Comparative Study of Intrathecal Bupivacaine versus Bupivacaine With Fentanyl for Post-Operative Analgesia in an Elective Cesarean Section at a Tertiary Care Centre

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Abstract

Introduction: Spinal anaesthesia for cesarean section has been the preferred technique for majority of anaesthesiologist. The finite duration of spinal anaesthesia is the only drawback as compared to general anaesthesia. Therefore combination of local anaesthetics with intrathecal opioids makes it possible to achieve prolonged post-operative analgesia without affecting the mother and the baby. **Aims And Objectives:** 1)To compare the effectiveness of plain bupivacaine with bupivacaine plus fentanyl for post -operative analgesia among the two groups. 2)To compare the adverse effects among both the groups. **Materials and Methods:** 154 patients undergoing elective cesarean section under spinal anaesthesia were randomly allocated to two equal groups; Group B patients received 10 mg (2 mL) of 0.5% hyperbaric bupivacaine and Group B + F received 9mg (1.8mL) of 0.5% hyperbaric bupivacaine plus 10 ug (0.2 mL) preservative free fentanyl. The clinical profile of subarachnoid block in two groups, duration of effective analgesia and its effect on maternal and neonatal outcome was studied. **Results:** The duration of effective analgesia was significantly more in Group B + F (225.03+2.81)mins compared to Group B (119.90+2.76)mins. The incidence of side effects was less in Group B + F than Group B. **Conclusion:** We can conclude that the addition of fentanyl to 0.5% hyperbaric bupivacaine for spinal anaesthesia in cesarean section provides effective analgesia with less side effects.

Keywords: Bupivacaine, Cesarean Section, Fentanyl, Spinal Anaesthesia

1. Introduction

Regional anaesthetic techniques present the most flexible, effective and most economical option when compared with parenteral and inhalation techniques. When it comes to anaesthetising a gravida for cesarean section, spinal anaesthesia appears to be the preferred technique nationwide. It allows the mother to remain awake, minimizes or completely avoids the problem with airway management and avoids possible neonatal drug induced depression from general anaesthetics.

Also the rapid onset of sensory analgesia and profound motor blockade shortens the surgical time and gives better surgical field. The technique is simple to perform with appearance of cerebrospinal fluid as the definitive end point, thus having a higher degree of success.

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Bupivacaine, an amino-amide has been the local anaesthetic of choice for spinal anaesthesia in parturient. The use of lignocaine for spinal anaesthesia has become controversial due to concerns related to transient radicular irritation. The incidence is greater with lignocaine than with bupivacaine¹.

Addition of opioids to local anaesthetic for spinal anaesthesia was first introduced in 1979 with intrathecal morphine. They act on opioid receptors present in the substantia gelatinosa of dorsal horn of spinal cord.They are synergistic with local anaesthetics and intensify the sensory block without increasing the sympathetic block. They are commonly used as additive with local anaesthetics for potentiating their effects, thus offering hemodynamic stability by reducing the dose and side effects of local anaesthetics. They also prolong the duration of post-operative analgesia².

Fentanyl, a lipophilic opioid, has rapid onset and offset of action. Given intrathecally it improves quality of anaesthesia, improves postoperative analgesia and offers hemodynamic stability. The present study was conducted to compare the effectiveness of plain bupivacaine with bupivacaine plus Fentanyl for post-operative analgesia among the two groups

2. Materials and Methods

- 1. Type of study: This is a Comparative Prospective Study
- 2. Study setting: Department of Anaesthesia in a tertiary health care center.
- 3. Study duration: August 2017 to December 2019
- 4. Study Population: Females undergoing elective cesarean section
- 5. Sample size: 154
- 6. Sampling technique: Complete enumeration method

2.1. Inclusion Criteria

- ASA physical status I or II
- Normal coagulation profile
- Age between 18 to 30 years
- BMI between 18-25

• Patient should be primi or multigravida who is delivering after completing full term.

2.2 Exclusion Criteria

- Patient refusal
- Infection at the site of injection
- Pre-existing neurological disease like stroke, CVA, h/o Seizure
- Cardiac or respiratory system failure
- Musculoskeletal deformity
- Uncooperative patient
- Allergy to local anaesthetics
- Complicated pregnancy such as multiple pregnancies, placenta praevia,
- pregnancy induced hypertension, foetal distress
- If additional anaesthesia required

3. Methodology

After approval of the Institutional Ethics Committee 154 eligible female patients posted for elective caesarean deliveries under spinal anaesthesia were enrolled in the study after their informed, written consent and randomly allocated to 2 groups, Group B (plain bupivacaine) and Group B+F (bupivacaine + fentanyl) with 77 patients each.

All patients were assessed clinically by general and systemic examination, airway assessment, spine examination. Routine preoperative investigations were done which included complete blood count, blood sugar, kidney function test, coagulation profile, urine routine and microscopy and electrocardiogram.

On arrival to the operating room fasting status was confirmed. The monitors (noninvasive blood pressure, electrocardiogram, pulseoximeter) were attached. Baseline systolic and diastolic blood pressure, heart rate, respiratory rate, oxygen saturation and electrocardiogram were recorded.

Emergency drugs and equipments for resuscitation were kept ready. A suitable peripheral vein was cannulated and I.V. Ringer solution 10ml/kg (preload) was given to all patients before the procedure. Inj. Ondansetron IV as a premedication was given to all the patients in both groups.

The position of the table was kept horizontal and patient were put in left lateral position. Sterilization was done. Dural puncture was performed at L3-4 or L4-5 interspace with 25 gauge Quincke spinal needle.

Group A (n=77): received intrathecal injection of 0.5% hyperbaric bupivacaine 2 mL (10 mg).

Group B + F (n=77): received intrathecal 1.8 ml (9 mg) of 0.5% hyperbaric bupivacaine plus 0.2 mL (10 ug) of Fentanyl

Immediately after intrathecal injection the patients were placed in supine position with a wedge under the right hip to maintain left uterine displacement. Oxygen supplementation was done by face mask at 5 L/min. Spinal anaesthesia was given by anaesthesiologist who will participate in recording patients data. Only patients were blinded to the drugs given.

All patients received Inj. Pitocin 20 units in drip after delivery of baby.

Sensory blockade was achieved at T6 dermatome and grade III motor blockade was achieved in all patients. 'Duration of effective analgesia' (time taken from the administration of subarachnoid block to the time patient's first dose of rescue analgesic) was calculated. Side effects if any were noted till complete recovery.

4. Results

4.1 Patients Demographic Variables



Figure 1. Shows the age distribution of patients among both groups. The patients were in a range of 18-30yrs. 15 and 22 patients were in a age group of 18-22 yrs in group B and group B+F respectively,33 and 29 patients were in a age group of 23-26yrs in group B and group B+F,29 and 26 patients were in a age group of 27-30 yrs in group B and group B+F.



Figure 2. Shows the distribution of patients among both the groups according to their BMI. The BMI of the patients were in the range between 18-25, 29 and 27 patients were in the range of BMI 18-20 among group B and group B+F respectively,33 and 32 patients belonged to BMI 18-20 among group B and group B+F, 15 and 18 patients were in the range of BMI 18-20 among group B and group B+F respectively.



Figure 3. The above figure shows distribution of patients belonging to ASA I and ASAII group.44.15% of people belong to ASA I and 55.84% of people belong to ASA II group among both the groups.

4.2 Comparison of Duration of Effective Analgesia

Table 1.Shows the mean duration of effective analgesia in group B+F is 225.03 mins which is more than 119.90mins achieved in group B and whose p value is <0.001 which is statistically significant</td>

Parameter	Gr Code	Mean	Std. Deviation	Т	P value		Significance
Duration of Effective Analgesia (In Mins)	Bupivacaine	119.90	2.76	-234.21	<0.001		Significant
	Bupivacaine + Fentanyl	225.03	2.81				
SIDE EFFECT	Type of Group					T (1(154)	
	Bupivacaines (n=77)		Bupivacaine + Fentanyl (n=77)			10ta1(n=154)	
BRADYCARDIA	6(7%)		3(4%)			9	
HYPOTENSION	23(29%)		6(7%)			29	
NAUSEA AND VOMITING	5(6%)		0(0%)			5	
PRURITIS	0(0%)		5(6%)			5	
SHIVERING	8(10%)		0(0%)				8
NO	359(46%)		63(82%)				98

Table 2. In group B, hypotension(29%), nausea and vomiting(6%), shivering(10%) and bradycardia (7%) were the statistically significant side effects as compared to group B+F. The incidence of pruritus (6%) was significantly higher in group B+F as compared to group B

Chi-Square Tests							
	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)			
Pearson Chi-Square	36.966	5	0.0000061	0.0000002			
Fisher's Exact Test	37.538			0.0000003			
N of Valid Cases	154						

a. 8 cells (66.7%) have expected count less than 5. The minimum expected count is 2.50.

p< 0.05 Significant association

4.3 Comparison of Foetal Outcome

Parameter	Gr Code	Mean	Std. Deviation	Т	P value	Significance
Apgar Score At 1 Min	Bupivacaine	8.43	0.50	0.489	0.626	Not Significant
	Bupivacaine + Fentanyl	8.39	0.49	0.489		
Apgar Score At 5 Min	Bupivacaine	9.40	0.49	-0.325	0.746	Not Significant
	Bupivacaine + Fentanyl	9.43	0.50	-0.325	0.740	

Table 3.Shows Apgar score at 1 min and 5 min among both the groups and there is no significant differencebetween the Apgar score at 1 and 5 mins in both groups

5. Discussion

Anaesthesia related complications accounted for 5.2% of maternal deaths. The relative risk of fatality during general anaesthesia is 16 times more than that for regional anaesthesia. Hence in absence of any contraindications spinal anaesthesia is preferred for cesarean section¹.

In this prospective randomized study the effect of addition of intrathecal Fentanyl to 0.5% hyperbaric bupivacaine was studied for duration of post-operative analgesia.

The 'duration of effective analgesia' was prolonged in Group B + F (224.80 mins) than Group B(120.02 mins). Bano F *et al.*¹¹, Tolia Geetanjali T *et al.*² and Agarwal A *et al.*² studies also found similar results.

Fentanyl due to its synergistic effect with bupivacaine prolongs the duration of analgesia thus decreasing the analgesic requirement post operatively. This contributes to patients comfort and satisfaction and allows for breast feeding. While adding any additive to intrathecal bupivacaine for cesarean section foetal safety and outcome is equally important to maternal outcome.

There was no neonatal depression in our study. Mean APGAR score at 1 min and 5 min was similar in both the groups. Bogra J *et al.*⁶, Agarwal A *et al.*⁹ Dahlgren G *et al.*¹⁰, all reported good neonatal outcome with intrathecal fentanyl.

5.1 Adverse Effects

Bradycardia was observed in 6 patients (7%) of group B and in 3 patients (4%) in group B+F. Hypotension was seen in 23 patients (29%) of group B and in 6 patients (7%) in group B+F. Nausea and vomiting was observed in 5 patients(6%) of group B and in 0 patients (0%) in group B+F. Pruritus was seen in 0 patients(0%) of group B and in 5 patients (6%) in group B+F. Shivering was observed in 8 patients(10%) of group B and in 0 patients (0%) in group B+F. Similar results were seen in studies conducted by Manoj *et al.*¹, Bogra *et al.*⁶ and Agrawal *et al.*⁹.

6. Conclusion

Thus, we conclude that intrathecal Fentanyl by its synergistic effect with 0.5% hyperbaric bupivacaine provides prolonged post-operative analgesia with less incidence of complications like nausea, vomiting and shivering without compromising the safety of mother and the foetus.

7. References

 Manoj Kumar N. Gajbhare, Neha P. Kamble, Comparative Study of Intrathecal Bupivacaine versus Bupivacaine with Fentanyl for Cesarean Section in 2016. Indian J ClinAnaesth. 2016;3(2):271–277. https://doi.org/10.5958/2394-4994.2016.00049.4

- Pollock JE, Neal JM, Stephenson CA, Wiley CE.Prospective study of the incidence of transient radicular irritation in patients undergoing spinal anaesthesia. Anaesthesiology 1996;84:1361–1367. https://doi.org/10.1097/00000542-199606000-00012
- Tan PH, Chia YY, Lo Y, Yang LC, Lee TH. Intrathecal bupivacaine with morphine or neostigmine for postoperative analgesia after total knee replacement. Can J Anesth. 2001;48(6):551–6. https://doi.org/10.1007/ BF03016831
- Panchal S, Arria AM, Labhsetwar SA: Maternal mortality during hospital admission for delivery: Aretrospective analysis using a state-maintained database. Anesth Analg. 2001;93:134–141. https://doi.org/10.1097/00000539-200107000-00028
- Hawkins JL, Koonin LM, Palmer SK, et al: Anaesthesia related deaths during obstetric delivery in the united states, 1979-1990. Anesthesiology. 1999;86:277–284. https://doi. org/10.1097/00000542-199702000-00002
- Bogra J, Arora N, Srivastava P. Synergistic effect of intrathecalfentanyl and bupivacaine in spinal anaesthesia for caesarean section. BMC Anesthesiol. 2005;5:5. https:// doi.org/10.1186/1471-2253-5-5
- Geetanjali T, Ajay K, Aruna J. Low dose intrathecal bupivacaine with fentanyl for caesarean delivery. JAnaesthClinPharmacol. 2008;24(1):201–204.
- Wang C, Chakrabarti MK, Whitwam JG. Specific enhancement by fentanyl of the effects of intrathecal bupivacaine on nociceptive afferent but not on sympathetic efferent pathways in dogs. Anaesthesiology. 1993;79;766– 73. https://doi.org/10.1097/00000542-199310000-00019
- 9. Agarwal A, Agarwal S, Asthana V, PayalYS.Comparison of intrathecalfentanyl and sufentanil inaddition to bupivacaine

for caesarean section under spinal anaesthesia. J Anaesth Clin Pharmacol. 2009;25(2):154–56.

- Dahlgren G, Hulstrand C, Jakobson J, Norman M. Intrthecalsufentanil, fentanyl or placebo added to bupivacaine for caesarean section. Anesth Analg. 1997;85:1288–93. https://doi.org/10.1097/00000539-199712000-00020
- 11. Bano F, Sabbar S, Zafar S, Rafeeq N, et al. Intrathecal fentanyl as adjunct to hyperbaric bupivacaine in spinal anaesthesia for caesarean section. JCPSP. 2005;16(2):87–90.
- Seyedhejazi M, Madarek E. The effect of small dose bupivacaine – fentanyl in spinal anaesthesia on hemodynamic, nausea and vomiting in caesarean section. Pak J Med Sci. 2007;23(5):747–50.
- Bader AM, Thornhill ML, Datta S. The antiemetic efficacy and safety of prophylactic metoclopramide for elective caesarean delivery during spinal anaesthesia. Reg Anaesth. 1992;17:126–30.
- 14. De Witte, Jan MD, Sessler. Perioperative shivering: physiology and pharmacology. Anaesthesiology. 2002;96,467–84. https://doi.org/10.1097/00000542-200202000-00036
- 15. Techanivate A, Rodanant O, Somsiri T. Intrathecalfentanyl for prevention of shivering in caesarean section.J Med Assoc Thai. 2005;88:1214–21.
- 16. Szarvas S, Harmon D, Murphy d. Neuraxialopioidinducedpruritus: a review. J Clin Anesth. 2003;15(3):234-9. PMID:12770663. https://doi. org/10.1016/S0952-8180(02)00501-9
- Belzarena S.D. Clinical effect of intrathecal administered fentanyl in patient undergoing caesarean section. Anaesth Analg. 1992;74:653–7. https://doi.org/10.1213/00000539-199205000-00006

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