“Comparison of Different Doses of Intrathecal Hyperbaric Bupivacaine in Combined Spinal Epidural Technique for Elective Caesarean Section”

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I. Introduction
The use of neuraxial anaesthesia has gained popularity in recent time over general anaesthesia for caesarean section. Neuraxial anaesthesia has several advantages, including a reduced risk of failed intubation and aspiration of gastric contents, avoidance of depressant drugs and the mother can remain awake and enjoy the birthing experience1,2. It has been found that blood loss is reduced under regional anaesthesia for caesarean section3. The combined spinal-epidural technique (CSE), first reported in cesarean section in 19844, has recently gained popularity. Spinal anaesthesia has a very rapid onset of action and provides a dense neural blockade but finite duration of action and the drawbacks are, that they carry a high incidence of nausea, vomiting, hypotension5 and even fetal acidemia. Epidural anaesthesia is more titratable, may produce less hemodynamic swings6, can be used for postoperative analgesia but slow onset, patchy blockade, catheter migration, large volume of local anaesthetic requirement are the drawbacks. CSE offers benefits of both spinal and epidural anaesthesia and decreases their failure rates when used alone. Both techniques have a failure rate of 2-5% even with experienced practitioners6, when used separately. The chance of both techniques failing at the same time, if combined, would be 0.16%. CSE is shown to produce a physiologically denser block than either technique performed separately7. CSE technique allows the use of smaller doses of local anaesthetics, which in turn reduces the incidence of high spinal block and hypotension8. This study was designed to evaluate the optimum dose of intrathecal hyperbaric bupivacaine 0.5% with epidural lignocaine in combined spinal epidural technique for caesarean section that can produce adequate anaesthesia without causing significant hemodynamic changes.

II. Aim Of The Study
This study aims to evaluate the optimum dose of intrathecal hyperbaric bupivacaine with epidural lignocaine in combined spinal epidural technique for caesarean section to achieve adequate anaesthesia with hemodynamic stability.

III. Materials And Methods
This study was conducted at the Govt. Kasturba Gandhi Hospital for Women & Children, Madras Medical College, Triplicane, Chennai-5, between January 2012 to March 2012 on 80 patients of ASA physical status I and II posted for elective caesarean section.

This study was started after ethical committee approval and after obtaining written informed consent from all the patients involved in this study.

IV. Study Design
Prospective, randomized, double blindered study.

GROUPS:
The patients were divided randomly into four groups and each group containing 20 patients

GROUP A:
Patients in this group received 0.5ml of 0.5% hyperbaric bupivacaine intrathecally.

GROUP B:
Patients in this group received 1 ml of 0.5% hyperbaric bupivacaine intrathecally.

GROUP C:
Patients in this group received 1.5ml of 0.5% hyperbaric bupivacaine intrathecally.

GROUP D:
Patients in this group received 2 ml of 0.5% hyperbaric bupivacaine intrathecally.

Selection of cases
Inclusion criteria:
- Age: 18 years and above
- Weight: BMI < 30 Kg/m2
- Height: >145 cm
- Surgery: Elective
- American Society of Anaesthesiologist Physical Status (ASA PS): I & II
- Who have given valid informed consent

Exclusion criteria:
- Not satisfying inclusion criteria.
- Patients posted for emergency surgery
- Lack of written informed consent
- If the epidural catheter failed to thread through the tuohy needle or the procedure took more than 15 mins
- Abnormal coagulation profile/local sepsis or any other contraindication for spinal/epidural anaesthesia

V. Methodology

METHODOLOGY

ETHICAL COMMITTEE APPROVAL

PATIENT SATISFYING INCLUSION CRITERIA

INFORMED CONSENT OBTAINED

RANDOMIZATION BY CLOSED ENVELOPE METHOD

GROUP A, B, C OR D

PREMEDICATION

HR, BP MEASURED

PATIENT IN LATERAL POSITION

EPIDURAL CATHETERISATION

SUBARACHNOID BLOCK

PATIENT TO SupINE POSITION

MEASUREMENT OF PT TIME

SURGERY PROCEEDS

END OF SURGERY

FURTHER PT TIMES MEASURED

DATA COMPILATION

STATISTICAL ANALYSIS

CONCLUSION
Pre-anaesthetic evaluation:
 Patients selected for the study are evaluated thoroughly, which involved

- **History**
  - Of underlying medical illness/co-morbidity
  - Previous surgeries in the past
  - Last oral intake
  - Any drug allergies

- **Physical Examination**
  - General condition
  - Height
  - Weight
  - Vital signs – BP, PR, SpO2
  - Systemic examination – CVS, RS, CNS, abdomen, spine and cranium
  - Airway assessment

- **Investigations**
  - Hemoglobin concentration
  - Complete blood count
    - blood urea
    - serum creatinine
    - serum electrolytes
  - Blood sugar
  - Urine routine
    - Albumin
    - Sugar
    - deposits
  - Bleeding time, clotting time
  - Blood grouping and typing
  - Electrocardiogram

* Patients satisfying inclusion criteria were explained about the procedure and the nature of the study.
* Written informed consent obtained from all the patients in their own language.

Preparation of the patient:

After assessing the patient, an intravenous line started under aseptic precautions with 18 G cannula in the assessment room. Premedication given with Inj. Ranitidine 50mg and Inj. Metoclopramide 10mg IV, half an hour before surgery. Patient shifted to operation theatre in left lateral position. Preloading was done with 20ml/kg of ringer Lactate over 15 minutes. Baseline pulse rate, blood pressure, arterial oxygen saturation (SpO2), respiratory rate and fetal heart sounds were noted.

Equipments:
The spinal tray (autoclaved) used for performing the combined spinal epidural technique contained the following equipments.

1. Graduated 2ml syringe
2. No. 22G hypodermic needle
3. No. 18G hypodermic needle
4. No. 25G spinal needle – Quincke
5. No. 18G epidural needle
6. No. 20G epidural catheter
7. 5ml syringe with freely moving plunger
8. 5ml loss of resistance (LOR) syringe
9. Skin towel
10. Galley pot with swabs
11. Sponge holding forceps

Drugs:

- Bupivacaine 0.5% hyperbaric solution – 4ml ampoule
- Lignocaine 2% with adrenaline (1:200000) solution
Performing the combined spinal epidural blockade:

The patient was placed in lateral position on a horizontal operating table. The back of the patient was cleaned with povidone iodine and spirit. The excess of spirit wiped using a dry gauze. The area of blockade was draped with sterile towel. L2-L3 space was selected for performing epidural catheterization and L3-L4 space was selected for subarachnoid blockade. L2-L3 space identified and epidural space identified using 18G epidural needle through loss of resistance technique. Epidural catheter threaded through that needle and tip placed 5cm cephalad. Epidural catheter secured using tapes. L3-L4 space identified and dural tap was performed using 25G spinal needle. After free flow of CSF, 0.5% bupivacaine was injected (0.5, 1, 1.5, 2 ml each according to their respective group) at a rate of 0.2ml/second. Immediately, the patients were turned on their back to supine position and a wedge placed under right gluteal region. Based on the level of sensory blockade achieved at 5th minute, epidural topup given with 2% lignocaine with adrenaline(1:200000) 3cc every 3 minutes till sensory level T4(thoracic segment 4) was achieved. 6 liters of Oxygen given through face mask, till extraction of the baby. Observations were recorded.

Outcome measures:

Sensory block:
- Assessment of loss of temperature sensation done immediately after the intrathecal injection was made and continued every 15 seconds
- Onset of sensory block was kept as the time taken from intrathecal injection to loss of temperature sensation, as assessed by a cotton piece soaked in surgical spirit, at T4 level
- If sensory level of T4 was not achieved by 5th minute, 2% lignocaine with adrenaline epidural topup given 3cc every 3 minutes till T4 sensory level was achieved.

Vital signs:
Pulse rate, systolic and diastolic blood pressure, SpO2, respiratory rate were recorded every 5 minutes throughout the intra-operative period.
- Hypotension, defined as fall of systolic BP 20% from the baseline or systolic BP of <90mm Hg whichever occurs first, was managed with rapid infusion of IV fluids and Inj. Ephedrine 6mg increments
- Bradycardia defined as Heart rate <60/min and was managed with Inj. Atropine 0.01mg/kg IV(if resistant to inj.ephedrine given for hypotension)
- Respiratory depression defined as RR<8/min or SpO2<92%, which was managed with bag and mask ventilation or intubation and IPPV if necessary.

Quality of surgical anaesthesia:
- Excellent – no complaints of pain anytime during the surgery
- Good – minimal pain or discomfort – to be treated with Inj. Pentazocine 0.5mg/kg IV
- Poor – GA needs to be administered

Neonatal apgar score:

<table>
<thead>
<tr>
<th>PARAMETERS</th>
<th>0</th>
<th>1</th>
<th>2</th>
</tr>
</thead>
<tbody>
<tr>
<td>HEART RATE</td>
<td>Absent</td>
<td>&lt;100</td>
<td>&gt;100</td>
</tr>
<tr>
<td>RESPIRATORY EFFORTS</td>
<td>Absent</td>
<td>Irregular, slow, gasping or shallow</td>
<td>Crying, robust</td>
</tr>
<tr>
<td>MUSCLE TONE</td>
<td>Absent</td>
<td>Some flexion of extremities</td>
<td>Active movement</td>
</tr>
<tr>
<td>CRY</td>
<td>No cry</td>
<td>Grimace</td>
<td>Active crying</td>
</tr>
<tr>
<td>COLOUR</td>
<td>Cyanotic</td>
<td>Acrocyanosis</td>
<td>Trunk pink</td>
</tr>
</tbody>
</table>

VI. Observation And Results

The study was conducted at Govt. Kasturba Gandhi Hospital for Women & Children, Madras Medical College, Triplicane, Chennai-5. 80 patients were included in the double blinded randomized controlled study. The patients were divided into four groups. Patient in group A received 0.5ml, group B received 1 ml, group C received 1.5ml and group D received 2ml of 0.5% bupivacaine intrathecally. Depending upon the level of sensory block achieved at 5th minute of intrathecal injection, 2% lignocaine given epidurally, to achieve a sensory block level of T4.
VII. Statistical Analysis

The four groups were matched in respect of their age, height and weight by ANOVA (Analysis of Variance). The difference between them, were interpreted by the Post hoc test of Bonferroni. Similarly, 2% Lignocaine used, Ephedrine administration, Neonatal Apgar at 1st and 5th min and duration of surgery were compared between groups by ANOVA and interpreted the difference by Post hoc test of Bonferroni. The sensory level of blockade achieved and the complications like dyspnea, shivering and vomiting were categorized and interpreted by ‘Z’ test of proportions. The above statistical procedures were performed by the statistical package IBM SPSS statistics 20. The P-values less than 0.05 (P<0.05) were treated as significant in two tail condition.

Demographic data:

The four groups were comparable in respect to their age, weight and height. There was no statistical difference among the four groups.

Table-1. Matching of the four groups according to the age.

<table>
<thead>
<tr>
<th>Group</th>
<th>Mean</th>
<th>SD</th>
<th>ANOVA “F”</th>
<th>df</th>
<th>Signific</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>25.4</td>
<td>2.6</td>
<td>0.089</td>
<td>3, 76</td>
<td>P&gt;0.05</td>
</tr>
<tr>
<td>2</td>
<td>25.1</td>
<td>3.0</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>25.2</td>
<td>3.2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>25.3</td>
<td>3.1</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The mean ages of four groups were shown in the above table-1. The four groups were not significantly differed in respect of the age.

Table-2. Matching of the four groups according to the height.

<table>
<thead>
<tr>
<th>Group</th>
<th>Mean</th>
<th>SD</th>
<th>ANOVA “F”</th>
<th>df</th>
<th>Signific</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>155.8</td>
<td>2.8</td>
<td>0.116</td>
<td>3, 76</td>
<td>P&gt;0.05</td>
</tr>
<tr>
<td>2</td>
<td>156.6</td>
<td>2.7</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>156.0</td>
<td>2.1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>155.8</td>
<td>3.1</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The mean height of the four groups were shown in the above table-2. The four groups were not significantly differed in respect of the Height (P>0.05)

Table-3. Matching of the four groups according to the weight.

<table>
<thead>
<tr>
<th>Group</th>
<th>Mean</th>
<th>SD</th>
<th>ANOVA “F”</th>
<th>df</th>
<th>Signific</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>55.8</td>
<td>2.7</td>
<td>2.469</td>
<td>3, 76</td>
<td>P&gt;0.05</td>
</tr>
<tr>
<td>2</td>
<td>55.2</td>
<td>2.5</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>55.2</td>
<td>2.3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>55.4</td>
<td>2.0</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The mean weight of the four groups were shown in the above table-3. The four groups were not significantly differed in respect of the weight (P>0.05).

Duration of surgery and baseline bp:

There was no statistical significance among the groups in terms of duration of surgery and baseline systolic blood pressure. They are comparable.

Table-4. Matching of the four groups according to their base sbp.

<table>
<thead>
<tr>
<th>Group</th>
<th>Mean</th>
<th>SD</th>
<th>ANOVA “F”</th>
<th>df</th>
<th>Signific</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>119.0</td>
<td>9.4</td>
<td>0.270</td>
<td>3, 76</td>
<td>P&gt;0.05</td>
</tr>
<tr>
<td>2</td>
<td>121.0</td>
<td>8.3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>119.6</td>
<td>8.4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>118.7</td>
<td>9.0</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The baselines SBP of four groups were matched in the above table-4. The mean SBP of four groups were not significantly differed between them (P>0.05).

Table-5. Comparison of surgery duration between the four groups.

<table>
<thead>
<tr>
<th>Group</th>
<th>Mean</th>
<th>SD</th>
<th>ANOVA “F”</th>
<th>df</th>
<th>Signific</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>65.2</td>
<td>4.9</td>
<td>2.469</td>
<td>3, 76</td>
<td>P&gt;0.05</td>
</tr>
<tr>
<td>2</td>
<td>63.9</td>
<td>6.8</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>60.8</td>
<td>8.5</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>60.6</td>
<td>5.3</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
The duration of surgery between four groups were compared in the above table-4. The mean duration of four groups were not significantly differed between them (P>0.05).

Level of sensory blockade:
Level of sensory blockade was assessed at 5th minute after intrathecal injection of 0.5% bupivacaine. The median level of sensory blockade achieved by Group A, B, C and D are T12, T6, T4 and T4 respectively and they were shown to be significant statistically with a P value <0.001.

<table>
<thead>
<tr>
<th>Level</th>
<th>Group A=2.5, B=5, C=7.5, D=10</th>
<th>Total</th>
<th>χ² / Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.00</td>
<td>6</td>
<td>6</td>
<td>122.000</td>
</tr>
<tr>
<td>2.00</td>
<td>12</td>
<td>4</td>
<td>P&lt;0.001</td>
</tr>
<tr>
<td>3.00</td>
<td>2</td>
<td>12</td>
<td></td>
</tr>
<tr>
<td>4.00</td>
<td>0</td>
<td>12</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>20</td>
<td>80</td>
<td></td>
</tr>
<tr>
<td>Median</td>
<td>T12, T6, T4, T4</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The above table -6 describes the level of Sensory blockade at 5th minute. Groups 1, 2, 3 and 4 were significantly associated with T12, T6, T4, T4 respectively (P<0.001).

Epidural topup requirements:
2% lignocaine administered epidurally, to attain a sensory block level of T4, was compared among the groups.
- 2% lignocaine was administered only in Groups A, B and C as group D achieved sensory level of T4 in all the patients.
- Group A with mean lignocaine use of 12ml was differed significantly from all other groups (p<0.001)
- Group B with mean lignocaine use of 4.5ml was differed significantly from all the other groups (p<0.001)
- Group C and D were not differed significantly (p>0.05). group C & D are comparable in respect to the lignocaine requirement.

<table>
<thead>
<tr>
<th>Group</th>
<th>Mean</th>
<th>SD</th>
<th>ANOVA F</th>
<th>df</th>
<th>Significance</th>
<th>Significantly differed</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>12.0</td>
<td>1.7</td>
<td></td>
<td></td>
<td></td>
<td>All differed except 3 and 4</td>
</tr>
<tr>
<td>2</td>
<td>4.5</td>
<td>3.2</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>1.2</td>
<td>3.1</td>
<td>102.897</td>
<td>3, 76</td>
<td>P&lt;0.001</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>0.0</td>
<td>0.0</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Ephedrine administration:
Ephedrine administration to treat hypotension was compared among the groups.
- Group A with a mean ephedrine usage of 10.8mg was differed significantly from groups B & C (p<0.001) but not group D.
- Group D with a mean ephedrine usage of 11.7mg was differed significantly from groups B & C (p<0.001) but not group A.
- Group B with a mean ephedrine usage of 1.2mg was differed significantly from groups A, C & D (p<0.05).
- Group A & D were comparable in respect to the ephedrine administration.

<table>
<thead>
<tr>
<th>Group</th>
<th>Mean</th>
<th>SD</th>
<th>ANOVA F</th>
<th>df</th>
<th>Significance</th>
<th>Significantly differed</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>10.8</td>
<td>3.7</td>
<td></td>
<td></td>
<td></td>
<td>All differed except 1 and 4</td>
</tr>
<tr>
<td>2</td>
<td>1.2</td>
<td>3.1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>5.7</td>
<td>4.6</td>
<td>31.098</td>
<td>3, 76</td>
<td>P&lt;0.001</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>11.7</td>
<td>4.1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Complications:
Certain complications like vomiting, dyspnea, shivering were compared among the groups.
- Vomiting occurred in Group C & D with 20% and 35% of patients respectively, which was statistically insignificant (p>0.05). Group C and D were comparable with respect to the occurrence of vomiting.
- The incidence of shivering in Groups A, B & C are 50%, 5% & 5% respectively. Group A differed significantly from Group B & C in respect to the incidence of shivering (p<0.001). Shivering was significantly associated with Group A.
- Dyspnea occurred only in one patient in Group D.

Table 9: Complications

<table>
<thead>
<tr>
<th>Complications</th>
<th>Group 1</th>
<th>Group 2</th>
<th>Group 3</th>
<th>Group 4</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No.</td>
<td>%</td>
<td>No.</td>
<td>%</td>
</tr>
<tr>
<td>Dyspnea</td>
<td>0</td>
<td>0.0</td>
<td>0</td>
<td>0.0</td>
</tr>
<tr>
<td>Vomiting</td>
<td>0</td>
<td>0.0</td>
<td>0</td>
<td>0.0</td>
</tr>
<tr>
<td>Shivering</td>
<td>10</td>
<td>50.0</td>
<td>1</td>
<td>5.0</td>
</tr>
</tbody>
</table>

Other parameters:
The quality of surgical anaesthesia rated as good, moderate or poor and the neonatal apgar at 1st and 5th minute after birth were compared and there was no statistical significance among the groups.

Table 10: NA administration at different time interval between the four groups

<table>
<thead>
<tr>
<th>Variable</th>
<th>Group</th>
<th>Mean</th>
<th>SD</th>
<th>ANOVA F*</th>
<th>df</th>
<th>Significance</th>
<th>Significantly different groups</th>
</tr>
</thead>
<tbody>
<tr>
<td>NA1 Min</td>
<td>1</td>
<td>5.4</td>
<td>0.5</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>5.6</td>
<td>0.5</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>5.4</td>
<td>0.5</td>
<td>0.704</td>
<td>3, 76</td>
<td>P&gt;0.05</td>
<td>Nil</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>5.45</td>
<td>0.5</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NA5 Min</td>
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<td>8.45</td>
<td>0.5</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>8.6</td>
<td>0.5</td>
<td>0.585</td>
<td>3, 76</td>
<td>P&gt;0.05</td>
<td>Nil</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>8.45</td>
<td>0.5</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>8.6</td>
<td>0.5</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

VIII. Discussion
Till today, spinal anaesthesia is the most versatile block available and is being used for various surgeries on the lower half of our body. Spinal anaesthesia is widely used for cesarean deliveries.

Conventionally, 10mg of 0.5% bupivacaine is used intrathecally for cesarean delivery. This results in greater hemodynamic instability and respiratory depression. Combined spinal epidural was introduced by Brownridge in the year 1981 for cesarean section. CSE technique allows the use of low dose intrathecal bupivacaine, which resulted in less hemodynamic instability. It had an added advantage of prolonging the anaesthesia through the epidural catheter. Moreover parturients can be rendered postop pain relief, which made the technique more popular. Low dose intrathecal bupivacaine in CSE technique offers better analgesia and hemodynamic stability, which allows its use in parturients with cardiac disease. This study compared four different doses of intrathecal bupivacaine in combined spinal epidural technique to evaluate the optimum dose of intrathecal bupivacaine with epidural lignocaine in CSE technique for cesarean section.

Level of sensory blockade:
Sensory blockade level (sensation to cold) necessary for a caesarean section is T4. Both groups C & D i.e, with 7.5mg & 10 mg of 0.5% bupivacaine attained T4 level at 5th minute after intrathecal injection. With 2.5mg of 0.5% bupivacaine, the mean level achieved was T12 and with 5mg of 0.5% bupivacaine the mean level achieved was T6. This correlated with the study done by Shou-Zen Fan et al, where they compared in the similar way and the sensory block heights produced by 2.5, 5, 7.5 & 10mg were T11, T9, T5 & T4 respectively. The result also correlates with the study done by Roofthoff E et al, where 5-7mg of 0.5% bupivacaine intrathecally was sufficient to provide effective anaesthesia, which is similar to our study, where 5mg of bupivacaine achieved a mean sensory block level of T6. Adequate level of sensory blockade (T4) achieved by 7.5mg bupivacaine intrathecally in 85% of the patients was supported by the study done by Leo Set al, in which the time taken to achieve T4 level in 7mg, 8mg and 9 mg groups of 0.5% bupivacaine were similar in all the groups, indicating that 7mg was enough to achieve adequate level of anaesthesia in caesarean section. Even 6.6mg of hyperbaric bupivacaine with sufentanyl as an adjuvant produced sensory block level of T4 without epidural supplementation in more than 80% of the patients involved in the study conducted by Marcel P Vercauteren et al, which strongly correlates with the results of our study.
Epidural topup requirements:  
2% lignocaine epidural topup requirement was more in Group A (2.5mg) requiring 12ml and minimal with group B(5mg) requiring 4.5ml. Group C & D i.e, 7.5mg & 10 mg groups rarely required epidural topups. 
This correlated with Shou-Zen Fan et al\textsuperscript{12} study, where 2.5, 5, 7.5 & 10 mg of 0.5% bupivacaine intrathecally required an epidural topup doses of 2% lignocaine of about 22ml, 10.1ml, 1.2ml & 0ml respectively. Though the amount of 2% lignocaine required in their study was larger than our study, the ratio of 2% lignocaine used among the groups correlated well with our study(2:1). The difference in amount of 2% lignocaine required might be due to the demographic pattern being different in each areas, where the studies were conducted. 

6.6mg of hyperbaric bupivacaine with 25 mcg fentanyl intrathecally was studied in caesarean section by Marcel P Vercauteran et al\textsuperscript{26}. Even at such low doses, sensory block level of T4 was achieved without the need for epidural topup in more than 80% of the study group, which strongly correlates with this study where little/no supplementation of epidural lignocaine was required in 5mg(4.5ml of lignocaine) and 7.5mg(1.2 ml of lignocaine) groups.

Complications:  
Hypotension:  
The occurrence of hypotension was assessed among the groups
- All the patients (100%), who received 2.5mg of 0.5% bupivacaine had hypotension because of high dose requirement of 2% lignocaine epidurally.
- All the patients (100%), who received 10mg of 0.5% bupivacaine also had hypotension
- In patients, who received 7.5mg of 0.5% bupivacaine, the incidence of hypotension was 70%.
- In patients, who received 5 mg of 0.5% bupivacaine, the incidence of hypotension was less 15%.

This correlated with the study by Shou-Zen Fan et al\textsuperscript{12}, where the incidence of hypotension was 5%, 5%, 35% and 50% in 2.5mg, 5mg, 7.5mg & 10mg of 0.5% bupivacaine groups respectively. 5mg bupivacaine group had good hemodynamic stability with minimal side effects in this study correlates well with the study done by Roofoothoof et al\textsuperscript{13}, where intrathecal bupivacaine between 5mg and 7mg was found to produce effective anaesthesia for caesarean section in CSE technique with improved hemodynamic stability.7mg bupivacaine provided adequate anaesthesia for cesarean delivery with reduced incidence of hypotension when compared to 8mg and 9mg groups in the study done by Leo S et al\textsuperscript{14}, which is similar to our study results.5 mg bupivacaine with fentanyl was shown to produce effective anaesthesia with less hypotension, vasopressor requirements and nausea than spinal anaesthesia with 10 mg bupivacaine, in the study conducted by David B et al\textsuperscript{18}. This correlated well with our study results. The study done by Langesaeter E et al\textsuperscript{19} also supports our study results, where better hemodynamic stability was achieved with less incidence of hypotension in parturients, who received 7mg spinal bupivacaine, when used along with low dose infusion of phenylephrine and minimal co-hydration.

Ephedrine use:
This correlated well with the incidence of hypotension.
- Group A(2.5mg) & group D(10mg) were similar in their ephedrine requirements with 10.8mg and 11.7mg mean respectively.
- Group C(7.5mg) required an average of 5.7mg of ephedrine
- Group B(5mg) required least amount of ephedrine which is about 1.2mg.

Vomiting:  
Vomiting occurred mainly in Group D(10mg) & Group C(7.5mg) and the incidence is 20% & 35% respectively. No vomiting was reported in 2.5mg and 5 mg group patients. This correlated with the study by Shou-Zen Fan et al\textsuperscript{12}, where the incidence of vomiting is 10% & 20% in 7.5mg & 10mg groups of 0.5% bupivacaine respectively.

Shivering:
Shivering occurred predominantly in group A(2.5mg) with an incidence of about 50%. In other groups it was found to be insignificant. This correlated with Shou-Zen Fan et al\textsuperscript{12} where the incidence of shivering was highest with 2.5mg group of 0.5% bupivacaine with 25% occurrence. Thermoregulatory control was impaired during regional anaesthetic technique, where the thermoregulatory processing is similar between epidural and spinal anaesthesia (Osaki M et al\textsuperscript{27}).
The high incidence of shivering in 2.5 mg bupivacaine group when compared to all other groups might be due to:
- Large amount of epidural supplementation
- The time taken to achieve adequate level of anaesthesia was high in 2.5mg bupivacaine group when compared to other groups.
- High spinal level achieved immediately in 10mg and 7.5mg bupivacaine group, might have masked the shivering response in these parturients.

**Dyspnea:**
Dyspnea occurred in only one patient in group D(10mg). No occurrence in other groups. This might probably be due to:
- High dose of the intrathecal bupivacaine used(10mg)
- Height of that parturient was in the lower range of the groups(150 cm)
- Twin pregnancy, which increases the cephalad spread of the intrathecal drug faster due to epidural venous engorgement.

The spread of spinal anaesthesia in singleton and twin pregnancies were compared in the study conducted by Jawan B et al28, where it was observed that fast onset and maximum cephalad spread was present among the twin pregnancies. The twin pregnancy group had heavier, large uterus and very high production of progesterone when compared to singleton pregnancies, which resulted in higher level of blockade and respiratory problems in this group.

**IX. summary**
This double blinded prospective randomized controlled study was designed to evaluate the optimum dose of hyperbaric bupivacaine with epidural lignocaine necessary to produce adequate anaesthesia without hemodynamic instability in combined spinal epidural technique for caesarean section. Four different doses of intrathecal hyperbaric 0.5% bupivacaine (2.5mg, 5mg, 7.5mg & 10mg) were compared.

**The following observations were made:**
- Both 7.5mg and 10mg of 0.5% bupivacaine intrathecally produced adequate level of anaesthesia (T4) in most of the cases. But the occurrence of hypotension and vomiting were very high in these groups.
- 2.5mg of 0.5% bupivacaine intrathecally produced a median sensory block level of T12, which required high doses of epidural supplementation of 2% lignocaine. This resulted in high occurrence of hypotension and shivering.
- 5mg of 0.5% bupivacaine intrathecally produced adequate level of anaesthesia with minimal supplementation of epidural topup with 2% lignocaine. The occurrence of hypotension, vomiting and shivering were very less compared to other groups.
- There was no significant difference among the groups in terms of heart rate changes, quality of surgical anaesthesia and neonatal apgar

**X. Conclusion**
We conclude that 5mg of 0.5% bupivacaine intrathecally with minimal epidural lignocaine can produce adequate and rapid anaesthesia for caesarean section with minimal adverse effects.

**Review Of Literature**
1. Shou-Zen Fan et al22 have compared four different doses of intrathecal hyperbaric bupivacaine combined with epidural lignocaine for caesarean section. A total of 80 parturients were taken into the study. They were divided into four groups by random allocation. Depending on the group to which they belong, they received 0.5ml, 1ml, 1.5ml or 2ml of 0.5% bupivacaine intrathecally. Sensory level of blockade was checked every 3 minutes till 15 minutes. If Thoracic level-4(T4) sensory blockade was not achieved by 15 minutes, epidural 2% lignocaine was supplemented by increments of 3ml every 3 minutes, till T4 level was achieved. The results were analysed on the basis of the initial level of sensory blockade achieved, epidural requirements, complications like vomiting, shivering, dyspnea etc. They have concluded that injecting 5 mg of hyperbaric bupivacaine intrathecally combined with epidural lidocaine can provide an effective and rapid onset of anaesthesia for caesarean section with minimal adverse effects.

2. Ranasinghe J S et al6 conducted a retrospective study to evaluate the significance of combined spinal epidural technique for cesarean deliveries. The study reviewed cesarean deliveries that were done under CSE technique, in their institution over 6 months. Successful CSE was defined as the absence of administering general anesthesia to the parturients during cesarean delivery. 99.4% success rate was observed for CSE technique. They have concluded that combined spinal epidural anaesthesia was a great
improvement to single shot spinal or continuous epidural anaesthesia by providing reliable and safe regional anesthesia for the parturients undergoing caesarean delivery.

3. **Roofthoof E et al** studied the effect of low dose intrathecal bupivacaine in reducing the incidence of maternal hypotension and providing adequate anesthesia for cesarean delivery. Intrathecal bupivacaine of about 5 to 7mg provided adequate anesthesia for cesarean deliveries. They have concluded that low dose spinal anesthesia as a part of combined spinal-epidural technique is a very valuable tool in improving maternal and fetal outcome during anesthesia for caesarean section.

4. **Leo Set al** studied the effects of using low-dose intrathecal bupivacaine in Combined spinal epidural method for cesarean section. 60 parturients, who were posted for elective cesarean section, were randomized to three groups. Hyperbaric bupivacaine of 7mg, 8mg and 9mg was deposited intrathecally for parturients in group 7, 8 and 9 respectively. All parturients, irrespective of their group, received morphine 100mcg intrathecally and Hydroxy ethyl starch of 15ml/kg given intravenously while starting the CSE technique. When sensory level blockade of T4 was reached, surgery was allowed to start. The clinical outcomes were monitored and recorded. In their study, they have concluded that lowest dose of spinal bupivacaine (7mg) provided equally rapid onset and effective anesthesia for caesarean section while reducing the occurrence of hypotension when compared with 8 and 9 mg.

5. **Choi D H et al** compared combined spinal-epidural with epidural anesthesia for cesarean delivery. 64 parturients posted for elective cesarean delivery were randomly divided into two groups. CSEA group received 1.5 to 1.6 cc of 0.5% bupivacaine heavy intrathecally, which was followed by 10 cc of 0.5% bupivacaine plain epidurally, 10 minutes after the intrathecal injection. EA group had 20 to 25 cc of 2% lignocaine along with fentanyl 100mg. 0.1 cc of 0.1% epinephrine and 8.4% NaHCO3 1.5 cc. the two groups were compared based on the anesthetic quality, intraop and postop problems. Intraop analgesia, motor blockade and good muscle relaxation were better with CSEA group than the EA group. They have concluded that, when combining the main spinal and the supporting epidural anesthesia, CSEA achieves greater efficacy and less side effects than the pH adjusted epidural anesthesia in caesarean delivery.

6. **Titti thoren et al** compared sequential combined spinal-epidural anesthesia with spinal anesthetic technique for cesarean delivery. 42 patients posted for cesarean delivery were randomly assigned into two group. First group received spinal anesthesia 12.5mg of 0.5% bupivacaine intrathecally. Second group received 7.5mg of 0.5% bupivacaine intrathecally and additional dose of epidural 2% lignocaine was administered, if necessary, to get a sensory block level of T4. The time taken, from the starting of regional technique to the initiation of surgery and till the time of delivery, was noted. They have found that the sequential CSE technique was proved to be safe and as effective as spinal anesthesia for cesarean delivery. There is a risk of hypotension with both the techniques, although it is more precipitous after conventional spinal anesthesia.

7. **Marc Van De Velde et al** studied the effects of different doses of spinal hyperbaric bupivacaine on maternal hemodynamic changes in the combined spinal epidural anesthetic technique. 50 parturients undergoing cesarean delivery were randomly allocated into two groups. The first group received 9.5mg of 0.5% bupivacaine with 25 mcg sufentanyl. The second group received 6.5mg of 0.5% bupivacaine with 25 mcg sufentanyl intrathecally. Various outcomes visual analogue scoring, hemodynamic changes, etc., were monitored and recorded. They have concluded that small dose spinal anaesthesia with bupivacaine (6.5mg) along with sufentanil (25 microg) better maintains the patient’s hemodynamics, in addition to providing adequate anesthesia.

8. **Ben David B et al** studied the effects of low dosage of bupivacaine along with fentanyl as an adjuvant intrathecally for cesarean section. 32 parturients posted for cesarean section were divided randomly into two groups. First group received 10 mg of 0.5% plain bupivacaine intrathecally and the second group received 5 mg of 0.5% plain bupivacaine along with 25 mcg of fentanyl. Intraop hemodynamics, the need for the inotropes/vasopressors and certain other parameters were monitored and recorded. They have concluded that bupivacaine 5 mg with fentanyl 25 microg provided adequate spinal anesthesia for cesarean section with less incidence of hypotension, vasopressor need and nausea than spinal anesthesia with 10mg bupivacaine.

9. **Langesaeter E et al** compared low dose and high dose spinal anaesthesia along with phenylephrine infusion for cesarean deliveries. Eighty parturients, who were posted for elective cesarean section, were divided into four groups. First group received 7mg of 0.5% bupivacaine intrathecally and the second group received the same along with low infusion of phenylephrine(0.25mcg/kg/min). Third group received 10mg of 0.5% bupivacaine intrathecally and the fourth group received the same along with low infusion of phenylephrine(0.25mcg/kg/min). All patients received 4mcg of sufentanyl, in addition, intrathecally. Hemodynamics were monitored and recorded. They have found that low dose bupivacaine along with an
infusion of phenylephrine and adequate co-hydration preserves the hemodynamics better during spinal anaesthesia for cesarean section.

10. Beale Net al studied the effects of the epidural volume extension on the intrathecally administered drug during cesarean section. They have estimated the ED50 of intrathecal bupivacaine along with 25 mcg fentanyl for cesarean section to be 6.1mg and at such doses, Epidural Volume Extension (EVE) doesn’t seem to produce reliable reductions in dosing along with intrathecal bupivacaine.

11. Farida Ithnin et al compared the level of blockade produced by Combined spinal-epidural technique with the single shot spinal technique. Thirty women posted for elective cesarean section were randomly allotted into two groups. Both the groups received 2cc of 0.5% bupivacaine intrathecally. In CSE group, the epidural space was identified by loss of resistance technique using 2cc of air and the epidural catheter was not placed. The maximum sensory blockade achieved in both the groups were noted and compared. It was found that CSE technique without epidural catheterisation or administration of epidural drug resulted in a significantly higher sensory blockade level than the single shot spinal technique when the same amount of local anaesthetic agent was used intrathecally.

12. Danelli G et al underwent a study to evaluate the lowest adequate dose of intrathecal hyperbaric bupivacaine for cesarean delivery. 24 parturients posted for elective cesarean delivery received CSE anesthesia. The intrathecal dose of hyperbaric bupivacaine was based on the height of the patient. Initially, for the first patient, 0.075mg/cm height of 0.5% bupivacaine was given intrathecally. When the sensory block level of T4 was achieved, the dosage for the next patient was reduced by 0.01mg/cm height. They showed that 0.06mg/cm height was the dose of intrathecal hyperbaric bupivacaine that provides good spinal anesthesia in 95% of the parturients posted for cesarean section.

13. Subedi A et al studied the effects of the height and weight on intrathecal bupivacaine for cesarean delivery. 100 women posted for elective cesarean delivery were randomly allocated into two groups. First group received the adjusted dose of intrathecal bupivacaine according to the height and weight of patients using Harten’s dose chart that was created from Caucasian parturients and the second group received 2.2ml of 0.5% hyperbaric bupivacaine intrathecally. The time for achieving T5 sensory block level, hemodynamic variables, neonatal outcome and certain other parameters were observed and noted. They have found that the dose adjustment significantly decreased the bupivacaine dosage with an added advantage of less incidence of hypotension and good neonatal outcome.

14. Sivevski A et al studied the effects of low dose of intrathecal hyperbaric bupivacaine along with fentanyl for cesarean deliveries. 40 parturients posted for elective cesarean delivery, were randomly allocated into two groups. The first group received 13.5mg of plain bupivacaine 0.5%. The second group received 9mg of isobaric bupivacaine 0.5% with 25 mcg fentanyl intrathecally. Hypotension, surgical relaxation and certain other parameters were monitored and recorded. Though sensory blockade and motor blockade were very intense with the plain bupivacaine group, the incidence of hypotension and vomiting were also very high in this group, when compared to the bupivacaine-fentanyl group. So, they concluded that bupivacaine 9 mg along with 20 mcg fentanyl produced adequate spinal anesthesia for cesarean section with less incidence of hypotension and vasopressor need while ensuring excellent surgical anesthesia.

15. Vanhelder T et al studied the role of CSE in managing parturients with valvular heart defects. They have presented a case of successful anaesthetic management of a parturient with moderate mitral stenosis and aortic insufficiency. They have concluded that carefully planned regional (CSEA) anaesthetic technique was safely used both for labor and cesarean section in pregnant patients with valvular heart disease.

Bibliography


