COMPARISON OF LOW-DOSE BUPIVACAINE WITH FENTANYL AND BUPIVACAINE ALONE FOR SPINAL ANAESTHESIA FOR LOWER LIMB SURGERIES

Karthi Vellakalpatti Mani1, Arunpandiyan Veerapandiyan, Shankar Radhakrishnan2

1Assistant Professor, Department of Anaesthesiology, IRT-PMCH, Perundurai, Erode.
2Consultant Anaesthesiologist, Department of Anaesthesiology, Erode Medical Centre, Erode.

ABSTRACT

BACKGROUND

Bupivacaine is the widely used anaesthetic agent for spinal anaesthesia. Though, it has some advantages of producing good surgical anaesthesia and a longer half-life when compared to other local anaesthetics, the incidence of adverse effects on haemodynamic stability like hypotension was found to be more common. Adjuvants like opioids have been used in combination with bupivacaine to lower the dose of each agent and maintain the analgesic efficacy and thereby reducing the incidence and severity of adverse effects. Fentanyl, a lipophilic opioid, has rapid onset and offset of action.

The aim of the study is to compare the efficacy and the incidence of adverse effects between bupivacaine alone and low-dose bupivacaine with fentanyl as spinal anaesthesia among the patients undergoing lower limb surgeries.

MATERIALS AND METHODS

A prospective longitudinal study was conducted for a period of one year in the Anaesthesiology Department at Vinayaka Mission Kirupananda Varyar Medical College Hospital. A total of 80 patients were included for the study. They were divided into two groups of 40 each, group H (bupivacaine 75 mg, n=40) and group L (bupivacaine 5 mg with 25 mg fentanyl, n=40). The patients were positioned in left lateral position and under sterile precautions 23G Quincke spinal needle was inserted between the L3 and L4 interspace, and depending on the patients allotted group, the anaesthetic agent was administered. Blood pressure, pulse rate, respiratory rate and saturation were recorded at 2 minute intervals for the first 10 minutes and then subsequently at 5 minutes interval. Adverse events such as nausea, vomiting, shivering, pruritus, respiratory depression and transient neurological symptoms if occurred were noted.

RESULTS

The maximum sensory level attainment was T9 in both the groups. The Bromage motor score was significantly higher in the fentanyl with low-dose bupivacaine group. The mean reduction of BP was higher among the patients who received high dose of bupivacaine and the difference was found to be statistically significant. No adverse events were reported in both the groups.

CONCLUSION

The combination of low-dose bupivacaine with fentanyl can be a preferred alternative for elective lower limb surgeries than a high dose of bupivacaine alone.

KEYWORDS

Bupivacaine, Fentanyl, Spinal Anaesthesia, Sensory and Motor Block.

HOW TO CITE THIS ARTICLE: Mani KV, Veerapandiyan A, Radhakrishnan S. Comparison of low-dose bupivacaine with fentanyl and bupivacaine alone for spinal anaesthesia for lower limb surgeries. J. Evid. Based Med. Healthc. 2017; 4(53), 3241-3246. DOI: 10.18410/jebmh/2017/643
act on opioid receptors present in the substantia gelatinsa of dorsal horn of spinal cord to produce the anaesthetic effect.

Fentanyl, a lipophilic opioid, has rapid onset and offset of action. Adjuvants like opioids have been used in combination with bupivacaine to lower the dose of each agent and maintain the analgesic efficacy and thereby reducing the incidence and severity of adverse effects.\textsuperscript{6-7} They have synergistic antinociceptive effects and the opioids have been shown to reduce the incidence of hypotension. Studies had shown that the addition of fentanyl to hyperbaric bupivacaine improves the quality of intraoperative and early postoperative subarachnoid block.\textsuperscript{8}

The present study was designed to evaluate whether a low dose of bupivacaine produces adequate surgical anaesthesia with lesser haemodynamic side effects when combined with fentanyl.

**Aim**
To compare the efficacy and the incidence of adverse effects between bupivacaine alone and low-dose bupivacaine with fentanyl as spinal anaesthesia among the patients undergoing lower limb surgeries.

**MATERIALS AND METHODS**
A prospective longitudinal study was conducted for a period of one year in the Anaesthesiology Department at Vinayaka Mission Kirupananda Varyiar Medical College Hospital. The study was started after getting approval from the institutional ethical committee. All adult patients with ASA staging 1 and 2 and are undergoing elective lower limb surgery were included in the study. Emergency trauma patients and paediatric patients were excluded from the study. A total of 80 patients were included for the study. All 80 patients were randomly allocated into two groups of 40 each by sealed envelope technique to either the group H (bupivacaine 75 mg, n=40) or group L (bupivacaine 5 mg with 25 mg fentanyl, n=40). After a preanaesthetic evaluation, the procedure was explained to the patient and informed consent was obtained. All patients were premedicated with Tab. Diazepam 5 mg orally 2 hours prior to procedure. On arrival at the operation theatre, the patients were positioned in left lateral position and under sterile precautions 23G Quincke spinal needle was inserted between the L3 and L4 interspace and depending on the patients allotted group, group H patients received 75 mg bupivacaine and group L patients received 5 mg bupivacaine with 25 mg fentanyl. Henceforth, the data was collected by an investigator who was not aware of the drug administered. Onset of sensory level, peak sensory level and motor blockade was noted. Blood pressure, pulse rate, respiratory rate and saturation was recorded at 2 minute intervals for the first 10 minutes and then subsequently at 5 minutes interval. Adverse events such as nausea, vomiting, shivering, pruritus, respiratory depression and transient neurological symptoms if occurred were noted.

All data were entered and analysed by using SPSS version 21. Intergroup difference among the parametric variables was analysed using Student’s t-test and among the nonparametric variables Chi-square test was used to assess the statistical significance. P value <0.05 was considered as statistically significant.

**RESULTS**
Table 1 shows the demographic characteristics along with weight and height comparison between the two groups. It is seen from the table that all the parameters were almost similar in both the groups without showing any statistical significant difference between the two groups. Similarly, the haemodynamic parameters like pulse rate, blood pressure, respiratory rate and oxygen saturation, which were measured at the baseline (before spinal anaesthesia) were almost similar in both the groups without showing statistical difference (Table 2). After the spinal anaesthesia, among the various vital parameters, which were measured, the maximum sensory level attainment was T9 in both the groups, which proves that there is no change in attaining sensory level between the two groups (Figure 2), whereas the motor score (score 4) was higher among the group, which received low dose of bupivacaine along with fentanyl (group L) than the group, which received high dose of bupivacaine alone (group H), which was assessed through Bromage scoring system and the difference between them was found to be statistically significant (Figure 1). Though the motor score was higher among the patients who received low dose of bupivacaine with fentanyl, none of the patients required general anaesthesia and only required some additional dose of sedative like midazolam and none of the patients in either group required vasopressor or atropine. The haemodynamic response was better among the patients in group L, which was shown by mean reduction in the blood pressure. The mean reduction of BP was higher among the patients who received high dose of bupivacaine and the difference was found to be statistically significant (Figure 3), whereas the heart rate (Figure 4) and respiratory rate did not show any statistical significant difference between the two groups. No adverse events like nausea, vomiting and pruritus were reported in any of the group (Table 3).

### Table 1. Demographic Characteristics Among the Study Population

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Group H (n=40)</th>
<th>Group L (n=40)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age in years (mean ± SD)</td>
<td>55 ± 10.4</td>
<td>52.2 ± 10.9</td>
<td>0.241*</td>
</tr>
<tr>
<td>Gender M:F ratio</td>
<td>31:9</td>
<td>28:12</td>
<td>0.510**</td>
</tr>
<tr>
<td>Weight in kg (mean ± SD)</td>
<td>60.7 ± 8.8</td>
<td>59.4 ± 8.1</td>
<td>0.504*</td>
</tr>
<tr>
<td>Height in cm (mean ± SD)</td>
<td>161.9 ± 1.1</td>
<td>161.1 ±1.2</td>
<td>0.661*</td>
</tr>
</tbody>
</table>

* p value derived by using Student’s T-test.

**p value derived by using Chi-square test.**
<table>
<thead>
<tr>
<th>Parameters</th>
<th>Group H (n=40)</th>
<th>Group L (n=40)</th>
<th>P Value (Derived by Applying Student's t-Test)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Systolic BP (mmHg)</td>
<td>18.9 ± 14.2</td>
<td>129.4 ± 12.4</td>
<td>0.887</td>
</tr>
<tr>
<td>Diastolic BP (mmHg)</td>
<td>75.0 ± 11.8</td>
<td>76.5 ± 10.0</td>
<td>0.538</td>
</tr>
<tr>
<td>Mean BP (mmHg)</td>
<td>89.1 ± 10.7</td>
<td>92.4 ± 10.3</td>
<td>0.167</td>
</tr>
<tr>
<td>Pulse rate (beats/minutes)</td>
<td>84.8 ± 13.0</td>
<td>81.4 ± 15.0</td>
<td>0.295</td>
</tr>
<tr>
<td>Respiratory rate (breaths/minutes)</td>
<td>17.5 ± 2.2</td>
<td>17.6 ± 1.8</td>
<td>0.812</td>
</tr>
<tr>
<td>Saturation</td>
<td>99.78 ± 0.6</td>
<td>99.97 ± 0.1</td>
<td>0.625</td>
</tr>
</tbody>
</table>

**Table 2. Pre-Anaesthetic Haemodynamic Parameters between the Two Groups**

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Group H (n=40)</th>
<th>Group L (n=40)</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximum sensory level (median and range)</td>
<td>T9 (T8-T10)</td>
<td>T9 (T8-T11)</td>
<td>0.643*</td>
</tr>
<tr>
<td>Modified Bromage score (median and range)</td>
<td>2 (2-4)</td>
<td>4 (4-6)</td>
<td>0.000**</td>
</tr>
<tr>
<td>Maximum fall of systolic BP from baseline in mmHg, mean ± SD</td>
<td>7.5 ± 2.3</td>
<td>2 ± 0.5</td>
<td>0.003**</td>
</tr>
<tr>
<td>Maximum fall of diastolic BP from baseline in mmHg, mean ± SD</td>
<td>6.9 ± 1.8</td>
<td>1.8 ± 0.8</td>
<td>0.0028**</td>
</tr>
<tr>
<td>Mephenetermine used</td>
<td>Nil</td>
<td>Nil</td>
<td>-</td>
</tr>
<tr>
<td>Atropine used</td>
<td>Nil</td>
<td>Nil</td>
<td>-</td>
</tr>
<tr>
<td>Supplement with midazolam (number of patients)</td>
<td>3/40 (7.5%)</td>
<td>5/40 (12.5%)</td>
<td>0.091*</td>
</tr>
<tr>
<td>Supplement with GA</td>
<td>Nil</td>
<td>Nil</td>
<td>-</td>
</tr>
<tr>
<td>Maximum fall in respiratory rate (mean ± SD)</td>
<td>1.7 ± 1.2</td>
<td>1.6 ± 1.3</td>
<td>0.673**</td>
</tr>
<tr>
<td>Adverse events reported</td>
<td>Nil</td>
<td>Nil</td>
<td>-</td>
</tr>
</tbody>
</table>

**Table 3. Comparison of Vital Parameters Measured after Spinal Anaesthesia between the Two Groups**

*p value derived by Chi-square test.

**p value derived by Student’s t-test.

Figure 1. Comparison of Modified Bromage Score between the Two Groups

Figure 2. Comparison of Sensory Level Block between the Two Groups
DISCUSSION

This study had shown that addition of fentanyl to low dose of bupivacaine provided the same level of anaesthesia as that of higher dose of bupivacaine given alone. It is known that local anaesthetic agents cause fall in blood pressure due to the sympathetic blockade. Fentanyl has no effect on the sympathetic nerves, and by means of its synergism with local anaesthetic agents, it gives the same level of anaesthesia as equivalent to higher dose of bupivacaine.9,10

The effect of decreasing the dose of bupivacaine usually causes a reduction in the density of blockade as proven by other studies.5,6 In the present study, it was shown that patients in the fentanyl group had a significantly lesser degree of motor blockade and especially one patient in the fentanyl group had the modified Bromage score of 6, which indicates absolutely no motor blockade, whereas all other sensory parameters were observed to be preserved. Few patients could perceive touch and pressure. Proprioception was also preserved in these cases. Some patients were trying to move their leg as they feel the limb to be numb and heavy and few patients were able to wriggle their toes as the patients were not able to perceive the movement. So, it resulted in giving additional dose of sedation intraoperatively. Anxious patients might be unsuitable for this drug combination considering the amount of stress the patient is put in when he feels the surgeon handling his limb. Patient cooperation is also required when the density of blockade is so low unlike when a conventional dose is used. Moreover, this dose combination might not be effective when muscle relaxation is required.

The baricity of the solution does not make any difference to the level of blockade or the density of blockade as shown by a study done by Roy G Soto et al.11 So, the decrease in the density of blockade is not explained by the decrease in density of the drug administered. It is explained only by the lower dose of bupivacaine used in the group in which fentanyl was added to make equal volume.

The sensory level as assessed by pinprick was the same in both the groups. All patients had adequate analgesia and supplemental analgesics or conversion to general anaesthesia was not required in any of the cases.

Blood pressure was stable during the entire course of surgery in all patients. Though, the fall in blood pressure was significantly greater in the high dose of bupivacaine than the fentanyl combination group, it did not cause severe hypotension and the results of our study was almost in par with the previous studies, which had shown a significant decrease in blood pressure among the group, which received high dose of bupivacaine, but in those studies, the patients had developed hypotension.5,6,12,13 Blockade of two sympathetic segments might not cause hypotension,14,15,16 which might be the cause for no hypotension reported in our study. Furthermore, all the patients selected for this study were classified as ASA I or II physical status. All of them had received an adequate preload before spinal anaesthesia was administered. Patients with a stable autonomic nervous system who have received adequate preloading and when only two sympathetic levels blocked can have a stable blood pressure.15 Moreover in the studies which had reported hypotension, the level of blockade was higher and the subjects chosen were elderly patients. This drug combination is proposed to be of use in patients who are haemodynamically unstable or have autonomic instability when a level of T10 itself might cause profound fall in blood pressure, it being dependent completely on the sympathetic nervous system in these patients.

The onset and duration of blockade was also similar between the groups. Patient related factors like height, weight and age seems to have a better correlation to the duration of blockade than addition of fentanyl to bupivacaine, although some studies have shown a difference in the duration of blockade age stratified comparison between the groups have not been done, which could have shown a different result.17-20

There were no adverse effects observed with the addition of fentanyl in our study population. Pruritus found to be a frequent adverse effect of intrathecal opioids and
previous studies had shown the incidence of pruritus to be between 20 to 70% in their study subjects. However, in our study, none of the patients getting fentanyl complained of pruritus. Respiratory depression was not observed in any of our patients receiving fentanyl. This is in agreement with previous studies. Because of its high lipid solubility, unlike morphine, it does not ascend cephalad to reach the respiratory centre to cause respiratory depression. Similarly, nausea, vomiting or urinary retention were not observed in any of our patients, whereas few other studies had reported these adverse effects. This study shows that fentanyl when added to bupivacaine provides the same level of analgesia as a higher dose of bupivacaine and this combination can be especially useful for patients having ischaemic heart disease, diabetics with end organ damage, renal failure without coagulopathy and in patients with autonomic neuropathy. It can be recommended only when the risk of using a higher dose of bupivacaine or giving general anaesthesia outweighs the minimal discomfort associated with this dose.

CONCLUSION
Thus, we conclude that adding fentanyl helps in reducing the dose of 0.5% hyperbaric bupivacaine for spinal anaesthesia in lower limb surgeries without showing any change in the sensory level block, but showing a minimal change in the motor level block. By its synergistic effect with 0.5% hyperbaric bupivacaine, it provides better intraoperative and postoperative analgesia, good haemodynamic stability with no incidence of complications like nausea, vomiting and shivering. Therefore, the combination of low-dose bupivacaine with fentanyl should be preferred alternative for elective lower limb surgeries than a high dose of bupivacaine alone.

REFERENCES


