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Original Research Article

COMPARATIVE EFFICACY OF FENTANYL VS DEXMEDETOMIDINE INTRATHECALLY AS AN ADJUVENT TO ISOBARIC LEVO-BUPIVACAINE IN INFRA-UMBILICAL SURGERY: A PROSPECTIVE RANDOMIZED STUDY.

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ABSTRACT:

Background: Fentanyl is a potent, highly lipophilic, synthetic opioid analgesic used as an adjuvant in spinal anaesthesia. Dexmedetomidine is also a potent, lipophilic, selective α2adrenergic agonist. Compared to Dexmedetomidine, it has an earlier onset of block, better intraoperative analgesia with increased side effects(such as, nausea, vomiting or respiratory depression).

AIM: To compare Fentanyl(25 ug) versus Dexmedetomidine(10 ug) as an adjuvant with 0.5% isobaric Levo-Bupivacaine in infra-umbilical surgeries.

MATERIAL & METHODS:

Study Design: A prospective, randomized, controlled study. **Study site:** Department of Anaesthesia, K. D. Medical College, Hospital and Research Centre in Mathura. **Study Period:** 6 months. **Study population**: Patients between 20-60 years of either sex, ASA Grade I – II, scheduled for elective infra-umbilical procedures with no co-morbid conditions.

Sample size: 60 cases. **Sampling method:** Simple random method(sealed envelope).

RESULTS:

The sensory block duration is 7.71±0.31 hrs in D group and 3.78±0.83 hrs in group F with p value <0.05. The mean time taken for attaining motor blockade is 2.06 ± 1.17 mins in D group, 2.45 ± 1.39mins in F group. but statistically not significant between group D and in F group (p=0.2). The motor block duration is 7.33 ± 0.28hrs in group D and 3.39 ± 0.91 hrs in F group which suggestive of statistically highly significant (p=0.001).

CONCLUSION:

In infra-umbilical surgery, levo-Bupivacaine with adjuvant dexmedetomidine(10 ug) intrathecally has a longer duration of sensory and motor block with preserved hemodynamic stability and lesser adverse effects in comparison to adjuvant fentanyl(25 ug). However, onset of sensory block is earlier with fentanyl.

Keywords: Fentanyl, dexmedetomidine, Levo-Bupivacaine, spinal anaesthesia, infraumbilical surgeries.

INTRODUCTION:

Pain, is a distressing physical and emotional sensation linked to or explained in terms of actual tissue damage[1]. It is the most distressing complication, so the aim of anaesthesia is to relieve pain during surgeries and treatment for postoperative pain including systemic (opioid and

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nonopioid) analgesics and regional techniques. For most infra-umbilical procedures, regional anaesthesia is the recommended approach. It keeps the patient awake and reduces or eliminates the problems associated with airway management. The procedure is simple to conduct, the onset of anaesthesia is faster, poly pharmacy is avoided, allowing the surgical incision to be completed sooner, and postoperative analgesia is provided.

Spinal anaesthesia is pioneered by German surgeon Dr. August Bier in1898[2] using the Quincke needle in intrathecal space. It requires a minimal dose of local anaesthetic yet produces motor, sensory blockade and spread of analgesic can be controlled.

Several intrathecal adjuvants are in use with local anaesthetics to provide prolonged spinal analgesia with less side effects. Drugs such as Epinephrine, Opioids, Clonidine, dexmedetomidine, magnesium sulphate, Neostigmine, Ketamine, Benzodiazepines, Dexamethasone. they prolong motor block with side effects like bradycardia, hypotension, nausea, vomiting due to sympathetic block.

Levo-Bupivacaine[3] is a more recent LA that has recently been licensed for intrathecal injection. Levo-Bupivacaine is a pure S (-) enantiomer of bupivacaine and an amide local anaesthetic. Levo-Bupivacaine is a potent, long-acting local anaesthetic with a gradual onset of action. When compared to bupivacaine, it has a reduced proclivity for blocking inactivated cardiac sodium and potassium channels and a faster rate of dissociation. It has lower cardiac toxicity in overdose/intravenous dosing due to its quicker protein binding rate. Plain LevoBupivacaine is isobaric. It has the benefit of having a more predictable distribution. Levo- Bupivacaine has the advantage of a longer sensory blockade and a faster recovery from motor blockade with less hypotension. With Levo-Bupivacaine, motor block is regressed sooner, and adjuvants work in tandem with the local anaesthetic. They improve the quality of intraoperative anaesthesia, speed up the onset of spinal anaesthesia and extend postoperative analgesia.

Fentanyl[4] is a potent, short acting, highly lipophilic, synthetic opioid analgesic most used adjuvant in spinal anaesthesia. It has quicker onset of the block, better intraoperative analgesia with side effects such as, nausea, vomiting or respiratory depression.

Dexmedetomidine[5] is a potent and highly selective α2-adrenergic agonist, which has sympatholytic, analgesic, sedative, hemodynamic stable effects and prolong duration of spinal anaesthesia.

Hence the present study was undertaken to compare and assess between Fentanyl, Dexmedetomidine intrathecally as adjuvants to Isobaric levo-bupivacaine 0.5 percent in participants undergoing infra-umbilical surgeries for onset, duration, hemodynamics and side effects.

AIM: To compare 25ug Fentanyl versus 10ug Dexmedetomidine as adjuvant with 0.5% isobaric Levo-Bupivacaine in infra-umbilical surgeries.

OBJECTIVES: To study the,

1. Onset, duration of sensory block
2. Onset, duration of motor block
3. Duration of postoperative analgesia
4. Time for 1st rescue analgesia
5. Hemodynamic parameters
6. Side effects if any

MATERIAL & METHODS:

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Study Design: A prospective, randomized, comparative study.

Study area: Department of Anaesthesia, K. D. Medical College, Hospital and Research Centre, Mathura.

Study Period: 6 months.

Study population: Patients aged 20 to 60 years of either sex, ASA Grade I – II, who were scheduled for elective infra-umbilical procedures and had no co- morbid conditions.

Sample size: 60 cases.

Sampling method: Simple random method. **Inclusion criteria:**

- Adult patients of either gender,
- between the ages of 20 and 60,
- ASA I and II
- No comorbid conditions
- elective surgery.

Exclusion criteria:

- Patient reluctance,
- Parturient.
- Morbid obesity.
- absolute contraindications to spinal anaesthesia- raised intracranial pressure, severe hypovolemia, bleeding diathesis, and local infections.
- co-morbid diseases such as diabetes, hypertension.

Ethical consideration: Institutional Ethical committee permission was taken prior to the commencement of the study.

Study tools and Data collection procedure:

A simple sealed envelope technique was used for randomization. 60 plain covers each with a single sheet written F in 30 sheets, D in 30 sheets were prepared and kept in the operation theatre. The covers were mixed thoroughly. Before the start of the surgery, the patient picked up a cover of his/her choice. If the cover contains a sheet written F, then the case was included in group F and if the sheet contains D then the case included in group D. This procedure was continued till all the 60 covers were used, hence enrolling 30 cases in each group.

Group D: received 12.5mg(2.5ml) isobaric Levo-Bupivacaine 0.5 with 10 ug(0.1ml) dexmedetomidine and normal saline(0.4ml) of 3ml total volume

Group F: received 12.5mg(2.5ml) isobaric Levo-Bupivacaine 0.5% with 25ug(0.5ml) fentanyl of 3ml total volume

Each patient will receive a preoperative evaluation, as well as written informed consent. Before surgery, patients kept NBM for 6 hours for meals and 2 hours for clear fluids. Tablet Ranitidine 150mg and Tablet Alprazolam 0.5mg were given to patients the night before surgery to help them relax. Airway management and emergency medications were maintained on hand in the operation room. The patients were sent to the operating room for treatment. The operation table was double-checked and positioned supine with the patients. Intra-operative monitoring was applied with ECG leads, pulse oximeter and noninvasive blood pressure monitor. Systolic and

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diastolic blood pressure, oxygen saturation, and pulse rate were all measured before surgery. Patients were primed with 500ml of ringer lactate and cannulated with an 18G intravenous cannula. In a sitting position, the patient was positioned. An antiseptic solution was used to clean the skin on the back, and a sterile towel was wrapped over it. Using a 25G Quincke Babcock spinal needle, lumbar puncture was conducted through midline approach at the L2 – L3 or L3 – L4 interspaces. The study medication was administered in a total amount of 3ml after ensuring the free flow of the CSF. The patients were placed in a supine position immediately after injection, and the time of the spinal anesthesia was recorded. The test medicines are prepared by a senior anesthesiologist who is not a participant in the research.

The parameters observed

1. Onset of motor, sensory blockade.
2. Duration of motor, sensory blockade.
3. Time for 1st rescue analgesia

Sensory blockade was assessed using the pinprick method with a blunt tipped 27G hypodermic needle until maximum sensory level was achieved (T8), and motor blockade was assessed using the modified Bromage scale with time noted to achieve grade 2, duration of sensory and motor block, level of sedation, and hemodynamic monitoring was done every 2 minutes during the block for the first 10 minutes, every 15 minutes until the end of surgery, and every 30 minutes until recovery.

Statistical analysis: The results of continuous variables are given as mean ± SD and proportion as percentage. Assessment of difference between the two groups was done by student's t test and chi-square test. A 'p' value of < 0.05 was taken as value of significance in the tests.

OBSERVATIONS & RESULTS:

Table 1: Demographic Profile

Demographic Profile	Group D	Group F	P value
Age (yrs)	37.96 ±10.99	38.76±13.47	0.8 (NS)
Height (cm)	166.5±7.92	163.9±8.33	0.22 (NS)
Weight (kg)	65.7±8.52	58.26 ±7.91	0.0009 (S)

No statistical significance in demographic distribution of Age, Height distribution of all groups with P>0.05 and observed significant difference was seen in weight with p <0.05.

Table 2: Sex distribution

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	Group D		Group F	
	No. of Pts	%	No. of Pts	%
Male	17	56.66	17	56.66
Female	13	43.33	13	43.33
Total	30	100	30	100

The sex distribution in all groups and no significant difference with (P> 0.05).

The mean surgery duration is 53±6.51mins in group D and 57.67±12.84mins in group F with no significant difference of (p>0.05).

Table 3: Onset of Sensory Blockade

Onset of sensory in mins	Group D	Group F	P Value
mean ±SD	3.8±1.52	2.95±1.16	0.018(s)
Minimum	1	1	
Maximum	6	5	

The sensory onset in D group is 3.8 ±1.52mins and group F is 2.95± 1.16mins. onset of sensory block was faster with fentanyl group with statistically significant (p=0.018).

Table 4 - Sensory block duration

Duration of analgesia in hrs	Group D	Group F	P Value
Mean± SD	7.71±0.31	3.78±0.83	0.001 (S)
Minimum	7	2.5	

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Maximum	8	5	

The sensory block duration is 7.71±0.31 hrs in D group and 3.78±0.83 hrs in group F which suggestive of statistically significant (p=0.001).

Table 5: Onset of motor blockade

Time taken for Onset of Motor Block in mins	Group D	Group F	P Value
Mean± SD	2.06±1.17	2.45±1.39	0.2(NS)
Minimum	1	1	
Maximum	4	6	

The mean time taken for attaining motor blockade is 2.06 ± 1.17 mins in D group, 2.45 ± 1.39mins in F group. but statistically not significant between group D and in F group (p=0.2).

Table 6: Motor block Duration

Duration of motor(hr)	Group D	Group F	P Value
Mean± SD	7.33±0.28	3.39±0.91	0.001(s)
Minimum	7	2.5	
Maximum	8	4.5	

The motor block duration is 7.33 ± 0.28hrs in group D and 3.39 ± 0.91 hrs in F group which suggestive of statistically highly significant (p=0.001). **Table 7: Heart rate(beats/min) at various intervals**

HR in Min	Group D	Group F	P Value
HR Basal	85.96±17.68	87.86±16.92	0.67
HR2min	82.46±15.54	88.1±18.59	0.20

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HR4min	76.96±13.83	85.23±18.60	0.05
HR6min	75.33±13.46	84.03±18.5	0.04
HR8min	72.3± 10.83	82.2±19.41	0.017
HR10min	72±10.39	81.3±19.33	0.023
HR15min	70.13±9.54	82.46±19.46	0.0028
HR30min	68.16±9.4	79.83±17.32	0.0020
HR45min	68.96±9.83	78.33±15.7	0.0075
HR60min	68.3±9.85	78.46±12.88	0.0011
HR75min	69.26±10.64	78.36±12.56	0.003
HR90min	68.53±9.68	77.36±11.48	0.0021
HR105min	69.26±10.64	78.13±9.91	0.0015
HR120min	71.83±11.16	77.43±8.98	0.036
HR150min	71±11.96	75.86±8.41	0.073
HR180min	73.06±12.80	75.1±8.10	0.46

The heart rate from basal to 180mins, showing statistically significant from 4th min to 120th min of mean heart rate with p value<0.05.

The SBP from basal to 180 mins, in both the group D and group F does not show any statistically significant decrease($p>0.005$).

The mean DBP from basal to 180 mins, there is no statistically significant decrease in group D and group F($P>0.005$).

The mean MAP in both the group D and group F, shows no statistically significant decrease($p>0.005$).

Table 8- Time to rescue analgesia

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Hours	Group D	Group F	P value
Time to rescue analgesia	8.12±3.26hrs	4.36±0.42hrs	P<0.001(s)

In this study, the Mean± SD time to rescue analgesia in fentanyl group is 4.36±0.42 hrs and in dexmedetomidine group is8.12±3.26 hrs with p value<0.001 which is statistically significant. The time to rescue analgesia is prolonged in dexmedetomidine group. **Table 9 - Side effects**

Side effects	Group D (30 pts)	Group F (30 pts)
Nausea	0	0
Vomiting	0	1
Bradycardia	0	0
Hypotension	0	0
Pruritus	0	2
Urinary retention	0	0
Total	0	3

In our study, no side effects observed in dexmedetomidine group, 1 patient had vomiting,2 patients had pruritus in fentanyl group with no significant difference in both groups.

DISCUSSION:

Fentanyl is a centrally acting synthetic opioid that is commonly used to treat pain. To improve anesthesia and analgesia, intrathecal fentanyl is frequently used with other local anesthetics. It prolonged spinal anesthesia while lowering anesthetic drug-related adverse effects as itching, nausea, and vomiting. In several procedures, dexmedetomidine and fentanyl have been utilized as adjuvants to local anesthetics to give better analgesia and lengthen the block. We intend to examine the properties of spinal blockade with isobaric Levo-Bupivacaine, fentanyl, and dexmedetomidine for onset, duration, hemodynamic parameters, and side effects in this study. Das et al[6], Singh et al[7] and Halder et al[8] conducted study with 5ug and 10ug Dexmedetomidine in abdominal hysterectomy, lower limb orthopedics and lower abdominal surgeries respectively along with 15mg Bupivacaine and assessed the onset, duration and hemodynamic parameters and concluded that sensory onset decreased by 0.69 min, motor onset decreased by 0.62mins and moto duration increased by 54.27 mins and sensory block by 36.06 mins with 10ug compared to 5ug. In comparison to 5 ug of Dexmedetomidine, 10 ug of Dexmedetomidine administered intrathecally with Levo-Bupivacaine resulted in a longer duration of sensory and motor block in our study.

In our study sensory onset was 3.8±1.52mins in Dexmedetomidine group and 2.95±1.16mins in Fentanyl group with p value =0.018. sensory onset is earlier with Fentanyl group which is

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statistically significant. Kashyap et al[9] conducted a study including patients getting spinal anaesthesia for elective lower limb orthopaedic surgery A total of 150 study participants were allocated into three groups at random, concluded that sensory onset is earlier with Fentanyl group which is statistically significant.

Vijayendra et al[10] conducted 210 patients with physical status I or II underwent elective lower limb orthopaedic surgery under spinal anaesthesia in research conducted by the American Society of Anaesthesiologists (ASA) concluded that The Fentanyl group has a faster onset of sensory block, which is statistically significant. Jain et al[11] conducted 180 study participants were divided into three groups at random, concluded that The Fentanyl group has a faster onset of sensory block, which is statistically significant.

Because Dexmedetomidine has a synergistic effect on spinal anaesthesia, higher doses result in a faster onset than lower doses. In our investigation, the start of motor block was 2.06±1.17 minutes in the Dexmedetomidine group and 2.45±1.39 minutes in the Fentanyl group, with a p value of 0.2, which is statistically insignificant. However, due to the high dose of Dexmedetomidine, i.e., 10ug, the onset of motor block was faster than with 5ug in the previous experiments.

Kashyap et al[9] conducted a study including patients getting spinal anaesthesia for elective lower limb orthopaedic surgery A total of 150 study participants were allocated into three groups at random, concluded that the beginning of motor block was 3.41±1.33 in the fentanyl group and 8.79±3.31 in the dexmedetomidine group, which is statistically significant. In our investigation, the onset of motor block was 2.06±1.17 minutes in the Dexmedetomidine group and 2.45±1.39 minutes in the Fentanyl group, with a p value of 0.2, which is statistically not significant, which is not identical to the above study.

The mean duration of sensory block in our study was 7.71±0.31 hours in the Dexmedetomidine group and 3.78±0.83 hours in the Fentanyl group, which is similar to other studies with p0.001 which is statistically significant. Vijayendra et al[10] conducted 210 patients with physical status I or II underwent elective lower limb orthopaedic surgery under spinal anaesthesia in research conducted by the American Society of Anaesthesiologists (ASA) observed sensory duration of 163.32±12.74mins in Fentanyl group and 206±6.42mins in Dexmedetomidine group, which is statistically significant with p0.05. similarly, the mean duration of sensory block in our study was 7.71±0.31 hours in the Dexmedetomidine group and 3.78±0.83 hours in the Fentanyl group, which is similar to other studies with p0.001 which is statistically significant.

In our investigation, the duration of motor block was statistically significant, with a p value of 0.001. In the Dexmedetomidine group, the average duration of motor block was 7.33±0.28 hours, while it was 3.39±0.91 hours in the Fentanyl group.

In our study, mean heart rate at basal is 85.96±17.68 mins in D group and 87.86±16.92 mins in F group with p value 0.67 but the heart rate is lower in Dexmedetomidine group from 4th min with 76.96±13.8 mins and in Fentanyl group 85.23±18.60 mins with p value 0.05 and maximum p value lowered at 105th min of mean 69.26±10.64mins in D group and 78.13±9.91mins in F group with p value 0.0015 and showed significance till 120th min of mean 71±11.96mins in Dexmedetomidine group and in Fentanyl group of mean 75.86±8.41 mins of p value 0.073 . but there is not bradycardia seen in our study.

Prashanth et al[9], Gupta et al[10] and Jain et al[11] conducted the participants and the study were separated into three groups at random. Group A: 2.5ml isobaric 0.5 percent LevoBupivacaine

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+ 0.5ml normal saline (total volume is up to 3.0 ml). Group F: 2.5ml isobaric 0.5 percent Levo-Bupivacaine + 25ug fentanyl (test solution will have diluted with normal saline to total volume of 3.0ml). Group D: 2.5ml isobaric 0.5 percent Levo-Bupivacaine + 5 ug dexmedetomidine (test solution will have diluted with normal saline to total volume of 3.0 ml). The hemodynamic parameters, the start and duration of sensory and motor block, postoperative analgesia, and side effects were all evaluated, and it was discovered that there was a significant difference in heart rate from 2 to 20 minutes intraoperatively, with a p value of 0.05. However, with a p value of >0.05, heart rate is not significant postoperatively. Similarly, in our study heart rate in Dexmedetomidine group is lowered from 4th min with 76.96±13.8 mins and in Fentanyl group 85.23±18.60 mins with p value 0.05 and maximum p value lowered at 105th min of mean 69.26±10.64mins in Dexmedetomidine group and 78.13±9.91mins in Fentanyl group with p value 0.0015 and showed significance till 120th min of mean 71±11.96mins in D group and in F group of mean 75.86±8.41 mins of p value 0.073.but no bradycardia was noted.

In our study, MAP from basal to 180th mins the p value is >0.05 which is statistically not significant. But lowered at 6th min with mean of 92.06±10.38mins in dexmedetomidine group and 89.32±7.82mins with p value 0.16 after spinal anesthesia and the MAP increased there after which is not significant due to fluid resuscitation with crystalloids and showed no further fall in MAP i.e.; no hypotension recorded.

Prashanth et al[9], Gupta et al[10] and Jain et al[11] conducted the participants in the study were divided into three groups at random. Group A: 2.5ml isobaric 0.5 percent Levo-Bupivacaine + 0.5ml normal saline (total volume is up to 3.0 ml). Group F: 2.5ml isobaric 0.5 percent Levo-Bupivacaine + 25ug fentanyl (test solution will diluted with normal saline to total volume of 3.0ml). Group D: 2.5ml isobaric 0.5 percent Levo-Bupivacaine + 5 ug dexmedetomidine (test solution will diluted with normal saline to total volume of 3.0 ml). Hemodynamic parameters, onset and duration of sensory and motor block, postoperative analgesia, and side effects were assessed, and a significant difference in mean arterial pressure was observed from 2 to 20 minutes intraoperatively, with hypotension treated with Inj. Mephentermine 3mg in incremental doses. After surgery, MAP did not reveal a significant difference (p>0.05).

But the mean MAP in both groups in our study shows p value >0.05 intraoperatively and postoperatively, because of preloading with crystalloids to the patient prior to the procedure (subarachnoid block).

Mechanism of sedation in the D group is due to action on the sleep promoting pathway. Prashanth et al[9] and Gupta et al[10] showed sedation scale 2 in their studies but we noticed no sedation in the patients received Dexmedetomidine in both intraoperatively and postoperatively.

CONCLUSION:

From our study it can be concluded that Levo-Bupivacaine with dexmedetomidine had a longer duration of sensory and motor block with good hemodynamic stability and a lower incidence of side effects in our study with 10 ug dexmedetomidine and 25 ug fentanyl as adjuvants to 0.5 percent Levo-Bupivacaine intrathecally in infra-umbilical surgeries, but onset of sensory block was earlier with the fentanyl group. In comparison to fentanyl, dexmedetomidine is a good intrathecal adjuvant with Levo-Bupivacaine.

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