International Journal of Research in Medical Sciences
Khadse PB et al. Int J Res Med Sci. 2018 Feb;6(2):521-527
www.msjonline.org
pISSN 2320-6071 | eISSN 2320-6012
DOI: http://dx.doi.org/10.18203/2320-6012.ijrms20180291

Original Research Article

Comparison of clonidine and fentanyl as an adjuvant to bupivacaine in unilateral spinal anaesthesia

Pradnya B. Khadse*, Swati S. Chhatrapati, Trupti S. Kamble

Department of Anaesthesia, Topiwala National Medical College, Mumbai, Maharastra, India

Received: 06 December 2017
Accepted: 11 January 2018

***Correspondence:**
Dr. Pradnya B. Khadse,
E-mail: khadse.pradnya@gmail.com

ABSTRACT

Background: Various adjuvants to local anaesthetics are added to improve the quality of subarachnoid block in unilateral anaesthesia during lower limb surgeries. The present study was conducted with the aim to evaluate the efficacy of combination of clonidine-bupivacaine and fentanyl-bupivacaine.
Methods: This randomized study was conducted on 60 patients at tertiary care center (Topiwala National Medical College, Mumbai) for 2 years. They were divided into 2 groups consisting of 30 in each. Group BC receives Inj. bupivacaine 0.5% (hyperbaric) 7.5 mg (1.5 ml) with inj. clonidine 15 µg (0.1 ml) intrathecally and Group BF receives Inj. bupivacaine 0.5% (hyperbaric) 7.5 mg (1.5 ml) with inj. fentanyl 15 µg (0.3 ml) intrathecally. The time of onset and duration and level of sensory and motor block, time to complete sensory and motor block recovery and duration of spinal anaesthesia, intraoperative and postoperative hemodynamics and side effects if any were noted.
Results: The time of onset and duration of sensory and motor block was lesser in group BF compared to BC but the difference was statistically not significant ($p>0.05$). Duration of analgesia was also higher in group BF. Intraoperative and postoperative changes in hemodynamic parameters, oxygen saturation, and respiratory rate were comparable, and no significant changes are observed, and all are with in normal range ($p<0.05$). Pruritus was noticed in group BF (10%). None of the patient in both groups show any side effects such as respiratory depression and nausea, vomiting.
Conclusions: We conclude that addition of fentanyl and clonidine to hyperbaric bupivacaine produces almost similar effect in unilateral spinal anaesthesia for lower limb surgery without prolonged motor blockade, haemodynamic instability, respiratory depression and nausea and vomiting with good sedation and postoperative analgesia. Although the incidence of pruritus is more with fentanyl, it is not distressing for patients.

Keywords: Bupivacaine, Clonidine, Fentanyl, Lower limb surgeries, Unilateral spinal anaesthesia

INTRODUCTION

Spinal anaesthesia has become the popular technique of choice for the lower extremity surgeries due to quick onset of action, ease of administration, minimal neurological effects, effective motor and sensory blockade, and protection against thromboembolic episodes. It also reduces risk of vomiting and pulmonary aspiration in patient with full stomach and also it is useful in patient with chronic airway diseases. It also provides effective pain relief in immediate postoperative period.[1]

Subarachnoid block is a relatively simple technique that uses a local anaesthetic agent to provide an intense and reliable block with virtually no systemic toxicity. This technique also has its own disadvantages such as risk of extensive block, precipitous hypotension, hemodynamic instability, fixed duration of analgesia and urinary

retention leading to prolonged observation of patient in post anaesthesia care unit. Due to this haemodynamic impact of spinal anaesthesia, care should be taken for patients with poor cardiovascular homeostasis like hypertensive patients and those with coronary artery disease and valvular heart disease.

Unilateral spinal anaesthesia is a technique in which use of small doses of hypobaric or hyperbaric local anaesthetic solutions slowly injected through directional, pencil point needle and lateral decubitus maintained for a certain period, restricts the distribution of spinal block preferentially to the operative side.[2] Most important advantage of this spinal anaesthesia is the reduced incidence of hypotension and high cardiovascular stability. In addition, this technique also provides increased autonomy after surgery, early recovery and short ambulatory stay and increased patient satisfaction.[3,4]

High-quality and long-duration analgesia can be obtained on the operative side with unilateral spinal anaesthesia with small-doses of bupivacaine with or without the addition of adjuvants.[5,6] But its quality in terms of requirement of postoperative analgesia is further improved by addition of additives such as opioids or non-opioids.

Fentanyl is an opioid commonly used intrathecally, together with local anaesthetics in spinal anaesthesia. Fentanyl is a lipophilic opioid and is preferred for having a rapid onset and short duration of action with lesser incidence of respiratory depression therefore it is safer especially in geriatric patients.[7]

Clonidine is an α2-adrenergic agonist, potentiates the effect of local anaesthetics.[8] It does not produce pruritus or respiratory depression. It also prolongs the sensory blockade and reduces the amount or concentration of local anaesthetic required to produce postoperative analgesia.[9]

In our institution, we routinely practice technique of unilateral spinal anaesthesia for orthopaedic surgeries. We prefer this technique in patients in whom it is possible to give lateral position for spinal anaesthesia and the expected duration of surgery is limited. We conducted this randomized double-blind study to compare and evaluate the efficacy and adverse effects of adding clonidine 15µg and fentanyl 15µg intrathecally to 7.5mg hyperbaric 0.5% bupivacaine in unilateral spinal anaesthesia in patients undergoing lower limb surgeries lasting for not more than 2hrs.

METHODS

This prospective randomized double blinded comparative study was conducted in the Anaesthesia Department of Tertiary Medical Centre (Topiwala National Medical College, Mumbai) after getting approval from the institutional ethics and research committee during the period of January 2011 to October 2012. After getting approval from institutional ethical committee total 60 patients of either sex, presenting for unilateral elective as well as emergency surgeries involving the lower limb were included in the study.

Patients of both sexes of age between 18-60years, physical status of ASA grade I and II were included in the study. Exclusion criteria included patients with weight >120kg, height <140cms, coagulopathy, peripheral neuropathy, spine deformity, local cutaneous infections, neurologic diseases, ASA grade III and IV, pregnant and lactating mothers, patients on chronic analgesics, abused substances, cardiovascular medications, and patients who had received opioids in past 12hours, patients allergic to lignocaine, bupivacaine, clonidine or fentanyl.

Detailed history of the patients was collected before surgery. All routine and relevant investigations were done and whenever required specific investigations were asked for and ASA grading of the patient was determined. Patient was informed about the anaesthesia procedure, drugs that would be used, its effects and side effects. Written informed valid consent was obtained. Visual analogue scale was explained to the patient. Patients were randomly allocated to two groups of thirty patients each as per computerized random table.

Patients are divided into two groups consisting of 30 in each and drugs are administered as given below. Drugs should be dissolved in 0.2ml of saline to make total volume of 2ml.

- Group BC = Inj. bupivacaine 0.5% (hyperbaric) 7.5mg (1.5ml) with inj. clonidine 15µg (0.1ml) intrathecally,
- Group BF = Inj. bupivacaine 0.5% (hyperbaric) 7.5mg (1.5ml) with inj. fentanyl 15µg (0.3ml) intrathecally.

Patient was taken on operation table and given supine position. Before surgery baseline parameters such as pulse rate, systolic blood pressure (SBP) and diastolic blood pressure (DBP), peripheral oxygen saturation (SpO2), and ECG were recorded. IV access was taken on the most prominent vein of non-dominant hand with appropriate size IV cannula. Preloading was done with crystalloid solution 10ml/kg lactated Ringer's solution or Normal saline. Infusion was maintained at 4-8ml/kg/hr during intraoperative period.

After explaining the procedure, patients were placed in lateral decubitus position with the limb to be operated in the dependent position. The vertebral column position was accurately visualized before dural puncture and maintained as horizontal as possible by tilting the operating table or by putting a pillow under the shoulder. Painting and draping was done under all aseptic precautions. Dural puncture was performed at L3-4

interspace using 25 G Quinke's spinal needle with the midline approach and the bevel turned towards dependent side. The drug was injected slowly over 5minutes. The lateral decubitus position was maintained for 15minutes from the time of termination of the injection. Then the patients were turned supine for the surgery. No intraoperative sedation was given. All the patients received oxygen via Hudsons mask at 4-6liters/min.

Intraoperative pulse rate, SBP, DBP, respiratory rate, SpO2 and sedation were monitored every 2minutes for first 10minutes, every 15minutes for next 60minutes then every 30minutes. No additional local anaesthetic was injected in any patient before or during the operation. Intraoperative parameters such as onset, duration and level of sensory and motor blockade, duration of postoperative analgesia and untoward side effects, if any were noted. Intraoperative sedation was noted as per Ramsey sedation score. Pain after surgery was assessed by using VAS score. Postoperative analgesia was provided by injection Tramadol 1mg/kg IV along with injection ondansetron 0.05 mg/kg to 0.15mg/kg on demand when VAS score was >3.

Statistical analysis

In our study, all the parameters of both groups were analysed by using statistical software, SSPS for Windows 17. Data is presented as number, median and range, mean±S.D. or percentage as appropriate. The continuous variables like demographic data, duration of surgery, pulse rate, systolic and diastolic blood pressure and respiratory rate were presented as mean ±S.D. Parametric data was compared using unpaired t test or students 't' test between the two groups. Intragroup comparisons were made using paired t test. Chi square test and Fisher's exact test were used to test the statistical significance of non-parametric data such as adverse effects like nausea, vomiting and pruritus. P value less than 0.05 was considered statistically significant.

RESULTS

Table 1 presents the demographic characteristics of the study participants of both the groups. Both the groups were similar with respect to age, height, weight, sex, ASA status and duration of surgery and there was no statistically significant difference between two groups (p>0.05).

Table 1: Demographic characteristics of study participants.

Parameters	Group BC (n=30)	Group bf (n=30)	*p value
Age (years)	46.27±2.11	48.47±2.23	0.476
Sex (m/f)	24/6	22/8	0.99
Weight (kgs)	55.13±4.24	54.57±5.12	0.441
Height (cms)	164.3±1.006	161.6±1.26	0.096
ASA status (i/ii)	13/11	17/19	

* Students 't' test.

Mean duration of surgery in group BC was 59.50±24.93 min and in group BF was 67.83±24.73 min. This difference was not statistically significant (p>0.05) (Figure 1).

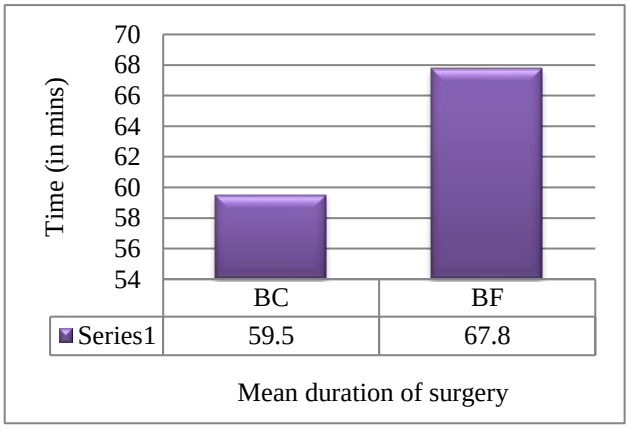

Figure 1: Mean duration of surgery.

The mean time of onset of sensory block in group BC was 5.10±1.40 min and in group BF was 3.23±1.01 min. This was statistically significant (p<0.05) but clinically this difference was not significant. The mean time to achieve maximum sensory level was 8.60±2.40 min in group BC and 4.77±1.61 min in group BF and the difference was statistically significant (p<0.05) (Table 2).

Table 2: Characteristics of sensory block.

Parameters	Group BC (N=30)	Group BF (n=30)	*p value
Onset of sensory block (in mins)	5.10±1.40	3.23±1.01	0.009
Time to achieve peak sensory level (in mins)	8.60±2.40	4.77±1.61	0.007
Duration of sensory block (in mins)	123.43±20.07	130.17±20.41	0.564
Median peak sensory level	T12 (16)	T12 (19)	0.147

* Unpaired t test

Mean duration of sensory block in group BC was 123.43±20.07 min and in group BF was 130.17±20.41 min. Median peak sensory level (Table 4a, Graph 4b) achieved was T12 in both groups. There was no statistically significant difference between both groups (p>0.05) (Table 2).

Maximum sensory level was achieved in all patients. The mean maximum sensory level achieved was T12 in both the groups. There was no statistically significant difference in both groups with respect to achievement of peak sensory level (p>0.05). This indicates that addition of fentanyl hastens the onset of sensory block and time to reach the peak sensory level significantly (Table 2).

Table 3 demonstrates the characteristics of motor blockade. The mean time of onset of motor block in group BC was 10.07±2.84min and in group BF was 5.33±1.54min. The mean time to achieve maximum motor block in group BC and BF was 13.80±2.20min and 9.60±1.83min and the difference was found to be statistically significant (p<0.05). The mean duration of motor block was 85.50±20.57min in group BC and 93.37±25.27min in group BF. The difference was not statistically significant (p>0.05). The modified Bromage score in operated limb was 0/1/2/3-0/0/4/26 in group BC and that in group BF was 0/1/2/3-0/0/5/25 and the difference was not significant statistically. All patients of Bromage score <3 were successfully operated upon without the need for supplemental analgesia or sedation.

None of the patients needed general anaesthesia to undergo surgical procedure. Thus, the addition of Fentanyl hastens the onset of motor block and time to reach the maximum motor block significantly.

Table 3: Characteristics of motor block.

Parameters	Group BC (n=30)	Group BF (n=30)	*p value
Onset of motor block (in mins)	10.07±2084	5.33±1.54	0.001
Time to achieve peak motor level (in mins)	13.8±2.20	9.60±1.83	0.005
Duration of motor block (in mins)	85.50±20.57	93.37±25.27	0.119
Modified bromage score (0/1/2/3)	0/0/4/26	0/0/5/25	0.690

* Unpaired t test

As shown in Table 4, 25 (83.3%) patients in group BC and 27 (90%) patients in group BF achieved successful unilateral block. The difference was not statistically significant between two groups (p>0.05). None in both groups developed failed block.

Table 4: Result of unilateral block.

Result	Group BC (n=30)	Group BF (n=30)	*p value
Successful unilateral block	25 (83.3%)	27 (90%)	0.997
Failed block	0 (0%)	0 (0%)	>0.05

* Students 't' test.

After surgery, the requirement of rescue analgesia was earlier for BC group (202min) rather than BF group (221min) (Table 5). The difference was not statistically significant.

Table 5: Duration of analgesia.

Duration of analgesia	Group BC (n=30)	Group BF (n=30)	*p value
First request for analgesia (mins)	202.33±38.41	221.33±44.43	0.082

* Unpaired t test

Figure 2 shows the baseline pulse rate was (86.77±6.13) bpm in group BC and (84.80±7.59) bpm in group BF and was comparable in both groups. There was no statistically significant difference in pulse rate between two groups throughout observation period. There was fall in mean pulse rate compared to baseline from 4 min to 60 min in group BC and from 8 min to 60 min in group BF.

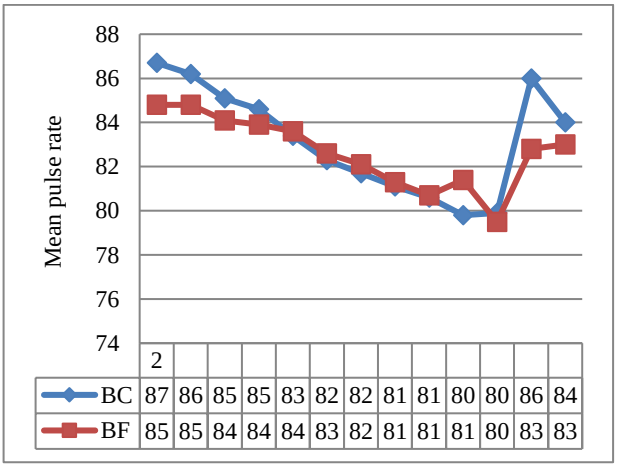

Figure 2: Comparison of pulse rate in two groups.

However, this was not clinically significant as the fall in pulse rate was within physiological range. None of the patients developed bradycardia (pulse rate <50 bpm).

Baseline systolic blood pressure in two groups was comparable. It was 121.47±9.29 mmHg and 121.87±12.36 mmHg in group BC and group BF respectively as shown in Figure 3. There was statistically significant decrease in mean systolic blood pressure (p<0.05) as compared to baseline from 6 min to 120 min in group BC and from 60 min to 120 min in group BF but clinically this difference was not significant. There was no statistically significant difference in systolic blood pressure between two groups throughout the observation period. Mean systolic blood pressure was well maintained within physiological range. None of the patients in both

groups developed hypotension (fall in SBP >20% baseline).

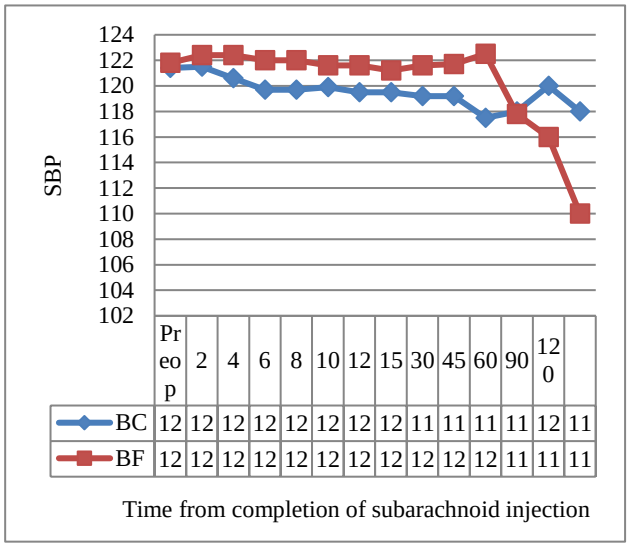

Figure 3: Comparison of SBP in two groups.

The baseline diastolic blood pressure in two groups was comparable. It was 77.67±7.74 mmHg and 76.20±9.60 mmHg in group BC and group BF. There was statistically significant fall in diastolic blood pressure as compared to baseline from 8 min to 120 min in group BC and 8 min to 15 min, at 60 min and 120 min in group BF but clinically this difference was not significant. Thus, both clonidine and fentanyl in the doses given do not produce hemodynamic instability (Figure 4).

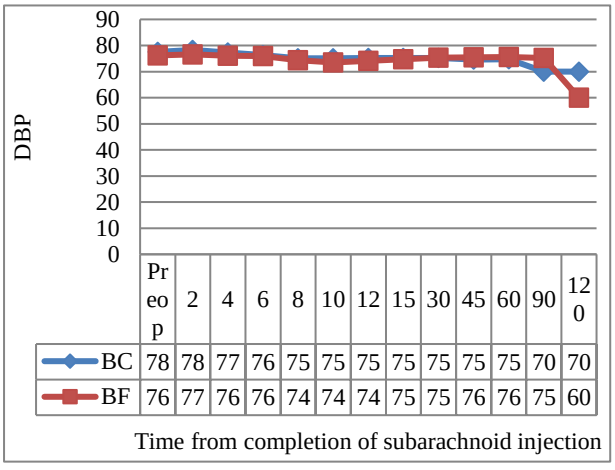

Figure 4: Comparison of DBP in two groups.

As shown in Figure 5 the two groups were comparable with respect to baseline respiratory rate (21±1.04 and 20±1.03 in group BC and group BF respectively). There was statistically significant difference between two groups in respiratory rate during initial 2, 4 and 6minute interval. The mean respiratory rate at 2, 4 and 6 minutes of observation period, in group BC was 21.70±1.93, 21.37±1.87 and 20.70±1.69 breaths per minute and in group BF was 20.53±2.27, 20.17±1.97 and 19.60±1.50 breaths per minute. Clinically this difference was not significant. None of the patients in both groups experienced respiratory depression (<8 breaths per minute).

There was statistically significant decrease in respiratory rate from 8 min to 120 min in group BC and from 12 min to 90 min in group BF compared to baseline, however it was within the physiological range.

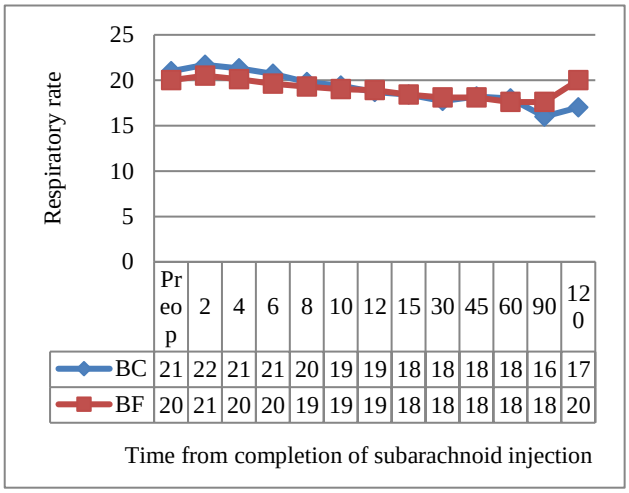

Figure 5: Comparison of respiratory rate in two groups.

The baseline SpO2 in both groups was comparable (99%) in both groups. None of the patients in two groups desaturated throughout the observation period. Saturation was well maintained upto 99% in all patients in both groups. Thus, both clonidine and fentanyl in the doses given do not produce respiratory depression (Table 6).

Table 6: Comparison of mean saturation in two groups.

Duration (in mins)	Group BC (n=30)	Group BF (n=30)	*p value
Baseline	99	99	Ns
2	99	99	Ns
4	99	99	Ns
6	99	99	Ns
8	99	99	Ns
10	99	99	Ns
12	99	99	Ns
15	99	99	Ns
30	99	99	Ns
45	99	99	Ns
60	99	99	Ns
90	99	99	Ns
120	99	99	Ns

Pruritus was observed in 3 (10%0) patients in group BF. None in group BC experienced pruritus. The difference was not statistically significant between two groups (p>0.05) as in Table 7.

Table 7: Side effects/complications.

Side effects	Group BC (n=30)	Group BF (n=30)	*p value
Nausea, vomiting	0 (0%)	0 (0%)	>0.05
Pruritus	0 (0%)	3 (10%)	0.076

*Unpaired 't'test

All patients in both groups achieved sedation score 2 (cooperative, oriented and tranquil). There was no statistically significant difference in both groups (p>0.05) with respect to sedation score achieved (Table 8).

Table 8: Sedation assessment by Ramsay sedation score.

Sedation score	Group BC (n=30)	Group BF (n=30)	*p value
1	0	0	>0.05
2	30	30	>0.05
3	0	0	>0.05
4	0	0	>0.05
5	0	0	>0.05
6	0	0	>0.05

DISCUSSION

The present study was conducted on 60 patients ASA I and II patients undergoing elective or emergency unilateral lower limb surgery. Patients in group BC received 0.5% hyperbaric bupivacaine 7.5mg with clonidine 15µg intrathecally and those in group BF received 0.5% hyperbaric bupivacaine 7.5mg with fentanyl 15µg intrathecally.

In our study, we used small dose of 0.5% hyperbaric bupivacaine (7.5mg) in unilateral spinal anaesthesia. This corresponds to that of Casati et al who administered hyperbaric bupivacaine at a dose of 8mg to obtain good quality of spinal anaesthesia with good haemodynamic stability.[10] 0.5% of hyperbaric bupivacaine was chosen in the present study because studies done by Casati et al and Atef et al found that highly concentrated solutions of hyperbaric bupivacaine are not advantageous in obtaining unilateral spinal anaesthesia when a small anaesthetic dose is injected slowly.[10,11]

In the present study, the mean time for onset of sensory block, was significantly lower in group BF (3.23±1.01mins) compared to group BC (5.10±1.40mins). Mean maximum cephalad spread of block for T12 was achieved in 63% patients of group BF and 53% patients in group BC. Time to achieve maximum sensory level was lesser in group BF (4.77±1.61mins) and duration of sensory block was higher in group BF (130.17±20.41mins). Thus, the addition of fentanyl hastens the onset of sensory block and time to reach the peak sensory level significantly. Similar results were observed by Bano et al, Merivita et al and Krobot et al.[12-14]

Similarly mean time for onset of motor block and duration of motor block was lesser in group BF compared to group BC. These observations are in accordance with the findings of Krobot et al.[14] The degree of motor block was assessed by modified Bromage scale. All patients of Bromage score <3 were successfully operated upon without the need for supplemental analgesia or sedation. In the present study, 4 (13.33%) patients in group BC and 5 (16.67%) patients in group BF achieved modified Bromage score of 2. 26 (86.67%) patients in group BC and 25 (83.33%) patients in group BF achieved modified Bromage score of 3. Time taken for complete motor block was significantly lesser in group BF (9.60±1.83mins) than group BC (13.80±2.20mins). Thus, the addition of fentanyl hastens the onset of motor block and time to reach the maximum motor block significantly. Similar findings were also noted by Bogra et al. In his study, complete motor block was achieved in 90-100% of patients. The depth of anaesthesia was equivalent in group BF and group B. This proves that by adding fentanyl the depth of spinal anaesthesia can be achieved at much lower doses of bupivacaine.[15]

In our study, 25 (83.3%) patients in group BC and 27 (90%) patients in group BF achieved successful unilateral block. The difference was not statistically significant between two groups (p> 0.05). These results are similar to the studies of Atef et al.[11] The time to first rescue analgesia was (202.33±38.41) min in BC group and (221.33±44.43) min in BF group. This difference was statistically not significant. Similar findings are noticed by Bhure et al.[16]

In the present study, we noticed stable hemodynamics among both the groups without any incidence of respiratory depression. This might be due to adequate preloading given in all the patients prior to subarachnoid block. In addition, the dose used in our study was less. Our results are similar to those of Singh et al and Nazareth et al.[17,18]

Duration of analgesia in Group BC was 202.33±38.41mins, and that in group BF was 221.33±44.43mins. The difference between groups BC and BF was not statistically significant. Thus, clonidine and fentanyl with low dose bupivacaine provided adequate duration of analgesia. None of the patients in study group developed bradycardia (pulse rate <50/min), hypotension (fall in SBP> 20% baseline), nausea, vomiting or respiratory depression (RR <8/min and SpO2 <90%). These findings are similar to the reports of Singh et al.[19] Pruritus was observed only in 3 (10%) patients in group BF experienced pruritus and none in group BC experienced pruritus. It was not uncomfortable to the patient and did not require any treatment. All patients of both groups were cooperative, oriented and tranquill (Ramsay sedation score >2). None of the patients required additional anxiolytics or sedatives intraoperatively. Similar results were also reported by Shende et al.[20]

CONCLUSION

The results of our study demonstrate both drugs, fentanyl 15 µg and clonidine 15µg when used as adjuvants to 0.5% hyperbaric bupivacaine 7.5mg are effective in unilateral spinal anaesthesia for lower limb surgeries with good sedation and post-operative analgesia. Although fentanyl enhances the onset of sensory and motor block and time to achieve peak sensory level and maximum motor block, it is associated with minimal incidence of pruritus. Neither of the drugs cause hemodynamic instability, prolonged motor block, respiratory depression and nausea, vomiting.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Khadse PB, Chhatrapati SS, Kamble TS. Comparison of clonidine and fentanyl as an adjuvant to bupivacaine in unilateral spinal anaesthesia. Int J Res Med Sci 2018;6:521-7.