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Effect of Dexmedetomidine on Blood Pressure in Hypertension Patients after Emergency Laparotomy for Trauma: A Randomized Double-blind Clinical Trial

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Abstract

Background: Patients with a history of hypertension experience higher postoperative complications than healthy individuals. The frequency of such complications is also higher in emergency patients than elective ones; therefore, it seems that preventive measures are essential.
Objectives: The present study aimed at determining the effect of dexmedetomidine on blood pressure in patients with hypertension after emergency laparotomy for trauma.
Methods: The present study was a randomized, double-blind clinical trial performed from 2019 to 2020 on patients with a history of hypertension undergoing emergency laparotomy. Patients received the intervention 15 minutes before surgery (the intervention group: intravenous (iv) dexmedetomidine and the control group: normal saline), and the intensity of the pain(VAS), agitation(RASS), and blood pressure were measured and compared at different time points. Data were compared using SPSS software (version 21) by t-test and Chi-square tests considering a significance level of <0.05.
Results: There were statistically significant differences between the two groups just after the drug infusion and at all studied time points (P<0.05), so that the intervention group had more stable blood pressure. Pain intensity (P<0.05) and the degree of agitation (P<0.05) in the intervention group were significantly lower than that in the control group at all studied time points.
Conclusion: Dexmedetomidine infusion leads to a stabilization of blood pressure during surgery and after surgery, pain relief, and agitation in patients with hypertension undergoing emergency laparotomy for trauma.

Keywords: Emergency Laparotomy, Trauma, Blood Pressure, Dexmedetomidine.

Introduction

Emergency laparotomy, like any other surgery, may lead to complications occurring more often in trauma patients. Complications of surgery include the occurrence of a known and predictable event or phenomenon during or after surgery, which usually curable, but prolongs recovery from surgery.[1,2] In laparotomy surgeries, especially emergency ones, some problems can delay the recovery time after surgery. The chance of these complications significantly is reduced by surgeon proficiency and expertise, and the probability coefficient of such complications is usually low.[3] Complications of laparotomy, although rare and unlikely, typically fall into two categories of [1] during surgery and [2] after surgery affected by during surgery ones.[4,5] Among secondary postoperative complications, acute postoperative pain, a complex physiological response to injury, and edema due to surgery are noteworthy. Patients often complain of postoperative pain, which is the most important reason for surgical fear. Unmanaged postoperative pain causes physical and mental complications in patients and reduces patients' satisfaction with the medical system due to increased mortality rate and treatment costs.[6] Also, controlling hemodynamic parameters and hemodynamic stabilization, along with the handling of bleeding during emergency laparotomy are among the elements of anesthesia management in patients. Mentioned elements reduce cardiovascular complications of the surgery and decrease the chance of blood transfusion and related complications, such as hemolysis, infection, non-hemolytic reactions, and pulmonary complications.[7]

Trauma patients who require emergency laparotomy undergoing surgery without any counseling or preoperative preparations may be affected with more uncontrollable complications comparing to those of elective surgeries.[8]

Therefore, controlling and managing such complications are necessary, as they may lead to adverse outcomes. On the other hand, there is a relationship between the emergence of postoperative complications and the history of hypertension. Patients with a history of hypertension are at much higher risk of complications during and after surgery compared to others. Therefore, by identifying such individuals and taking preventive and controlling measures during surgery, the emergence of such postoperative consequences can be greatly reduced.[9-11] Dexmedetomidine is an agent, which hemodynamic stabilizing effects are proven. The present study aimed at investigating the impacts of this agent on patients with a history of hypertension undergoing emergency laparotomy for trauma.

Objectives

The present study aimed at investigating the impacts of this agent on patients with a history of hypertension undergoing emergency laparotomy for trauma.

Materials and Methods

Study design

The present randomized, double-blind clinical trial was performed from 2019.05.05 to 2020.12.20 in the operating room of Imam Reza Hospital, Tabriz, Iran. The sample size was determined 38 considering a 95% confidence interval, 80% test power, and 5% acceptable error rate, using the Pocock sample size formula, and increased to 41 in each group considering the probability of 20% dropouts. Patients meeting the inclusion and exclusion criteria were divided into two groups of intervention and control using the table of random numbers. For blinding, the drugs were prepared in similar syringes in terms of shape and size by the first author and delivered to the operating room (the syringes were coded and only the first author knew their contents), and the anesthesiologist, anesthesiology technician, and statistical consultant were blind to groupings and drugs.

Inclusion and exclusion criteria

Trauma patients who were candidates for emergency laparotomy and were above the age of 18were included in this study. They also had a Hemoglobin level above 12 g/dL, an informed consent provided by a first-degree relative for participation in the research project, and a history of hypertension collected from patients' relatives. Individuals who were above the age of 90 and suffered from drug addiction, severe debilitating systemic diseases, allergy to dexmedetomidine (based on information provided by a first-degree relative), mental illness, and chronic pain disorders were excluded. Patients with preoperative transfusion of blood and other blood products and uncontrollable bleeding during surgery (More than 1000 cc) and who required mechanical ventilation after surgery for any reason were also excluded.

Method of intervention

After transferring to the operating room, implanting a suitable iv line, and delivering 500 mL normal saline, patients were monitored for vital signs (ie, arterial oxygen saturation, non-invasive blood pressure, and electrocardiogram). Then, patients were anesthetized by an anesthesiologist. Induction and maintenance of anesthesia were the same in all the subjects. Patients in the intervention group received 0.5 µg/kg of dexmedetomidine in 5 mL normal saline iv, 15 minutes before the end of surgery (at the beginning of closing the abdomen) the control group received the same amount of normal saline slowly iv. Blood pressure was measured and recorded before and after the injection. After extubation, the patients were transferred to the recovery room, underwent monitoring, and received oxygen via a face mask. Blood pressure, pain, and agitation were recorded in datasheets for both groups. After the confirmation of the recovery by the nurse and anesthesiologist, the patients were transferred to the ward, and their blood pressure, pain, and agitation were recorded again, first every 15 minutes (up to one hour) and then once every two hours (up to six hours).

Data collection instruments

In the present study, the following instruments were used for collecting data:

1. Demographic information form: It contained items on age, gender, weight, duration of surgery, and duration of anesthesia.

2. Visual analogous scale (VAS): It is like a ruler numbered from 1 to 10, and higher numbers indicate more pain. It is used when the patient is conscious, and in case of unconsciousness or semi-consciousness, the faces rating scale is used to predict pain intensity.

3. The Richmond agitation-sedation scale (RASS) was used to assess the awakening and consciousness of agitated patients and those receiving sedatives. RASS consists of three steps: 1. Observation: The patient is only observed; he is scored 0 to +4 based on consciousness. However, if he is not conscious, step 2 is conducted. Step 2. Verbal stimulation: the

patient's name is called loudly and he is asked to make eye contact. If he responds, he is scored (-1 to -3), and if not, the next step is performed. Step 3. Physical stimulation: The patient's shoulder is shaken. If there is no reaction, his sternum is pressed hard and then he is scores -5 to +4. To interpret the scores: +4 aggressive (angry, hurts staff); +3 very agitated (pulls pipes aggressively), +2 agitated (restlessness with ventilator and aimless intermittent movements), +1 restless (anxious - movements without aggression), 0 conscious/calm (paying attention to the caregiver), -1 drowsiness (not fully conscious but opens his eyes to sound and makes communication for more than 10 seconds), -2 light anesthesia (briefly responds to sound, but communicates less than 10 seconds), -3 medium anesthesia (opens his eyes aimlessly), -4 deep anesthesia (response to physical stimuli), and -5 does not wake up (does not respond to sound and physical stimuli)

Ethical considerations

The present study protocol was approved by the Ethics Committee of Tabriz University of Medical Sciences (ethical code: IR.TBZMED.REC.1397.343). The study was registered in the Iranian Registry of clinical trials (Reg. No. IRCT20150217021121N3). The patients were enrolled in the study after explaining the study objectives to their first-degree relatives and obtaining the written informed consent. Participation was voluntary and free, based on written consent.

Statistical analyzes

The collected data were entered into SPSS software (version) 21 by a statistical consultant (out of the research team). The t-test and Chi-square tests were used to compare the data, and P-values less than 0.05 were considered significant.

Results

In the present study, 82 trauma patients who were candidates for emergency laparotomy during the study period were enrolled and received the relevant intervention after random allocation. All the subjects completed the study, and none of them were dropped out. Data analysis was performed in both groups and all the subjects (Figure-1).

According to the results, there was no significant difference between the groups in terms of demographic information, including gender, mean±standard deviation (SD) of age, mean±SD of weight, mean±SD of anesthesia duration, and mean±SD of surgery duration (Table-1).

Pretest blood pressure level had no significant differences between the two groups (P<0.05) at the end of infusion, and at all studied time points, there were significant differences between the two groups (P<0.05), and the intervention group had more stable blood pressure. The comparison of blood pressure at different time points between the two groups is shown in (Table-2).

Pain intensity and agitation were measured hourly when the effects of the anesthetic agent terminated (one hour after surgery). The results showed that both the pain intensity (p<0.05) and degree of agitation (P<0.05) at all studied time points were lower in the intervention group than the control group (Table-3).

Discussion

The present study aimed at evaluating the effect of dexmedetomidine on blood pressure in patients with hypertension undergoing emergency laparotomy. According to the results of the study, dexmedetomidine infusion significantly reduced agitation and pain intensity in the intervention group compared to controls. Also, systolic and diastolic blood pressure in the intervention group was significantly lower than the controls. Finally, systolic and diastolic blood pressure in the intervention group was significantly more stable and lower than the control group receiving normal saline. As expected, dexmedetomidine was successful in reducing the controlled blood pressure.

Table-1. Comparison of Demographic Characteristics and Basic Information of the Study Participants

	Intervention group(N=41)	Control group(N=41)	P Value
Age (M±SD)	63.11±14.8	63.49±13.03	0.519*
Sex (m)	21(51.21%)	23(56.09%)	0.483**
Weight (M±SD)	75.19±05.29	73.89±05.12	0.319*
Anesthesia Time (M±SD)	241.49±35.89	250.69±36.18	0.303*
Surgery Time (M±SD)	211.59±33.79	215.71±33.96	0.533*

*. T-Test **. Chi- Square

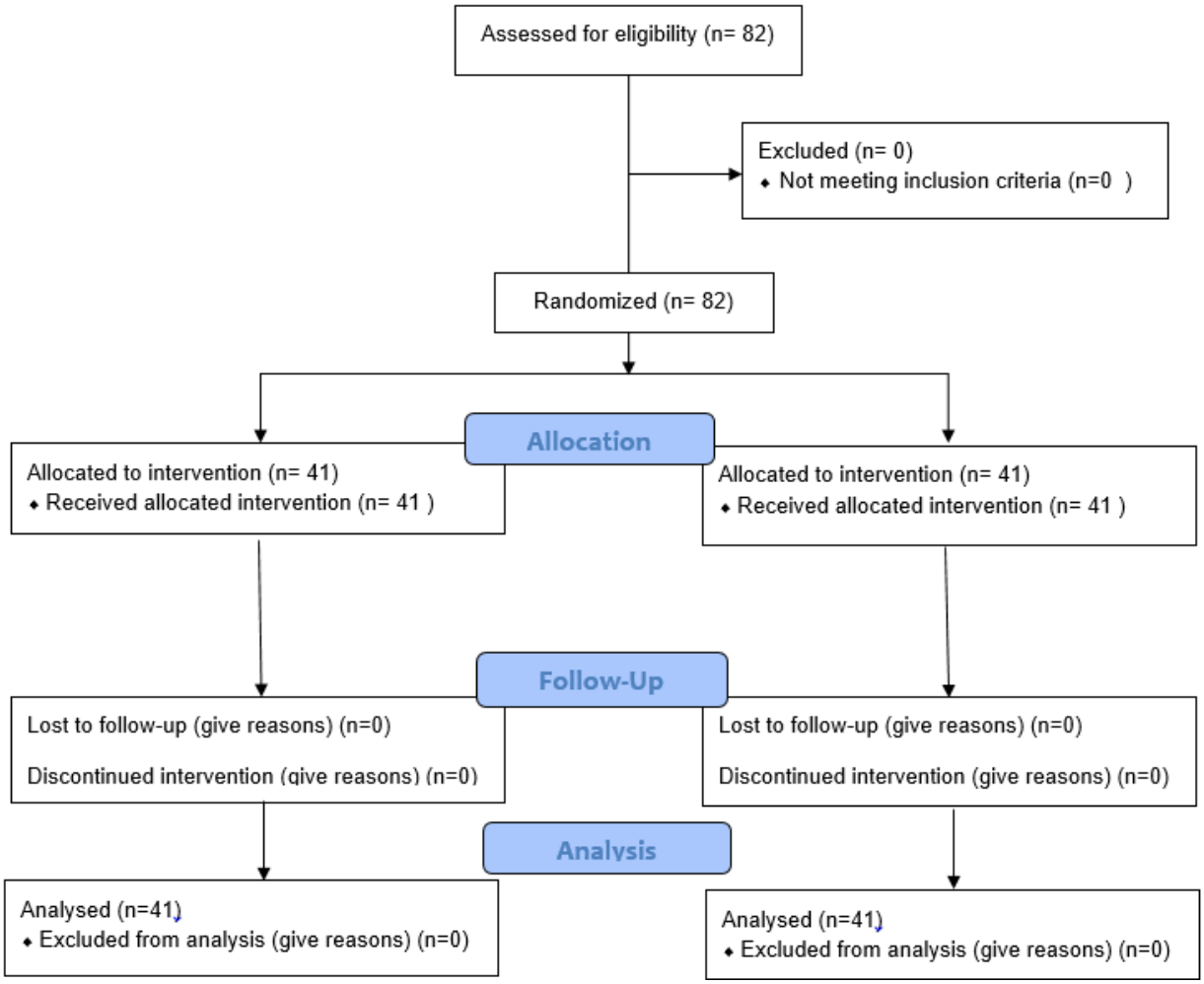

Figure-1. The Flow Diagram of the Study

Table-2. Comparison of systolic and diastolic blood pressure between the two groups participating in the study

Systolic Blood Pressure	Intervention group(N=41)	Control group(N=41)	P Value
Before injection	159.24±21.86	163.30±22.41	0.214
After injection	132.49±18.35	159.51±22.01	0.019
First fifteen minutes	127.75±16.98	161.33±23.13	0.011
Second fifteen minutes	125.18±15.35	165.14±25.10	0.009
Third fifteen minutes	127.17±18.49	166.86±26.41	0.005
Fourth fifteen minutes	128.66±17.37	164.73±25.69	0.010
second hour	125.25±16.47	161.59±25.26	0.007
fourth hour	128.49±16.33	157.45±24.33	0.009
sixth hour	131.58±17.63	169.10±27.39	0.003
Diastolic Blood Pressure			
Before injection	92.74±10.35	93.89±10.89	0.449
After injection	84.69±8.12	92.03±9.63	0.031
First fifteen minutes	82.49±8.73	95.30±10.66	0.014
Second fifteen minutes	80.45±7.15	94.44±10.67	0.011
Third fifteen minutes	81.69±7.24	96.11±11.17	0.009
Fourth fifteen minutes	82.80±8.01	95.47±11.19	0.008
second hour	85.17±8.74	97.45±11.56	0.006
fourth hour	84.17±8.64	98.63±11.47	0.004
sixth hour	85.51±8.31	98.66±11.19	0.004

Table-3. Comparison of Pain Intensity and Agitation in the Study Participants at Different Time Points

Pain	Intervention group(N=41)	Control group(N=41)	P Value
First hour	4.16±1.45	6.79±1.69	0.019
Second hours	4.29±1.19	6.99±1.89	0.009
Third hours	4.09±1.11	6.25±1.79	0.011
Fourth hours	4.01±1.14	5.89±1.74	0.021
Fifth hours	3.18±1.03	5.24±1.47	0.009
Sixth hours	3.04±1.17	5.04±1.85	0.003
Agitation			
First hour	1.19±0.42	2.06±0.69	0.039
Second hours	1.05±0.36	2.01±0.14	0.041
Third hours	0.94±0.41	1.96±0.54	0.036
Fourth hours	0.81±0.37	2.03±0.39	0.013
Fifth hours	0.91±0.33	2.14±0.43	0.009
Sixth hours	0.79±0.29	1.99±0.59	0.003
T-Test			

In various non-elective surgeries performed as emergency, different methods are used for further hemodynamic stabilization in order to minimize complications occurring after apparent hemodynamic changes- e g, non-emergency cesarean section,[12] emergency laparotomy, etc. The purpose of using various drugs, such as magnesium sulfate, dexmedetomidine, etc., is hemodynamic stabilization in emergencies.

Regarding the effect of dexmedetomidine on hemodynamic stabilization, the result of the present study was consistent with those of the meta-analysis by Tsaousi et al. (2018) on patients undergoing spinal surgery.[13] The role of dexmedetomidine in stabilizing blood pressure, observed in the present study, was in agreement with the findings of the study conducted by Kim et al. (2018).[14] Their research on patients who were candidates for spinal surgery also showed that dexmedetomidine was effective in hemodynamic stabilization and reduction of bleeding. In a study by Elgebaly et al. (2018),[15] dexmedetomidine was used in women with preeclampsia undergoing cesarean section. They reported better hemodynamic stabilization, decreased sedative use, and more analgesia in the dexmedetomidine group than in the control group. The results of their study were in agreement with those of the present study. In the current study, pain reduction was faster, and agitation was lower in the dexmedetomidine group than in the control group. Sebastian et al.[16] examined the effect of dexmedetomidine infusion on stress responses during intubation and the length of surgery. They concluded that it could reduce stress responses during intubation and lower systolic and diastolic blood pressure in the control group. Further decrease in systolic and diastolic blood pressure was observed during surgeries in the dexmedetomidine group. Their results were most consistent with those of the present study, despite the point that the current study's subjects had a history of hypertension.

Based on the present study results and comparison with previous studies, dexmedetomidine can play a positive protective role in intraoperative hemodynamics and be effective in reducing agitation after laparotomy. On the other hand, opioids are not required due to the positive effects of this agent on pain intensity. In the present study, the pain intensity was much lower in the dexmedetomidine group than in the control group; the study results were in line with similar studies.[17-19]

Lack of information about medications used by patients, the last time patients took the medications, the exact history of hypertension, and also the postoperative pain management protocol applied in the ward were some of the study limitations.

It is recommended to eliminate the present study limitations in future research. Also, considering the positive effects of dexmedetomidine on trauma patients with a history of hypertension, it is recommended using this agent in similar cases.

Conclusions

Dexmedetomidine infusion leads to a stabilization of blood pressure during and after surgery, pain relief, and agitation in patients with hypertension undergoing emergency laparotomy for trauma.

Acknowledgments

None.

Authors' Contribution

All authors pass the four criteria for authorship contribution based on the International Committee of Medical Journal Editors (ICMJE) recommendations.

Conflict of Interests

The authors declared no potential conflict of interests with respect to the research, authorship, and/or publication of this article.

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