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Original Research Article

"A COMPARITIVE CLINICAL STUDY OF EFFECT OF INTRAVENOUS DEXMEDETOMIDINE ON INTRATHECAL LOW DOSE HYPERBARIC BUPIVACAINE V/S HYPERBARIC BUPIVACAINE WITH FENTANYL IN PATIENTS UNDERGOING INFRAUMBILICAL SURGERIES"

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ABSTRACT:

Background: Spinal anaesthesia has many advantages like low cost, reduced risk of aspiration even in patients who are considered to be full stomach and reduced blood loss. There is relaxation of abdominal muscles and this facilitates surgical approach. The main limitation of spinal anaesthesia is that it is limited in duration[2] and patient's anxiety which adds to the technical difficulties.

OBJECTIVES:

1. To assess the Duration of onset of sensory and motor blockade and Total duration of sensory and motor blockade.
2. To find out the Changes in hemodynamic parameters; Heart rate (HR), Systolic blood pressure (SBP), Diastolic blood pressure (DBP), Mean arterial pressure (MAP) at various intervals following subarachnoid block, Sedation scores using Ramsay sedation score(RSS) and Adverse effects of drugs like excessive sedation and post-operative nausea and vomiting.

MATERIAL & METHODS: Study Design: A prospective, randomized, comparative study. **Study area:** Department of Anaesthesia, Mysore Medical College, Karnataka. **Study Period:** 1 year. **Study population**: Adult patients of either sex, aged between 18-55 years belonging to ASA class I and II without any severe co morbid diseases scheduled for elective infra umbilical surgeries. **Sample size:** study consisted a total of 80 cases. **Study tools and Data collection procedure:** The data was collected in a pretested proforma, after obtaining clearance from the institutional ethical and scientific committee and informed written consent from the patients, 80 ASA class I and II patients posted for elective infra umbilical surgeries were selected. They were randomly divided using shuffled opaque envelope technique into 2 groups of 40 patients each.

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Results: There was no statistical difference regarding the mean time taken for sensory block to reach T10 i.e., 4.04+/-0.65 in group B v/s 4.23+/-0.64 mins in group BF, mean time taken for maximum sensory blockade 7.72+/-0.98 mins in group B Vs 7.59+/-0.94 mins in group BF, mean time for two segments sensory regression is 142.38+/-14.08mins in group B v/s 146.48+/- 9.075 mins in group BF, mean total duration of sensory blockade is 274.5+/-24.05 mins in group B Vs 284.6+/-23.31 mins in group BF.

CONCLUSION: Therefore, this study demonstrates that the duration of spinal anaesthesia with bupivacaine alone is non inferior to that of bupivacaine with intrathecal fentanyl adjuvants in patients receiving intravenous dexmedetomidine infusion undergoing infraumbilical surgeries. Hence addition of fentanyl can be avoided for prolongation of sensory and motor blockade for spinal anaesthesia.

KEY WORDS: Hyperbaric Bupivacaine; Fentanyl; Intrathecal; Infraumbilical surgeries; Dexmedetomidine.

INTRODUCTION:

Subarachnoid block is a widely used regional anaesthesia technique, particularly advantageous for lower abdominal and lower limb surgeries[1]. Spinal anaesthesia produces intense sensory, motor and sympathetic blockade with significantly lesser concentration of local anesthetics when compared to other modes of regional anesthesia. Although the operating site is ana esthetized and the patient cannot appreciate pain, he or she remains awake during the whole procedure which contributes to mental stress ranging from mild to severe depending on the patient's mentality.

Spinal anaesthesia has many advantages like low cost, reduced risk of aspiration even in patients who are considered to be full stomach and reduced blood loss. There is relaxation of abdominal muscles and this facilitates surgical approach. The main limitation of spinal anaesthesia is that it is limited in duration[2] and patient's anxiety which adds to the technical difficulties. Usually spinal anesthesia with hyperbaric bupivacaine lasts for 2 to 2.5 hours[2].However bupivacaine alone will not produce sufficient duration of postoperative analgesia. To extend the duration of spinal anaesthesia adjuvants like opioids, epinephrine and neostigmine are added to local anesthetics and instilled into the subarachnoid space. These added substances have their own advantages and disadvantages. Recently there has been a move towards non–opioid-based anaesthesia to avoid opioid-related adverse effects like depression, urinary retention, nausea and vomiting, constipation, itching, opioid-induced hyperalgesia, tolerance, addiction, and immune system disorders.

Opioid free anaesthesia (OFA) avoids intraoperative opioids by any route. It has specific advantages and is indicated in a selected group of patients such as the obese, those with obstructive sleep apnoea syndrome (OSAS), chronic obstructive pulmonary disease and asthma.

Sedation in adequate dose during neuraxial block alleviates the anxiety of the patient[3]. In day to day practice although we use midazolam and propofol for sedating patients, they are vulnerable to cause significant reduction in blood pressure and respiratory function. This effect can sometimes be deleterious to the patient. Hence there has been always a search for the ideal sedative which can be used to relieve anxiety.Alpha 2-adrenergic receptor (α2-AR) agonists have been used in varied clinical situations because of their actions like sedation,

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analgesia, anxiolysis, perioperative sympatholysis, cardiovascular stabilizing effects, reduced anaesthetic requirements and preservation of respiratory function. Many studies are available in the literature which prove the efficacy of clonidine ,a first generation alpha2 agonist to prolong spinal anesthesia whether administered by intravenous or intrathecal route.[2, 5] Clonidine is also known to decrease the anaesthetic requirements in general anaesthesia.[6] Dexmedetomidine is a more selective alpha 2 adrenoreceptor agonist with sedative and analgesic properties.[7] Intravenous dexmedetomidine has been found to reduce the anaesthetic requirements during general anaesthesia.[6] Dexmedetomidine has been found to exert its analgesic actions both at spinal and supraspinal levels.[8] Food and Drug Administration (FDA) approved the use of dexmedetomidine in 1999 for short term sedation and analgesia (<24 hours) in the intensive care unit. It is becoming most popular because it does not cause significant respiratory depression and maintains hemodynamic stability.

Among the opioids, fentanyl is the drug used for intrathecal injection as adjuvant to local anaesthesia, approved by FDA. Administration of fentanyl intrathecally is a common method of intraoperative anaesthesia and for postoperative analgesia. It has faster onset of action and acts within 5-10minutes of administration.[9]It is also known to have synergistic effect and thus reduce the dose of local anaesthetics when given intrathecally. Even though dexmedetomidine is not being approved by FDA for intrathecal injection, it has same action if it is given intravenously.[8] It produces same effects as intrathecal injection like prolongation of analgesia, muscle relaxation, sedation like fentanyl.

This study was undertaken to know whether intravenous dexmedetomidine is beneficial in increasing the duration of anaesthesia after spinal anaesthesia with bupivacaine when compared with bupivacaine and fentanyl.

OBJECTIVES:

Primary: To compare the onset of sensory and motor blockade and to compare the Total duration of sensory and motor blockade.

Secondary: To study the effect on the hemodynamic parameters; Heart rate (HR), Systolic blood pressure (SBP), Diastolic blood pressure (DBP), Mean arterial pressure (MAP) at various intervals following subarachnoid block, to assess the Sedation scores using Ramsay sedation score(RSS) and to study Adverse effects of drugs like excessive sedation and post-operative nausea and vomiting.

MATERIAL & METHODS:

Study Design: A prospective, randomized, comparative study.

Study area: Department of Anaesthesia, Mysore Medical College, Karnataka.

Study Period: 1 year.

Study population: Adult patients of either sex, aged between 18-55 years belonging to ASA class I and II without any severe co morbid diseases scheduled for elective infra umbilical surgeries.

Sample size: study consisted a total of 80 cases.

Inclusion criteria: Adult patients of either sex, aged between 18-55 years belonging to ASA class I and II without any severe co morbid diseases scheduled for elective infra umbilical surgeries.

Exclusion criteria:

1. Age group less than 18years and more than 55 years.

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2. Patients belonging to ASA class III, IV, V

3. Patients posted for emergency surgeries.

4. Patients having any absolute contraindications for spinal anaesthesia like raised intracranial pressure, severe hypovolemia, bleeding diathesis, local infection.

5. Patients with severe co morbid diseases like diabetes, hypertension, cardiovascular diseases and any other are excluded from the study.

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

Study tools and Data collection procedure:

The data was collected in a pretested proforma, after obtaining clearance from the institutional ethical and scientific committee and informed written consent from the patients, 80 ASA class I and II patients posted for elective infraumbilical surgeries were selected. They were randomly divided using shuffled opaque envelope technique into 2 groups of 40 patients each.

• Group B –Received IV dexmedetomidine 50mcg diluted to 50ml of normal saline(1mcg/kg) infusion over 10 minutes before spinal anaesthesia+0.5% hyperbaric bupivacaine 12.5mg intrathecally+0.5ml of normal saline intrathecally.

• Group BF-Received IV dexmedetomidine 50mcg diluted to 50ml of normal saline (1mcg/kg) infusion over 10 minutes before spinal anaesthesia+0.5% hyperbaric bupivacaine 12.5mg intrathecally+25mcg of fentanyl intrathecally.

Study drug was loaded by the senior anaesthesiologist who was not involved in the study. All spinal blockade was performed by the same anaesthesiologist and who also was the observer. Thus both patient and observer were blinded for the study.

Monitoring was done using multiparameter monitor having pulse oximetry (SpO_2), electrocardiograph(ECG) and noninvasive blood pressure(NIBP). Both group B and group BF received intravenous dexmedetomidine 50mcg diluted to 50ml of normal saline (1mcg/ml) infusion over 10 minutes. Patients were placed in flexed lateral position with operative side downwards.

Under aseptic precautions spinal block was performed at level of L3-L4 through a midline approach using 25G Quincke spinal needle. For Group B patients 0.5% hyperbaric bupivacaine 12.5mg with 0.5 ml of normal saline and for Group BF patients 0.5% hyperbaric bupivacaine 12.5mg with 25mcg of fentanyl was injected into intrathecal space at the rate of 0.2 ml/second with operative table kept flat.

Patients were turned to supine posture immediately and supplemental oxygen given. The following parameters were noted.

• Duration of onset of sensory blockade and motor blockade.

• Maximum level of sensory blockade attained and the time taken for the same were noted.

• Two segments sensory regression time was noted.

• Total duration of sensory blockade and motor blockade were noted.

Sensory blockade was tested using cold spirit swab method at every 30 seconds for first 2 minutes, every minute for next 5 minutes and every 5 minutes for next 15 minutes and every 10 minutes for next 30 minutes and every 15 minutes till the end of surgery and there after every 30 minutes until sensory block is resolved.

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Quality of motor blockade was assessed by modified Bromage scale. Level of sedation noted using modified Ramsay Sedation Score. Total duration of surgery and side effects were noted.

Hemodynamic monitoring like heart rate, systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure(MAP), ECG and arterial pulse saturation (SpO2) was done at every 1 minute, 3 minutes and 7 minutes and 9 minutes during infusion of the study drug and after the subarachnoid block every 1 minute for first 5 minutes, every 5 minutes for next 15 minutes, every 10 minutes for next 30 minutes and once in 15 minutes till the end of surgery using monitor EDAN im70. Patients were monitored during the post-operative period for analgesia, and side effects like sedation, post-operative nausea and vomiting.

Post-operative pain assessment was done using Visual Analogue Scale (0-10) and rescue analgesic inj. Paracetamol 20mg/kg iv infusion was given if score 4 or above and total requirement of inj. Paracetamol in 24 hours was recorded.

Statistical analysis:

Data will be analysed using SPSS 21.0 software. Descriptive parameters will be represented as mean with SD or median. Continuous variables will be compared using unpaired t test /Mann Whitney u test. Chi-square or t test will be used to determine significant outcome difference. Categorical data will be represented as frequency with percentage. For all tests a p value of <0.05 will be considered as statistically significant.

OBSERVATIONS & RESULTS:

This study was carried out on a total number of 80 patients posted for elective infraumbilical surgeries. They were randomly divided into two groups of 40 each (n=40).

- Group B –Received IV Dexmedetomidine 50mcg diluted to 50ml of normal saline(1mcg/kg) infusion over 10 minutes before spinal anaesthesia+0.5% hyperbaric Bupivacaine 12.5mg intrathecally+0.5ml of normal saline intrathecally.
- Group BF-Received IV Dexmedetomidine 50mcg diluted to 50ml of normal saline(1mcg/kg) infusion over 10 minutes before spinal anaesthesia+0.5% hyperbaric Bupivacaine 12.5mg intrathecally+25mcg of Fentanyl intrathecally.

Table 1: Age distribution among two groups

Age (years)	**Group B/BF**		**Total**
	Group B	**Group BF**	
20 or less	2(5%)	5(12.5%)	7(8.75%)
21 to 30	7(17.5%)	7(17.5%)	14(17.5%)
31 to 40	6(15%)	10(25%)	16(20%)
41 to 50	20(50%)	14(35%)	34(42.5%)
51 to 60	5(12.5%)	4(10%)	9(11.25%)
Total	40(100%)	40(100%)	80(100%)

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There was no statistical difference in the age wise distribution of patients between the two groups.

Table 2: Distribution of subjects according to sex among two groups

SEX	Group B/BF		Total
	Group B	Group BF	
Female	16(40%)	19(47.5%)	35(43.75%)
Male	24(60%)	21(52.5%)	45(56.25%)
Total	40(100%)	40(100%)	80(100%)

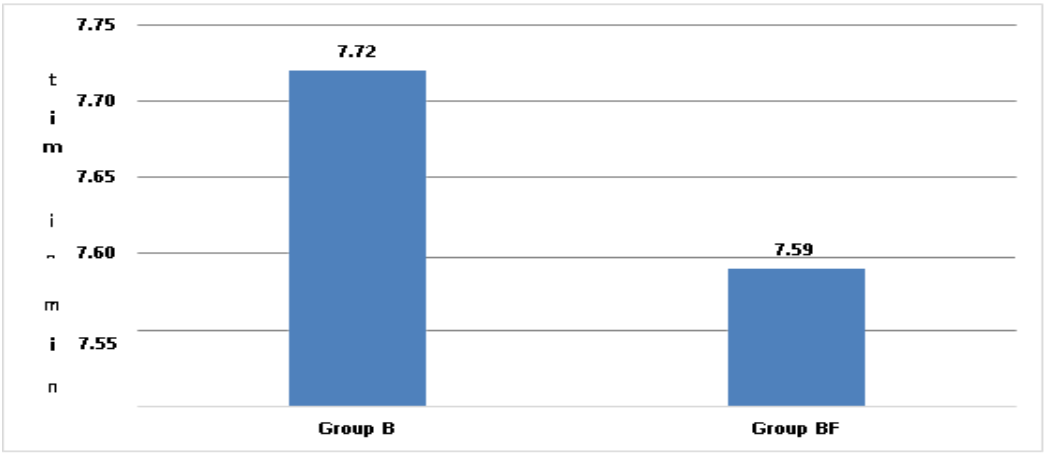
In Group B 60% of the subjects were male and 40% were female. In Group BF 52.5% of the subjects were male and 47.5% were female. There was no statistical difference found between two groups with respect to sex.

Table 3: Comparison of mean time taken for sensory block to reach T10 (minutes) between two groups

	Mean	SD	P Value
Group B	4.04	0.65	0.18
Group BF	4.23	0.64	

Mean time taken for sensory block to reach T10 level in group B was 4.04+/-0.65mins and in group BF was 4.23+/-0.64 mins. There was no statistical difference found between the two groups with regards to time taken for sensory block to reach T10 level (p=0.18).

Figure 1: Comparison of mean time taken for maximum sensory blockade (minutes) between two groups



There is no statistical difference found between two groups in time taken for maximum sensory blockade with p value 0.56.

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Table 4: Comparison of mean time of two segments sensory regression (minutes) between two groups

	Mean	SD	P Value
Group B	142.38	14.08	0.126
Group BF	146.48	9.075	

There was no statistical difference found between two groups with respect to time of two segments sensory regression (p=0.126).

Table 5: Comparison of mean onset of motor blockade (minutes) between two groups

	Mean	SD	P Value
Group B	3.44	0.67	0.43
Group BF	3.34	0.44	

There was no statistical difference found between two groups with respect to mean onset of motor blockade with p value of 0.43.

Table 6: Comparison of mean total duration of motor blockade (minutes) between two groups

	Mean	SD	P Value
Group B	198.98	17.79	0.871
Group BF	199.55	13.426	

There was no statistical difference found between two groups with respect to total duration of motor blockade with p value of 0.871.

Table 7: Comparison of mean Duration of surgery (mins) between two groups

	Mean	SD	P Value
Group B	91.7	40	0.28
Group BF	83.2	29.68	

There was no statistical difference found between two groups with respect to duration of surgery.

Table 8: Comparison of maximum level of sensory blockade between two groups

MAX.LEVEL OF SENSORY BLOCKADE	**Group B/BF**		**Total**	**p value**
	Group B	Group BF		
>/T4	6(15%)	2(5%)	8(10%)	

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T5	3(7.5%)	6(15%)	9(11.25%)	0.096
T6	18(45%)	16(40%)	34(42.5%)	
T7	3(7.5%)	10(25%)	13(16.25%)	
T8	10(25%)	6(15%)	16(20%)	
Total	**40(100%)**	**40(100%)**	**80(100%)**	

In our study 6 patients in group B and 2 patients in group BF had higher level of blockade with mild hemodynamic disturbances which were clinically managed with supplementation of required drug. There was no statistical and clinical difference found between two groups in maximum level of sensory blockade with p value 0.096.

Table 9: Comparison of mean Heart Rate in both groups at various time interval

Heart rate(bpm)	Group B (Mean±SD)	Group BF (Mean±SD)	p value
HR BASAL (BEFORE INFUSION)	88.05(±11.74)	91.15(±11.98)	0.25
HR DRUG INFUSION (01MIN)	87.78(±10.39)	89.53(±10.72)	0.46
HR DRUG INFUSION (03MIN)	84.53(±9.7)	86.9(±11.11)	0.31
HR DRUG INFUSION (07MIN)	84.23(±9.6)	85.95(±11.7)	0.47
HR DRUG INFUSION (09MIN)	83.63(±9.66)	84.3(±10.72)	0.77
HR BASAL (DURING SAB) 00MIN	83.5(±9.16)	84.6(±10.24)	0.61
HR 01MIN	81.98(±8.87)	84.1(±8.5)	0.28
HR 02MIN	79.78(±7.45)	82.1(±7.25)	0.16
HR 03MIN	78.08(±7.44)	80.1(±7.31)	0.22
HR 04MIN	75.88(±6.73)	78.55(±6.93)	0.08
HR 05MIN	74.28(±5.63)	75.6(±7.25)	0.36
HR 10MIN	72.75(±5.71)	72.73(±6.71)	0.99
HR 15MIN	70.8(±5.06)	70.53(±6.38)	0.83
HR 20MIN	67.98(±5.72)	68.68(±6.25)	0.60
HR 30MIN	66.6(±5.92)	66.08(±6.45)	0.71
HR 40MIN	63(±6.23)	64.43(±6.03)	0.30
HR 50MIN	62.38(±5.93)	63.5(±5.38)	0.38

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HR 75MIN	60.73(±6.49)	61.48(±5.17)	0.57
HR 90MIN	60.78(±8.29)	60.2(±5.02)	0.71
HR 105MIN	61.5(±6.58)	60.55(±6.08)	0.50
HR 120MIN	63.33(±4.94)	61.58(±5.01)	0.12
HR 135MIN	63.95(±4.85)	62.83(±5.17)	0.32
HR 150MIN	63.73(±4.76)	62.18(±4.68)	0.15

Mean HR at 9th min after iv dexmedetomidine infusion in Group B is 83.63±9.66 bpm and in Group BF is 84.3±10.72 bpm (p value=0.77). Mean HR at 20th minute after spinal anaesthesia in Group B is 67.98±5.72 bpm and in Group BF is 68.68±6.25 bpm (p value=0.60). In our study, Heart rate was lower in both the groups. Thus no significant difference was observed in the incidence of bradycardia between two groups. Only 5 patients (12.5%) in each group required Injection Atropine 0.6 mg iv. Thus there was no statistical and clinical difference observed in mean heart rate between two groups at various time intervals.

Table 10: Comparison between mean arterial pressure (MAP) (mm Hg) among two groups at various interval

Variable	Group B (Mean±SD)	Group BF (Mean±SD)	p value
MAP BASAL (BEFORE INFUSION)	93.25(±10.09)	91.46(±9.06)	0.41
MAP DRUG INFUSION (01MIN)	92.38(±8.03)	92.08(±8.7)	0.87
MAP DRUG INFUSION (03MIN)	92.65(±8.61)	91.01(±8.27)	0.39
MAP DRUG INFUSION (07MIN)	92.33(±9.14)	90.15(±7.48)	0.25
MAP DRUG INFUSION (09MIN)	89.75(±7.65)	89.23(±7.61)	0.76
MAP BASAL (DURING SAB) 00MIN	87.73(±7.34)	86.11(±7.08)	0.32
MAP 01MIN	86.7(±7.61)	83.94(±7.54)	0.11
MAP 02MIN	84.78(±7.4)	83.03(±6.87)	0.28
MAP 03MIN	82.75(±6.38)	83.48(±7.77)	0.65
MAP 04MIN	81.53(±5.07)	81.63(±7.13)	0.94
MAP 05MIN	79.83(±6.45)	81.28(±6.94)	0.34
MAP 10MIN	78.45(±4.65)	80.98(±6.73)	0.06
MAP 15MIN	79.08(±6.51)	80.08(±6.22)	0.49

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MAP 20MIN	77.9(±5.5)	79.58(±6.41)	0.21
MAP 30MIN	78.2(±5.44)	79.37(±5.53)	0.34
MAP 40MIN	77.83(±5.86)	78.98(±5.05)	0.35
MAP 50MIN	78.35(±6.36)	78.8(±6.25)	0.75
MAP 75MIN	78.05(±4.49)	78.3(±5.35)	0.82
MAP 90MIN	78.03(±4.67)	77.93(±5.65)	0.93
MAP 105MIN	77.68(±4.94)	77.78(±6.6)	0.94
MAP 120MIN	78.45(±6.18)	78.13(±6.85)	0.82
MAP 135MIN	77.2(±5.86)	78.58(±6.5)	0.32
MAP 150MIN	76.03(±3.54)	77.8(±4.75)	0.06

In our study, the average intra operative systolic blood pressure (SBP), diastolic blood pressure(DBP) and mean arterial blood pressure (MAP) showed decreasing trend after spinal anaesthesia in both the groups. Hypotension was observed in 2 patients in each group required injection Mephentermine 3mg incremental doses, which was not statistically and clinically significant. At any given point of time MAP has been >75 mm Hg with the given dose of dexmedetomidine. Thus there was no statistical difference found between two groups with respect to Mean Arterial Blood Pressure at various time interval.

Table 11: Comparison of Ramsay Sedation Score (RSS) between two groups

Variable	Group B [Median (IQR)]	Group BF [Median (IQR)]	p value
RSS/INTRA OP	3(3-3)	3(2-3)	0.34
RSS/POST OP	3(2-3)	3(2-3)	0.94

There was no statistical difference found between two groups in RSS during intraoperative and postoperative period.

Table 12: Comparison of intraoperative complications between two groups

INTRA OP COMPLICATION	Group B/BF		Total	p value
	Group B	Group BF		
Bradycardia	5(12.5%)	5(12.5%)	10(12.5%)	
Hypotension	2(5%)	2(5%)	4(5%)	1
None	33(82.5%)	33(82.5%)	66(82.5%)	

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Total	40(100%)	40(100%)	80(100%)	

There was no statistical difference found between two groups with respect to intraoperative complications.

Table 13: Comparison of postoperative complications between two groups

POST OP COMPLICATION	**Group B/BF**		**Total**	**p value**
	Group B	Group BF		
Nausea and vomiting	1(2.5%)	2(5%)	3(3.75%)	
None	39(97.5%)	38(95%)	77(96.25%)	1
Total	40(100%)	40(100%)	80(100%)	

In our study one patient in group B and two patients in group BF had postoperative nausea and vomiting, which was not clinically and statistically significant between two groups.

Table 14: Comparison of mean value of all parameters

Parameters	**Group B** **Mean ±SD**	**Group BF** **Mean±SD**
Mean age(years)	40.75±10.01	37.4±11.05
Mean height(cms)	162.65±5.73	163.18±6.03
Mean weight(kgs)	61.25±6.31	62.2±5.98
Mean BMI	23.08±1.17	23.31±1.27
Mean duration of surgery(mins)	91.7±40	83.2±29.68
Mean time taken for sensory block to reach T10(mins)	4.04±0.65	4.23±0.64
Mean time taken for maximum sensory blockade (mins)	7.72±0.98	7.59±0.94
Mean time for 2 segments sensory regression(mins)	142.38±14.08	146.48±9.075
Mean total duration of sensory blockade (mins)	274.5±24.05	284.6±23.31
Mean time of onset of motor blockade (mins)	3.44±0.67	3.34±0.44
Mean total duration of motor blockade (mins)	198.98±17.79	199.55±13.426
Mean time for first rescue analgesia (hrs)	5.62±0.44	5.52±0.42

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DISCUSSION:

There has been immense research to improve the effects of spinal anaesthesia by changing various drug regimens and technical methods. Usually adjuvants like epinephrine, phenylephrine, adenosine, magnesium sulphate, sodium bicarbonate, neostigmine and alpha2 agonists like clonidine, dexmedetomidine, opioids like fentanyl, morphine and buprenorphine, ketamine and midazolam (all drugs preservative free) are added to local anaesthetics to prolong the duration of spinal anaesthesia.[9] These adjuvants act perineurally or at different sites in the spinal cord and exert their antinociceptive action. They prolong both sensory and motor blockade and provide post-operative analgesia.

The patients in our study, belonging to American Society of Anaesthesiologists (ASA) physical status classI and II posted for infra umbilical surgeries were divided into 2 groups of 40 each. There was no significant difference regarding the age, gender, body weight, height, BMI, between two groups. There was no significant difference in type of surgical procedures or mean duration of surgeries between the two groups.

Bupivacaine causes onset of spinal blockade within 5-8 minutes. By the addition of drugs like fentanyl and intravenous dexmedetomidine reduces the time for onset of spinal blockade. Hence in our study there was significant reduction in onset of action, but there was no difference between bupivacaine and bupivacaine with fentanyl. The mean time of onset of sensory block to T10 level in Group B was 4.04±0.65 minutes and in Group BF was 4.23±0.64 minutes (p=0.18). This finding is consistent with studies of Reddy et al[10] where onset of sensory block to T10 level was 2.91±1.16 minutes in dexmedetomidine group. In our study there was no significant difference found in the time of onset of sensory block between 2 groups. This result is consistent with study of Sun-kyung park et al.[11]

In our study, maximum level of sensory block in group B was T4 (15%) and in group BF was T4 (5%).There was no statistical difference found between the two groups in maximum level of sensory blockade achieved. This result is consistent with value of maximum sensory level achieved in dexmedetomidine Reddy et al[10] study. In our study, time for maximum sensory level in group B was 7.72±0.98 min and in group BF was 7.59±0.94min(p=0.56). This difference in achieving maximum sensory level between the 2 groups is not statistically significant. This result was comparable with value of time taken for maximum sensory block in dexmedetomidine group in Dinesh CN et al[12], Reddy et al[10]. Thus patients receiving intravenous dexmedetomidine either before or after spinal anaesthesia, have more number of dermatomes blocked in shorter duration.

In our study, the mean time for onset of motor blockade in Group B is 3.44±0.67min and in Group BF is 3.34±0.44 min (P Value =0.43). Thus in our study there is no significant difference found between group B and group BF in mean time for onset of motor blockade. This result is consistent with Reddy et al[10] [Time of onset of motor block was reduced by dexmedetomidine (3.64 ± 0.75 min) but not by clonidine (4.21 ± 1.49 min) when compared with placebo (4.57 ± 0.83 min)]. Harsoor et al[13](3.76±2.02 min),Bhagavath et al[9] (2.92±0.73 min) mean time for onset of motor blockade in dexmedetomidine group is consistent with our study.

Mean HR at 9th min after iv dexmedetomidine infusion in Group B is 83.63±9.66 bpm and in Group BF is 84.3±10.72 bpm (p value=0.77). Mean HR at 20th minute after spinal anaesthesia in Group B is 67.98±5.72 bpm and in Group BF is 68.68±6.25 bpm (p

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value=0.60). In our study, Heart rate was lower in both the groups. Thus no significant difference was observed in the incidence of bradycardia between two groups. Only 5 patients (12.5%) in each group required Injection Atropine 0.6 mg iv.our results are comparable with Sun-kyung park et al[11] where 4 patients in bupivacaine group and 5 patients in bupivacaine with fentanyl group had bradycardia. Many studies like Tekin et al[14], Hong et al[15], Al-Mustafa et al[16] have reported significant incidences of bradycardia in their patients varying upto 30% to 40% and requirement of atropine to treat in some instances during the study. That may be attributed to higher bolus and maintenance dose of intravenous dexmedetomidine.

In our study, the average intra operative systolic blood pressure(SBP), diastolic blood pressure(DBP) and mean arterial blood pressure (MAP) showed decreasing trend after spinal anaesthesia in both the groups. Hypotension was observed in 2 patients in each group required injection Mephentermine 3mg incremental doses, which was not statistically significant. At any given point of time MAP has been >75 mm Hg with the given dose of dexmedetomidine. Incidence of hypotension in our study is comparable with studies like Sun-kyung park et al[11].where 17 patients in bupivacaine group and 19 patients in bupivacaine with fentanyl group had hypotension with p value 0.577. Incidence of hypotension in our study is also consistent with other studies like Al-Mustafa et al[16], Harsoor et al[13].

In our study median intraoperative Ramsay sedation scores in group B was 3 with interqartile range(IQR) (3-3) and in group BF was 3 with IQR (2-3) (P Value =0.34). Median postoperative Ramsay sedation scores in group B was 3 with IQR (2- 3) and in group BF was 3 with IQR (2-3) (P Value =0.94). Thus there is no statistical difference found between 2 groups in sedation scores during both intraoperative and postoperative periods. Maximum scores in both the Groups ranged between 3 & 4. However, in post-operative period there was no significant difference between the groups. Similar studies like Al Mustafa et al[16] (3.96±.55), Hong et al[15](4 Vs 2), Reddy et al[10][Sedation score (>3) 3 vs 6 vs 17 in dexmed Group P<0.0001)], Harsoor et al[813], Annamalai A et al[17], kaya et al[18], Bhagavath et al[9], suggest that intravenous dexmedetomidine either before or after spinal anaesthesia, provides significantly higher average sedation score.

In our study none of the patients had shivering,2.5% of patients in group B and 5% patients in group BF had postoperative nausea and vomiting.Thus no significant difference found in the incidence of post-operative complications between two groups which is consistent with the study of Sun-kyung park et al[11], Tekin et al[19].

CONCLUSION:

Therefore this study demonstrates that the duration of spinal anaesthesia with bupivacaine alone is noninferior to that of bupivacaine with intrathecal fentanyl adjuvants in patients receiving intravenous dexmedetomidine infusion undergoing infraumbilical surgeries.Hence addition of fentanyl can be avoided for prolongation of sensory and motor blockade for spinal anaesthesia.

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