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COMPARISON OF ANALGESIC EFFECT OF ADDITION OF TWO DIFFERENT DOSES OF DEXMEDETOMIDINE AS AN ADJUVANT TO INTRATHECAL HYPERBARIC BUPIVACAINE FOR LOWER ABDOMINAL SURGERY : A RANDOMIZED DOUBLE BLIND INTERVENTIONAL STUDY

Anaesthesiology

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ABSTRACT

Background: The aim of this study is to assess and compare the analgesic effect of intrathecal dexmedetomidine 2 mcg + hyperbaric bupivacaine vs dexmedetomidine 4 mcg + hyperbaric bupivacaine in lower abdominal surgeries.

Methods: The study was done on 60 patients of (age 30-65 years, weight 45-70 kilograms) ASA grade 1&2. These were randomly allocated in 2 groups of 30 each. They were undergoing lower abdominal surgeries. Group A patients received 3 ml of 0.5% hyperbaric bupivacaine + 2 mcg dexmedetomidine diluted in 1 ml normal saline (Total volume 4 ml). Group B patients received 3 ml of 0.5% hyperbaric bupivacaine + 4 mcg dexmedetomidine diluted in 1 ml normal saline (Total volume 4 ml). Mean time of onset of sensory and motor block, mean time to first rescue analgesia, mean VAS score and proportion of cases with complications was recorded.

Conclusion: Higher doses (4 mcg) of intrathecal dexmedetomidine as adjuvant provides longer duration of post-operative analgesia and significantly decreases requirement of total number of rescue analgesia in first 24 hours in compare to smaller doses (2 mcg) of dexmedetomidine. It was also observed that onset of sensory block was earlier, duration of sensory and motor block was longer in higher doses group (4 mcg dexmedetomidine).

KEYWORDS

Spinal anaesthesia, Lower abdominal surgery, Dexmedetomidine, Duration of analgesia.

INTRODUCTION

Pain as defined by the International Association for the study of Pain (IASP) is "An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage".

Pain is frequently the result of nociception; an activity in the nervous system that results from the stimulation of nociceptors. This activity is carried to the brain, usually via the spinal cord, conveys information, without conscious awareness, about damage or near damage in body tissues.

Uncontrolled postoperative pain resulting from any kind of surgery may produce a range of detrimental acute and chronic effects. The transmission of nociceptive stimuli from the periphery to the CNS results in neuro-endocrine stress response resulting in increased sympathetic tone, increased catecholamine levels and catabolic hormone secretion.

Many options are available for the treatment of postoperative pain, including systemic (i.e. opioid and non-opioid) analgesics and regional techniques. Efficacy of intravenous opioids is typically limited by the development of tolerance or opioid related side effects. Intravenous opioids are commonly used for moderate to severe postoperative pain. Neuraxial and peripheral techniques can provide superior analgesia compared to systemic drugs.

Spinal anaesthesia, a common technique in anaesthesia practice, has got inherent advantages like intense motor and sensory blockade, good relaxation, reliability, avoids side effects of multiple drugs used in general anaesthesia, no postoperative respiratory depression, nausea, vomiting, drowsiness etc. It also has good patient and surgeon acceptability as well as safe enough for early discharge from the hospital.

Bupivacaine, an amide type of local anaesthetic, has high potency, slow onset and long duration of action is commonly employed for spinal anaesthesia. Local anaesthetic provide good analgesia for surgical and immediate post-operative period but duration is limited so for postoperative analgesia it has to be given by continuous epidural or spinal infusion, at the cost of motor paralysis or reflex suppression which is not beneficial in post-operative period.

Dexmedetomidine, a new highly selective α_2-agonist, is under evaluation as a neuraxial adjuvant as it provides stable hemodynamic conditions, good quality of intraoperative and prolonged postoperative analgesia with minimal side effects.

In this study, our aim is to compare the analgesic effect of two different doses (2 mcg and 4 mcg) of dexmedetomidine given in combination with 0.5% hyperbaric bupivacaine via intrathecal route in lower abdominal surgery with regards to the onset and duration of sensory and motor block, duration of analgesia and incidence of side effects.

METHODS

The present study was carried out in the Department of Anaesthesiology at SMS Medical College and Hospital, Jaipur, Rajasthan. After obtaining institutional ethical committee approval and patients written informed consent, the study was conducted in 60 patients, aged 30-65 years, weight 45-70 kgs of ASA Grade 1&2 scheduled for lower abdominal surgery. The patients were randomly allocated using sealed envelope method in 2 groups (30 of each).

- Group A (n=30) :Patients received 3.0 ml of 0.5% hyperbaric bupivacaine + 2 mcg of dexmedetomidine diluted in 1 ml normal saline intrathecally (Total volume 4 ml)
- Group B (n=30) :Patients received 3.0 ml of 0.5% hyperbaric bupivacaine + 4 mcg dexmedetomidine diluted in 1 ml normal saline intrathecally (Total volume 4ml)

Patients with cardiovascular, respiratory, neurological and liver diseases, patients who are on narcotic therapy were excluded from study. A detailed pre-anaesthetic evaluation including history and a thorough general and systemic examination and all relevant investigations were done for all the patients.

After taking informed written consent and confirming overnight fasting, patient was taken on the operation table after explained about VAS. Then patient was connected to monitors and baseline vitals like BP, pulse rate, respiratory rate was recorded. 18 gauge intravenous (IV) cannula had been inserted at the forearm level and lactated Ringer's solution was administered as a bolus of 10 ml/kg before subarachnoid block to all patients.

Vitals were noted just before lumbar puncture. Spinal anaesthesia was performed at L3-L4, L4-L5 interspace with the patient in left lateral position by using a 25 Gauge Quincke's needle under strict aseptic conditions, free flow of cerebrospinal fluid was verified before injection of the anaesthetic solution, which was administered over 30 seconds. The direction of the needle aperture was cranial during the injection. All patients were immediately placed in a supine position following the injection with a head down tilt to achieve desired level of block of T6-T8. Monitoring was done using continuous electrocardiography (lead II & V), heart rate, non-invasive blood pressure and continuous pulse oximetry and patients was given 6.0 L/min of oxygen by face mask. Pulse rate, NIBP, respiratory rate and SPO2 was monitored. Episodes of intra-operative hypotension were managed with colloids and if required with incremental doses of inj. Mephentermine 6 mg intravenously. Bradycardia was treated with 0.6mg of inj. Atropine intravenously. Intra-operative nausea was treated with inj. Ondansetron 4mg.

The onset of sensory and motor block was defined as time from intrathecal injection of bupivacaine to time taken to desired level of sensory and motor block.

Postoperatively, the pain was assessed by using visual analogue pain scale (VAS) between 0 and 10 (0 = no pain, 10 = most severe pain). It was assessed at every 30 min. Time of completion of surgery to patients first demand of rescue analgesia was noted. Inj. Tramadol 100 mg iv will be given.

STATISTICALANALYSIS

All Statistical analysis was performed with the SPSS. The Categorical variables were summarized as percentage and were analysed using Chi square test. The quantitative data was presented as mean and standard deviation were compared by student t-test. A Probability (p value) less than 0.05 was considered as statistically significant.

Observations

The demographic profiles with regard to age and weight was comparable. The distribution as per ASA status was similar. The duration was surgery in both the groups was also similar and statistically insignificant.

Pre-induction heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure, spo2 were comparable in both the groups with a statistically no significant difference between them ($p<0.05$).

Table 1: Mean time to onset of sensory block (min)

	Group A		Group B	
	Mean	SD	Mean	SD
Sensory Block	4.03	0.89	3.67	0.48
P VALUE	0.048 (S)			

Above table shows the mean time to onset of sensory block. it was 4.03±.089 min in group A and 3.67±0.48 min. in group B, difference was statistically significant (p =0.048) and onset of sensory block was earlier in group B.

Table 2: Mean time to onset of motor block (min)

	Group A		Group B	
	Mean	SD	Mean	SD
Motor Block	5.13	0.78	4.77	0.77
P VALUE	0.072 (NS)			

As depicted in above table the mean time to onset of motor block . the mean time of onset of motor block in group A was 5.13±0.78 (min)in group A and in group B it was 4.77±0.77 min. Difference in mean time of onset of motor block was statistically not significant (p=0.072).

Table 3: Comparison of VAS among two groups

	Group A		Group B		P VALUE
	Mean	SD	Mean	SD	
0 min	0.03	0.18	0.00	0.00	0.321 (NS)
30 min	0.87	0.86	0.77	0.94	0.668 (NS)
1 hr	1.57	1.22	1.57	1.25	1.00 (NS)
2 hr	2.50	0.82	2.43	0.86	0.759 (NS)
4 hr	2.97	0.18	2.73	0.58	0.040 (S)
6 hr	3.00	0.00	2.73	0.45	0.003 (S)
12 hr	3.00	0.00	3.00	0.00	-
18 hr	3.00	0.00	3.00	0.00	-
24 hr	3.00	0.00	3.00	0.00	-

Above table shows comparison of VAS score. Rescue analgesic was given for VAS Score ≥ 3. Comparison of the mean VAS between both groups which is statistically significant at 4 hours and 6 hours ($p<0.05$).

Table-4: Mean time of first rescue analgesia

	Group A		Group B	
	Mean	SD	Mean	SD
Mean Time of first rescue analgesia	227.33	17.06	387.17	26.96
P value	p<0.001 (S)			

Above table shows the mean time to first rescue analgesia in patients of group A was 227± 17.06(min) and in group B was 387.17±26.96 (min). Difference was statistically significant. (p value <0.001). Mean time to first rescue analgesia was more in group B as compared to group A.

Table 5: Number of rescue analgesia in 24 hours (Number)

	Group A		Group B	
	No.	%	No.	%
1	12	40.00	28	93.33
2	17	56.67	2	6.67
3	1	3.33	0	0.00
Total	30	100.00	30	100.00
P value	p<0.001 (S)			

As shown in above table, In group A 40.00% of the patients were required only 1 rescue analgesia 56.67% of the patients were given 2 rescue analgesia and 3.33% were given 3 rescue analgesia. While in group B 93.33% of the patients were required only one rescue analgesia, 6.67% of the patients were given 2 rescue analgesia and none of patient required 3 rescue analgesia which is significantly less than group A ($p<0.001$).

Table 7: Adverse Effects

	Group A (N=30)		Group B (N=30)		P value
	No.	%	No.	%	
HYPOTENSION	2	6.67	3	10.00	1.000(NS)
BRADYCARDIA	2	6.67	3	10.00	1.000(NS)
NAUSIA VOMITTING	1	3.33	2	6.67	1.000 (NS)
RESPIRATORY DEPRESSION	0	0.00	0	0.00	-
SHIVERING	1	3.33	0	0.00	1.000(NS)

Above table shows comparison of the incidence of side effects in both groups. Hypotension occurred in 2 patients (6.67%) in groups A and 3 patients(10.0%) in group B. Bradycardia occurred in 3 patients (10.0%) in groups A and 2 patients (6.67%) in group B. Nausea occurred in 1 patients (3.33%) in groups A and 2 patients (6.67%) in group B. Shivering occurred in 1 patient (3.33%) in group A.

DISCUSSION

Spinal anaesthesia is the most commonly used technique for abdominal hysterectomy surgeries, as it is cost effective and easy to administer. However, postoperative pain control is a major concern, because spinal anaesthesia using only local anaesthetic drugs is associated with relatively short duration of action and thus early rescue analgesic is needed in the postoperative period.

Demographic variables like age, weight, height ASA grade was comparable in both the groups with $p<0.05$.

The mean duration of surgery was comparable in both the groups. It was 68.67±15.92 min in group A while 65.00 ±15.92 min. in group B (P value =0.376)

The mean time of onset of sensory block in group A was 4.03 ± 0.89 and in group B was 3.67 ±0.48 minutes. Mean time of onset of sensory

block was earlier in group B as compared to group A. This was statistically significant as p value was 0.048.

Results of this study coincides with study done by **Bansal P et al (2016)**[1]. They observed that adding 10 mcg dexmedetomidine fastens onset of sensory and motor block in comparison of 5 µg dexmedetomidine. **Halvadia S et al (2019)**[2] also concluded that 10 µg dexmedetomidine enhances the onset of sensory block in comparison of 5 mcg dexmedetomidine when used as an adjuvant to intrathecal hyperbaric bupivacaine. They reported that onset of sensory block was faster in 10 mcg dexmedetomidine in Comparison to 5 mcg dexmedetomidine and control group. **Abdulkadir Y et al (2014)**[5] also found that onset of sensory block was earlier in 4mcg dexmedetomidine as compare to 2 mcg dexmedetomidine and control group. Our result correlates with the above-mentioned study in terms of onset time of sensory block.

The mean time to onset of motor block in group A was 5.13 ± 0.78 minutes and in group B was 4.77 ± 0.77 minutes. Mean time of onset of motor block was earlier in group B as compared to group A but the difference was statistically non-significant as p value was 0.072. Results of this study coincides with study done by **A das et al (2015)**[6], they found that the mean onset of motor block was earlier in group D10 (10 mcg) as compare to group D5 (5 mcg) dexmedetomidine but difference was statistically not significant. Study done by **Halvadia S et al (2019)**[2]**.** They also observed that the mean onset of motor block was earlier in 10mcg dexmedetomidine as compare to 5 mcg dexmedetomidine but difference was statistically not significant. Our result correlates with the above-mentioned study in terms of onset of motor block.

Mean duration of sensory block was 152.50 ± 22.81 minutes in group A while in group B the mean duration of sensory block was 203.67 ± 26.81 in minutes. Duration of sensory block was prolonged in group B as compared to group A and difference was statistically significant as p value <0.001. Result of our study was supported by study done by **Halder S et al (2014)**[6]. They concluded that the mean time duration of sensory block was prolonged with10 mcg dexmedetomidine as compared to 5 mcg dexmedetomidine. **Abdulkadir Y et al (2014)**[5] also found that mean duration of sensory block was prolonged in 4 mcg dexmedetomidine compared to 2 mcg dexmedetomidine and control group. Difference was statistically significant. Result of our study correlates with the above-mentioned study in terms of duration of sensory block.

Mean duration of motor block was 196.33± 21.25 minutes in group A while in group B the mean duration of motor block was 241± 27.46 in minutes. There was statistically significant difference in duration of motor block as p value <0.001 and duration of motor block was longer in group B. Results of this study was supported by the study done by **Halder S et al (2014)**[6]. They also found that the mean duration of motor block was prolonged with 10 mcg dexmedetomidine as compared to 5 mcg dexmedetomidine. **Abdulkadir Y et al (2014)**[5] also concluded that mean duration of motor block was prolonged in 4 mcg dexmedetomidine as compare to 2 mcg dexmedetomidine and control group.

Mean VAS score was significantly higher in group A as compared to group B at 4 hours and 6 hours postoperative. The difference was statistically significant (p<0.05).

The mean time to first rescue analgesia was 227.33±17.06 min. in group A while 387.17±26.96min. in group B. The duration of analgesia was longer in group B as compared to group A. The difference was statistically significant (p<0.001). Result of this study is supported by the study done by **Halder S et al study (2014)**[6]. They observed prolonged mean duration of analgesia with 10µg dexmedetomidine as compared to 5 mcg dexmedetomidine. **Abdulkadir Y et al (2014)**[5] also observed longer mean duration of analgesia with 4 mcg dexmedetomidine as compared to 2 mcg dexmedetomidine and control group. Study done by **Shaik S et al (2014)**[5]. They also found prolonged duration of analgesia with 10 mcg dexmedetomidine as compare to 5 mcg dexmedetomidine and control group.

In group A 40.00% of the patients were given 1 rescue analgesia,56.67% of the patients were given 2 rescue analgesia and 3.33% were given 3 rescue analgesia, While in group B 93.33% of the patients were given 1 rescue analgesia, 6.67% of the patients were given 2 rescue analgesia and none of patient required 3 rescue analgesia which is significantly less than group A (p<0.001). **Abdulkadir Y et al (2014)**[5] also observed that more number of analgesic dose were required in plain bupivacaine (group A) and 2 mcg dexmedetomidine (group B) as compared to 4 mcg dexmedetomidine (group C).

Hypotension occurred in 2 patients of group A and 3 patients of group B. The difference in occurrence of hypotension was statistically not significant (p=1.00).

Bradycardia was seen in 2 patients of group A and 3 patients of group B. The difference was statistically not significant (p=1.00).

Nausea and vomiting occurred in 1 patient of group A and 2 patients of group B and the difference was statistically not significant (p=1.00).

Shivering was seen in 1 patient of group A and none of the patients in group B complained of shivering. The difference was statistically not significant (p=1.00)

CONCLUSION

We concluded that higher doses (4 mcg) of intrathecal dexmedetomidine as adjuvant provides longer duration of post-operative analgesia and significantly decreases requirement of total number of rescue analgesia in first 24 hours in compare to smaller doses (2 mcg) of dexmedetomidine. It was also observed that onset of sensory block was earlier, duration of sensory and motor block was longer in higher doses group (4 mcg dexmedetomidine).

Hence, we conclude that dexmedetomidine 4mcg is better for post-operative analgesia and it can be used safely.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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