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Fixed Dose versus Height and Weight Adjusted Dose of Bupivacaine for Spinal Anesthesia in Elective Caesarean Section

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ABSTRACT

Background: Spinal anesthesia is gaining global popularity. Caesarian section with spinal anesthesia are considered one of the comment applied surgeries. Hypotension is one of most frequent side effect of spinal anesthesia, if uncorrected causes adverse effect on the mother and neonate .

The aim of this study is to assess the hemodynamic measures and anesthetic outcome between fixed dose and adjusted for weight and height dose of bupivacaine.

Patients and method: A comparative clinical trial double-blinded study was conducted in the operation theatre of the obstetric surgical department, Baghdad Teaching Hospital, Baghdad, Iraq during the period from the 1st of April 2022 to the 1st of July 2023.

A total of 100 pregnant women were included in this study who underwent cesarean section under spinal anesthesia and met the inclusion criteria. These women were allocated randomly into two groups:

Group A: Fixed dose group: 50 patients received an intrathecal dose of heavy bupivacaine (0.5%) 2.5 ml.

Group B: adjusted dose group: 50 patients received intrathecal adjusted dose heavy bupivacaine (0.5%) according to height and weight of patient from Hartens chart.

Results: A higher mean SBP was reported among the adjusted dose group at 15 min., 20 min., 30 min., and 40 min. (P=0.002, 0.002, <0.001, and <0.001 respectively). A higher mean DBP was reported among the adjusted dose group at 10 min., and 20 min. (P=0.037, and 0.005 respectively). A higher mean MBP was reported among the adjusted dose group at 30 min., and 40 min. (P=0.001, and <0.001 respectively). A lower mean HR due to bradycardia among some cases was reported among the fixed-dose group at 10 min., 30 min., and 40 min. (P=0.024, 0.034, and <0.001 respectively) lowest 10 min., 30 min., and 40 min. (P=0.024, 0.034, and <0.001 respectively). There 40.0% (20) patients in the fixed-dose group received an ephedrine dose once and 24.0% (12) patients in the fixed-dose group received an ephedrine dose more than once, and this was significantly higher than the adjusted dose (P=0.027).

Conclusion: Adjusting bupivacaine dose in spinal anesthesia for elective cesarean sections provides favorable hemodynamic stability with adequate anesthetic outcome in both groups.

KEYWORD: spinal anesthesia, fixed dose, adjusted dose, bupivacaine, hemodynamic stability.

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INTRODUCTION

Cesarean sections with spinal blocks are considered one of the comments applied surgeries. The anesthesiologist's efforts continuously focus on reducing the anesthetic unfavorable side effects that could affect both mothers and newborns.[1] The commonly observed hypotension during spinal block, if uncorrected, causes adverse effects on the mother and the neonate.[2] The means to reliably prevent maternal hypotension

under spinal anesthesia continues to be avoided by practicing anesthetists. Thus, one of the important methods to reduce hemodynamic changes would be to limit widespread sympathetic block during spinal anesthesia. This can be achieved by restricting the spinal segment block desired for a cesarean section.[3] While some studies have identified the patient's height and the sensory block level as risk factors for hypotensive episodes in the mother during cesarean section others have been inconclusive. Nevertheless, the use of a dose of hyperbaric bupivacaine adjusted to the patient's weight and height has been shown to limit the spinal segment block spread.[4] The dose adjustment study has been based on different populations. Globally the height of women is generally variable according to genetical and racial reasons. Thus, our study focused on reporting whether the dose adjusted to weight and height bupivacaine would be one of the measures to reduce maternal side effects due to spinal anesthesia.

Hypotension is common with CNB anesthesia, especially spinal anesthesia. Preventing hypotension, rather than treating it after it has occurred, is associated with better fetal and maternal outcomes. Aim to maintain the systolic BP at ≥90% of baseline. Prophylactic pressor agents are key, but it is also important to minimize aortocaval occlusion (i.e. lateral tilt) and a fluid co- load (10-15mL/kg of crystalloid) should be routine unless fluid is being restricted.[5]

PATIENTS AND METHOD

A comparative clinical trial double blinded study was conducted among pregnant women admitted for elective cesarean section. The study was undertaken in the operation theatre of the obstetric surgical department, Baghdad Teaching Hospital, in, Iraq during the period from 1st of April 2022 to 1st of July 2023.

Inclusion Criteria:

- Age > 18 years.
- ASA physical status II.
- Term pregnancy.
- Singleton pregnancy
- Presenting for elective cesarean section under spinal anesthesia.
- BMI 18-29.9

Exclusion Criteria:

- Patient refusal.
- Preexisting hypertension.
- Preeclampsia.
- Contraindication to spinal anesthesia.
- Placenta previa or accrete.
- Patients with contra indication to any drugs used during surgery.
- Patients with failure of trial spinal anesthesia and conversion to general anesthesia.

Written consent was taken from all the patients included in the study. The objectives of the study were informed to the patients by the researcher and all the data will be used for study purposes, and their personal information was collected via serial number or ID number without any Identity.

A total of 100 pregnant women were included in this study who underwent cesarean section under spinal anesthesia and met the inclusion criteria. These women were allocated randomly into two groups:

- Group A: Fixed dose group: 50 patients received an intrathecal dose of heavy bupivacaine (0.5%) 2.5 ml.
- Group B: adjusted dose group: 50 patients received intrathecal adjusted dose heavy bupivacaine (0.5%) according to height and weight of patient from Harten's chart.[7]

Table 1: Adjusted dose regimen for hyperbaric bupivacaine 0.5% when used for spinal anesthesia for Caesarean section. Values are milliliters.[7]

Patient weight (kg)	Patient height (cm)								
	140	145	150	155	160	165	170	175	180
50	1.5	1.7	1.8	1.9					
55	1.5	1.6	1.8	1.9	2.0				
60	1.4	1.6	1.7	1.8	2.0	2.1			
65	1.4	1.5	1.7	1.8	1.9	2.1	2.2		
70	1.3	1.5	1.6	1.8	1.9	2.0	2.2	2.3	
75		1.4	1.6	1.7	1.9	2.0	2.1	2.3	2.4
80		1.4	1.5	1.7	1.8	2.0	2.1	2.2	2.4
85			1.5	1.6	1.8	1.9	2.1	2.2	2.3
90			1.4	1.6	1.7	1.9	2.0	2.2	2.3
95				1.5	1.7	1.8	2.0	2.1	2.3
100				1.5	1.7	1.8	1.9	2.1	2.2
105					1.6	1.7	1.9	2.0	2.2
110						1.7	1.8	2.0	2.2

The enrollment of the patients was random. The random allocation was ensured by simple random sampling (each patient admitted and fulfilled the inclusion criteria was enrolled by lottery method to either group A or group B). The allocation was ended when each group fulfilled 50 patients.

The data was collected using a structured data collection that recorded the following information:

- Age, parity, gestational age, height, and weight.
- Monitoring at baseline, 5, 10, 15, 20, 30, and 40 minutes for systolic, diastolic, and mean blood pressure, heart rate.
- Use of 6 mg ephedrine (as bolus dose) and total dose of ephedrine
- The level of block by temperature sensation at 5 minutes, and after 40 minutes.
- The episodes of nausea and vomiting.

Preoperative patient information was taken from the chart and direct assessment. The age, weight, height, and past medical and surgical history were obtained for each participant. Upon arrival at the operating room and before the induction of the anesthesia.

Two IV lines were inserted 18G to each patients. Non-invasive blood pressure cuff, pulse oximeter, and electrocardiogram were conducted to the patients with continuous monitoring of them during the operation. Premedication on as (Metoclopramide 10 mg) intravenously was given 10 min before the operation. The patient was put in a sitting position, aseptic measures used included (proper hand washing, wearing of aseptic gown and a sterile surgical gloves, surgical mask) skin was sterilized with povidone iodine in a proper manner, and skin infiltration was made at the entry point of L3/L4 or L4/L5 with lidocaine 2 ml of 2%. Spinal anesthesia was given for group A fixed dose of hyperbaric bupivacaine 0.5% 2.5 ml (12.5mg) and group B was given height and weight adjusted dose of hyperbaric bupivacaine 0.5% according to Hartens chart after confirmation with CSF drops using 25 G pencil point.

Spinal needles were inserted in the midline at L3 L4 or L4-5 vertebral interspace, and started co-load with lactated ringer's 10ml /kg.

The patient was put in the supine position with a wedge put under the right hip immediately after spinal anesthesia.

The level of the block was checked by bilateral sensory block height, in the midclavicular line, and was determined by a single anesthesiologist in all cases, 5 minutes after subarachnoid injection, using cold sensation modalities, for the assessment of block.

For block height for temperature sensation, ice cube was used moving caudad from unblocked cervical segments to blocked segments. In this case, the patient was first asked, "How does this feel? When a an ice cube made contact with her skin.

Achieving a bilateral sensory block of cold sensation to the T4 dermatome level. Block height was assessed again at 40 minutes. (which represents the period that Marcaine approximately reach its maximal effect).

Hemodynamic data including systolic, diastolic, mean arterial (MAP) and heart rate was recorded every 5 minute for the duration of surgery . Hypotension, as a (20 % decrease from baseline (MAP) was treated with 6 mg IV ephedrine as boluses.

Any patient developed hemodynamic instability managed accordingly and considered in our results.

Any patient developed partial spinal anesthesia managed accordingly and considered in our results.

Any patient developed nausea and vomiting managed accordingly and considered in our results.

Approval was obtained from the Scientific Council of Anesthesia and Intensive Care of the Iraqi Board of Medical Specializations and the Ministry of Health.

Data were introduced into Microsoft Excel sheet 2019 and loaded into SPSS (Statistical Package for Social Sciences) version (24). Parametric data are presented as mean and standard deviation. Categorical data was presented as numbers and percentages. Chi-square test and Fisher exact test was used to test homogeneity. An independent t-test was used to measure the difference between groups' parametric variables. P-value < 0.05 was considered as discrimination of significance.

RESULTS

The study sample were two groups the fixed-dose 2.5 mL group and the adjusted dose group, 50 patients who succeeded in spinal anesthesia and fulfilled the inclusion criteria were enrolled in each group. No failure cases in the study.

In this study There was no significant difference in the mean age distribution between the two groups (P=0.122). There was no significant distribution in the mean BMI distribution between the two groups (P=0.094). As shown in the Table 2.

Table 2: Demographic and obesity characteristics among the study groups.

Variables	Study group	N	Mean ± SD	P- value
Age	Fixed dose 2.5 ml	50	28.42 ± 5.510	0.122
	Adjusted dose	50	29.96 ± 4.275	
Height	Fixed dose 2.5 ml	50	164.08 ± 4.534	0.011
	Adjusted dose	50	166.64 ± 5.329	

Weight	Fixed dose 2.5 ml	50	78.14 ± 8.012	0.004
	Adjusted dose	50	82.60 ± 7.239	
BMI	Fixed dose 2.5 ml	50	28.98 ± 2.196	0.094
	Adjusted dose	50	29.75 ± 2.343	

There was no significant difference in the history of parity between the two groups (P=0.600). As shown in the Table 3.

Table 3: Obstetric history among the study groups.

Variables		Study group				P- value
		Fixed dose 2.5 ml		Adjusted dose		
		N.	%	N.	%	
Parity	< 3	28	56.0	28	56.0	0.600
	3-5	22	44.0	21	42.0	
	> 5	0	0.0	1	2.0	

There were no significant differences in the systolic blood pressure measurements between the two groups at the baseline, 5 min., and 10 min. (P=0.985, 0.093, 0.099 respectively). A higher mean SBP was reported among the adjusted dose group at 15 min., 20 min., 30 min., and 40 min. (P=0.002, 0.002, <0.001, and <0.001 respectively). As shown in the Table 4.

Table 4: The differences in systolic blood pressure measurements between the study groups.

Variables	Study group	N	Mean	SD	P-value
Baseline SBP	Fixed dose 2.5 ml	50	118.4400	13.12757	0.985
	Adjusted dose	50	118.4000	8.17163	
SBP at 5 min.	Fixed dose 2.5 ml	50	93.28	16.024	0.093
	Adjusted dose	50	98.24	13.112	
SBP at 10min.	Fixed dose 2.5 ml	50	99.80	13.349	0.099
	Adjusted dose	50	105.16	18.467	
SBP at 15min.	Fixed dose 2.5 ml	50	107.68	10.631	0.002
	Adjusted dose	50	116.00	15.439	
SBP at 20min.	Fixed dose 2.5 ml	50	114.84	9.696	0.002
	Adjusted dose	50	120.24	7.484	
SBP at 30min.	Fixed dose 2.5 ml	50	113.24	8.331	<0.001
	Adjusted dose	50	124.04	8.549	
SBP at 40min.	Fixed dose 2.5 ml	50	115.28	8.516	<0.001
	Adjusted dose	50	127.56	8.036	

There were no significant differences in the diastolic blood pressure measurements between the two groups at the baseline, 5 min., 15 min., 30 min., and 40 min. (P=0.797, 0.727, 0.724, 0.112, and 0.469 respectively). A higher mean DBP was reported among the adjusted dose group at 10 min., and 20 min. (P=0.037, and 0.005 respectively). As shown in the Table 5.

Table 5: The differences in diastolic blood pressure measurements between the study groups.

Variables	Study group	N	Mean	SD	P- value
Baseline DBP	Fixed dose 2.5 ml	50	75.32	8.910	0.797
	Adjusted dose	50	75.72	6.468	
DBP at 5 min.	Fixed dose 2.5 ml	50	55.00	12.920	0.727
	Adjusted dose	50	55.92	13.382	
DBP at 10 min.	Fixed dose 2.5 ml	50	57.92	11.295	0.037
	Adjusted dose	50	62.68	11.247	
DBP at 15 min.	Fixed dose 2.5 ml	50	67.16	7.265	0.724
	Adjusted dose	50	67.68	7.432	
DBP at 20 min.	Fixed dose 2.5 ml	50	70.08	7.439	0.005
	Adjusted dose	50	73.92	5.784	
DBP at 30 min	Fixed dose 2.5 ml	50	71.40	6.779	0.112
	Adjusted dose	50	74.00	9.236	
DBP at 40 min.	Fixed dose 2.5 ml	50	73.48	6.528	0.469
	Adjusted dose	50	74.64	9.200	

There were no significant differences in the mean blood pressure measurements between the two groups at the baseline, 5 min., 10 min., 15 min., and 20 min. (P=0.958, 0.855, 0.100, 0.260, and 0.732 respectively). A higher mean MBP was reported among the adjusted dose group at 30 min., and 40 min. (P=0.001, and <0.001 respectively). As shown in the Table 6.

Table 6: The differences in the mean blood pressure measurements between the study groups.

Variables	Study group	N	Mean	SD	P- value
Baseline MBP	Fixed dose 2.5 ml	50	92.40	7.273	0.958
	Adjusted dose	50	92.32	7.859	
MBP at 5 min.	Fixed dose 2.5 ml	50	69.88	14.805	0.855
	Adjusted dose	50	70.44	15.719	
MBP at 10 min.	Fixed dose 2.5 ml	50	72.48	9.710	0.100
	Adjusted dose	50	75.84	10.504	
MBP at 15 min.	Fixed dose 2.5 ml	50	81.08	8.599	0.260
	Adjusted dose	50	82.80	6.407	
MBP at 20 min.	Fixed dose 2.5 ml	50	85.72	7.185	0.732
	Adjusted dose	50	86.16	5.530	
MBP at 30 min.	Fixed dose 2.5 ml	50	84.72	7.605	0.001
	Adjusted dose	50	89.56	6.797	
MBP at 40 min.	Fixed dose 2.5 ml	50	85.60	6.773	<0.001
	Adjusted dose	50	91.96	6.983	

There were no significant differences in the mean heart rate measurements between the two groups at the baseline, 5 min., 15 min., and 20 min., (P=0.190, 0.088, 0.366, and 0.541 respectively). A lower mean HR due to bradycardia among some cases was reported among the fixed-dose group at 10 min., 30 min., and 40 min. (P=0.024, 0.034, and <0.001 respectively). As shown in the Table 7.

Table 7: The differences in heart rate measurements between the study groups.

Variables	Study group	N	Mean	SD	P-value
Baseline HR	Fixed dose 2.5 ml	50	98.76	7.104	0.190
	Adjusted dose	50	96.40	10.466	
HR at 5 min.	Fixed dose 2.5 ml	50	92.72	16.680	0.088
	Adjusted dose	50	98.28	15.590	
HR at 10 min.	Fixed dose 2.5 ml	50	90.84	14.853	0.024
	Adjusted dose	50	97.68	15.069	
HR at 15 min.	Fixed dose 2.5 ml	50	90.52	10.254	0.366
	Adjusted dose	50	92.68	13.323	
HR at 20 min.	Fixed dose 2.5 ml	50	92.84	7.900	0.541
	Adjusted dose	50	94.00	10.777	
HR at 30 min.	Fixed dose 2.5 ml	50	84.28	7.094	0.034
	Adjusted dose	50	89.92	12.466	
HR at 40 min.	Fixed dose 2.5 ml	50	86.92	5.197	<0.001
	Adjusted dose	50	91.60	8.633	

Figure 1 shows that patients in the fixed-dose group required an ephedrine dose at 5 minutes 28 patients vs. 18 in the adjusted group, at 10 minutes 16 patients in the fixed-dose group vs. 14 in the adjusted group, and only 2 patients at 15 minutes received ephedrine dose were in the fixed-dose group.

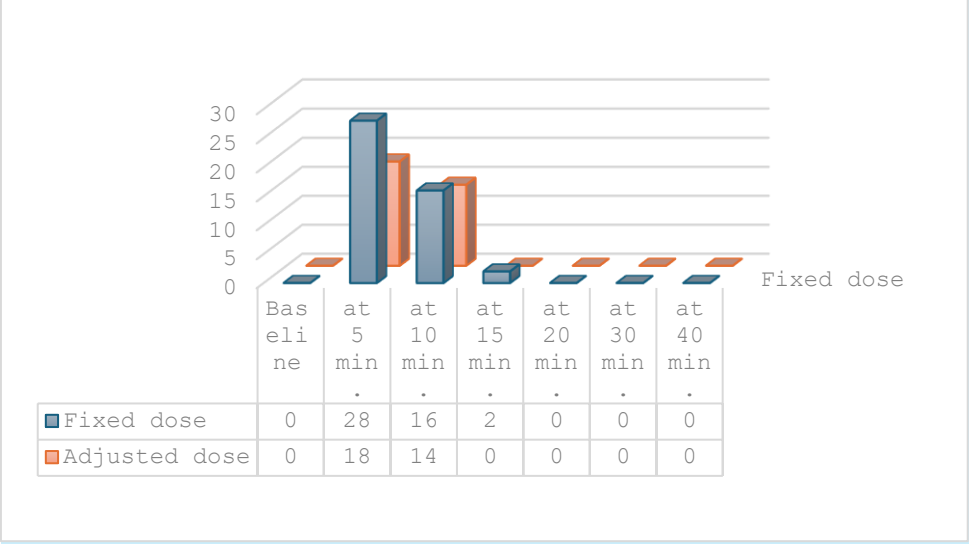

Figure 1: The time of ephedrine doses used among the study groups.

There 40.0% (20) patients in the fixed-dose group received an ephedrine dose once and 24.0% (12) patients in the fixed-dose group received an ephedrine dose more than once, while 18.0% (9) patients in the adjusted dose group received an ephedrine dose once and 22.0% (11) patients in the adjusted dose group received an ephedrine dose more than once, and this difference was significant (P=0.027). As shown in the Table 8.

Table 8: The number of ephedrine doses used among the study groups.

Ephedrine dose (6 mg) used	Study group				P - value
	Fixed dose 2.5 ml		Adjusted dose		
	N.	%	N.	%	
None	18	36.0	30	60.0	0.027
Once	20	40.0	9	18.0	
More than one time	12	24.0	11	22.0	

Figure 2 shows that 20 patients from the fixed-dose group and 9 patients from the adjusted-dose group needed 6 mg of ephedrine. There were 6 patients (first boluses) from the fixed-dose group and 9 patients from the adjusted-dose group who needed 12 mg(second boluses) of ephedrine. There were 5 patients from the fixed-dose group and 2 patients from the adjusted-dose group who needed 18 mg (third boluses) of ephedrine. There were 1 patient from the fixed-dose group who needed 24 mg (fourth boluses) of ephedrine.

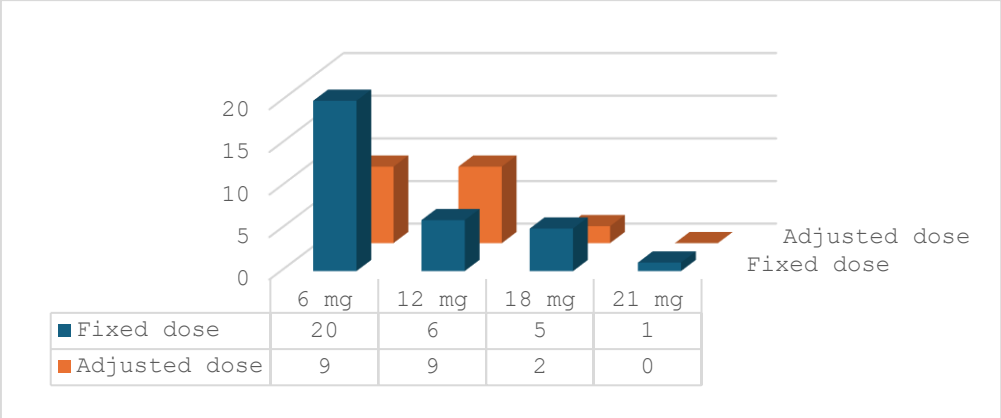

Figure 2: The total doses of ephedrine used among the study groups.

The majority of patients with a higher level of the block by temperature at 5 minutes were among patients in the fixed-dose group (P<0.001). The majority of patients with a higher level of block by temperature at 40 minutes were among patients in the fixed-dose group (P=0.199). As shown in the Table 9.

Table 9: The differences in the level of the block by touch and temperature between the study groups.

		Study group				P-value
		Fixed dose 2.5 ml		Adjusted dose		
		N.	%	N.	%	
Level block temperature at 5 min.	T 3	10	20.0	2	4.0	<0.001
	T 4	20	40.0	36	72.0	
	T 5	10	20.0	10	20.0	
	T6	10	20.0	2	4.0	
Total		50	100.0	50	100.0	
Level block temperature at 40 min.	T 3	5	10.0	1	2.0	0.209
	T 4	30	60.0	38	76.0	
	T 5	10	20.0	6	12.0	
	T 6	5	10.0	5	10.0	
Total		50	100.0	50	100.0	

The highest proportion of patients within the fixed-dose group developed nausea and vomiting 52.0% (26), while the highest proportion of patients within the adjusted-dose group did not develop nausea and vomiting 80.0% (40). As shown in the Table 10.

Table 10: The distribution of nausea and vomiting among the study groups.

Nausea and vomiting	Study group				P- value
	Fixed dose 2.5 ml		Adjusted dose		
	N.	%	N.	%	
Yes	26	52.0	10	20.0	0.001
No	24	48.0	40	80.0	
Total	50	100.0	50	100.0	

DISCUSSION

Spinal anesthesia in cesarean section is gaining popularity nowadays. Due to its relatively safe and accepted approach.[8] It accounts for nearly 95% of elective and 45% of emergency procedures performed under spinal or spinal-epidural anesthesia.[9,10] However, studying the differences in dosing regimens and their effects on hemodynamic stability and the anesthetic block was the scope of the current study.

Besides, the two groups in our study were without significant differences in parity and in the baseline readings of systolic, diastolic, and mean blood pressure and heart rate. This goes in line with previously published studies[11-13] and Saad et al., study.[12]

The current study found that systolic blood pressure was significantly higher among patients in the adjusted group at 15, 20, 30, and 40 minutes. Also, diastolic blood pressure was significantly higher among patients in the adjusted group at 10, and 20 minutes, furtherly mean blood pressure was significantly higher among patients in the adjusted group at 30, and 40 minutes. Shrestha et al.,[12] studied the differences between fixed-dose bupivacaine and adjusted dose by Harten chart and reported that hypotensive episodes among patients in the fixed-dose group were significantly higher than the adjusted group (40.0% vs. 16%, P=0.003). They also reported 3 cases of bradycardia among the fixed-dose. Another study by Harten et al.,[13] reported hypotension among 28 (71.7%) parturient in the fixed bupivacaine dose group and 22 (50.0%) parturient in the adjusted dose group which was significant P=0.035. Subedi et al.,[14] also found similar results and reported that lower mean systolic blood pressure and more frequent hypotensive episodes were among the fixed-dose group. These findings might be attributed to the fact that some parturient may have taken a higher than required bupivacaine dose and subsequently a higher block level.

Our study reported that the total number of ephedrine 6 mg doses used was significantly higher among the fixed-dose group. Similar to Saad et al.,[15] that reported the mean of ephedrine doses among normotensive parturient with fixed-dose bupivacaine was a highly significant than the adjusted for weight and height group (25.1±14.7 vs. 5.8±4.4 P=0.0001). Furthermore, Harten et al., study[13] reported that the proportion of parturient needed ephedrine was significantly higher among the fixed group than the adjusted group (79.5% vs. 56.8% respectively, P=0.022). The higher proportion of hypotensive episodes among patients in the fixed-dose group and the significantly lower mean SBP, DBP, and MBP reported in our study and the previously mentioned studies explained the higher ephedrine doses needed in the fixed-dose group.

The current study reported a significantly higher level of block by temperature reported among the fixed-dose group at 5 minutes, and no significant difference at 40 minutes. While Białowolska et al., study[8] reported no significant difference between the highest level of block between the two groups. They also explained that the difference in block level might not be influenced by the dose itself, but also by the height of the patients, and remaining in a sitting position for at least 10 minutes after the injection.

The current study reported that nausea and/or vomiting episodes were both higher among the fixed-dose group. Similar to what was reported in previous studies.[13,14] Nausea and vomiting are common side effects of both hypotension and ephedrine[16,17], since the cases with lower blood pressure and needed ephedrine were higher among the fixed-dose group, thus, more patients developed nausea and vomiting were reported among the fixed-group.

CONCLUSION

- The mean of systolic, diastolic and mean blood pressure was significantly higher among cases with an adjusted dose of bupivacaine
- The mean of heart rate was significantly lower among cases with a fixed dose of bupivacaine.
- A significantly higher total dose of ephedrine was used among cases with a fixed dose of bupivacaine.
- Nausea and vomiting were significantly higher among cases with a fixed dose of bupivacaine.

RECOMMENDATIONS

Spinal anesthesia with an adjusted dose of bupivacaine was recommended since it provides a significantly more favorable hemodynamic stability.

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