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COMPARISON OF SPINAL BLOCK CHARACTERISTICS BETWEEN HEIGHT AND WEIGHT BASED DOSAGE VERSUS FIXED DOSAGE OF INTRATHECAL BUPIVACAINE FOR ELECTIVE CAESAREAN SECTION: A RANDOMIZED CLINICAL TRIAL

Dr. Rohit Kamal [1]*, Dr. Keerthana. M [2], Dr. Gunasekaran. K [3] and Dr. Reesha Joshi [4]

[1] Senior Resident, Department of Anaesthesiology, Al Azhar Medical College.
*Corresponding Author Email: rohankamal@gmail.com
[2] Post Graduate, Department of Anaesthesiology, Saveetha Medical College and Hospital.
[3] Professor, Department of Anaesthesiology, Saveetha Medical College and Hospital.
[4] Assistant Professor, Department of Anaesthesiology, Saveetha Medical College and Hospital.

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Abstract

Introduction Obstetric anesthesia is a unique subspecialty of anesthesia which demands understanding of maternal physiology, co morbid conditions complicating pregnancy, and management of critical events during child birth and surgery. The purpose of this study is to analyse the characteristics of spinal block achieved with height and weight based dose of bupivacaine with fentanyl versus a fixed dosage of bupivacaine with fentanyl in elective caesarean section patients so as to find the optimum dose of drug required for adequate anaesthesia, which in turn could reduce the usage of vasopressors. **Material and Methods** The study utilized a prospective, randomized, double-blind design to evaluate two spinal anesthesia approaches in elective LSCS. Inclusion criteria comprised ASA I and II term parturients, while exclusion criteria included emergency LSCS and specific medical conditions. Patients were allocated into AD Dose and Fixed Dose groups, with sample size determined via power analysis. Data analysis involved SPSS software, assessing sensory blockade, hemodynamics, and postoperative outcomes. **Results** In the AD group, maximal sensory blockade was achieved in 138 secs vs. 104.14 secs in FD, statistically significant (p=0.003). Time to T6 blockade was 98.35 secs in AD vs. 76.59 secs in FD, significant (p=0.013). Time to T4 blockade was 136.46 secs in AD vs. 103.51 secs in FD, significant (p=0.013). Onset of motor blockade was significantly faster in AD (164 secs) vs. FD (122 secs) with p=0.0005. APGAR scores and block quality showed no significant differences between groups, and no complications or bradycardia occurred in either group. **Conclusion** Our study demonstrates that adjusting the dosage of bupivacaine based on height and weight effectively provided adequate anesthesia for elective cesarean sections, while also promoting greater hemodynamic stability and reducing the requirement for vasopressors to manage maternal hypotension.

Keywords: Caesarean Section, Body Height, Body Weight, Local Anesthetics, Spinal Anesthesia, İntrathecal Bupivacaine.

INTRODUCTION

Obstetric anesthesia is a unique subspecialty of anesthesia which demands understanding of maternal physiology, co morbid conditions complicating pregnancy, and management of critical events during child birth and surgery.[1] The anaesthesiologist provides analgesia during vaginal delivery and anesthesia for surgical delivery of the foetus in both elective and emergent situations. In addition they take the role as a perioperative physician and intensivist for high risk obstetric patients. The increasing trend of caesarean sections (in the setting of increasing maternal age, obesity and other concomitant diseases) is a challenge for the anaesthesiologist for providing regional and general anaesthesia. Providing anaesthesia to the parturient is a dynamic, multistep process. The most appropriate anaesthetic technique for caesarean delivery depends on maternal, foetal and obstetric factors. Central neuraxial blockade is the most common technique advocated for lower segment

caesarean section (LSCS) as it provides reliable surgical anesthesia, prevents airway related adverse events and aspiration of gastric contents.[2] Early bonding of the mother with the neonate and avoidance of use of multiple anaesthetic drugs are the added benefits of regional anaesthesia.[2]

Bupivacaine is the routinely used local anaesthetic and the dose of bupivacaine is reduced in obstetric patients due the increased sensitivity of neural tissue, alteration in cerebrospinal fluid volume, weight gain and exaggerated lordosis. The combination of these patient related factors ultimately result in significant cephalad spread resulting in higher level of blockade causing maternal discomfort, vomiting, and hypotension. Hypotension results from a decrease in peripheral resistance and peripheral venous pooling resulting in decreased venous return, cardiac output and arterial blood pressure. Also, the gravid uterus plays an important role in the compression of the inferior vena cava, pelvic veins and the aorta and its branches which can contribute to hypotension.[3] The ED95 dose of bupivacaine for patients undergoing LSCS under spinal is almost 12mg (12.78 mg) for normal weight and 11.86 mg for obese population.[4] Other studies have proved that ED95 dose of bupivacaine based on height for spinal anaesthesia in LSCS patients is 0.06mg/cm.[5]

The use of low dose of bupivacaine in the range of 8mg to 10mg along with opioids has been shown to decrease the incidence of hypotension (6). But the incidence of maternal discomfort and break through pain in the intraoperative period was more, demanding supplementary analgesia. So there is wide variation in the dose of bupivacaine administered to LSCS patients. The use of conventional FD of bupivacaine in the range of 10- 12mg is preferred by anaesthesiologists to avoid conversion to general anesthesia and in such cases vasopressors are used routinely to maintain blood pressure and placental perfusion.[6] The minimum effective dose of hyperbaric bupivacaine providing effective spinal anaesthesia has not been defined still. Various strategies employed to prevent hypotension are preloading with intravenous fluid, leg elevation, prophylactic administration of vasopressors, usage of lower dose of local anaesthetic agents, usage of additives like opioids etc.[7] A study by Harten et al. has shown the effect of height and weight AD dose of spinal bupivacaine on the onset of motor and sensory blockade. The study found that the incidence of decrease in mean arterial pressure was lesser when dosage of bupivacaine was based on height and weight. [8] The purpose of this study is to analyse the characteristics of spinal block achieved with height and weight based dose of bupivacaine with fentanyl versus a fixed dosage of bupivacaine with fentanyl in elective caesarean section patients so as to find the optimum dose of drug required for adequate anaesthesia, which in turn could reduce the usage of vasopressors.

MATERIAL AND METHODS

The study employed a prospective, randomized, double-blind trial design to investigate the effects of two different approaches to spinal anesthesia in parturients undergoing elective lower segment cesarean section (LSCS). The study period spanned from February 2021 to July 2022, and it was registered under the Clinical Trials Registry of India (CTRI NO.: SMCH/1EC/2021/02/006). Inclusion criteria encompassed term parturients aged 18 to 40 years with singleton pregnancies and an ASA II classification, scheduled for elective LSCS. Exclusion criteria comprised patients undergoing emergency LSCS, those refusing spinal anesthesia, and individuals with specific medical conditions such as bleeding diathesis, neurological diseases, or

spinal deformities. Patients were randomly assigned to two groups using computer-generated numbers, and allocation concealment was ensured through the Serially Numbered Opaque Sealed Envelope (SNOSE) technique. The two groups were designated as the AD Dose Group and the Fixed Dose Group. The former received a dose of 0.5% hyperbaric bupivacaine plus 0.2 ml fentanyl based on weight and height, while the latter received a fixed dose of 2 ml (10 mg) of 0.5% hyperbaric bupivacaine plus 0.2 ml fentanyl. Preoperative assessments were conducted the day prior to surgery, and baseline monitoring including ECG, NIBP, and pulse oximetry was initiated upon the patient's arrival in the operating room. Intravenous fluids (Ringer Lactate) were administered at 10 ml/kg, and anesthesia was administered by an anesthesiologist not involved in the study to maintain blinding. Spinal anesthesia was performed at the L3-L4 interspace using a 25G QUINCKE spinal needle, and various parameters including time to achieve sensory and motor blockade, as well as hemodynamic parameters, were recorded. Inadequate blockade or hemodynamic instability was managed accordingly. The study also assessed postoperative outcomes including APGAR scores, quality of block as evaluated by the surgeon and patient, and any complications observed. The regression of sensory blockade and return of motor function were monitored postoperatively.

The sample size for the study was determined using a power analysis, referencing a study by Katarzyna et al. in 2020. A superiority margin of 0.20 and an expected difference of 0.50 were considered, with a standard deviation of bupivacaine dosage in the AD study group of 0.6. The effect size was calculated to be 0.5, with a desired power of 80% and an alpha error of 5%. Based on these parameters, the required sample size for each group was calculated to be 49. Considering a 10% dropout rate, the final sample size for each group was set at 55.

The collected data were analyzed using IBM SPSS Statistics software version 23. Descriptive statistics such as frequency analysis, percentage analysis for categorical variables, and mean, standard deviation, and median for continuous variables were utilized. Paired sample t-tests were employed for significance testing within paired groups, while unpaired sample t-tests were used for independent groups. A significance level of $p \leq 0.05$ was considered statistically significant.

RESULTS

Table 1: Distribution of demographic profile of the study participants (N=90)

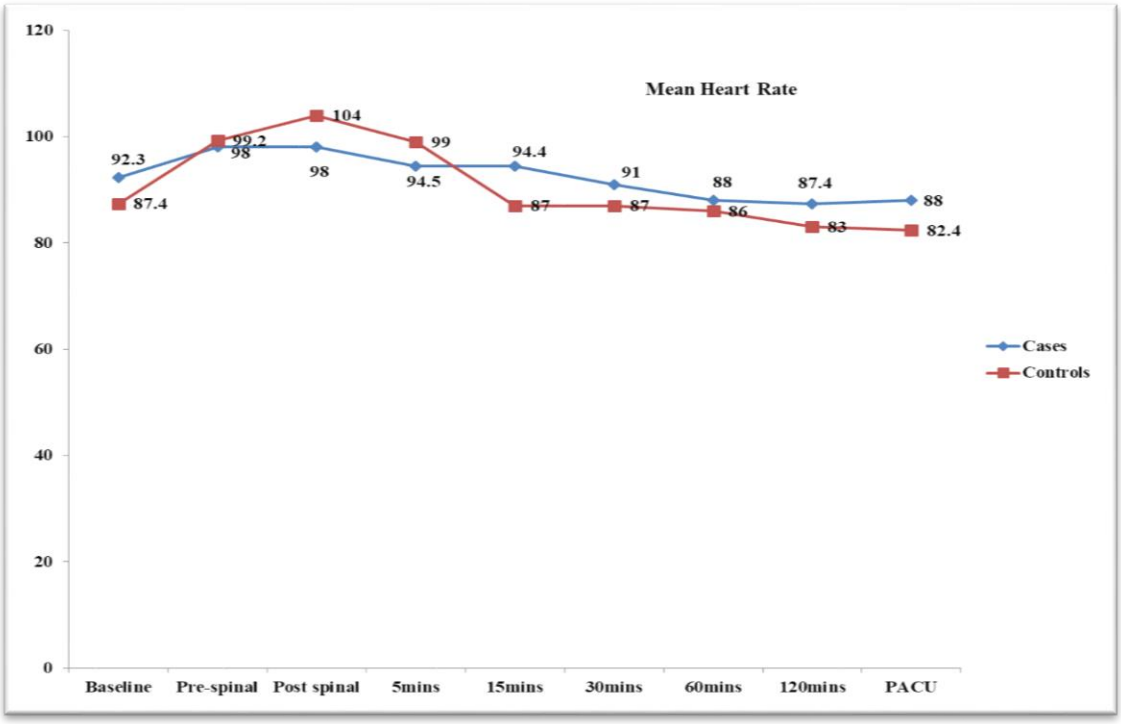
Parameters (Mean)	Group A (AD) (n= 45)	Group B (FD) (n= 45)	p-value
Age(yrs)	26.7	27.1	0.714
Weight (kg)	69.5	71.2	0.549
Height (cms)	155.4	156.9	0.166

The groups were comparable with respect to their age with p-value of 0.714. The groups were comparable with respect to their weight with p-value of 0.451. The groups were similar with respect to their height with p-value of 0.166 (Table 1).

Table 2: Distribution of dose of 0.5% bupivacaine between groups (N=90)

Parameter	Group A (AD) (n=45)	Group B (FD) (n=45)
	Mean± SD	Mean ± SD
Dose (ml)	1.77ml±0.15 (8.83mg)	2.00±0.0 (10mg)

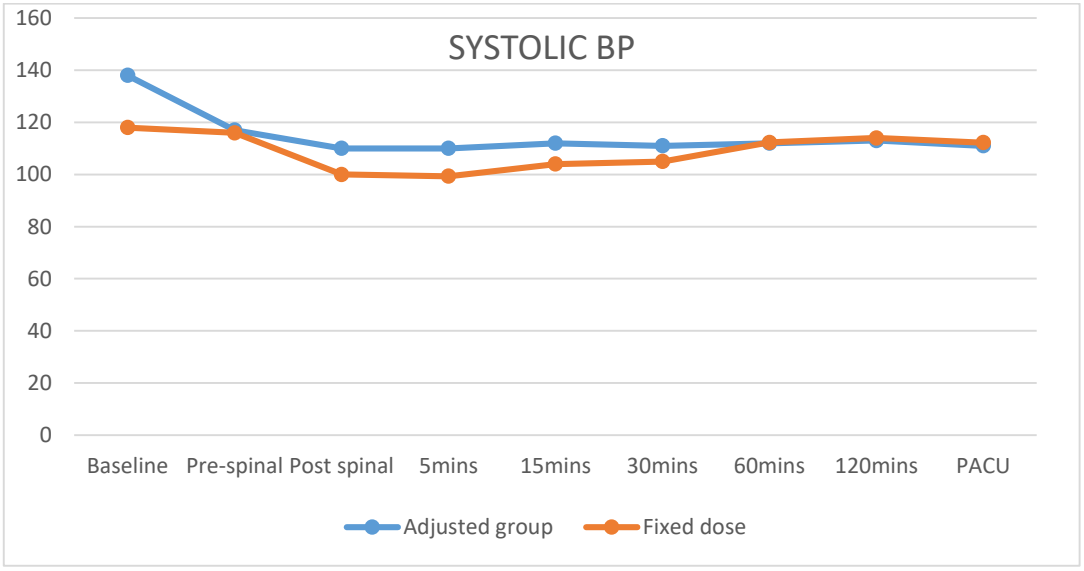
The mean dose of 0.5% bupivacaine in the AD DOSE Group is 8.83mg ± 0.15 (1.766ml) check the volume and the mean dose in FD group is 10mg± 0 (2.0 ml ± 0) (Table 2).



x-axis – Time; y axis- Heart rate (beats/min

Figure 1: Distribution of heart rate between the 2 groups (N=90)

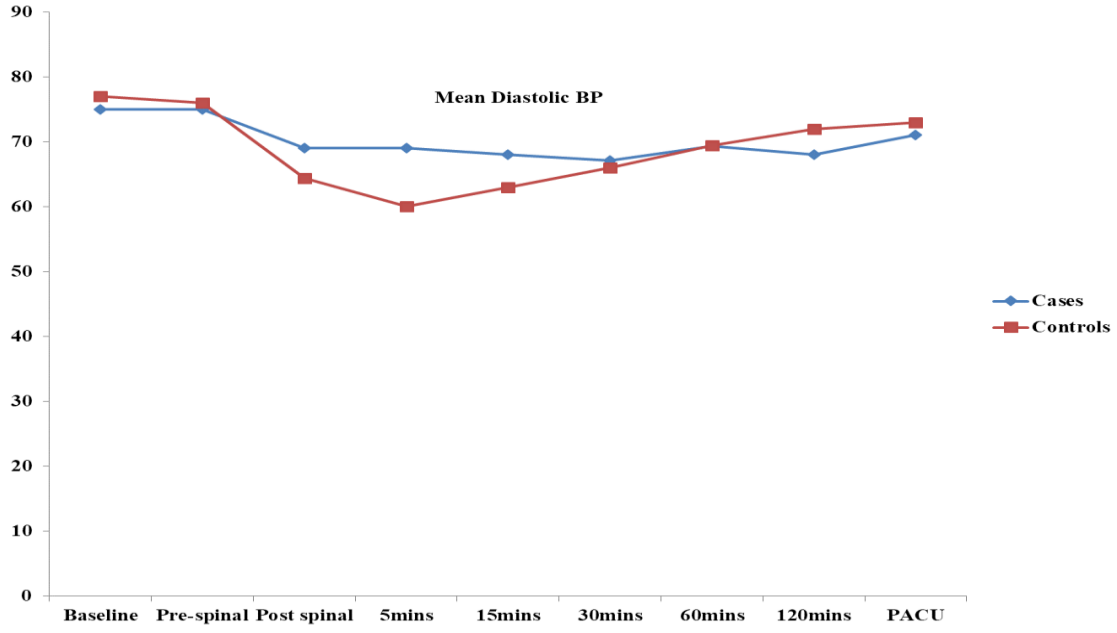
Heart rate was higher in FD group post spinal which was statistically significant (AD= 97.60; FD= 103.60; p=0.05). There was higher fall in heart rate in the FD group at 15mins (AD= 94.46; FD= 86.78; p=0.05) and in the PACU (AD= 87.80; FD= 82.45; p=0.000) which was statistically significant (Figure 1).



x-axis – Time; y axis- Mean Systolic BP

Figure 2: Distribution of Mean systolic BP between the 2 groups (N=90)

Fall in SBP was higher in FD group post spinal (AD= 110.5; FD= 100; p=0.00) at 5mins (AD= 110.6; FD= 99.3; p=0.00) and at 15mins (AD= 112; FD= 104; p=0.004) (Figure 2).



(x-axis – Time; y axis- Mean Diastolic BP)

Figure 3: Distribution of Mean diastolic BP between the 2 groups (N=90)

Fall in DBP was higher in FD group post spinal (AD= 69; FD= 64.4; p=0.034) at 5mins (AD= 69; FD= 60; p=0.00) and at 15mins (AD= 68; FD= 63; p=0.005 (Figure 3).

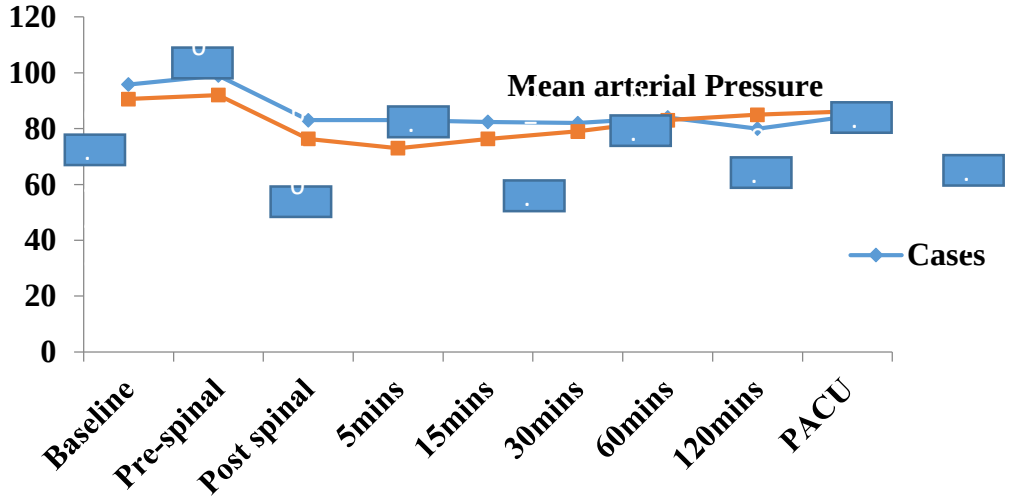


Figure 4: Distribution of Mean arterial pressure between the 2 groups (N=90)

Fall in MAP was higher in FD group post spinal (AD= 83; FD= 76.34; p=0.02) at 5mins (AD= 82.5; FD= 73; p=<0.001) and at 15mins (AD= 82.4; FD= 76.3; p=0.003). Total vasopressor requirement was higher in the FD group than AD group (AD=2.57mg ;FD=6.72mg p=<0.001) (Figure 4).

Table 3: Distribution of highest sensory blockade distribution between the groups (N=90)

Slno	Group	T2	T3	T4	T5	T6	p
1	AD	6 (12)	3 (6)	39 (78)	0 (0)	2 (4)	**0.44**
2	FD	7 (14)	6 (12)	34 (68)	2 (4)	1 (2)	

The highest level of sensory blockade greater than T4 level was seen in 9 patients of the AD group and 13 patients in FD group. (p value = 0.441). 49 (98%) patients in FD group achieved a block above T6 level whereas 48 (96%) of patients in the AD group reached the same. 6 patients (12%) in the AD group achieved a level of T2 as against 7(14%) patients in FD group (Table 3).

Table 4: Distribution of study variables among the study participants (N=90)

Slno	Study variable	AD (Mean±SD)	FD (Mean±SD)	P value
1	**Level of sensory blockade (in sec)** T4 T6	 98.35 ± 20.15 136.46± 32.74	 76.59 ±19.63 103.51 ± 37.39	 0.002 0.003
2	**Onset of Motor blockade (jn sec)**	164.66±27.37	122±20.155	<0.001
3	**Vasopressor requirement (mg)**	2.6±0.60	6.2±0.72	0.85
4	**Time taken for regression of motor blockade (in sec)**	108.70±30.65	109.60±14.32	0.94
5	**Regression of Motor Blockade** **Bromage 2** **Bromage 0**	 138.96±21.616 220.58±27.313	 141.90±28.544 221.10±26.094	 0.56 0.92

The mean for maximal sensory blockade was 138 secs in the AD group and 104.14 secs in the FD group which was statistically significant (p-value of 0.003). The mean time taken to achieve T6 blockade was 98.35secs in the AD group and 76.59 secs in the FD group which was statistically significant (p-value=0.013). The mean time taken to achieve T4 blockade was 136.46secs in the AD group and 103.51secs in the FD group which was statistically significant (p-value=0.013). The mean for maximal sensory blockade was 138 secs in the AD group and 104.14 secs in the FD group which was statistically significant (p-value of 0.003). The mean time for onset of motor blockade was 164 seconds in AD group and 122 seconds in FD group which was highly statistically significant with a p value of 0.0005**.** The mean requirement of vasopressor was 2.6mg in the AD group and 6.2mg in the fixed group which was significant statistically (p-value=0.85). The mean time for regression of sensory blockade by 2 levels was 108.70 minutes in the AD group and 109.60 minutes in the FD group which was not statistically significant. The mean time for regression of motor blockade (Bromage score-2) was 138.96±21.616 minutes in AD group and 141.90±28.544 minutes minutes in FD group which was highly statistically insignificant with a p value of 0.563. The mean time for complete regression of motor blockade (Bromage score-0) was 220.58±27.313 minutes in AD group and 221.10±26.094 minutes in FD group which was highly statistically insignificant with a p value of 0.923 (Table 4).

There was no significant difference in the APGAR scores between the AD group and the FD group at 0 (AD=8.22; FD=8.42; p- value=0.295) and 5 minutes (AD= 9.8; FD= 10; p-value=0.31). The quality of block was adequate for all the patients in both the groups. There was no significant difference. There was no bradycardia in either of the groups and hence no usage of atropine in either of the groups. The quality of block

was adequate for all the patients in both the groups. There was no significant difference. There was no incidence of complications in either of the groups

DISCUSSION

In our study the age, weight, height, abdominal girth and parity were comparable between both the groups. Harten et al[8] reported reduction in the dosage of bupivacaine needed for satisfactory anesthesia in LSCS when the dose of bupivacaine was titrated to the height and weight of patients. The height and speed of sensory blockade are influenced by various factors which are- patient related like age, sex, height and weight; and drug related like Baricity, concentration, volume that affect the spread of local anaesthetics in the subarachnoid space. Harten also reported a reduction in the requirement of Bupivacaine dose when titrated according to the patient's height and weight. In our study, the median dose of 0.5% bupivacaine in the AD group is 1.8ml and the median dose in FD group is 2.0 ml**.[8]** Owing to its ease of administration, avoiding problems related to intubation and maternal aspiration, effective intraoperative analgesia and the early mother-child bonding, spinal anaesthesia is often the preferred anaesthetic technique of choice for elective LSCS**.[9]** The routine drug in practice is Bupivacaine with or without additives. However, hypotension with the possibility of fetal acidemia, greater difficulty in finding the subarachnoid space because of the increased lumbar lordosis, headache and other side effects are more common in pregnant patients.[10] Danelli[5] reported that the effective spinal dose in 95% of women undergoing lscs as 0.06mg/cm height. In a study by Siddique[11,] ephedrine requirement was higher in the height based group (mean dose 16mg) than the height weight AD group (mean dose 8mg) with a p-value of 0.03. The fall in MAP and diastolic BP (≥20% from the baseline) was significant in the FD group compared to the AD dose group during the post spinal period, at 5mins and 15mins. Also the fall in systolic BP was greater in the FD group compared to the AD dose group during the post spinal period, at 5minsAD, 15mins and AD30mins. All these could be attributed to the higher dosage in the fixed group. Harten recorded that the incidence of hypotension after spinal anaesthesia was 71.7% in the FD Group and 50.0% in the AD Dose Group (p=0.035). Fall in heart rate was more significant post spinal (AD= 97.60; FD= 103.60; p=0.05), at 15mins (AD dose = 94.46; fixed= 86.78; p=0.05) and in the PACU (AD dose = 87.80; FD= 82.45; p=0.000). Siddique[3 reported] that mean heart rate did not differ between groups but a significant within-group difference was seen in mean heart rate ($P < 0.05$). G.Hocking[12] that hypotension and bradycardia are related to block height, but are not specific.

Kiran S[13] compared three different dosages (7.5mg, 8.75mg and 10mg) of hyperbaric Bupivacaine and concluded that lower the dose, lower the incidence of hypotension and bradycardia. The mean time taken to achieve T4 blockade was higher in the AD group (136.46sec) than the FD group (103.51sec). Also the mean time taken to achieve T6 blockade was higher in the AD group (98.35secs) than in the FD group (76.59secs). According to Harten et al[14], onset of sensory blockade to T4 level was 480sec in the AD dose group and 360sec in the FD group. The median time taken for T6 level were 360sec in both the groups. This difference in the timing between this study and Hartens study could be attributed to the difference in the physical parameters of the patients in the studies. In our study, mean height was 155cm in the adjusted group and 156cm in FD group whereas the mean height in Hartens study[14]

was 161cm in FD group and 162cm in the AD dose group. Harten used cold sensation to assess the level of blockade.

The mean time taken for maximal sensory blockade was 138 sec in the ADAD dose group and 104.14 sec in the FD group which was statistically significant (p-value of .003) in our study. Ying-Jun She et al[15] et al reported the median time to achieve a blockade to T4 level as 396 sec with AD dose and 480sec in the FD group. Ousley1[16] concluded that there was variation in the height of blockade using hyperbaric 0.5% Bupivacaine based on the methods of assessment. The height of blockade was seen to be maximum for ice cold sensation followed by cold, pin prick and touch. The methodology of assessing could be the reason for the difference in the onset time of blockade in our study. The onset of motor blockade (Modified Bromage 3) was slower in the AD group (164 seconds) than in FD group (122seconds) (p value of 0.0005).In a similar study by Kiran Kumar[17] comparing FD and height weight based bupivacaine in LSCS patients, the median time to motor blockage, Bromage-III in FD was faster in comparison to the AD dose group (4 minutes vs 6 minutes) owing to the higher dosage in the FD group. In our study, the mean requirement of vasopressor was 2.6mg in the AD group and 6.2mg in the fixed group which was significant statistically (p-value=0.00). In Harten's[13] study, more patients in the FD Group were given ephedrine (79.5% vs. 56.8%, p=0.02), and a larger median dose was administered (9mg vs. 6mg, p=0.042). Our results correlated with the results of Hartens study in this regard.

The mean time for regression of sensory blockade by 2 levels was faster in the AD group (108.70±30.653) than in the FD group (109.60±14.323). In a study by Greene[18], it was shown that patients receiving larger doses of bupivacaine had significantly longer sensory regression times which was consistent with our results as the FD group recived a higher dose compared to the AD dose group. The mean time for regression of motor blockade (Bromage score-2) was 138.96±21.616 minutes in AD group and 141.90±28.544 minutes in FD group. The mean time for complete regression of motor blockade (Bromage score-0) was 220.58±27.313 minutes in AD group and 221.10±26.094 minutes in FD group. In a study by Jeon et al[19] comparing phenylephrine and ephedrine vs phenylephrine alone as prophylactic vasopressor, there were no differences in Apgar scores (1 and 5 min), the incidence of 5 min Apgar score < 7, However, the incidence of 1 min Apgar < 7 was decreased during the period of phenylephrine use compared with the period of phenylephrine and ephedrine use (P = 0.002). There was no incidence of bradycardia in both of the groups and hence there was no usage of atropine. There was no incidence of any complications in any of the patients in either of the groups. Kiran[17] concluded that the incidence of nausea & vomitting, hypotension and shivering was more prevalent in the FD group compared to the AD dose group probably due to the higher spread of anaesthesia resulting in hypotension as a result of which there is reduced cerebral perfusion activating vomitting centres.[10] There was no significant difference in the quality of analgesia between both the groups.

Limiting the study to only ASA 1 and II patients posed a limitation as it prevented the assessment of the effect of the AD dose group in hemodynamically unstable patients. Hypotension was defined in the study as a 30% drop in blood pressure from baseline, which may not capture all instances of clinically significant hypotension. Defining stricter blood pressure margins could have potentially provided a different perspective on the results. Additionally, the inclusion of patients with extremes of weight and height, while adjusting the dose accordingly, might have introduced variability that

could have impacted the outcomes. Furthermore, the study acknowledges a limitation of a small sample size, which could affect the generalizability and statistical power of the findings.

CONCLUSION

In conclusion, our study demonstrates that adjusting the dosage of bupivacaine based on height and weight effectively provided adequate anesthesia for elective cesarean sections, while also promoting greater hemodynamic stability and reducing the requirement for vasopressors to manage maternal hypotension. However, it's important to note that this approach resulted in a slower onset of sensory and motor blockade and faster regression. Despite these considerations, the benefits of improved hemodynamic stability may outweigh the trade-offs in blockade characteristics, highlighting the potential clinical utility of personalized dosing strategies in obstetric anesthesia. Further research with larger sample sizes and refined dosing protocols could provide additional insights into optimizing anesthesia management for cesarean deliveries.

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