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Original Article

Comparative Study of Intrathecal 0.5% Hyperbaric Bupivacaine with Dexmedetomidine and Fentanyl for Lower Abdominal Surgeries: A Randomized Double-blind Clinical Trial

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Abstract

Background: In this modern year, the intrathecal adjuvants use has gained good acceptance in the field of anesthesiology. The spinal anesthesia quality is very much improved with addition of opioids and other drugs and as we know, no drug is without side effects. Spinal block has rapid onset, lower risk of infection rate and is very cost effective. However, post-operative pain is a very significant problem as the drugs used have limited duration of action. Hence, the administration of analgesics plays a key role postoperatively. To increase the duration and to reduce side effects, various local anesthetics and analgesics are used in combination. Some of the drugs have been used as adjuvants in spinal anesthesia to prolong intra- and post-operative analgesia which includes opioids, $\alpha 2$ agonists, vasoconstrictors, and other drugs.

Aim of the Study: The aim of the current study is to compare the efficacy of dexmedetomidine and fentanyl added to intrathecal bupivacaine to evaluate the onset and duration of sensory and motor block, post-operative analgesia, hemodynamic effects, and adverse effects of either drug in lower abdominal surgeries.

Materials and Methods: Sixty patients with the American Society of Anesthesiologists Grade I and II posted for lower abdominal surgeries were allocated to two groups randomly (30 patients each): Group D received 2.5 ml 0.5% hyperbaric bupivacaine and 5 μg of dexmedetomidine intrathecally and Group F received 2.5 ml 0.5% hyperbaric bupivacaine and 25 μg of fentanyl intrathecally.

Results: Patients in Group F had faster onset of sensory block and motor block than Group D ($P = 0.000$). Patients in Group D had significantly longer duration of motor and sensory blockade as compared to those in Group F ($P = 0.000$). Post-operative analgesia was significantly longer in Group D than Group F ($P = 0.000$). Incidence of side effects among the two groups was not statistically significant.

Conclusions: Fentanyl has its own benefits like faster onset compared with dexmedetomidine, but prolonged duration of motor and sensory blockade with post-operative analgesia was seen with dexmedetomidine without significant side effects.

Key words: Dexmedetomidine, Fentanyl, Intrathecal, Pain management, Post-operative analgesia, Spinal anesthesia, Spinal block

INTRODUCTION

Lower abdominal surgeries can be performed under local, general, and neuroaxial anesthesia, wherein, neuroaxial block is the most preferred method. Spinal block has rapid onset, lower risk of infection rate and is very cost effective. However, post-operative pain is a very significant problem as the drugs used have limited duration of action. Hence, the administration of analgesics plays a key role postoperatively.[1,2] To increase the duration and to reduce side effects, various local anesthetics and analgesics are used in a combination.[3] Some of the drugs have been used as adjuvants in spinal anesthesia to prolong intra- and post-operative analgesia,[1,2] which includes opioids, $\alpha 2$ agonists, vasoconstrictors, and other drugs.

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Dexmedetomidine and clonidine are two α2 agonists affecting through pre- and post-synaptic α2 receptors.[4] Dexmedetomidine has been used widely for anesthesia and analgesic purposes. Dexmedetomidine has sedative, analgesic, anti-anxiety, neuroprotective, and additional anesthetic effects.[5] To increase the duration of analgesia, dexmedetomidine along with other drugs has been used in caudal, subarachnoid, and epidural blocks.[6,7]

Fentanyl is the most common short-acting opioid which is used intrathecally along with local anesthetics and also has synergistic effects with local anesthetics where it improves the outcome and post-operative analgesia.[8] It also has been reported that intrathecal administration of fentanyl at the dose of 10–25 mg can prolong the duration of post-operative analgesia for approximately 180–240 min.[5] However, intrathecal opioids can cause some side effects such as itching, vomiting, urinary retention, nausea, and also respiratory depression.[6,7] Intrathecally, fentanyl has rapid onset of action being lipophilic opioid. It does not tend to migrate to the fourth ventricle in sufficient concentration to cause delayed respiratory depression. It provides better intraoperative analgesia and a safer alternative than morphine for the management of early post-operative pain.[9-11]

MATERIALS AND METHODS

The study entitled – A comparative study of intrathecal 0.5% hyperbaric bupivacaine with dexmedetomidine and fentanyl for lower abdominal surgeries is a prospective, randomized, double-blind clinical trial was conducted after approval by the Ethics Committee of Viswabharathi Medical College and Hospital, Kurnool, from April 2018 to March 2019. The research plan is carried out safely and methodologically and probable side effects of the drugs used were explained to the patients in their native language and were included in the study after obtaining written informed consent from all patients.

The participants included 60 patients of both sexes that were scheduled for elective lower abdominal surgeries under spinal anesthesia in the age group of 18–55 years and belonging to American Society of Anesthesiologists (ASA) I and II were enrolled for the study.

The patients with emergency conditions, contraindication to spinal anesthesia, history of valvular heart disease, history of allergy or sensitivity to applied drugs, as well as failed blockade or need for induction of general anesthesia were excluded from the study. The enrolled patients were randomized to one of two groups of equal sized prospective comparative study group using a computer-based program.

Group F (n = 50) received 2.5 mL volume of 0.5% hyperbaric bupivacaine with 25 ug fentanyl intrathecally and Group D (n = 50) received 2.5 mL volume of 0.5% hyperbaric bupivacaine with 5 ug dexmedetomidine intrathecally.

After detail history, complete physical examination and laboratory investigations were carried out. Standard monitors with non-invasive arterial blood pressure, electrocardiogram, and oxygen saturation were applied. All patients were preloaded with intravenous (IV) lactated Ringer's solution 10 ml/kg. Under aseptic precautions, spinal anesthesia was induced in the sitting position at the L3–L4 interspace using a 23 G or 25 G Quincke's spinal needle. To implement and conduct the double-blind clinical trial, our study drugs were prepared by experienced anesthesiologist who was not involved in on coming observations of the patients.

Procedures and Intervention

Study design

This was a prospective, randomized, double-blind study.

Group D

Inj. dexmedetomidine 5 μg plus Inj. bupivacaine 0.5% (H) 2.5 cc (12.5 mg).

Group F

Inj. fentanyl 25 μg and Inj. bupivacaine 0.5% (H) 2.5 cc (12.5 mg).

The above injection was given over 10–15 s and patients were made to lie supine immediately. All patients were given 3 l/min supplemental oxygen with face mask. Blood pressure and pulse rate (PR) were monitored instantly after injection and then every 2 min till 10 min and every 5 min for 30 min and thereafter every 15 min till the end of surgery and recovery period from block. The same was monitored every 2 h till 24 h. Decreased blood pressure <30% of baseline recording (hypotension) was treated with IV fluids and IV 3 mg mephentermine. Decreased heart rate (HR) less than or equal to (bradycardia) 50 beats/min treated with IV 0.6 mg of atropine. The occurrence of adverse effects such as bradycardia, nausea, shivering, vomiting, pruritus, hypotension, and respiratory depression was recorded simultaneously.

Sensory, Motor, and Post-operative Assessments

The sensory block was checked by the pinprick test, and motor block was assessed using the Bromage scale.[12] When the adequate level of sensory block (T4–T6) was reached and confirmed, the surgery was allowed to begin. The onset of sensory block (time to reach T4–T6) was assessed with a pinprick test (using a blunt 25-gauge

needle along the mid-clavicular line bilaterally) every 2 min and modified Bromage scale (0 = no motor block, 1 = inability to flex the hip, 2 = inability to flex the knee, and 3 = complete motor block of limb) was used to evaluate motor block.

Patient's pain score was assessed using visual analog scale (VAS) score, scored from 0 to 10 (where 0 = no pain and 10 = the worst pain imaginable) during the recovery room 0 h (T0) and at 1, 3, and 6 h (T1, T3, and T6) in the post-operative period. If the VAS score was more than 3, a rescue dose of tramadol (50 mg) was administered intravenously after a prophylactic dose of antiemetic.

Duration of analgesia was defined and noted as the time interval between block onset and the first analgesic request. The duration of surgery was recorded. The respiratory depression (respiratory rate <10/min) and the incidence of nausea, vomiting, and shivering were assessed and recorded during 6 h after the surgery.

Analysis of Data

Quantitative data are presented with the aid of mean and standard deviation. Comparison among study groups was done with the help of unpaired *t*-test or Mann–Whitney U-test as per results of normality test. Qualitative data are presented with frequency and percentage tables. Association among study parameters is assessed with the help of Chi-square test (Fisher's exact test for 2 × 2 tables). $P < 0.05$ is taken as statistically significant.

RESULTS

In our study, patients were distributed according to age, gender, height, and weight which was compared and were statistically insignificant ($P > 0.05$) [Tables 1 and 2]. Onset of sensory block was significantly longer ($P < 0.001$) in Group D (461 ± 62.33 s) as compared to Group F (370.30 ± 40.30 s) [Table 3].

The mean time to achieve maximal sensory block in Group D is 10.64 ± 1.72 min and in Group F is 7.93 ± 0.63 min [Table 3]. Similar maximal sensory dermatomal level was achieved by dexmedetomidine and fentanyl in equal potent doses.

The mean time to achieve onset of motor block in Group D (541 ± 65.85 s) was remarkably higher ($P = 0.000$) than Group F (471 ± 50.15 s) [Table 3].

The reason for the observed differences between the results and that seen in the other studies can be attributed to the methodological differences like difference in the drug dosage and baricity or total volume of drug used. Mean time required for two segment regression was significantly higher ($P = –0.000$) in Group d (137.83 ± 12.5 min) than Group F (115.4 ± 9.93 min) [Table 3].

Table 1: Comparison of demographic characteristics including age, height, and weight

Study parameter	Group D	Group F	*P*-value
Age (years)	32.6±10.74	31.6±9.02	0.436 (NS)
Weight (kg)	65.4±5.25	63.76±6.57	0.617 (NS)
Height (cm)	161.5±5.42	159.72±6.35	0.288 (NS)

(*t*-test applied, *P*-value is significant if <0.05) Values are represented as mean±SD

Table 2: Comparison of demographic characteristics including gender

Sex	Group D	Group F	*P*-value
Male	21	24	0.371
Female	9	6	0.371
Total	30	30	0.371

(*t*-test applied, *P*-value is significant if <0.05) Values are represented as mean±SD

Table 3: Comparison of study group parameters

Study parameter	Group D	Group F	*P*-value
Onset of sensory block	461±62.33	370.30±40.30	0 (significant)
Time to cephalic spread	10.64±1.72	7.93±0.63	0 (significant)
Two segment regressions	137.83±12.5	115.4±9.93	0 (significant)
Onset of motor block	541±65.85	471±50.15	0 (significant)
Duration of motor block	301.67±19.45	268.50±8.2	0 (significant)
Post-operative analgesia	344.67±25.43	241.83±23	0.387 (Not significant)
Duration of surgery	101.17±11.72	97.33±14.41	0 (significant)

(*t*-test applied, *P*-value is significant if <0.05) Values are represented as mean±SD

Mean duration of motor block was significantly higher in Group D (301.67 ± 19.45 min) as compared to Group F (268.50 ± 8.2 min) [Table 3]. Duration of post-operative analgesia was significantly longer in Group D (344.67 ± 25.43 min) as compared with Group F (241.83 ± 23 min) [Table 3].

Thus, dexmedetomidine prolongs the duration of sensory block and also prolongs the duration of the motor block. Dexmedetomidine acts on 2 adrenoreceptors in substantia gelatinosa of spinal cord and blocks C and A delta fibers and increases the potassium conductance intensive the conduction block of local anesthetics.[13] Further, it may have an additive or synergistic effect with local anesthetic in increasing the time of two segment regressions and total duration of complete analgesia. The potentiation of motor block by dexmedetomidine may be an additive or synergistic effect to the local anesthetics or related to the interference with neuromuscular activity or binding of α2-agonists to motor neurons in the dorsal horn.[14] In this study, the mean sedation scores were found to

be comparable and statistically insignificant ($P > 0.05$) preoperatively and intraoperatively among the two groups. Preoperatively and intraoperatively, the difference between mean PR, systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), RR, and SpO2 was insignificant ($P > 0.005$).

Intrathecal narcotics enhance the sensory blockade and prolong post-operative analgesia. They are associated with increased risk of nausea, vomiting, itching, and respiratory depression. Opioids are known to depress all phases of respiration by their action on the opioid receptors in the ventral medulla, irrespective of administration route. Fentanyl is a μ receptor agonist which can be administered safely intrathecally. It is highly lipophilic which prevents its rostral spread. However, systemic absorption of the drug could attribute to the lower respiratory rates by direct depressant action on μ receptors in brainstem [Table 4].

DISCUSSION

In the present study, administration of dexmedetomidine and fentanyl intrathecally combined with bupivacaine is compared in patients undergoing lower abdominal surgeries. The results revealed that adding 5 μg of dexmedetomidine to bupivacaine has a better effect on post-operative pain management compared to 25 μg fentanyl.

Today, intrathecal administration of dexmedetomidine has drawn considerable attention during spinal anesthesia with the aim of increasing the duration of analgesia and decreasing post-operative pain. It appears to be that dexmedetomidine induces the activation of α2-agonist receptors in the spinal cord, which leads to a decrease in the transmission of nociceptive signals like substance P and it has also been revealed that its analgesic effects after the surgery are due to the inhibition of the intracellular potassium transport activities.[15,16] As dexmedetomidine binds to α2 receptors in the locus coeruleus, it reduces norepinephrine release, and inhibits sympathetic activity and can cause hypotension and bradycardia. For this reason, evaluation of hemodynamic changes in patients was of great importance in this study.[17] There was no significant difference between the D and F groups in terms of SBP, DBP, HR, MAP, and SpO2 at most of the studied times, which is in accordance with the results of the previous studies.[3,14,18,19] Number of studies have addressed the administration of different doses of intrathecal dexmedetomidine (3 μg, 5 μg, 10 μg, and 15 μg) as an adjuvant to local anesthetics.[14,18,20,21]

Table 4: Comparison of overall incidence of side effects and complications

Complication	Group D (%)	Group F (%)	Total (%)
Hypotension	3 (10)	2 (6.7)	5 (8.3)
Bradycardia	4 (13.3)	1 (3.3)	5 (8.3)
Nausea and vomiting	1 (3.3)	2 (6.7)	3 (5)
Shivering	0 (0.0)	2 (6.7)	2 (3.3)
Pruritus	0 (0.0)	2 (6.7)	2 (3.3)
No complication	22 (73.3)	21 (70)	43 (71.7)
Total	30 (100)	30 (100)	60 (100)

(χ^2=6.357, d(f)=5, *P*-value-0.273 (not significant), (Chi-square test is applied. *P*-value is significant if <0.005)

In addition, the findings of this study have shown that the usage of mephentermine and atropine had no significant difference between the D and F groups, which were similar to the other studies.[3,22,23] However, Contractor *et al.* showed that the possibility of MAP and HR decrease was higher in the dexmedetomidine group compared to the fentanyl group.[8] The results of this study strongly suggest that the onset of block in Group D was faster than in Group F. There was no significant difference between the two groups in sensory block level, which was steady with the findings of other studies.[2,23]

Taking into consideration, the pain intensity based on VAS score, the results revealed that pain intensity was less in Group D during recovery room period (T0). However, at T1, T3, and T6 in the post-operative period, no significant difference was seen between the groups. The observation mentioned may be due to the effects of dexmedetomidine on the inhibition of pain receptors at the spinal cord that decreased c-fiber translocation and hyperpolarization of dorsal horn neurons.[22] This finding was in accordance with opinion with the results of studies conducted by Gupta *et al.* and Mahendru *et al.*[15,23] and was consistent with the study by Sun *et al.*, in the 1st h while at 2 and 4 h after the surgery, patients in the fentanyl group experienced less pain.[22]

Moreover, compared with Group F, the duration of analgesia in Group D was significantly longer. The mentioned findings were entirely consistent with the results of studies by Jain *et al.* and Gupta *et al.*[8,15]

In another observational study, Shukla *et al.* compared the effect of adding dexmedetomidine and MgSO4 to intrathecal bupivacaine and found that the onset of block was faster in the dexmedetomidine group and analgesia duration was also significantly longer in dexmedetomidine group.[18]

The results of this study indicated that the duration of motor block and the length of surgery were almost identical between the two groups. The study findings were in line and in contrast with the findings of Sun *et al.* study in terms of the length of surgery and the motor block duration,

respectively,[22] which dexmedetomidine group in the mentioned study had a longer duration of block that may be due to the higher dose of dexmedetomidine (10 μg) in the mentioned study, whereas the present study used 5 μg dexmedetomidine.

In regard to other complications such as shivering, nausea and vomiting, and respiratory depression, there were no major differences between these two groups in the present study, which was in accordance with the results of other studies.[13] However, Sun *et al*. indicated that shivering, nausea, and vomiting were most commonly observed in the fentanyl group.[2]

CONCLUSIONS

Based on this study result, it can be stated that intrathecal administration of dexmedetomidine is superior to intrathecal fentanyl in lower abdominal surgeries. This study also shown that dexmedetomidine also caused faster block but also led to more extended post-operative analgesia and minimal pain. Moreover, dexmedetomidine provided more stable hemodynamic conditions. Therefore, addition of 5 μg of dexmedetomidine to bupivacaine can be considered as an adjunct to local anesthetic during lower abdominal surgeries under spinal anesthesia.

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AUTHORS' CONTRIBUTIONS

All authors made substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data. All authors played an important role and contributed equally in designing and concepting of this article and also participated in data acquisition, analysis, and data interpretation.

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DISCLOSURE

The authors report no conflicts of interest in this work.

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