutes, provide consent from both the patient and one first-degree relative, and not meet exclusion criteria, which include a body mass index exceeding 40 Kg/m^2, uncontrolled underlying diseases, patients with severe cardiovascular diseases, including but not limited to, uncontrolled hypertension, severe congestive heart failure, severe arrhythmias, and ischemic heart disease, patients with severe renal dysfunction (eGFR < 30 $mL/min/1.73m^2$) or hypermagnesemia, patients with a history of psychiatric disorders or substance abuse that may compromise their ability to provide informed consent or adhere to study procedures, allergies to the studied drugs, use of heart rate-increasing medications, consumption of magnesium-containing supplements before surgery, involvement in multi-trauma incidents, administration of blood or blood products pre-anesthesia, spine and skull trauma history, and a record of previous abnormal rhythms, pregnant or breastfeeding women, patients with a known history of bradycardia or high-degree atrioventricular (AV) blocks, patients with preoperative systolic blood pressure (SBP) <90 mmHg or diastolic blood pressure (DBP) <50 mmHg, patients with severe hepatic dysfunction (Child-Pugh class C), and patients with a history of epilepsy or seizures.

2.4. Randomization

The participants were allocated to one of two research groups through a block randomization technique. To achieve this, a total of 20 blocks were employed, with each block containing an equal number of individuals from both study groups. The sequence of these blocks was established through a random draw, and depending on the block they were assigned to, the patients were subsequently categorized into either the group D (dexmedetomidine group) or group M (magnesium sulfate group).

Table 1 Comparison of basic characteristics of study participants

Variables		Study groups (n=80)		P value
		Group M (n=40)	Group D (n=40)	
Age * (years), mean±sd		55.59±5.69	55.01±3.89	0.759
BMI * (Kg/m^2), mean±sd		30.85±2.59	31.02±2.11	0.553
NPO duration * (hours), mean±sd		9.48±0.14	9.14±0.45	0.859
Duration of surgery (minute) *, mean±sd		103.57±10.53	98.57±12.57	0.985
Duration of anesthesia (minute) *, mean±sd		120.57±10.53	123.57±12.57	0.596
Male (n)	| Gender **	21 (52.5%)	18 (75%)	0.469
	| Female (n)	19 (47.5%)	22 (25%)	
ASA class **	| I (n)	33 (82.5%)	30 (75%)	0.603
	| II (n)	7 (17.5%)	10 (25%)	
Surgery side **	| Right (n)	18 (45%)	20(50%)	0.445
	| Left (n)	22 (55%)	20 (50%)	

*: T test; **: Chi-square; sd: Standard deviation; BMI: Body mass index; ASA: American anesthesiology association.

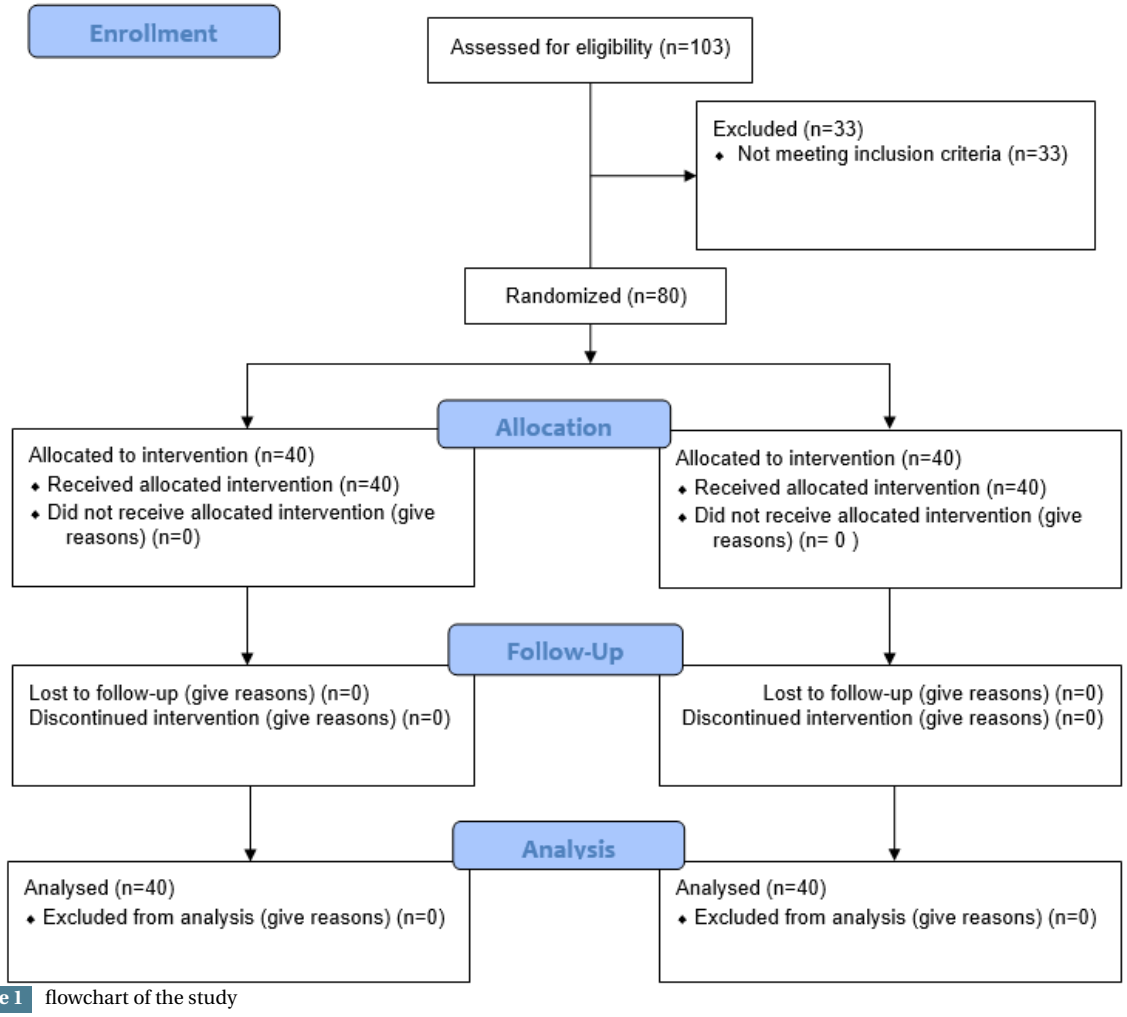

Figure 1 flowchart of the study

2.5. Blinding

The individual responsible for documenting data and recording outcomes on the data collection form remained unaware of the patient groupings throughout the study. Subsequently, the collected data were provided to an independent statistician unaffiliated with the research team, who was also kept in the dark about the groupings. Consequently, the current study adhered to a double-blind research design.

2.6. Anesthetic method and drug protocol

All patients received standardized preoperative care and were instructed to fast for 8 hours before surgery. In the operating room, standard monitoring, including electrocardiog-

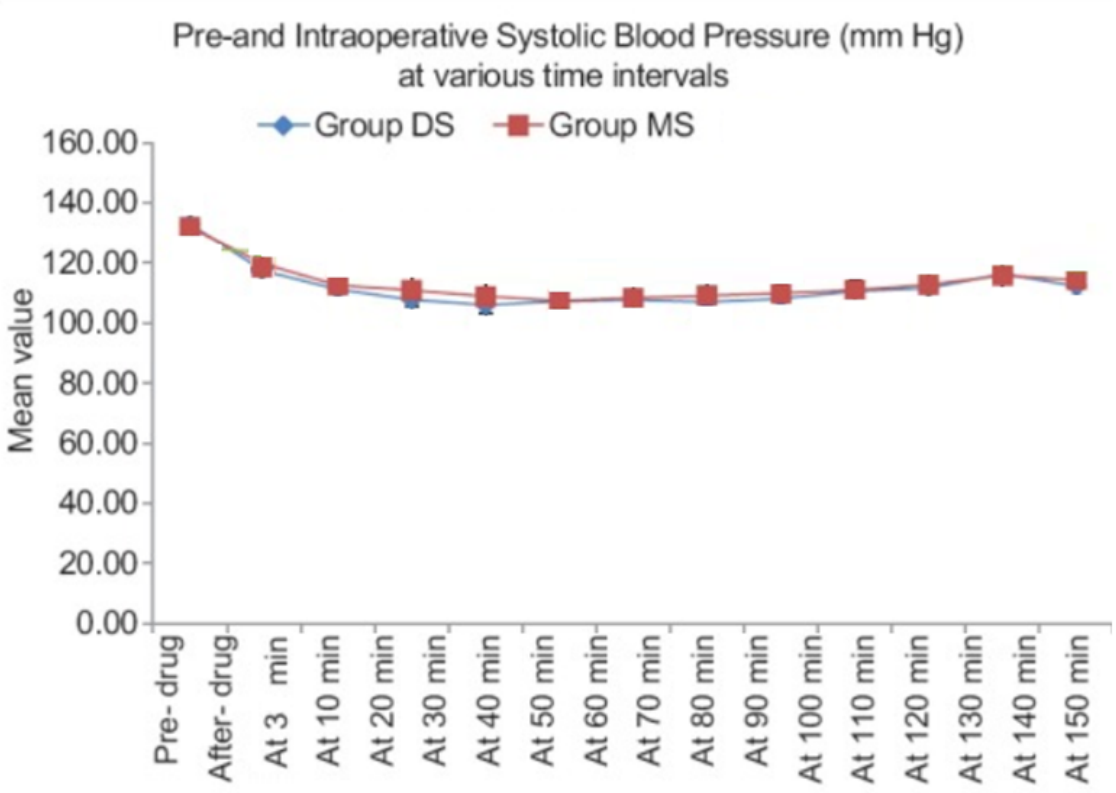

Figure 2 Comparison of SBP in the intraoperative period (P value between groups>0.05)

raphy, non-invasive blood pressure, pulse oximetry, and end-tidal carbon dioxide monitoring, was initiated. Intravenous access was established, and a crystalloid infusion was initiated. The initial steps in administering spinal anesthesia with bupivacaine (20 mg) involved precise patient positioning, identification of anatomical landmarks, and the aseptic preparation of the injection site. Following the infiltration of local anesthesia, a fine-gauge spinal needle (No. 25G) was cautiously inserted into the subarachnoid space, specifically at the L4-L5 level, as confirmed by cerebrospinal fluid aspiration. Subsequently, the predetermined dose of bupivacaine (20 mg) was administered, and post-injection, continuous monitoring of vital signs and sensorimotor blockade was diligently carried out. It is noteworthy that the anesthesia method, needle number, chosen space, and trial dose administered remained consistent across all patients in the study.

• Group D (dexmedetomidine group)

Dexmedetomidine was administered as an intravenous bolus at a loading dose of 1 mcg/kg over 10 minutes, followed by a continuous infusion at a rate of 0.2-0.7 mcg/kg/hour, depending on patient response. This infusion was initiated 15 minutes before induction of anesthesia and continued until the end of surgery.

• Group M (magnesium sulfate group)

Magnesium sulfate was administered as an intravenous bolus at a loading dose of 50 mg/kg over 10 minutes, followed by a continuous infusion at a rate of 15-20 mg/kg/hour. This infusion was initiated 15 minutes before induction of anesthesia and continued until the end of surgery.

We checked the hemodynamic status (DBP, SBP, MAP, and HR) before drug injection, after drug injection, after intubation, every ten minutes until the end of surgery (up 120 minutes) and then in the recovery unit (at the time of arrival until discharge to duration once every ten minutes: measured four times in total).

2.7. Ethical consideration

This study was conducted in accordance with the principles outlined in the Declaration of Helsinki and good clinical practice guidelines. Informed consent was obtained from all participants. Patients were informed of the potential risks and benefits of both dexmedetomidine and magnesium sulfate. The trial was conducted with full consideration of patient safety and privacy. This study has been registered in clinical trial site (No: IRCT20191220045829N1).

2.8. Statistical analysis

Statistical analysis was performed using SPSS software (version 25, IBM Corp., Armonk, NY, USA). Descriptive statistics were presented as means±standard deviations for continuous variables and as frequencies (%) for categorical variables. The normality of the data was checked and confirmed with the Kolmogorov-Smirinov test, and it was found that the data have a normal distribution. T-test, repeated measure test and chi-squared statistical tests were used to compare variables between groups.

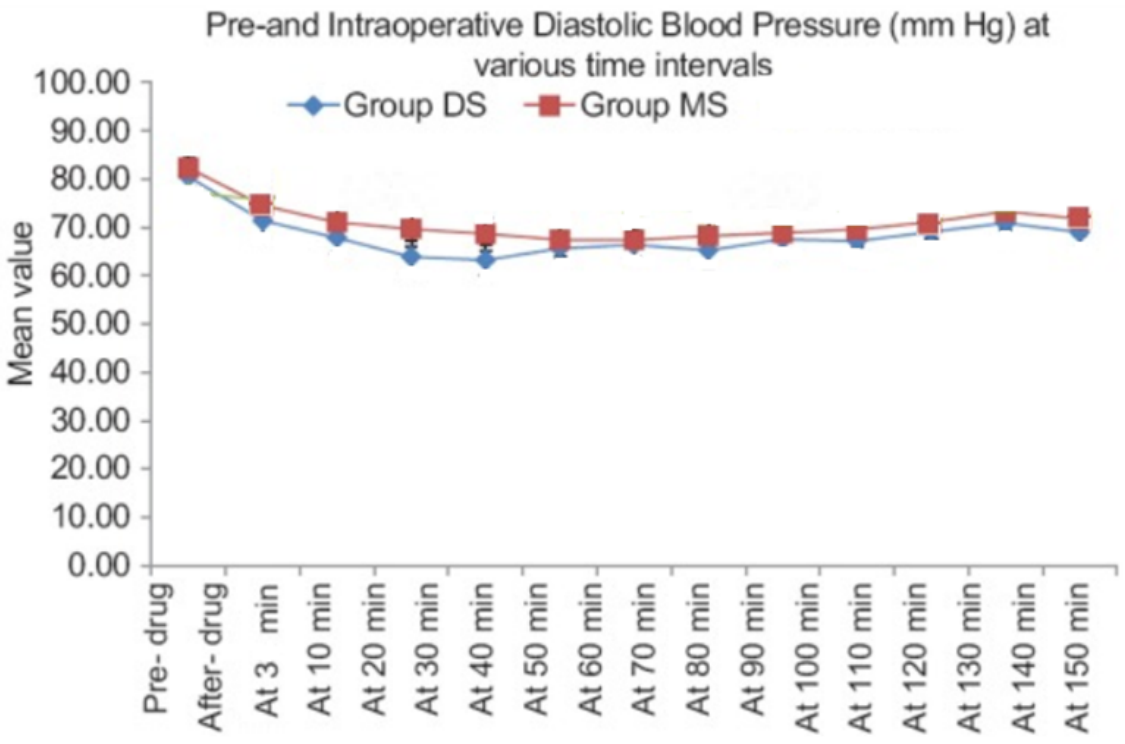

Figure 3 Comparison of DBP in the intraoperative period (P value between groups>0.05)

3. Results

During the mentioned period, there were 103 patients, of which 80 patients were included in the study and were present until the end of the study; in other words, the sample drop in this study was equal to 0 (Figure 1).

3.1. Basic characteristics

Comparing the demographic information of the participants, such as the age of the participants in the study equal to 55.5±2.69 years (P=0.759), gender (P=0.469), the length of fasting time equal to 9.48±1.29 hours (P=0.895), duration of surgery equal to 100.59±12.25 minutes (P=0.985), duration of anesthesia equal to 121.95±11.41 minutes (P=0.596), ASA class (P=0.603) and surgery side (P=0.445) had no statistically significant difference. The average body mass index of the participants in the study was equal to 31.85±3.25 between the two groups of participants in the study without significant statistical difference (P=0.553) (Table 1).

3.2. Hemodynamic parameters

The primary outcome of this study was the assessment of hemodynamic parameters, including MAP, SBP, DBP, and HR, at various time points throughout the perioperative period. Similarly, SBP (Figure 2) and DBP (Figure 3) remained relatively stable in both groups during surgery. No significant differences were observed in SBP or DBP between the dexmedetomidine and magnesium sulfate groups at any time point. Changes in SBP over time were lower in group D (P=0.411) than in the group M (P=0.375); also changes in DBP over time were lower in the group D (P=0.527) than in the group M (P=0.459). Heart rate (Figure 4) profiles also showed no significant differences between the two groups during the perioperative period. Both group D and group M had comparable HR values at all time points; changes in HR over time were lower in group D (P=0.429) than in group M (P=0.388). The results demonstrated that patients in both Group D and Group M experienced stable MAP levels throughout the perioperative period. Changes in HR over time were lower in group D (P=0.6) than in group M (P=0.558). There were no statistically significant differences in MAP between the two groups at any time point (Figure 5).

The average post-anesthesia care unit (PACU) time in the magnesium group (22.45±5.89 minutes) was non-significantly less than the group of patients receiving dexmedetomidine (28.30±4.41 minutes) (P=0.360). In PACU, 3 patients who received dexmedetomidine needed to receive atropine, while none of the patients who received magnesium need to receive atropine (P=0.063); 3 patients receiving dexmedetomidine needed to receive anti-nausea and vomiting drug (ondansetron), while 4 patients receiving magnesium needed to receive this drug (P=0.512).

The amount of opioid drug injected for each patient was recorded in milligrams of pethidine; the results indicated that the average opioid drug injected for patients receiving dexmedetomidine (20.14±5.29 mg) was insignificantly less than magnesium sulfate receiving patients (28.11±5.49 mg) (P=0.326). Adverse events related to dexmedetomidine,

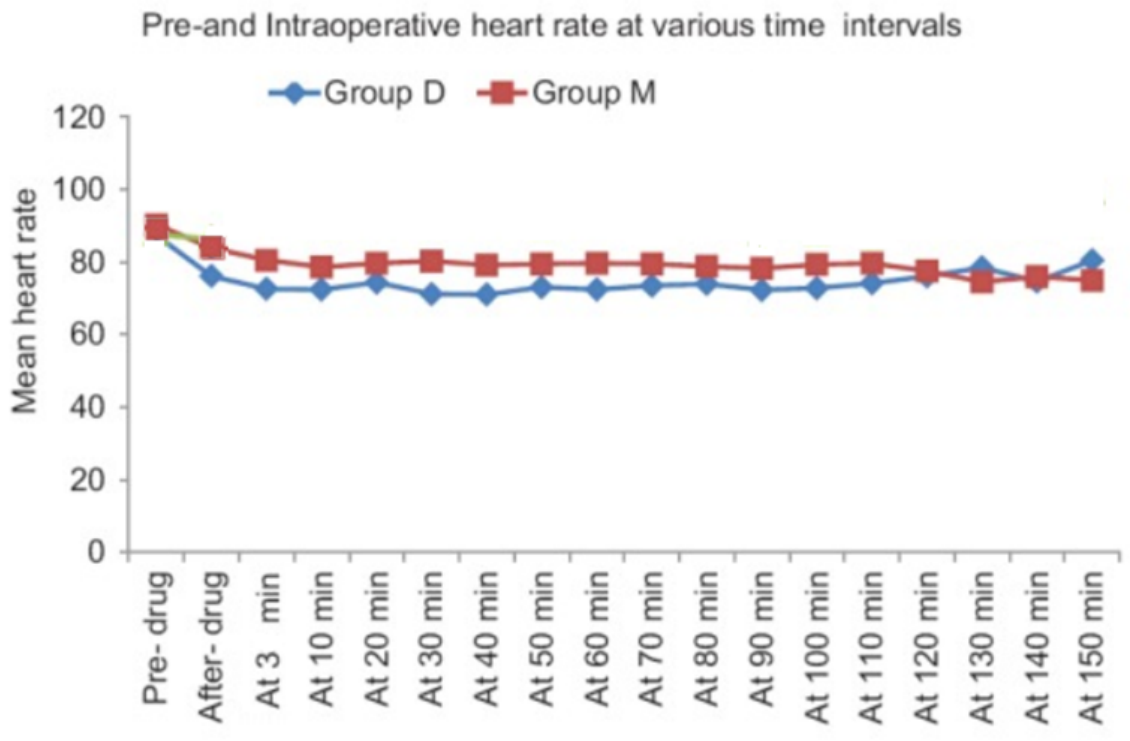

Figure 4 Comparison of HR in the intraoperative period (P value between groups>0.05)

and magnesium sulfate were monitored. No severe adverse events, such as bradycardia or hypotension, were reported in either group. Both agents were well-tolerated, with no significant complications attributed to their administration.

4. Discussion

The current study aimed to compare the effects of dexmedetomidine and magnesium sulfate infusions in maintaining stable hemodynamic conditions during emergency orthopedic surgery. The findings revealed that there was no statistically significant difference between the two drugs administered in this study and their impact on hemodynamic status.

Our findings reveal that both dexmedetomidine and magnesium sulfate are effective in maintaining stable hemodynamic parameters during elective orthopedic surgeries. There were no statistically significant differences between the two groups in terms of MAP, SBP, DBP, HR, or the incidence of hypertension and tachycardia. These results suggest that both agents can be considered suitable options for achieving hemodynamic stability in this patient population.

A randomized controlled trial study by Kokhaei et al. (2022) compared the hemodynamic effects of dexmedetomidine and magnesium sulfate injections in patients undergoing orthopedic surgery. This study showed that both drugs effectively maintain hemodynamic parameters, but dexmedetomidine provides better control of heart rate and blood pressure (25).

A comparative study by Kamel et al. (2021) evaluated hemodynamic stability during spinal anesthesia with dexmedetomidine or magnesium sulfate in orthopedic surgery. The findings showed that both drugs had stable hemodynamics, but dexmedetomidine had better control over heart rate and blood pressure fluctuations (26).

A comparative study by Mehta et al. (2021) investigated the effect of dexmedetomidine and magnesium sulfate infusion on hemodynamic changes during total hip replacement surgery. The results showed that both drugs effectively control hemodynamic parameters, but dexmedetomidine showed better control over heart rate and blood pressure (27).

Another noteworthy aspect of this study is the favorable safety and tolerability profile of both dexmedetomidine and magnesium sulfate. No severe adverse events, such as bradycardia or hypotension, were reported in either group, indicating that both agents were well-tolerated by the patients. This aligns with the broader safety profile of these drugs and reinforces their potential as valuable tools for maintaining hemodynamic stability (28-34).

In summary, our study aligns with the broader literature on optimizing hemodynamic control during orthopedic surgery. Dexmedetomidine and magnesium sulfate, like other agents investigated in similar studies, offer valuable options for achieving stable hemodynamics. The choice of agent should be guided by patient characteristics, surgical requirements, and clinician expertise (25,36).

These comparative findings contribute to the growing knowl-

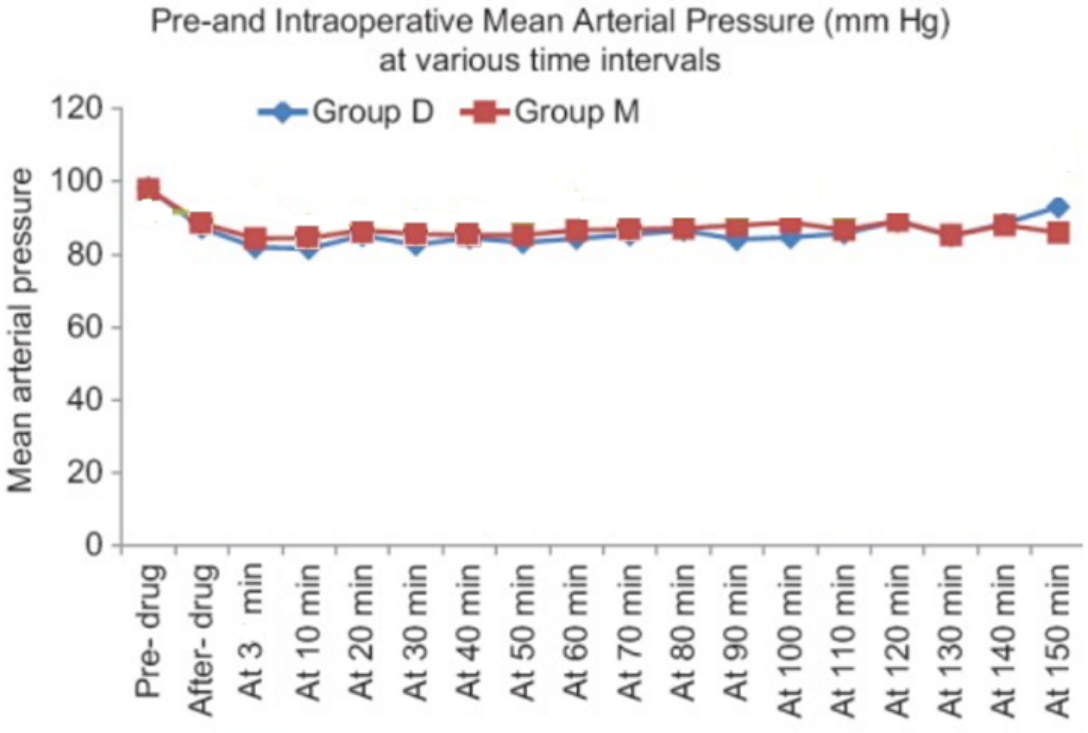

Figure 5 Comparison of MAP in the intraoperative period (P value between groups>0.05)

edge base in perioperative care, facilitating evidence-based decisions for anesthesiologists and surgeons. While individual studies provide valuable insights, meta-analyses and systematic reviews may further enhance our understanding of the comparative effectiveness of various pharmacological interventions in achieving hemodynamic stability during orthopedic surgery. Further research can also explore the long-term outcomes and postoperative recovery parameters associated with different agents to optimize patient care in this context (37-40).

While no statistically significant changes were observed in the hemodynamic status between the two groups, a slightly higher consumption of opioids was noted in the magnesium sulfate group within the PACU. This finding prompts further investigation into why magnesium sulfate administration led to increased opioid consumption. One possible explanation could be related to the potential interaction between magnesium sulfate and opioid receptors, resulting in enhanced opioid effects or increased opioid requirements for adequate pain management.

Alternatively, magnesium sulfate may influence pain perception or tolerance through mechanisms independent of opioid receptors, thereby necessitating higher opioid doses for effective analgesia. Understanding the underlying reasons for this observed increase in opioid consumption in the magnesium sulfate group is crucial for optimizing pain management strategies in orthopedic surgery patients and warrants future research in this area.

The clinical implications of these findings are significant for anesthesiologists and surgeons involved in orthopedic procedures. The ability to maintain stable hemodynamics during surgery is pivotal for minimizing bleeding, reducing surgical complications, and facilitating optimal surgical conditions. Our study suggests that both dexmedetomidine and magnesium sulfate can serve as valuable tools in achieving these objectives.

However, the choice between these agents should be made based on individual patient characteristics, surgical requirements, and clinician expertise.

5. Limitations

While our study contributes important insights into hemodynamic stability during orthopedic surgery, it is not without limitations. These include the relatively small sample size and the single-center nature of the study. Future research with larger sample sizes and multi-center designs may further strengthen the generalizability of our findings. Additionally, long-term outcomes and postoperative recovery parameters should be explored in greater detail to provide a more comprehensive assessment of the clinical implications of using dexmedetomidine and magnesium sulfate in this context.

6. Conclusion

In conclusion, the results of this study affirm that both dexmedetomidine and magnesium sulfate are effective and safe options for achieving hemodynamic stability during

elective orthopedic surgery. The choice of the optimal agent should be guided by patient-specific factors and the unique demands of the surgical procedure. This research contributes to the growing body of knowledge in perioperative care, aiming to enhance patient outcomes, minimize complications, and improve the overall quality of orthopedic surgical procedures.

7. Declarations

7.1. Acknowledgement

The authors thank the research vice-chancellor of Tabriz University of Medical Sciences for financially supporting the research.

7.2. Authors' contribution

All steps of this study have been done with the participation of all authors.

7.3. Conflict of interest

The authors declare no conflict of interest.

7.4. Funding

This study was supported by the Tabriz University of Medical Science in the context of a dissertation project.

7.5. Ethical Statement

This study was approved by the institutional review board of Tabriz University of Medical Sciences (Approval ID: IR.TBZMED.REC.1400.998)

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