Egyptian Journal of Medical Research

Print ISSN: 2682-4396 / Online ISSN: 2682-440X

Original article

Efficacy of intrathecal Dexamethasone to decrease the incidence of postspinal hypotension in geriatric patients undergoing orthopedic surgery.

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Article Info

Article history:

Received 9 August 2023

Accepted 22 October 2023

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Keywords:

Spinal Anesthesia

Geriatrics

Dexamethasone

Hypotension.

Abstract

Background: It might be difficult to treat hypotension after spinal or epidural anesthesia in older adults. There is a danger of volume overload or cardiac compromise when PSA hypotension is treated with fluids (colloids or crystalloids) or vasoconstrictors. When decreased peripheral vascular resistance is present, dexamethasone is utilized as a treatment.

Methods: Eighty patients, aged 60 years or more were recruited to receive a single preoperative intrathecal dose of dexamethasone 8 mg (dexamethasone group) (40 patients), and 40 patients were given placebo receiving normal saline (Control group) in a randomized, double-blind trial. Variations in blood pressure and heart rate in addition to the needs of

ephedrine and/or atropine following spinal anesthesia (SA) were recorded . **Result:** The mean age of patients in 4dexamethasone group was 67.8±6.8 years and most of them were females (72.5%). The mean arterial blood pressure showed no significant difference between the studied groups regarding their baseline and all measures of mean arterial blood pressure. However, at all measures the MAP was higher in the dexamethasone group than the control group. **Conclusion:** Post-spinal anesthesia hypotension in elderly patients was less common after receiving a single preoperative intrathecal dose of dexamethasone 8 mg than control.

1. Introduction:

Even though hypotension is the most common consequence, occurring in up to one-third of non-obstetric populations, most anesthesiologists still favor spinal anesthesia for their older patients [1]. Reduced sympathetic output leads to increased arterial vasodilation and decreased venous return, which in turn activates the Bezold-Jarisch response and causes hypotension after spinal anesthesia (PSA) (BJR) [2], it causes bradycardia, vasodilation, and even lower blood pressure [3].

Human tissue peripheral vascular resistance (PVR) is increased by dexamethasone through several mechanisms [4], and it has been extensively studied for its function in preserving blood flow during extreme vasodilation, such as in septic shock and anaphylaxis [5, 6]. Patients over the age of 65 who are having orthopedic surgery benefit from a single preoperative dosage of dexamethasone 8mg IVI, as reported by Ashoor et al. [7].

In a study including obstetric patients, Tkachenko R found that intrathecal dexamethasone reduced the occurrence of post spinal hypotension [8]. The aim of our study is to test the role of intrathecal dexamethasone in decreasing the incidence of post spinal anesthesia hypotension in geriatric patients undergoing orthopedic surgery.

2. Patients and Methods:

Setting Study design

This research was conducted at Beni-Suef University Hospital between April 2022 and October 2022 with consent from the hospital's research and ethical council and the department of anesthesiology, surgical critical care, and pain management at Beni-Suef University. Before any surgeries were performed, we made sure to get each parent's written permission.

This was a randomized, placebo-controlled, double-blind study. Patients were randomly assigned to one of two research groups using a computer-generated randomization list with an allocation ratio of 1:1. Group assignments were determined by selecting an opaque envelope at random from a stack of sealed envelopes by a nurse. The anesthesiologist who prepared the research drugs was not engaged in any other aspect of the trial, and the anesthesiologist who administered the drugs and collected the data was also blinded to the identity of the study drug.

Subjects

The patients were randomly divided into two groups (40 patients each). Patients in both groups were given 3 milliliters of a 5% solution of bupivacaine intravenously (Marcaine® Spinal Heavy 0.5 percent; Sunny pivacaine, Manufactured by Sunny Pharmaceutical, Cairo, Egypt) under hyperbaric conditions. Group A (40 patients) also got 2 ml of a saline-like placebo injected intrathecally. Patients in Group B (n = 40) also got an intrathecal injection of 8 mg dexamethasone in 2 ml (EIpIco company).

Inclusion Criteria. Patients who are 65 or older, Patients who have a physical status of I, II, or III according to the American Society of Anesthesiologists (ASA), Getting orthopedic work done on my legs.

Exclusion Criteria Patients who can't get spinal anesthesia due to medical reasons (e.g.- coagulopathy, thrombocytopenia, allergy to local anesthetic agent). Patients using corticosteroids or drugs that affect serotonin (e.g., selective serotonin reuptake inhibitor).

Prior to surgery, all patients had normal preoperative laboratory examinations, such as a complete blood picture, prothrombin time and concentration, liver and kidney function tests, electrocardiogram (ECG), and echocardiogram (Echo). An intravenous cannula was placed as soon as they got to the surgery room. After non-invasively measuring blood pressure (BP), electrocardiogram (ECG), and pulse oximetry

(SpO2) in each patient, 1 mg of midazolam was administered intravenously (IV) to put them to sleep. Beginning during SA and continuing for the next 20 minutes, an infusion of NS solution (maximum 500 mL) was started. Spinal anesthesia was performed with the patient in the setting position by injecting 3 ml of 0.5% hyperbaric bupivacaine solution (Marcaine® Spinal Heavy 0.5%; Sunny pivacaine, manufactured by Sunny Pharmaceutical - Cairo - Egypt) at L3-L4 or L4-L5 level using 25gauge Quincke spinal needle and adding 2 ml normal saline or 2ml dexamethasone 8mg according to patient group. After completing the subarachnoid injection, patients were positioned supine. Surgical procedure, positioning of the patient or application of tourniquet were allowed during the study period.

The primary outcome: MBP measured 4 times during SA at 5-minute intervals before and after study drug administration (baseline). When commencing the surgical operation, if the patient's mean arterial pressure (MAP) drops by 25% or more from their baseline reading during the first 20 minutes following SA induction, intravenous doses of 5 to 10 mg as required, not to exceed 50 mg ephedrine, will be administered (chemipharm company).

The secondary outcomes: Patients' demographic information (Age, ASA physical status and weight). Prior to receiving study medicines (baseline) and then every 5 minutes for 4 measurements during SA, systolic and diastolic blood pressure (SBP and DBP) were measured. Patients requiring ephedrine treatment, as a count. Alterations in heart rate (HR), bradycardia (HR 50 bpm) treated with boluses of 0.01 mg/kg atropine (El-Nile Company). Modified Bromage Score (9) and alcohol swab assessments of motor blockage every 5 minutes revealed the following pattern **[9].**

Data Collection and Statistical analysis of the data:

IBM's statistical analysis program, SPSS, version 27.0, was used to process the data (Armonk, NY: IBM Corp). Pearson's Chi-square test for independence of attributes/exact Fisher's test was used to compare groups based on categorical variables represented as numbers of patients or percentages of patients. The independent T test was used to compare continuous variables across groups, with means and standard deviations calculated. A 5% alpha level was used, therefore results with a P value below 0.05 were considered significant.

Sample size:

The sample size of 40 per group was determined by power analysis; due to the preliminary study results to detect 30% absolute difference in the incidence of hypotension, with power of 80% and α 0.05. Using G power (G*Power 3.1.9.2, Heinrich-Heine-University Düsseldorf, Germany).

Ethical considerations:

Beni-Suef University's medical school's research ethics committee gave their stamp of approval to the study's methodology No. FMBSUREC/08032022/Hassan. All patients gave an informed consent, and the study was done according to Helsinki declarations.

3. Results :

This study included 2 randomly assigned groups; Group A included 40 patients that administered intrathecal normal saline; Group B included 40 patients that administered intrathecal Dexamethasone. This table showed that there was no significant difference between the studied groups regarding their age and sex (P-value>0.05). This table showed that there was no significant difference between the studied groups regarding their ASA classification and body weight (P-value>0.05) (Table 1).

Table (1): Baseline characteristics of the studied groups:

Items	Group A (no=40)	Group B (no=40)	P-value
Age	67.2±2.6	67.8±2.8	0.704
Sex **Males** **Females**	 16(40.0%) 24(60.0%)	 11(27.5%) 29(72.5%)	0.237
ASA **I** **II** **III**	 23(57.5%) 15(37.5%) 2(5.0%)	 25(62.5%) 13(32.5%) 2(5.0%)	0.582
Body weight	76.9±10.6	76.6±10.3	0.906

There was no significant difference between the studied groups regarding their baseline systolic blood pressure (136.9±16.1 vs 135.6±13.2) for group A and group B respectively. There was a significant high systolic BP in group B than group A group in the 1st (125.7±16.3 Vs 116.1±18.3) respectively, 2nd (123.9±12.4 Vs 110.9±18.1) respectively, 3rd (119.9±14.1 Vs 107.1±17.9) respectively and the 4th (118.4±13.4 Vs 106.2±15.9), respectively. There was significant difference between the studied groups regarding their systolic blood pressure, high systolic BP in group B than group A from 1st to 4th measure post spinal (P-value <0.015, 0.001,0.001, 0.001 respectively) (Table 2).

Table (2): Follow up of systolic blood pressure of the studied groups.

Items	Group A (no=40)	Group B (no=40)	P-value between groups
Pre SBP	136.9±16.1	135.6±13.2	0.689
SBP Post 1	116.1±18.3	125.7±16.3	0.015*
SBP Post 2	110.9±18.1	123.9±12.4	<0.001*
SBP Post 3	107.1±17.9	119.9±14.1	0.001*
SBP Post 4	106.2±15.9	118.4±13.4	<0.001*

***P-value is significant** **DBP: Diastolic blood pressure**

There was no significant difference between the studied groups regarding their baseline diastolic blood pressure (74.1±11 Vs 77.7±10.9) for group B and group A respectively. Following up of diastolic blood pressure demonstrated that there was a significant decrease of diastolic blood pressure in both groups at different times. However, there was higher diastolic BP in group B than group A first rom 1st (68.8±13.4Vs 63.1±10.7) to 2nd (64.7±8.2Vs60.3±9.3) 3rd (64.4±8.7 Vs 59±10.3), respectively. There was a significantly higher diastolic pressure in group B than group A from 1st to 3rd measure post spinal (P-Value= 0,041,0.027,0.014 respectively) (Table 3).

Table (3): Follow up of diastolic blood pressure of the studied groups.

Items	Group A (no=40)	Group B (no=40)	P-value
Pre DBP	77.7±10.9	74.1±11	0.145
DBP Post 1	63.1±10.7	68.8±13.4	0.041*
DBP Post 2	60.3±9.3	64.7±8.2	0.027*
DBP Post 3	59±10.3	64.4±8.7	0.014*
DBP Post 4	62.6±9.6	64.7±10.1	0.339

***P-value is significant DBP: Diastolic blood pressure**

There was no significant difference between the studied groups regarding their baseline Mean arterial blood pressure (93.3±10,8 Vs 94.5±8.9) (P-value>0.05) and there was significant difference between the studied groups regarding Mean arterial blood pressure , There was high mean arterial blood pressure in group B than group A from 1s t (84±10.3 Vs 95.5±8.7) Respectively 2nd (82.2 ± 11.7 Vs 94.8 ±7.6) respectively 3rd (81 ±11.6 Vs 92. ±8.1) respectively 4th (80.1 ±10.2 Vs 93.8 ±8.7) measure post spinal (P-Valu<0.001) (Table 4).

Table (4): Follow up of mean arterial blood pressure of the studied groups.

Items	Group A (no=40)	Group B (no=40)	P-value
Pre MAP	93.3±10.8	94.5±8.9	0.598
MAP Post 1	84±10.3	95.5±8.7	<0.001*
MAP Post 2	82.2±11.7	94.8±7.6	<0.001*
MAP Post 3	81±11.6	92.9±8.1	<0.001*
MAP Post 4	80.1±10.2	93.8±8.7	<0.001*

***P-value is significant MAP: Mean arterial blood pressure**

There was no significant difference between the studied groups regarding their baseline heart rate (P-value>0.05) and there was increased heart rate in group A than group B from 2^{nd} to 4^{th} measure. (P-Value =0.001,0.006,0.003 respectively) (Table 5).

Table (5): Follow up of Heart Rate of the studied groups.

Items	Group A (no=40)	Group B (no=40)	P-value
Pre HR	91.4±13.5	90.8±15.9	0.856
HR Post 1	92.2±15.9	87.2±15.6	0.158
HR Post 2	93.7±16.5	84.8±14	0.011*
HR Post 3	93.9±16.2	84.1±14.3	0.006*
HR Post 4	93.2±15.6	83.5±13.1	0.003*

***P-value is significant**

There was a significant increase of Bromage score in group B after 5 minutes postoperative only (P-value=0.030). There was insignificant difference of Bromage score in both groups after 10 and 15 minutes postoperative and in each group at different times (P-value>0.05) (Table 6).

Table (6): Follow up of Bromage score 9 every 5 minutes of the studied groups.

Items	Group A (no=40)	Group B (no=40)	P-value
1st Bromage score 9	3.8±0.5	4±0.0	0.030*
categories			
II	2(5.0%)	0(0.0%)	
III	3(7.5%)	0(0.0%)	0.055
IV	35(87.5%)	40(100%)	
2nd Bromage score 9	3.9±0.3	4±0	0.179
categories			
II	1(2.5%)	0(0.0%)	
III	1(2.5%)	0(0.0%)	0.494
IV	38(95.0%)	40(100%)	
3rd Bromage score 9	3.9±0.2	4±0	0.320
categories			
III	1(2.5%)	0(0.0%)	0.999
IV	39(97.5%)	40(100%)	
4th Bromage score 9	4±0	4±0	----
categories			
IV	40(100%)	40(100%)	----

***P-value is significant**

This table showed that there was a significant higher proportion of patients not in need to Ephedrine and atropine in group B than group A (P-value<0.001). There was insignificant higher proportion of patients without complications in group B than group A (P-value>0.05) but with clinical significance (Table 7).

Table (7): Comparison between the studied groups regarding the need to ephedrine or atropine and its dose and postoperative complications.

Items	Group A (no=40)	Group B (no=40)	P-value
Need			
No	15(37.5%)	39(97.5%)	
Ephedrine	24(60.0%)	1(2.5%)	<0.001*
Atropine	1(2.5%)	0(0.0%)	
Dose of ephedrine	(no=24) 26.3±11.1	(no=1) 15±.	0.329
No			
Vomiting and	35(87.5%)	40(100%)	
shivering	1(2.5%)	0(0.0%)	
Nausea and vomiting	1(2.5%)	0(0.0%)	
Shivering	1(2.5%)	0(0.0%)	0.055
Nausea & vomiting &	2(5.0%)	0(0.0%)	
Shivering			

***P-value is significant**

4. Discussion:

This study was carried out at Beni-Suef University Hospital patients aged 60 years or older undergoing lower limb orthopedic surgeries to evaluate the role of intrathecal dexamethasone in decreasing the incidence of post spinal anesthesia hypotension in geriatric patients undergoing orthopedic surgery.

There was no significant difference between the studied groups regarding their baseline systolic blood pressure (136.9±16.1 vs 135.6±13.2) for group A and group B respectively. There was a significant high systolic BP in group B than group A group in the 1st (125.7±16.3 Vs 116.1±18.3) respectively, 2nd (123.9±12.4 Vs 110.9±18.1)

respectively, 3rd (119.9±14.1 Vs 107.1±17.9) respectively and the 4th (118.4±13.4 Vs 106.2±15.9), respectively.

There was no significant difference between the studied groups regarding their baseline diastolic blood pressure (74.1±11 Vs 77.7±10.9) for group B and group A respectively. Following up of diastolic blood pressure demonstrated that there was a significant decrease of diastolic blood pressure in both groups at different times. However, there was higher diastolic BP in group B than group A from 1st (68.8±13.4Vs 63.1±10.7) to 2nd (64.7±8.2Vs60.3±9.3) 3rd (64.4±8.7 Vs 59±10.3), respectively.

There was no significant difference between the studied groups regarding their baseline Mean arterial blood pressure (93.3±10,8 Vs 94.5±8.9) (P-value>0.05) and there was significant difference between the studied groups regarding Mean arterial blood pressure, there was high mean arterial blood pressure in group B than group A from 1s t (84±10.3 Vs 95.5±8.7) Respectively 2nd (82.2 ± 11.7 Vs 94.8 ±7.6) respectively 3rd (81 ±11.6 Vs 92. ±8.1) respectively 4th (80.1 ±10.2 Vs 93.8 ±8.7) measure post spinal (P-Valu<0.001).

To our knowledge few studies have evaluated the use of intrathecal dexamethasone for post-spinal hypotension. Ashoor et al., (2021) in their study about the use of dexamethasone in blunting post-spinal hypotension in geriatric patients undergoing orthopedic surgery agreed with this study and revealed that SBP at 5th and 10th minutes were statistically significantly higher among dexamethasone group than control group, while DBP and MBP at 5th, 10th, and 15th minutes were statistically significantly higher among dexamethasone group than control group [7].

Several studies evaluated the use of intrathecal dexamethasone for different purposes and assessed the changes in hemodynamics of patients. The study of Esmat et al., (2022) [10] about the prevention of post-spinal anesthesia shivering in gynecological surgeries using dexamethasone found that the repeated measured values of MBP (5 min, 10 min, 15 min, 20 min and 25 min after intrathecal injection) were statistically significant lower at the control group than the dexamethasone group. Pyasetska in 2020 [11] demonstrated in their study about the efficacy of intrathecal dexamethasone for prevention of early complications following Caesarean Section that the mean arterial pressure (MAP) was statistically significant higher in the group received dexamethasone at 5 min and 10 min. Kalani et al., (2017) [12] studied the effect of ondansetron and dexamethasone on nausea

and vomiting under spinal anesthesia and found that in dexamethasone group, the mean systolic pressure was 125.60±5.07 and the mean diastolic pressure was 78.93±3.54. Only 9.1% of patients had systolic hypotension and 6.6% experienced diastolic hypotension. Shah & Habeeba in 2022 [13] compared dexamethasone and dexmedetomidine for decreasing the post spinal shivering during cesarean section and revealed that the mean SBP and DBP were significantly high in dexamethasone group compared to dexmedetomidine group. There was no significant difference between the studied groups regarding their baseline heart rate (90.8±15.9Vs 91.4±13.5) and there was an increased heart rate in group A than group B from 2nd (84.8±14 Vs93. 7±16.5) 3rd (84.1±14.3Vs93.9±16.2) 4th measure, (83.5±13.1Vs93.2 ±15.6) with (P-Value=0.001,0.006,0.003 for all measures, respectively

Also, Esmat et al., (2022) [10] revealed in their study about the prevention of post-spinal anesthesia shivering in gynecological surgeries using dexamethasone found that the changes in heart rate values during the study period were comparable between the studied groups with lower rates in the dexamethasone group.

Chavan et al., (2021) demonstrated in their study about the effectiveness of preoperative dexamethasone on postoperative pain during gynecological surgeries under spinal anesthesia that the difference between mean heart rate at baseline, at induction, during surgery and immediately after surgery was not statistically significant between patients in dexamethasone group and control group. However, at all periods the mean heart rate was higher in dexamethasone than in the control group. The lower heart rate in dexamethasone group in our study could be due to the effectiveness of dexamethasone in controlling the post spinal hypotension [14].

Near results were reported by the study of Ashoor et al., (2021) about the use of dexamethasone in blunting post-spinal hypotension in geriatric patients undergoing orthopedic surgery who found that the mean age of patients was 75.8±5.4 years and most of them were females (66%) but most of them were ASA II. There was a significant increase of Bromage score in group B after 5 minutes postoperative only (4±0.0 Vs 3.8±0.5). There was insignificant difference of Bromage score in both groups after 10 and 15 minutes postoperative and in each group at different times [7].

Approximately near results were reported by the study of Elshahawy et al., (2022) [15]

about the comparison between dexmedetomidine and dexamethasone as adjuvants to intrathecal bupivacaine in emergency orthopedic lower limb operations. They reported that patients in dexamethasone group had a significantly earlier start of motor block compared to the control group however, later on both dexamethasone group and the control group had the same Bromage score. Chavan et al., (2021) in their study evaluating the effectiveness of dexamethasone on postoperative pain during gynecological surgeries Modified Bromage Score did not differ significantly between patients received dexamethasone and those in control group before induction, with induction, during and after surgery [14].

There was a significantly higher proportion of patients not in need to ephedrine and atropine in group B than group A (97.5% Vs (37.5%). The mean dose of ephedrine required by group B was 15±0.0 and for group A was 26.3±11.1. Bani-Hashem et al., (2011) in their study evaluating the addition of dexamethasone to spinal anesthesia in orthopedic surgeries found that hypotension was mild to moderate in control and dexamethasone groups bur more hypotension prevalence was observed in control group and required 20 mg IV ephedrine to restore his blood pressure. There was an insignificant higher proportion of patients without complications in the form of nausea, vomiting and shivering in dexamethasone group than control group (100% Vs 87.5%)) but with clinical significance [16].

In consistence with our results was Moeen & Moeen, (2017) [17] who revealed in their study comparing intrathecal dexamethasone and meperidine for prevention of shivering during transurethral prostatectomy revealed that only 1 patient complained of nausea and vomiting, and 2 patients complained of shivering. Abdel-Aleem et al., (2012) [18] evaluated in their study the co-administration of dexamethasone with morphine in cesarean section and found that patients in the dexamethasone group were 3 times less likely to develop either nausea or vomiting than those in the placebo group. When vomiting did occur, the number of attacks was significantly lower in the dexamethasone group than in the placebo group.

Imeh et al., (2014) [19] found in their study about the use of dexamethasone and its combination with ondansetron as prophylactic antiemetic in caesarean section that in dexamethasone group (63%) of patients had no nausea and vomiting, (16.7%) had nausea only and (20.3%) had vomiting. The difference could be explained due to the different nature of surgery as in Caesarian

section, it is and abdominal surgery with intestinal manipulation unlike the orthopedic surgeries in our study. The exact mechanism of dexamethasone in preventing nausea and vomiting is still unknown, but it may be due to inhibition of prostaglandin synthesis [12].

5. Conclusion and recommendations:

In Conclusion, intrathecal dexamethasone is highly effective in controlling the post-spinal hypotension in geriatric population undergoing lower limb orthopedic surgeries under spinal anesthesia maintaining the hemodynamics stability of the patients without major adverse effects. In order to prevent post-spinal hypotension in the elderly, intrathecal dexamethasone is recommended to be administered as an adjuvant in spinal anesthesia. There has to be more research done with bigger samples, more kinds of procedures, and older participants. Further research is needed to compare various dosages of dexamethasone and the systemic route to find the best effective dose with lowest adverse effects. Researchers have suggested looking into alternatives to dexamethasone as an anesthetic adjuvant.

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