INTERNATIONAL JOURNAL OF CURRENT MEDICAL AND PHARMACEUTICAL RESEARCH
ISSN: 2395-6429, Impact Factor: 4.656
Available Online at www.journalcmpr.com
Volume 8; Issue 03(A); March 2022; Page No.105-109
DOI: http://dx.doi.org/10.24327/23956429.ijcmpr20220024

Research Article

INTRATHECAL FENTANYL AND DEXMEDETOMIDINE WITH HYPERBARIC BUPIVACAINE FOR PROLONGATION OF ANALGESIA IN ELDERLY PATIENTS UNDERGOING LOWER ABDOMINAL AND LOWER LIMB SURGERIES- A PROSPECTIVE RANDOMIZED STUDY

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ARTICLE INFO

Article History:
Received 06th December, 2021
Received in revised form 14th January, 2022
Accepted 23rd February, 2022
Published online 28th March, 2022

Key words:
Subarachnoid block, Intrathecal adjuvant, Dexmedetomidine; Fentanyl.

ABSTRACT

Background: Subarachnoid block is still the most commonly used anesthetic technique for lower abdominal and lower limb surgeries, however local anesthetics alone are associated with relatively short duration of action. Intrathecal adjuvants have been reported to improve the quality of anesthesia along with prolongation of postoperative analgesia and are gaining popularity nowadays. The aim of our study was to compare dexmedetomidine and fentanyl as intrathecal adjuvants to 0.5% hyberbaric bupivacaine with respect to onset and duration of sensory and motor block, duration of analgesia, hemodynamic variations and incidence of side effects.

Method: Fifty two patients of either sex aged 65 to 85 yrs belonging to ASA grade I and II posted for lower limb and lower abdominal surgeries were randomly divided into two groups. Group D was administered hyperbaric bupivacaine 15 mg + dexmedetomidine 5 µg in 0.5 ml normal saline, group F was administered hyperbaric bupivacaine 15 mg + fentanyl 25 µg (0.5 ml)

Result: There was no statistically significant difference between the two groups with respect to onset of sensory and motor block ($p > 0.05$). The mean time for two segment sensory regression was significantly lower in group D as compared to group F ($p < 0.05$).Patients in group D had significantly prolonged duration of sensory and motor block as compared to group F ($p < 0.05$). The duration of analgesia was significantly prolonged in group D ($p < 0.05$), along with reduced requirement of rescue analgesia. The patients in the two groups did not show any significant difference with respect to hemodynamic changes and incidence of side effects ($p > 0.05$).

Conclusion: Dexmedetomidine as intrathecal adjuvant in elderly patients was found to prolong sensory and motor block, provided good quality of intraoperative analgesia, prolonged postoperative analgesia with reduced demand for rescue analgesia as compared to fentanyl along with stable hemodynamics and minimal side effects.

INTRODUCTION

Among the regional anesthetic techniques used for lower abdominal and lower limb surgeries, subarachnoid block is still the most commonly used technique, as it is easy to perform, has rapid 9 onset of anesthesia, provides adequate muscle relaxation with excellent operating conditions, is economical with less failure rates.[1, 2] The major disadvantage with subarachnoid block using local anesthetics alone is its relatively short duration of action and inadequate postoperative analgesia.[2]

Various intrathecal adjuvants like fentanyl, morphine, dexmedetomidine, clonidine, neostigmine, and ketamine are being increasingly used with local anesthetics nowadays. These adjuvants prolong the duration of block associated with improved quality of block; reduce the local anesthetic dose requirement and their side effects.

Recently, bupivacaine is the most commonly used local anaesthetic agent. It has satisfactory sensory and motor blockade with limited duration of action. Fentanyl is a potent, short acting, lipophilic synthetic opioid analgesic commonly used as an adjuvant for postoperative analgesia. So there is a constant need to search a drug which provides adequate intraoperative as well as postoperative analgesia with prolonged duration of block and minimal side effects.[3,4] Dexmedetomidine a highly selective α-2 adrenergic agonist is emerging as a useful intrathecal adjuvant and has gained popularity, as it has been reported to potentiate the effect of local anesthetics and prolongs both the duration of block and

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postoperative analgesia along with stable hemodynamics and minimal side effects.[5,6]

Elderly patients have a particularly high incidence of hypotension during spinal anaesthesia because of co-existing cardiac or pulmonary disease. But regional anaesthesia is better tolerated by geriatric patients undergoing lower abdominal & lower limb surgery, producing less postoperative confusion and delirium.[7] The advantages and risks of this procedure have not been fully examined in the elderly.[8]Varrassi *et al*[9] have reported respiratory depression after the administration of 50µg of intrathecal fentanyl.

In the non geriatric population, the association of fentanyl and dexmedetomidine with local anaesthetics improves the sensory block induced by spinal administration of local anaesthetics in the intra and postoperative period. Though there are very few articles on intrathecal fentanyl and dexmedetomidine in elderly Indian population. Since regional anaesthesia is routinely used for lower abdominal and lower limb surgeries in the geriatric population, we conducted a study to observe the differences in the duration of analgesia, adverse effects with intrathecal dexmedetomidine and fentanyl with hyperbaric bupivacaine in elderly patients undergoing lower abdominal and lower limb surgeries.

Aim: The aim of our study was to observe the effect of intrathecal dexmedetomidine and fentanyl with hyperbaric bupivacaine on duration of analgesia in elderly patients undergoing lower abdominal and lower limb surgeries.

Objectives

- The Primary objective was to observe any difference in the duration of analgesia of dexmedetomidine and fentanyl.
- The Secondary objective was to record any difference in the adverse effect of dexmedetomidine and fentanyl.

METHODOLOGY

After approval from the Institutional Scientific and Ethics Committee, this prospective study was conducted from January 2017 to June 2018 on 60 patients in the age group of 65-85 years of ASA grade I and II, who underwent lower abdominal and lower limb surgeries under subarachnoid block. Patients having major cardio respiratory diseases, allergy to study drugs ,bleeding and coagulation disorders, chronic use of any α-2 agonist and calcium channel blockers, psychiatric disorders or who refused for the study were excluded from the study.

After performing thorough pre-anaesthetic check-up, written informed consent was obtained from all the patients who were explained the procedure and its associated risk. Patients were shifted to operation theater and multipara monitor (Schillers B1589 model) was attached to all the patients and baseline vitals were recorded. Two intravenous lines were secured with 20 G cannula and all patients were preloaded with 10 ml/kg RL solution preoperatively. All patients were premedicated with intravenous ranitidine 50mg and metoclopramide 10 mg. Under all aseptic precautions and with the patient in sitting position, using a midline approach subarachnoid block was performed at the L3–L4 intervertebral space using 25 G Quincke spinal needle and 3.5 ml of drug was injected over 30 sec, according to the assigned group.

Group D received 3 ml of 0.5% hyperbaric bupivacaine and 5 µg dexmedetomidine diluted in 0.5 ml preservative free normal saline [normal saline was added to 1 ml (100µg/ml) of dexmedetomidine to make it 10 ml (10 µg/ml) from this, 0.5 ml (5µg) of solution was taken with the help of 1 ml tuberculin syringe] while Group F received 3 ml of 0.5%hyperbaric bupivacaine and 25 µg (0.5 ml) fentanyl. Immediately after completion of the injection patients were made to lie supine.
The time of intrathecal injection was considered as zero (0) and following parameters were noted heart rate (HR), NIBP, and SpO_2 ; time of onset of sensory block and highest level achieved by pin prick (cold saline) bilaterally at mid-clavicular line, time of onset of motor block by using modified Bromage scale and duration of surgery. Side effects like hypotension, bradycardia, pruritus, respiratory depression (defined as arterial oxygen saturation less than 90%), shivering, and nausea or vomiting were also recorded Mephentermine 6 mg i.v was given to treat intra-operative hypotension (defined as a decrease in systolic blood pressure by more than 20% of baseline), and atropine 0.3-0.5 mg i.v was given to treat bradycardia (defined as heart rate < 50 bpm). Intraoperative nausea or vomiting was treated with ondansetron 2-4 mg i.v. NIBP, HR and SpO_2 were recorded at every 5mins up to 30 min, thereafter every 15 mins till the end of procedure and post operatively at 30 min intervals until rescue analgesia was given.

The level of sensory block was tested at frequent intervals of time till the highest level of block was reached and then, postoperatively, at 2 hour intervals till the patient complained of pain. Onset of sensory block was defined as the time taken to achieve highest level of sensory block. The onset of motor block was defined as the time taken to achieve a score of 3 on Bromage scale (complete motor block) from the time of subarachnoid block.

Immediately after operation, patients were shifted to recovery room and HR, NIBP and SpO_2 were recorded at 30 min intervals for four hours. Two segment regression time was taken as time of regression of sensory block by two segments from the highest level of block achieved.

Duration of sensory block was measured as the time taken for the sensory block to regress up to S1 dermatome from the highest level achieved.

Postoperatively, the pain scores were recorded by using Visual analog pain scale (VAS 0 to 10), initially every hour for 2 hrs, and then every 2 h for the next 8 hrs and then every 4 hrs till 24 hrs. Visual analogue score read; 0: no pain; 1-3: mild pain; 4-6: moderate pain; 7-9: severe pain; and 10: the worst imaginable pain.

Patient's first demand for rescue analgesia constituted the end point of the study. Patients were allowed to receive rescue analgesics (i.v.paracetamol) on demand or on VAS > 4.

Duration of analgesia was measured as time from the drug administration in subarachnoid space to the time of patient's first request for rescue analgesia.

Statistical Analysis

Patients were randomized using computer generated random chart Statistical analysis was performed by using Unpaired student t test. p value was calculated using graph pad software. $P<0.05$ was taken as significant and $p<0.001$ was taken as highly significant.

RESULTS

The demographic profile was comparable between the two groups with respect to age, weight, type and duration of surgery (Table 1).

Table 1 Demographic data

Variable	Group D	Group F	p-value
Age(y)	67.370 ±3.520	66.884±3.922	0.6407
Weight(kg)	63±6.533	62.423±5.123	0.7245
Height (cm)	159.592±5.123	160.769±4.519	0.3839
Duration of surgery(min)	139.629±37.87	137.69±27.900	0.8344

Values are expressed as Mean ± SD and n (%)

There was no statistically significant difference between two groups with respect to onset of Sensory block, ($p > 0.05$). The mean time for onset of sensory block was 4.259 ± 0.446 min and 4.461 ± 0.508 min in Groups D and F respectively. There was no statistically significant difference in the highest level of sensory block achieved in the two groups (T6.5 ± 0.9 in each group) or in the time to reach the highest level ($p > 0.05$)(Table 2).

The mean time for two segment sensory regression was 115.370 ± 5.450 min in Group D and 75.153 ± 5.766 min in Group F ($p < 0.0001$) which was highly significant. The mean duration of sensory block was 391.481 ± 35.049 min in Group D and 202 ± 22.546 min in Group F ($p < 0.0001$) which was also highly significant (Table 2). Both, the time to two segment regression and time to S1 regression were significantly prolonged in Group D ($p < 0.05$).

There was no statistically significant difference between the two groups with respect to onset of motor block ($p > 0.05$). The onset of motor block was 6 ± 0.877min and 6.346 ± 0.745 min in Groups D and F respectively ($p = 0.1315$). The duration of motor block was 336.15 ± 10.741 min and 157.88 ±11.676 min in Group D and F respectively ($p < 0.0001$) which was found to be statistically significant ($p < 0.05$). The time to regression of motor block to Bromage 0 (no block) was significantly prolonged in dexmedetomidine group (Table 2).

The mean duration of analgesia in the postoperative period was 292.307 ± 18.012 min in Group D and 171.923 ± 10.851 min in Group F ($p = 0.0001$). Statistically significant difference ($p< 0.05$) was found between Group D and group F. The time to rescue analgesia was significantly longer in Group D as compared to Group F. The requirement of paracetamol in the first 24 h was significantly lower in Group D as compared to Group F(Table 2).

Table 2 Characteristics of subarachnoid block (Data presented in minutes)

Parameters	Group D	Group F	p-value
Onset of sensory block	4.259±0.446	4.461±0.508	0.1339
Highest sensory level	6±0.877	6.346±0.745	0.7756
Time for 2 segment regression	115.370±5.450	75.153±5.7667	<0.001
Duration of sensory block	391.481±35.049	202±22.546	<0.0001
Onset of motor block	6±0.877	6.346±0.745	0.1315
Duration of motor block	336.15±10.741	157.88±11.676	<0.0001
Total duration of analgesia	292.307±18.012	171.923±10.851	0.0001

Values are expressed as Mean ± SD; $p < 0.05$ or 0.01 (significant); $p < 0.001$ (highly significant).

The patients in both groups remained haemodynamically stable throughout the study period. There was significant difference in heart rate over time in both groups, but there was no significant difference among two groups in the pattern of decrease in heart rate ($p > 0.05$) (Figure 1).Similarly there was significant difference in mean blood pressure over time in both groups, but there was no significant difference among two groups in the pattern of decrease in mean blood pressure ($p > 0.05$) (Figure 2).

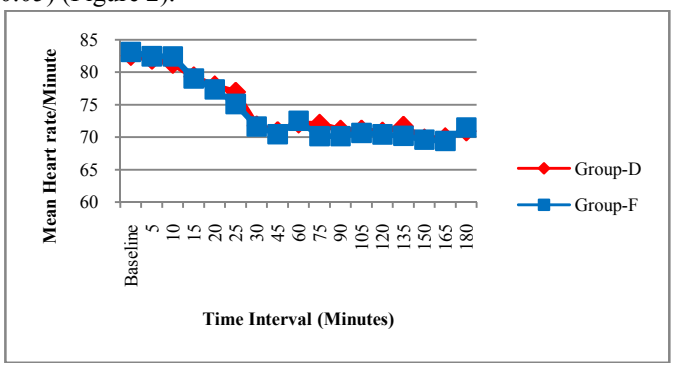

Figure 1 Comparison of mean heart rate at various time intervals

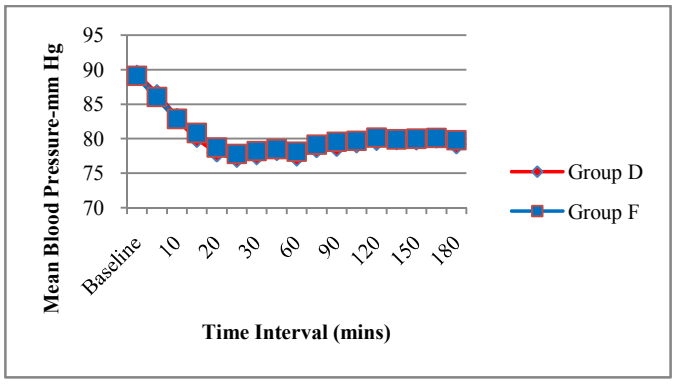

Figure 2 Comparison of mean blood pressure at various time intervals

In our study, hypotension was more in Group D than in Group F which was statistically insignificant. One patient in Group D had bradycardia (HR < 50/min) but it was managed successfully with atropine 0.5 mg IV. Patients in both groups did not show statistically significant difference in the incidence of adverse effects (Table 3).

Table 3 Hemodynamics and incidence of side effects (Intraoperative and early postoperative period)

Side effects	Group D(%)	Group F(%)	p-value
Hypotension	3(11.55)	2(7.7)	>0.05
Bradycardia	2(7.7)	1(3.85)	>0.05
Nausea, Vomiting	2(7.7)	1(3.85)	>0.05
Pruritus	0	1(3.85)	>0.05
Respiratory Depression	0	0	>0.05
Shivering	0	0	>0.05
Urinary retention	0	0	>0.05

Values are expressed as number (percentage); $p > 0.05$ (not significant)

None of the patients experienced respiratory depression or arterial oxygen desaturation. One patient in fentanyl group (3.85%) and two patients of dexmedetomidine group (7.7 %) experienced nausea and vomiting which was not statistically significant ($p > 0.05$). One patient of fentanyl group (3.85%) experienced pruritus while none from dexmedetomidine group ($p > 0.05$) (Table 3). The sedation score was significantly more in Group D patients. The mean sedation score was 1.5 ± 0.5 in Group D as compared to1.1 ± 0.2 in Group F, which was statistically significant ($p < 0.05$).

DISCUSSION

Dexmedetomidine, a new highly selective α-2 agonist, is merging as an intrathecal adjuvant with local anesthetics as it provides adequate intraoperative analgesia along with

prolonged postoperative analgesia, stable hemodynamics and minimal side effects. The affinity of dexmedetomidine to α-2 adrenoceptor agonists is 10 times as compared to clonidine.[10] The mechanism by which intrathecal α-2 adrenergic agonists prolong sensory and motor block is not clear. However, dexmedetomidine acts by binding to presynaptic C-fibers and post-synaptic dorsal horn neurons and their analgesic action is due to inhibition of the release of C-fiber transmitters and hyper polarization of postsynaptic dorsal horn neurons.

Intrathecal dexmedetomidine was found to have antinociceptive action for both somatic as well as visceral pain.[6, 11] Local anesthetics act by blocking sodium channels and the synergistic effect of local anesthetic. α-2 adrenoceptor agonists seems to prolong the duration of action of local anesthetics given intrathecally, while the prolongation of motor block may result from the binding of α-2 adrenoceptor agonists (dexmedetomidine) to motor neurons in the dorsal horn.[12, 13] Various studies using intrathecal dexmedetomidine along with bupivacaine in human beings without any postoperative neurological deficit have been reported.[14]

Dexmedetomidine causes dose dependent decrease in heart rate and blood pressure associated with concomitant decrease in the level of plasma catecholamines which would be of considerable benefit in patients with tachycardia and hypertension. Dexmedetomidine typically improves hemodynamic stability in the perioperative period. Intrathecal local anesthetics decrease mean arterial pressure and sympathetic outflow, presumably by blocking axonal transmission along spinal roots and nerves.

Fentanyl acts through interaction with opioid receptors in the dorsal horn of spinal cord and may also have its action via supraspinal spread when given intrathecally and has been used as an adjuvant to local anesthetics in subarachnoid block. It reduces both visceral and somatic pain but its use is now limited due to its dose dependent adverse effects.

The time of onset of sensory block in our study was comparable between the two groups. Our results are similar with the findings of Suryasree T *et al*[15] because T10 level block was considered as onset of sensory block in both the studies. Also 3.5ml of drug was instilled in subarachnoid space. Since a higher block level was considered by some authors as the onset of sensory block i.e. T8 level by Routray S S *et al*[16] and Mahendru V *et al*[6] and T7-T8 by Khanna MS *et al*[17] onset of sensory block was delayed in these studies In our study, T10 level block was considered as onset of sensory block. Similarly there was no significant difference between the two groups with regard to onset of motor block which were consistent with Mishra P R *et al*[18]and Routray S S *et al*[16]The difference in results obtained by different authors regarding onset of motor block may be due to different volumes, concentration and baricity of local anesthetic solutions used. In our study the time for 2 segment regression was significantly prolonged in the dexmedetomidine group as compared to fentanyl group, which showed the improved quality of block in dexmedetomidine group.

The duration of sensory block was 391.481 ± 35.049 min and 202 ± 22.546 min in Groups D and F respectively which was statistically significant, ($p < 0.0001$). Similarly the duration of motor block was 336.15 ± 10.741 min and 157.88 ± 11.676 min in Group D and F respectively, which was statistically significant between the two groups ($p < 0.05$). Our study has shown that dexmedetomidine (5 µg) as an adjuvant with hyperbaric bupivacaine significantly prolongs both sensory and motor block compared with fentanyl (25 µg) given intrathecally. Our results coincide with Routray S S *et al*[16] and Suryasree T *et al*[15] because same amount of drug i.e. 3.5ml was administered in subarachnoid space in all of the above studies. Shorter duration of sensory block was observed in the following studies as lesser amount of drug was given by all of them, 1.5 ml of drug was given by Kararmaz A *et al*[19] and Mahendru *et al*[6], whereas 3.5 ml of drug was given in our study. The prolongation of sensory block maybe attributed to synergism between local anesthetics and dexmedetomidine whereas prolongation of motor block may result from the binding of dexmedetomidine to motor neurons in dorsal horn.

In our study, the mean duration of analgesia was 292.307 ± 18.012 min and 171.923 ± 10.851min in Group D and F respectively which was statistically significant ($p =0.0001$). The total duration of analgesia was significantly prolonged in dexmedetomidine group. Our study has shown that the addition of 5µg dexmedetomidine with 0.5%hyperbaric bupivacaine significantly prolongs the duration of analgesia as compared to Group F and reduced the rescue analgesic requirement significantly. Our results coincide with findings of Routray S S *et al*[16] and Suryasree T *et al*.[15]

No clinically significant difference in the hemodynamic parameters and adverse effects were reported between the two groups. In our study, hypotension and bradycardia were more in Group D than in the fentanyl group, but it was statistically in significant. Similarly pruritus after intrathecal fentanyl is well known but it was found to be insignificant in our study. No shivering was found in any patient in either group. Nausea and vomiting were observed in 7.7% and 3.85 % patients in Group D and F respectively. This suggested that the incidence of nausea and vomiting was not significantly different among the groups. Similar results were found in earlier studies.

Although the patients in both groups remained haemodynamically stable intraopeatively, the mean sedation score was significantly more in patients in Group D. It was 3.0 ± 0.0 in Group D as compared to 2.0 ± 0.0 in Group F which was statistically significant ($p <0.05$). However this was in acceptable range as we have used lower dose of dexmedetomidine and patients remained easily arousable and co-operative.

CONCLUSION

Intrathecal 5µg dexmedetomidine proved to be a better alternative to 25 µg fentanyl as an adjuvant to 0.5% hyperbaric bupivacaine in subarachnoid block for lower abdominal and lower limb surgeries as it was found to be associated with prolonged motor and sensory blockade, provided good quality of intraoperative analgesia, stable hemodynamics, minimal side effects and prolonged postoperative analgesia along with reduced demand for rescue analgesics as compared to fentanyl.

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How to cite this article:

Jaya Lalwani *et al* (2022) 'Intrathecal Fentanyl And Dexmedetomidine With Hyperbaric Bupivacaine For Prolongation of Analgesia In Elderly Patients Undergoing Lower Abdominal And Lower Limb Surgeries- A Prospective Randomized Study', *International Journal of Current Medical and Pharmaceutical Research,* 08(03), pp 105-109.

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