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Original Research Article

Epidural Anaesthesia for Cesarean Section: A Comparison of 0.5% Bupivacaine and 0.5% Bupivacaine Plus 50µg Fentanyl

Dr Anurag Agarwal[1], Dr Manoj Kumar Upadhyay[2], Dr Veena Arora[3], Dr Shivshankar Tripathi[4], Dr Chandrashekhar Singh[5], Dr Shivani Rastogi[6]

[1]Associate Professor, Dr Ram Manohar Lohia Institute of Medical Sciences, Lucknow
[2]Associate Professor, G. S. V. M. Medical College, Kanpur
[3]Dept. of Anesthesia, GSVM Medical College, Kanpur
[4]Associate Professor, Dept of Emergency Medicine, Dr Ram Manohar Lohia Institute of Medical Sciences, Lucknow
[5]Associate Professor, Anesthesia, GSVM Medical College, Kanpur
[6]Associate Professor, Anesthesia, Dr Ram Manohar Lohia Institute of Medical Sciences, Lucknow

Corresponding Author: Dr Manoj Kumar Upadhyay

ABSTRACT

Introduction: There is no one ideal method of anesthesia for cesarean section, but epidural anesthesia is definitely one of the most popular technique used for cesarean section. Combining the epidural local anesthetic solution with opioids has become a common practice in obstetric anesthesia. The use of combination of local anesthetic solutions with opioids fastens the onset of surgical anesthesia; reduces the incidence of patchy anesthesia and improved analgesia. Fentanyl 50-100 µg or Sufentanil 10-20 µg are the opioids most commonly used to combine with local anesthetic solution used for epidural anesthetic.

Aims and Objectives:

1. To compare the onset of surgical anesthesia and analgesia of epidural 0.5% bupivacaine with or without 50 µg of fentanyl.
2. To compare the intensity and quality of surgical anesthesia with I.V analgesics and /or N_2O-O_2 by mask, of epidural blocks with 0.5% bupivacaine with or without 50µg of fentanyl.
3. To evaluate the newborn condition by Apgar score.
4. To study side effects and complication (if any) of addition of 50µg of fentanyl with 0.5% bupivacaine for epidural anesthesia for cesarean section.

Materials & Methods: In our study we randomized 40 parturients to receive epidural anesthesia with either 0.5% bupivacaine only or 0.5% bupivacaine with 50µg of fentanyl for elective cesarean section, to compare the effect of bupivacaine alone and bupivacaine+fentanyl in surgical anesthesia as well as the maternal and fetal outcome. The patients were randomly divided into two groups of 20 patients each. In Group A, parturient were given epidural block with 18ml of 0.5% bupivacaine + 2m1 of placebo (Normal Saline). In Group B, parturient were given epidural block with 18m1. of 0.5% bupivacaine + 50µg(1m1) of fentany1+1m1 normal saline.

Result: The mean total dose of bupivacaine 0.5% was 20.85±3.07 ml. in Group A and 18.75±1.87 ml. in Group B, so the total dose of bupivacaine required by Group A patients was significantly greater than Group B. Addition of 50µg fentanyl with 0.5% bupivacaine for epidural anaesthesia for cesarean section does not affect the I-S; S-D; U-D intervals significantly. Regarding the intra-operative complications, incidence of Nausea/Vomiting and shivering was slightly more in the Group-B

(bupivacaine+fentanyl) than the Group A (bupivacaine only), but the difference was statistically not significant. None of infant was severely depressed at 5 mins in either group in our study.

Conclusion: This can be concluded that addition of 50µg fentanyl with 0.5% bupivacaine for epidural anesthesia for elective cesarean section provides a faster, better quality of intraoperative anesthesia without any adverse effect on maternal and newborn outcome.

Key words: epidural anesthesia, cesarean section, bupivacaine, fentanyl.

INTRODUCTION

Important issues when anesthetizing the pregnant woman for labour, vaginal delivery or cesarean section include: physiologic changes of pregnancy, the direct and indirect effects of anesthetics on the fetus and neonates and the benefits and risks of various anesthetic techniques to the mother. The most commonly available methods, to comply the wishes of a parturient, are spinal or epidural anesthesia.

Though spinal block is a simple and effective method, because of its reliability and rapid onset of block, it provides precipitous hypotension and difficulty in controlling the level of analgesia limits its use.

On the other hand, epidural block with the catheter technique gives a better control of level of analgesia and can be used for post-operative analgesia. Beside this, epidural block, epidural block can be lengthened by giving top up doses by epidural catheters. Incidence of hypotension is also less common with epidural block and it is generally less severe than the spinal block.

However, in spite of advantages associated with epidural blocks, there are certain drawbacks also. Despite adequate administration of epidural block, some patients may have inadequate analgesia due to large amounts of drugs used in epidural blocks patient will be exposed to larger quantities of drugs, which may result in harmful effects.

The choice of anesthesia for cesarean section depends on the reason of operation, degree of urgency, desire of patient and judgment of anesthesiologist

There is no one ideal method of anesthesia for cesarean section, but epidural anesthesia is definitely one of the most popular technique used for cesarean section. Flexibility is one of the main reasons why epidural anesthesia is used more often than spinal anesthesia for cesarean delivery Hawkines JL, Gibbs CP et al (1997). Despite some decrease in blood pressure during the induction of a surgical level of epidural anesthesia, remarkable stability of maternal cardiac output has been reported Robson SC, Boys RJ et al (1992).

In some maternal conditions, in which less rapid onset of sympathetic block is desirable, epidural block is preferred as in severe hypertension and pre-eclampsia.

The commonly used drugs for epidural anesthesia for cesarean section include 2% lidocaine, 3% 2-chloroprocaine; 0.5% bupivacaine and 0.5% ropivacaine. Usually 15ml to 25ml of local anesthetic is used for cesarean section. Its relatively long duration and apparent lack of tachyphylaxis are attractive featured Crawford JS (1972).

Bupivacaine is highly protein bound and its placental passage is low Belfrage P, Berlin A et al (1975).

A concern with the use of bupivacaine is its potential for causing cardiac arrhythmias, especially in obstetrics patients, which are resistant to treatment and may result in death Albright GA (1979). Due to this finding, U.S. FDA has banned the use of o.75% bupivacaine in obstetrics.

Combining the epidural local anesthetic solution with opioids has become a common practice in obstetric anesthesia. The use of combination of local anesthetic solutions with opioids fastens the onset of surgical anesthesia; reduces the incidence of patchy anesthesia and improved analgesia [Prestons PG, Rosen MA (1988) AND Noble Dw, Morrison LM et al (1991)].

Fentanyl 50-100 µg or Sufentanil 10-20 µg are the opioids most commonly

used to combine with local anesthetic solution used for epidural anesthetic.

In this study we compared the advantages and disadvantages of addition of Inj. Fentanyl 50 µg with 0.5% bupivacaine for epidural anesthesia for cesarean section.

The combination of bupivacaine and fentanyl is not associated with identifiable significant adverse effect in the newborn.

James FM et al (1980), however found that the incidence of maternal hypotension was more with the use of combination of bupivacaine and opioid All Hypotensive episodes responded readily to treatment.

No significant differences in the incidence of nausea or vomiting, pruritus, dizziness, changes in mental status or urinary retention were found when combination therapy was compared to epidural bupivacaine alone.

Milon D et al (1983), found that 100 µg of epidural fentanyl for caesarian delivery resulted in an average umbilical artery concentration of 0.6 mg/ml. Which is below the concentration implicated in respiratory depression of the newborn .But further studies are required to evaluate the effects of fentanyl addition to epidural bupivacaine on the newborn and to verify the incidence of maternal hypotension.

AIMS AND OBJECTIVES

1. To compare the onset of surgical anesthesia and analgesia of epidural 0.5% bupivacaine with or without 50 µg of fentanyl.
2. To compare the intensity and quality of surgical anesthesia with I.V analgesics and /or N2O-O2 by mask, of epidural blocks with 0.5% bupivacaine with or without 50µg of fentanyl.
3. To evaluate the newborn condition by Apgar score.
4. To study side effects and complication (if any) of addition of 50µg of fentanyl with 0.5% bupivacaine for epidural anesthesia for cesarean section.

MATERIALS AND METHODS

The present study was carried out in the Department of Anaesthesiology, G. S. V. M. Medical College, Kanpur, UP.

A total of 40 cases of ASA grade I/II fullterm pregnant patients who were candidates for cesarean section for various indications were chosen for study for maternal and fetal outcome under epidural anesthesia in this study.

Criteria for exclusion of cases

- ASA grade III/IV patients who were poor surgical candidates
- Patients with eclampsia
- Patients with coagulopathy.
- Patients with known contraindication of epidural block, as local site infection etc.
- Non-reassuring fetal condition
- Patient refusal.

All the selected patients were subjected to detailed pre-anesthetic examination and investigations.

History

a) General - Patients name, age address were noted.
b) A detailed history of any previous exposure to anesthesia and/or blood transfusion taken.
c) A detailed history of any systemic disease e.g.-
   - Chronic hypertension
   - Chronic renal failure
   - Diabetes mellitus
   - Tuberculosis
   - Convulsive disorders, if any
   - Heart disease etc.

a) Family history - A relevant family history with reference to
   - Hypertension
   - Diabetes
   - Toxemia
   - Any convulsive disorder was taken.

Clinical examination

After taking the detailed history, thorough clinical examination of the cases was carried out on the following lines

a) General condition: In each case, a general examination was performed.

- Pulse
- Blood pressure
- Respiratory rate Pallor
- Icterus
- Cyanosis
- Clubbing
- Lymphadenopathy
- Temperature Oedema

b) Systemic examination –
- Heart and lungs were auscultated
- Detailed examination of CNS was done for any pre-existing neurologic abnormality.

c) Examination of Back / Vertebral Column - for any localized pathology like infection at injection site or any evidence of vertebral anomaly like Kyphosis or scoliosis.

Investigations: Following investigations were carried out in every case

a) Blood
- Hemoglobin %
- Blood Grouping and cross matching.
- B. Sugar
- BI. Urea
- S. Creatinine

b) CXR - P.A. view whenever indicated

c) Urine
- Albumin
- Sugar

Indications for cesarean section-

- Non-progression of labour
- Cephalo pelvic Disproportion.
- Pre-eclampsia
- Previous LSCS
- All other obstetrical indications for cesarean section.
- Patients with Fetal distress were not included in this study.

All patients requiring cesarean section for delivery were randomly allocated to two groups-

1. Group - A: consisted of 20 patients who received 0.5% bupivacaine for Epidural block.
2. Group - B: consisted of 20 patients who received 0.5% bupivacaine and 5014 fentanyl for epidural block.

Anesthesia

Pre medication

Tab Alprazolam 0.5mg was given; a night before the operation and patient was kept on fasting for adequate specific period.

A premedication of 0.6mg Atropine sulphate was given IM half-n-hour before the operation in elective cases.

- Left uterine tilt
- 100% Oxygen by a clear face mask

Method

All patients were given epidural injection in the sitting posture. After localizing L2-L3 intervertebral space, a 16G Tuohy needle was introduced by midline approach and the epidural space was identified by the "loss of resistance" technique. After a negative aspiration test; 3 ml of 0.5% bupivacaine was injected as a test dose. After 3 minutes, 0.5% bupivacaine 16ml with or without of 50µg fentanyl was injected and an epidural catheter introduced.

Patient was laid supine with a left lateral tilt and received 100% 02 by mask. Additional doses of 0.5% bupivacaine were given if the block was not reached up to T6 level, as 1.5 ml/segment by epidural catheter.

The total dose required of Epidural Bupivacaine was recorded to attain T6 block. Sensory block was tested by pin prick method and motor blockade was assessed by using bromage score.

0° no paralysis, full flexion of knees and feet.

1° just able to flex knees, full flexion of feet.

2° unable to flex the knees but some flexion of feet possible. 3° unable of flex the ankle.

- All patients were preloaded with 1000ml of lactated Ringer's solution.

Cesarean Section:

Lower segment caesarean section was done in all the cases. Post operative period:

Patients were observed in the recovery room for at least 24 hours.

Monitoring of the patient regarding vital signs, input, output was done carefully.

Patients were put on I/V fluids antibiotics and analgesics

Assessment of results:

Observations were made for maternal and foetal outcome after different anaesthetic techniques used on the following points:

Maternal:

Demographic data:

It comprised of - Name, Age, Sex, Address, Caste/ Religion, Weight, Height

Blood Pressure changes:

Blood pressure was measured intermittently at intervals of 2 minutes upto delivery and at intervals of 10 minutes after delivery

Any episode of hypotension of >30% of preoperative S.B.P. or S.B.P. of less than 100mmHg was managed by I.V. fluids, foot end elevations & lnj. Ephidrine I.V.

*** Duration of surgery:**

a) Anaesthesia induction to skin incision (min.) (C-S interval)- time taken from induction of anaesthesia to skin incision was noted.

b) Skin incision to delivery interval (min.)- Time from skin incision to the delivery of the baby was also recorded because this is an important factor as far as the baby (Apgar scoring) is concerned.

c) Uterine incision to delivery (min.)

- Intravenous Fluid measurement
- Preinduction I/V fluid (ml)
- Total intraoperative I/V fluid (ml)

FOETAL ASSESSMENT

Monitoring regarding foetal outcome (in relation to the type of anaesthesia used) was done under the following heads:

a) **Apgar Scoring: Virginia Apgar,** in 1952 put forward 5 criteria which could be easily evaluated without special equipments and were found fairly accurate in judging the condition of the newborn and analyse the need or otherwise for immediate resuscitation.

Sign		Score		
		0	1	2
1	Appearance	Blue, pale	Body pink extremities blue	Completely Pink
2	Pulse (heart rate)	Absent	Below 100	Over 100
3	Grimace (Reflex irritability in response to stimulation of foot sole).	No response	Grimace	Cry
4	Activity (Muscle tone)	Limp	Some flexion of extremities	Active motion
5	Respiration	Absent	Slow, irregular	Good, strong cry

Apgar scores were recorded at one minute and five minutes after birth. A new born with a score of:

0-4 points - Severely depressed

5-7 points - Moderately depressed

>8 points - Normal

- Intrauterine foetal demise, if any, was noted.

Statistical analysis: Statistical analysis of the observation was done by applying 't' test to the values observed under the two study group. $p<0.05$ was considered significant, $p<0.01$ was considered highly significant. χ^2 test was applied to compare the percentages.

OBSERVATIONS

Table 1. Demographic Data

Variables	Group A	Group B	T	P
Age (Yrs)	26.30 + 5.29	24.50+4.06	1.207	p>0.05
Height (cms)	153.92 +7.87	156.08+3.55	1.906	p>0.05
Wt. (Kg)	54.95+4.82	58.05+5.78	1.842	p>0.05

The above table shows that the both groups were comparable with each other and subjects were similar in respect to age, weight and height. There was no significant difference in age, height or weight in both groups.

TABLE – 2: Distribution of cases according to Meternal Age

Maternal Age (Yrs)	Group A		Group B	
	No.	%	No.	%
<20	2	10	4	20
21 – 30	14	70	15	75
>30	4	20	1	5
Total	20	100	20	100
Mean SD	26.30 + 5.29		24.50+4.06	

t 1.207 p>0.5

The above table shows that maximum subjects were in age range of 21-30 yrs in both study groups (70 % in Group A & 75% in group 8). Also there was no statistically significant difference in mean age of both groups.

TABLE – 3 Indications for Cesarean section in two groups

Indications	Group A		Group B	
	No.	%	No.	%
CPD	5	25	10	50
Previous LSCS	13	65	9	45
Bad Obstetric History	-	-	-	-
APH	-	-	-	-
NPOL	1	5	4	20
Abnormal Presentation	5	25	1	5
IUGR	-	-	-	-
Others	2	10	1	5

Table 3 shows the various indications for cesarean section in both study groups. The most common indication for cesarean section A was previous (SCS (65%), which was the indications for cesarean section in 45% of subjects in Group B but the most common indication of cesarean section in Group B was cephalo-pelvic disproportion (50%).

TABLE – 4 Time to reach T10 level

Time (Min.)	Group A		Group B	
	No.	%	No.	%
<5	1	5	-	-
6-10	-	-	-	-
11-15	1	5	7	35
16-20	13	65	10	50
21-25	5	25	3	15
26-30	-	-	-	-
31-35	-	-	-	-
>35	-	-	-	-
Total	20	100	20	100
Mean SD	18.10+3.67		17.80+3.37	
	t=0.269		p>0.5	

Non progression of labor (NPOL) was the indication of cesarean section in 5% subjects in Group A and 20% subjects of group B Abnormal presentation of fetus (Breach presentation transverse lie) was indication of cesarean section in 25% subjects of Group A & 6% subjects of Group B.

The above table shows distribution of subjects of subjects according to time of onset of sensory block (at T 10 level) in maximum subjects of both groups, onset of sensory block at T10 was in between 16 – 20 minutes but there was no statistically (p>0.05) difference in mean time taken for onset of sensory block between Group A (18.10+3.67) and Group B (17.80+3.37).

Table – 5: Time to reach T6 level

Time (Min.)	Group A		Group B	
	No.	%	No.	%
<5	-	-	-	-
6-10	-	-	-	-
11-15	1	5	-	-
16-20	1	5	8	40
21-25	11	55	8	40
26-30	7	35	4	20
31-35	-	-	-	-
>35	-	-	-	-
Total	20	100	20	100
Mean SD	24.45+3.54		22.50+3.84	
	T=1.670		p>0.5	

The table shows the time duration of establishment of sensory block up to T6 level which is the minimum necessary level of sensory anesthesia required for cesarean section.

Maximum subjects (55%) of control group (group A) time taken to reach T6 level of sensory block was in between 21 – 25 mins, but 35% subjects of Group A took 26 – 30 mins for T6 level sensory block.

In Group B in 40% subjects sensory block up to T6level was established in 16 -20 mins and the same percentage of subjects took 21 – 25 mins for the same.

Though the mean time for the sensory block up to T5 level was 22.50+ 3.84 mins in group B which was less than the mean time taken by Group A (24.45 + 3.54 mins), this difference is not statistically significant (p>0.05).

TABLE 6 Degree of motor block

Motor Block (Bromage Scale)	Group A		Group B	
	No.	%	No.	%
0	-	-	-	-
1	14	70	1	5
2	4	20	8	40
3	2	10	11	55
		X^2 18.83	P= 0.05	

This table shows the degree of motor block, assessed by Bromage Scale, attained by subjects of both groups.

In group A, maximum (70%) subjects attained only Bromage Scale 1 at the time of incision, while only 20% and 10% subjects attained Bromage 2 and 3 scale respectively.

At the same time, maximum subjects (55) in group B had Bromage 3 motor block, 40% had Bromage 2 and only 5% subjects had Bromage 1 motor blockage.

So, it can be concluded that the motor blockage was significantly better in Group B subjects than group A subjects ($p<0.05$).

Table – 7 Need of top up doses

Time (Min.)	Group A		Group B	
	No.	%	No.	%
0	9	45	17	85
1	5	20	1	5
2	4	20	2	10
3	2	10	-	-
>3	-	-	-	-

45% subjects of group A and 85% subjects of group B did not require any top up dose of inj. Bupivacaine 0.5% by epidural catheter, while 25% and 20% subjects of group A required single and two top up dosage of epidural bupivacaine 10% subjects of group A required even 3 top up dose of epidural bupivacaine.

At the same time none of the subjects of group B required more than 2 top up doses, but 10% subjects required 2 doses of epidural top- ups.

So, it is evident by this table that the demand for epidural top up doses was significantly higher in group A subjects ($p <0.05$).

Table -8 Total dose of bupivacaine (in ml)

Time (Min.)	Group A		Group B	
	No.	%	No.	%
<18	9	45	17	85
19-21	5	25	1	5
22-24	4	20	2	10
25-27	2	10	-	-
>27	-	-	-	-
Total	20	100	20	100
Mean SD	20.85+3.07		18075+1.87	
	T = 2.613		P <0.05	

The above table shows the total dose of epidural bupivacaine 0.5% required for sensory level of T6 in both the study groups. We gave initial doses of inj. Bupivacaine 0.5% 18 ml epidurally than top up doses of 1.5ml of bupivacaine 0.5% per unblocked segment to get the sensory level of T6.

In group A mean total dose of inj bupivacaine 0.5% was 20.85 + 3.67 ml which was significantly higher ($p<0.05$) than the mean total dose of inj. Bupivacaine 0.05% (18.75 + 1.87 ml) required by group B subjects.

TABLE 9 Supplementation

Time (Min.)	Group A		Group B		T	p
	No.	%	No.	%		
IV	13	65	3	15	4.6078	<0.05
IV+GOM	8	40	1	5	4.5455	<-0.05

The above table shows the need of supplementation analgesia in intraoperative period in both groups.

In Group A, 13 out of 20(65%) patients required supplementation with IV. Analgesics and 40% patients even required N20 – O_2 by mask in addition to I.V. analgesics.

In group B, only 15% patients required supplementation with I.V. analgesics and only 55 required N_2O-O_2 by mask in addition.

So, it is evident that demand for supplementation analgesics was significantly greater in Group A subjects ($p<0.05$).

Table 10 Induction to skin incision time (minutes) I-S interval)

l-S Interval	Group A		Group B	
	No.	%	No.	%
<20	1	5	1	5
20-25	1	5	10	50
25-30	12	60	7	35
30-35	6	30	2	10
>35	-	-	-	-
Total	20	100	20	100
Mean SD	27.80+4.58		26.30+3.86	

The above table shows that the mean time duration of induction to skin incision time in minutes in group A was 27.80 + 4.58 mins, which was longer than the mean time required by group B subjects (26.30+3.86 min) but the difference was not statistically significant ($p>0.05$).

Table – 11 Skin incisions to delivery time (minutes) S-D interval)

Time (Min.)	Group A		Group B	
	No.	%	No.	%
<8	5	25	5	25
8-12	12	60	14	70
12 – 16	2	10	1	5
16-20	-	-	-	-
20-24	1	5	-	-
>24	-	-	-	-
Total	20	100	20	100
Mean SD	10.50+3.31		0.85+1.71	

T = 0.780 P > 0.05

The table shows that the mean time duration of skin incision to delivery time (SD interval) in group A was 10.50+3.31 minutes and in group B was 9.85 + 1.71

mins, but the difference between both groups was statistically not significant (p>0.05).

Table 12 Uterine incision to delivery time (minutes) (U-D interval)

U=D interval	Group A		Group B	
	No.	%	No.	%
<1	3	15	2	10
1.1 – 1.5	6	30	5	25
10.5 -2.0	6	30	9	45
2.1 – 2.5	1	5	3	15
>2.5	4	20	1	5
Total	20	100	20	100
Mean SD	2.12.+1.48		1.89+0.53	
		T=0.654	p>0.5	

The above table shows comparison of uterine incision to delivery time between both groups.

The mean U-D interval in group A was 2.20 + 1.48 minutes which was statistically comparable to group B's U-D interval (1.83 + 0.53 mins) (p p>0.05).

Table – 13 Neonatal Assessment by Using APGAR Score at 1 min.

Apgar Score	Group A		Group B	
	No.	%	No.	%
<8	4	20	3	15
6 – 7	11	55	11	55
7 – 8	4	20	5	25
8 – 9	1	5	1	5
>9	0	0	0	0
Total	20	100	20	10
Mean SD	6.90+1.34		7.20+0.87	
		T=0.84	P>0.5	

Table 13 & 14 shows assessment of neonatal condition using APGAR Score at 1 & 5 mins after delivery.

Table 13 shows the mean APGAR score at 1 min was 6.90+1.34 in group A and 7.20+0.87 in group B and the difference between two group was statistically not significant (p>0.05).

Table – 14 Neonatal Assessment by using APGAR SCORE at 5 min

Apgar Score	Group A		Group B	
	-	-	-	-
<5	-	-	-	-
6 – 7	-	-	1	5
7 – 8	3	15	1	5
8 – 9	10	50	9	45
>9	7	35	9	45
Total	20	100	20	100
Mean SD	9.20+0.68		9.35+0.79	
		T=0.664	P>0.5	

Table 14 shows that the Apgar Score at 5 min interval after delivery was 9.20 + 0.68 in group A, which was statistically comparable to mean APGAR Score of 6.35 + 0.79 in group B (p>0.05).

Table 15 Intra operative Complications

Complications	Group A		Group B	
	No.	%	No.	%
Shivering	2	10	4	20
Nausea/Vomiting	3	15	4	20
Chest discomfort	3	15	3	15
Respiratory depression	0	0	0	0
Hypotension	0	0	2	10
Restlessness	1	5	0	0
Bradycardia	0	0	1	5
	d.f. 6	χ^2 3.9040	p>0.05	

The table given above shows the intra operative complications encountered during the epidural block for caesarean section.

In Group A most common complications were nausea vomiting and chest discomfort in 15% subjects in 10% subjects there was complaint of shivering and in 5% subjects restlessness occurred.

While in group B most common complications were shivering and nausea/vomiting which occurred in 20% subjects in 15% subjects of group B chest discomfort was the intraoperative complaint. At the same time, 10% patient developed hypotension out of which 5% had bradycardia.

But the overall comparison of intraoperative complications between group A and group B was statistically not significant (p>0.05).

TABLE-16: PULSE RATE

Group	No. of patients	Statistical	Base	Before	After	5min	10min	15min	20min	25min	30min	40min	50min	60min
I	20	Mean	87.44	89.16	87.28	85.36	84.48	83.76	82.32	81.28	82.24	82.72	82.72	83.60
		S.D.	6.18	5.45	5.63	6.01	7.57	5.58	5.24	4.93	4.09	4.56	4.49	5.06
		t		1.044	0.096	1.206	1.514	2.210	3.160	3.896	3.508	3.073	7.160	2.404
		p		>0.05	>0.05	>0.05	>0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05
II	20	Mean	87.52	89.08	87.68	86.32	84.64	83.36	82.08	81.92	82.64	83.28	83.60	84.48
		S.D.	5.55	5.75	5.21	5.05	4.95	6.03	4.75	5.26	4.99	4.30	4.49	4.54
		t.		0.976	0.105	0.800	1.936	2.538	3.723	3.662	3.269	3.020	2.746	2.120
		p		>0.05	>0.05	>0.05	>0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05
Comparision of		t	0.048	0.050	0.261	0.611	0.088	0.243	0.170	0.444	0.310	0.447	0.693	0.647
I & II Group		p	>0.05	>0.05	>0.05	>0.05	>0.05	>0.05	>0.05	>0.05	>0.05	>0.05	>0.05	>0.05

TABLE 17: SYSTOLIC BLOOD PRESSURE

Group	No. of patients	Statistical	Base	Before	After	5min	10min	15min	20min	25min	30min	40min
I	20	Mean	127.20	128.40	126.56	124.00	119.92	118.48	115.28	115.28	117.44	120.32
		S.D.	10.20	9.65	9.68	9.23	10.05	10.31	10.02	11.17	10.10	8.42
		t		0.472	0.228	1.163	2.542	3.006	4.168	3.940	3.400	2.601
		p		>0.05	>0.05	>0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05
II	20	Mean	127.44	128.40	127.26	124.48	121.52	118.00	115.52	115.12	118.16	121.04
		S.D.	9.08	8.65	8.64	8.43	8.68	8.80	8.90	9.23	8.12	7.78
		t.		0.383	0.008	1.195	2.356	3.733	4.688	4.758	3.809	2.676
		p		>0.05	>0.05	>0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05
Comparision of		t	0.088	0.000	0.347	0.192	0.602	0.177	0.090	0.055	0.278	0.314
I & II Group		p	>0.05	>0.05	>0.05	>0.05	>0.05	>0.05	>0.05	>0.05	>0.05	>0.05

TABLE 18 : DIASTOLIC BLOOD PRESSURE

Group	No. of patients	Statistical	Base	Before	After	5min	10min	15min	20min	25min	30min	40min	50min	60min
I	20	Mean	77.40	75.95	73.85	84.30	94.10	97.25	93.05	85.60	80.55	76.60	73.05	70.95
		S.D.	6.0	6.5	9.4	11.7	8.6	12.5	14.4	9.8	10.4	11.6	11.3	10.0
		t		0.733	1.424	2.347	7.122	6.402	4.486	3.191	1.173	0.274	1.384	2.473
		p		>0.05	>0.05	<0.05	<0.05	<0.05	<0.05	<0.05	>0.05	>0.05	>0.05	<0.05
II	20	Mean	77.90	75.65	74.50	87.15	95.75	90.80	85.95	81.90	77.25	73.15	71.65	70.60
		S.D.	4.6	7.2	6.3	9.6	7.7	8.6	7.4	7.8	7.1	7.1	6.8	5.4
		t.		1.178	1.949	3.886	8.900	9.876	4.132	1.975	0.344	2.511	3.405	4.602
		p		>0.05	>0.05	<0.05	<0.05	<0.05	<0.05	>0.05	>0.05	<0.05	<0.05	<0.05
Comparision of		t	0.296	0.138	0.257	0.842	0.639	1.901	1.901	1.321	1.065	1.314	0.475	0.138
I & II Group		p	>0.05	>0.05	>0.05	>0.05	>0.05	>0.05	>0.05	>0.05	>0.05	>0.05	>0.05	>0.05

DISCUSSION

Regional anesthesia has become more popular in cesarean deliveries because most of the parturients prefer to remain awake during the delivery of the baby. In addition, regional anesthesia may be safer method than general anesthesia (Hawkins et al 1997). Epidural Anesthesia is still the most commonly used anesthetic technique for cesarean delivery (Carries et at 1990).

Because of potential cardiotoxicity associated with 0.75% bupivacaine, anesthesiologists have been using 0.5% concentration of bupivacaine since 1983 (Kileff ME et at 1984). The lower concentration of bupivacaine is adequate for sensory analgesia but it does not provide optimal conditions for surgical analgesia. (Thorburn J et al 1980, Marites P Gaffrud et at 1986), also reported that in their study, 7 out of ten patients given epidural bupivacaine 0.5%, despite having a T6 sensory level block, complained of pain after surgical stimulation, these patients required supplemental analgesia.

Bupivacaine (0.5%) is the most commonly used drug epidurally for analgesia and anaesthesia for cesarean sections. The addition of an opiate to an epidurally administered local anesthetic has been suggested to improve the quality of analgesia provided by 0.5% bupivacaine. (Milon D et al 1983) found that the combination of 0.5% bupivacaine and 100mg of fentanyl administered epidurally was more effective than epidural 0.5% bupivacaine alone.

In the present study, we used the pin prick testing method for assessment of sensory level of epidural block.

The onset of sensory block upto T10 level in our study was 18.10±3.6 mins in Group A and 17.80±3.37mins in Group B but the difference between Group 1 & 2 was statistically not significant ($p>0.05$).

In our study, sensory level of T6 or higher was achieved by Group A & B, candidates in 24.45±3.54 mins and 22.50±3.84 mins. respectively. Again the difference was not significant ($p>0.05$).

Wojciech Pietrzyk, Laura Wolo Wicka et al (2001) found in their study of CSE analgesia for elective cesarean section, mean time of onset of block at T4 level 26.7±5.1 min, which was comparable to our results.

But, D.H. Choi; J.A. Kim et al (2000) found that the mean time of onset of sensory block was 18.3±7.15 mins.

Helbo-Hansen S. et al (1988) found mean time of onset of sensory block at T4 level, 30 mins, which was a little longer than this present study.

These differences in the times taken for onset of sensory level of T4 could be due to regional differences of height of the subjects.

Degree of motor block

In our present study, degree of motor blockade was judged by Bromage scale assessment.

In Group A; maximum (14 out of 20) i.e. 70% subjects had only Bromage 1° of motor block; 20% subjects had Bromage 2° of motor block and only 2 patients had complete motor block i.e. Bromage 3°.

In Group B, i.e. bupivacaine-fentanyl group; motor blockade was significantly better than Group A. Maximum number of patients (11 out of 20); i.e. 55% patients had complete motor block; i.e. Bromage 3° score. 8 out of 20 patients had Bromage 2° of motor block and only 5%, i.e. 1 out of 20 patients; had Bromage 1° motor block.

So, the difference in the degree of motor blockade in Group A (bupivacaine only) and Group B (bupivacaine-fentanyl) was statistically significant ($p<0.05$).

Wojciech Pietrzyk; Laura Wolowicka et al (2001) found in their study that 67.5% patients had bromage 3° score and 32.5% patients had Bromage 2° of motor block.

Stephenie J. Davies et al (1997) also found better motor blockade with epidural fentanyl in their study.

D. Jill Ellis, Walter L. Miller et al (1990) also found the Epidural Fentanyl produced effective and intense analgesia & anesthesia in their study.

Need & Number of Top up doses to reach T6 level.

As the minimum level of sensory anesthesia, necessary for cesarean section is T6; we often had to give epidural top up doses of 0.5% bupivacaine after the initial dose of 18m1 0.5% bupivacaine.

We gave 1.5ml/unblocked segment of 0.5% bupivacaine, in aliquots of 3m1 by epidural catheter to achieve level of T6.

In this present study, in Group A; 55% of patients required one or more top up doses of 0.5% bupivacaine to achieve T6 sensory level; while only 15% patients required epidural top ups and this difference was statistically significant ($p<0.05$).

Milon D, Bantu Ferrer D et al (1983) concluded in their study that combination of epidural bupivacaine and fentanyl provides a better and faster analgesia than the epidural bupivacaine alone. Their findings were confirmed by Marties P, Gaffud et al (1986). The number of epidural top ups were also less in the combination (bupivacaine-fentanyl) group.

Total dose of epidural bupivacaine 0.5% - Table 8 shows the total dose of 0.5% bupivacaine given epidurally in our study to achieve sensory level of T6 or higher; necessary for cesarean section.

In group A, mean total dose of 0.5% bupivacaine required was 20.85±3.07 which was significantly higher ($p<0.05$) than mean total dose of 0.5 bupivacaine required by Group B subjects (18.75±1.87 ml).

The finding of our study was in accordance with the study of Marites P. Gaffud, Pratibha Bansal et al (1986), who also reported higher dose required in the bupivacaine and placebo group (118±13mg of 0.5 bupivacaine) versus bupivacaine and fentanyl (109.5±12.5mg) group.

Also N, Rawal, J.Schollin et al (1988) reported the mean total dose of epidural bupivacaine 0.5% to be 125±2.67mg which was also comparable to our study. Also Froncis M. James; J. Selwyn Crawford et al used in their study A comparison of general anesthesia & lumber epidural analgesia for cesarean section; the total mean dose of 0.5% bupivacaine epidurally 19.4m1; which was comparable to dose used in this study.

Need of supplementation

Supplementation with I.V. analgesics alone and I.V., analgesic with N20-02 by mask is often needed for the complete pain relief during intra operative period in epidural anesthesia.

Because of potential cardio-toxicity associated with 0.75% bupivacaine, now 0.5% bupivacaine is being used in epidural anesthesia (Kileff ME, Jamer T.M. et al, 1984).

Thorburn J, Moir DD stated in their study "Epidural anesthesia for elective cesarean section" that though the lower concentration of bupivacaine is adequate for sensory analgesia; however, it does not provide for optimal conditions for surgical anesthesia. This observation was made by Milon et at (1983) and was also confirmed by Maritus P. Gaffud, Pratibha Bansal et at (1986): In their study, 70% patient, who were given 0.5% bupivacaine only, despite having a T4-sensory level, complained of pain after surgical stimulation and required supplementation with I.V. analgesics and/or N20-02 by mask.

The above observation was also confirmed by our present study.

In this present study; 13 out of 20 (65%) of patients, who were given epidural 0.5% bupivacaine only, required supplementation with I.V. analgesics and out of these 13 patients 8 patients required N20-02 analgesia by mask in addition of I.V. analgesics.

In comparison in the group B patients, who received epidural bupivacaine 0.5% and 50mg fentanyl combination, only 15% subject complained of intra operative pain on surgical stimulation and required i.v. analgesics out of which only 5% patients required N20-02 by mask in addition to I.V. analgesics. This finding is in

accordance with the observation made by Milan D et al, that the quality of epidural analgesia can be improved by combining fentanyl with epidural bupivacaine 0.5%.

Marites P. Gaffud, P. Bansal et al also found that only 20% patients, who were given combination of epidural bupivacaine with 100mg of fentanyl epidurally, complained pain on surgical stimulation and only 10% required supplementation with I.v. analgesics.

N. Rawal et al (1988) also reported pain on surgical stimulation in their study of 'epidural vs CSE anesthesia for cesarean section', in epidural group. In their study 73% patients who had recieved epidural bupivacaine 0.5%; complained of pain & required i.v. analgesics. Furthermore, 13% patients in epidural group in their study, required N20-02 anesthesia in addition to I.V. analgesics.

D.H. Choi; J.A. Kim et al (2000) found that despite giving combination of lidocaine with epinephrine, sodium bicarbonate & fentanyl epidurally, 22% patients complained of pain during surgical stimulus & required supplementation.

So it is evident that addition of an opioid as fentanyl greatly reduces the incidence and severity of intraoperative pain, when given epidurally with local anesthetic solution.

Time Intervals

Induction to skin incision time (mins.) (I-S interval).

This is the time from induction of epidural anesthesia to skin incision; which was little longer (3-5mins.) from the time interval of block establishment up to T6 sensory level. This little (3-5 mins) interval gap was due to surgical preparations for cesarean section, such as painting & draping of the patient.

In our study, the mean time duration of anesthesia induction to skin incision (S-D interval) was 27.80±4.58 mins. in group A patients, which was little longer than the time duration taken by Group B patient (26.30±3.86 mins.) but the difference was not statistically significant (p>0.05).

Wojjiech Pietrzyk, Laura Wolo-Wicka et al (2001) found in their study, 'CSE analgesia for elective cesarean section in intra operative period', that induction to skin incision time was 30.7±9.5 mins, which is comparable to our results.

Stephanie J. Davies, Michael J. Paech et al (1997) in their study 'maternal experience during epidural or CSE anesthesia for cesarean section: A prospective, randomized trial", reported induction to skin incision time of 36 min (30-42), when using 2% lidocaine & 50mg fentanyl.

D.H. Choi, J.A. Kim et al (2000) reported Induction-skin incision time interval of 17.9±3.44 mins. They used 2% carbonated lidocaine solution with 10014 of fentanyl with 0.1m1 of 0.1% epinephrine for epidural block.

Skin incision to delivery time (mins') (S-D interval)

Skin incision to delivery time (S-D interval) mainly depends on the surgeons performing the operation; but degree of motor block also plays a role. As previously stated, the degree of motor block was significantly better in the group B in our study. No wonder; that mean S-D interval too was shorter in Group B (9.85±1 .71 mins.) than the group A (10.50±3.31mins.) patients. But the difference was not statistically significantly.

J.W. Downing, P.C. Houlton et al (1979) reported S.D. interval of 7.9 mins in their study Extradural analgesia for cesarean section: A comparison with general anesthesio. The difference could be due to more experienced surgeon team in their study.

WojciechPietrzyk, Laure Wolowicka et al (2001) found in study of 'combined spinal epidural analgesia for elective cesarean section in intraoperative period', that SD interval was 11.1±6.7min. Their results were comparable to our present study.

Bjom Holmstorm et al (1994) reported in their study the SD time of 7.8±1.7 mins.

Stephanie J, Davies: Michael J. Parch et al (1997), in their study of 'Maternal experience during epidural or combined spinal epidural anesthesia for cesarean section: A prospective; randomised trial', found the skin to delivery interval of 11 mins which is comparable to our findings.

Uterine incision to delivery time

Uterine incision to delivery time interval should be as minimal as possible as it does affect the neonatal condition.

In our present study U-D interval was 2.12±1.48 mins in Group A subjects and 1.89±0.53 mins in Group B patients.

Though the U-D time interval was little longer in group A than Group B; but the difference was statistically not significant ($p>0.05$).

Ray V. Brizgys et al (1987) found the mean U-D interval of 127±5 sec. in their study, which was comparable to our findings.

In 1977, Francis M. James et al reported the U-D interval of 102 secs. in their study. A comparison of general anesthesia and lumber epidural analgesia for elective cesarean section.

Wojciech Pietrzyk; Laura Wolowicka et at (2001) found U-D interval of 70.4±29 secs in their study, 'combined spinal epidural analgesia for elective cesarean section in intra operative period'.

Intraoperative complication

Milon D., Bentue-Ferrer D et al (1983) has shown the quality of epidural analgesia can be improved by combining 0.5% bupivacaine with fentanyl. A faster onset of action and more effective analgesia was seen with the combination therapy. No adverse effects were noted by them.

The findings of Milon D et al (1983) were confirmed by Marites P. Gaffud, P. Bansal et al (1986) in their study, surgical analgesia for cesarean delivery with epidural bupivacaine and fentanyl. They reported more incidence of maternal hypotension associated with epidural fentanyl and bupivacaine than epidural bupivacaine only. All hypotensive episodes responded rapidly to treatment. They could not find any significant difference in the incidence of nausea or vomiting; pruritus; dizziness, changes in mental status between both groups.

The more incidence of hypotension in Marites P. Gaffud's study than our study might be because of increase dose of epidural bupivacaine used in their study.

In the present study; the incidence of shivering in group A and group B was 10% and 20% respectively.

The incidence of nausea and vomitting in our present study was 15% in group A and 20% in group B. All episodes of nausea and vomiting were treated by I.V. ondansetron and they respondend quickly.

Chest discomfort was presenting complaint in 15% of patients in each group in our study. Surprisingly all episodes of chest discomfort were occurred after delivery of newborn. Inj Ranitidine i.v. was given for this complaint.

None of the subjects showed any sign/symptom of respiratory depression in either group in our study.

Hypotension occurred in 10% of patients in group B. Hypotension was defined as >30% drop in systolic blood pressure than the preoperative value or systolic blood pressure of <100 mmHg. All hypotensive episodes responded quickly to foot end elevation with or without i.v. ephedrine in small doses.

None of the patients in group A had any hypotensive episode, this may be due to gradual establishment of epidural blockade.

In group A, 5% subjects had complaint of restlessness.

Only reassurance was required and it worked well.

Bradycardia was reported in 5% patients of Group B, and it was associated with hypotension and it responded quickly to restoration of blood pressure. None of the group A patients had any episode of hypotension or bradycardia.

Though the incidence of Shivering, nausea/vomiting, hypotension and bradycardia were higher in Group B

(bupivacaine + fentanyl); none of them posed any serious problem and the overall difference between group A and group B was not statistically significant (p>0.05).

Wojciech Pictrzyk; Laura Wolowicka et al (2001) reported in their study an incidence of nausea/vomiting (22.5%), shivering (30%), hypotension (65%). They used a combination of 0.5% bupivacaine and 75mg of fentanyl for epidural anesthesia in their study.

D.H. Choi, J.A. Kim et al (2000) used a combination of cabonated solution of 2% lidocaine with 100jig of fentanyl and they found incidence of hypotension to be 22%, of nausea 19% and of shivering 34% in their study. There results were comparable with our results.

Epidural opioids have been reported to cause shivering in many previous studies. In comparision of incidence of shivering in our study with Wojciech Pietrzyk study and D.H. Choi study, it was found that shivering was more common in their study. This might be because of increased dose of epidural fentanyl in their study.

Stephanie J. Davies, Michael J. Paech et al (1997) in their study-Maternal experience during epidural or combined spinal epidural anesthesia for cesarean section; used carbonated lidocaine 2% with 10014 of fentanyl for epidural anesthesia. They reported incidence of nausea/vomiting or both to be 33%.

Maritus P. Gaffud; P. Bansal et at (1986) in their study surgical analgesia for cesarean delivery with epidural bupivacaine and fentanyl; reported incidence of hypotension 30% in bupivacaine only group and 50% in the bupivacaine fentanyl group. 40% patients in bupivacaine only group experienced nausea and vomiting compared with 50% of bupivacaine-fentanyl group. None of their patient in either group had any respiratory depression. Neonatal Assessment by Apgar Score In our present study; we used Apgar score to assess the neonatal condition to judge any adverse effect of epidural anesthesia with combination of bupivacaine and fentanyl. Apgar score was calculated at 1 and 5 mins after delivery of new born.

The mean Apgar score at 1 min was 6.90±1.34 in group A and 7.20±0.87 in group B, but the difference was not statistically significant (p>0.05).

In group A, 20% newborn had Apgar score of <6 compared to 15% newborns in Group B but the difference is statistically not significant. This lower Apgar score was probably due to maternal conditions rather than because of addition of fentanyl to bupivacaine.

The mean Apgar score at 5 mins was 9.20±0.68 in Group A and 9.35±0.79 in Group B and again the difference between Group A and Group B was not statistically significant.

In their study, Maritus P, Gaffud; P. Bansal et al (1986) reported the mean Apgar score at one mins. were 7.9±0.7 for the bupivacaine fentanyl group and 8.1±0.7 for the local anesthesia only group. All Apgar score were 9 at 5 mins in their study. Comparison of Apgar scores revealed no differences between treatment groups (p>0.05). So they concluded that the combination of bupivacaine and fentanyl was not associated with identifiable significant adverse effects in the newborn. Their findings were in accordance with the results of our study.

In their study of extradural analgesia for cesarean section: A comparison with general anesthesia, J.W. Downing; P.C. Houlton et al (1979), found no difference between the two groups studied with respect to Apgar score.

J.W. Downing et al (1979) also found a significant increase in fetal acidemia with lengthening of Induction to delivery time and uterine incision to delivery time in extradural group.

But despite the relatively unfavourable maternal and fetal acid base status of the extradural group, the clinical condition was generally superior after extra-dural analgesia relative to general anesthesia (J.W., Downing, P.C. Houlton et al, 1979).

Marx GF et al (1973) and Benson RL et al (1969) reported in their studies that fetal depression after cesarean section is less common with regional anesthetic techniques as opposed to general anesthesia.

Stenger V., Andersen T et al (1965) reported that epidural anesthesia as compared to spinal anesthesia produces less maternal hypotension and deviation of newborn acid base status.

Francis M, James et al (1977) stated that though fetal acid base status was better after cesarean delivery with general anesthesia, the clinical condition of new born assessed by Apgar score and TSR, was better in epidural block for cesarean section.

In this present study also it is evident that most of newborns in both groups studied had Apgar score of 9 at 5 mins and none of them was severely depressed (Apgar score <6) in either group. So, it is evident that addition of fentanyl to epidural bupivacaine produces relatively more reliable, intense analgesia of better quality for surgical purposes without any adverse effect on the newborn.

CONCLUSION

Our study could not find any evidence of any adverse effect of addition of 50µg fentanyl to 0.5 bupivacaine for epidural anesthesia for cesarean section.

This can be concluded that addition of 50µg fentanyl with 0.5% bupivacaine for epidural anesthesia for elective cesarean section provides a faster, better quality of intraoperative anesthesia without any adverse effect on maternal and newborn outcome.

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