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Comparison of Dexmedetomidine and Fentanyl as Adjuvants to Intrathecal Levobupivacaine in Patients Undergoing Infra-Umbilical Surgeries

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Abstract: ***Background**: Spinal anaesthesia is a common technique for infra-umbilical surgeries; however, its limited duration necessitates rescue analgesics. **Aim**: To compare the efficacy of Fentanyl (25mcg) vs. Dexmedetomidine (5mcg) as adjuvants to intrathecal Hyperbaric Levobupivacaine in infra-umbilical surgeries with respect to characteristics of spinal blockade, hemodynamic effects, post-op analgesia, sedation, motor block duration, and adverse effects. **Study Design**: Prospective, Randomized & Double-blind study. **Material And Methods**: The study was conducted at Hi-Tech Medical College & Hospital, Bhubaneswar, from March 2023 to February 2025. The study included 120 ASA I and II patients of either sex, aged 18-60 years, scheduled for elective infra-umbilical surgeries. Patients were randomly assigned to two groups: Group D: 0.5% Hyperbaric Levobupivacaine 2.5 ml + 5 mcg Dexmedetomidine. Group F: 0.5% Hyperbaric Levobupivacaine 2.5 ml + 25 mcg Fentanyl Haemodynamic Parameters such as Heart Rate, Systolic Blood Pressure, Diastolic Blood Pressure, Mean Arterial Pressure, SpO2, were recorded at baseline. Spinal anaesthesia was administered at the L3-L4 interspace. Vitals and block characteristics were monitored at specified intervals intraoperatively and postoperatively. Side effects were documented and managed accordingly. Postoperative rescue analgesia was given as per requirement. **Results and Discussion**: This prospective, randomized, double-blind study compared the effects of Dexmedetomidine (5 mcg) and Fentanyl (25 mcg) as adjuvants to 0.5% hyperbaric Levobupivacaine in 120 patients undergoing infra-umbilical surgeries. The findings indicate that Dexmedetomidine significantly prolongs sensory and motor blockade, provides superior postoperative analgesia, and delays rescue analgesia requirements compared to Fentanyl ($p<0.0001$). Both drugs exhibited comparable side effects, with Dexmedetomidine offering an opioid-sparing benefit without significant hemodynamic instability. These results suggest Dexmedetomidine as a more effective intrathecal adjuvant for infra-umbilical procedures." **Conclusion**: Intrathecal Dexmedetomidine with 0.5% hyperbaric Levobupivacaine provided superior surgical and prolonged postoperative analgesia with faster onset and extended sensory-motor blockade. It demonstrated opioid-sparing benefits without significant hemodynamic instability, making it an effective adjuvant for infra-umbilical surgeries.*

Keywords: Spinal anaesthesia, Intrathecal adjuvants, Dexmedetomidine, Fentanyl, Postoperative analgesia

1. Introduction

Spinal anaesthesia has been a cornerstone technique for infra-umbilical surgeries since its accidental discovery by J. Leonard Corning in 1885 and its first deliberate clinical use by August Bier in 1898. It provides rapid onset, reduced airway complications, and enhances postoperative analgesia. However, the limited duration of local anaesthetics often necessitates early rescue analgesia [1].

Historically, lignocaine was favoured for its rapid onset and effective motor block but was later limited due to transient neurological symptoms and cauda equina syndrome [2]. Bupivacaine and levobupivacaine, being more potent and longer-acting, have largely replaced it. Levobupivacaine, in particular, is preferred for its greater cardio stability and lower toxicity than bupivacaine. However, it still lacks prolonged postoperative analgesia, necessitating the use of adjuvants.

Opioids have been extensively studied as neuraxial adjuvants, with fentanyl being widely used due to its minimal cephalad spread and local anaesthetic-like effects on sensory nerve fibres [3]. However, opioids are associated with side effects such as respiratory depression, nausea, and pruritus. Dexmedetomidine, a highly selective α2-adrenergic agonist, has emerged as a promising alternative offering prolonged analgesia, extended sensory and motor blockade, and opioid-sparing effects without significant hemodynamic instability [4].

This study provides valuable insights into optimizing spinal anaesthesia by evaluating two commonly used adjuvants, potentially influencing clinical decision-making in pain management for infra-umbilical surgeries

2. Material & Methodology

Study Setting & Design: This study was conducted in the Department of Anaesthesiology, Hi-Tech Medical College & Hospital, Bhubaneswar, from March 2023 to February 2025 after obtaining the ethical committee clearance.

Study Population: A total of 120 ASA I and II patients, aged 18–60 years, scheduled for elective infra-umbilical surgeries, were enrolled after obtaining informed consent. Patients were randomly assigned to two groups (n=60 each):

- **Group D**: 2.5 ml of 0.5% hyperbaric levobupivacaine + 5 µg Dexmedetomidine (final volume 3 ml).
- **Group F**: 2.5 ml of 0.5% hyperbaric levobupivacaine + 25 µg Fentanyl (final volume 3 ml).

Inclusion Criteria: ASA I & II patients aged 18–60 years, weighing 45–85 kg, undergoing elective Infra-umbilical Surgeries.

Exclusion Criteria: Patient refusal, local infection, coagulopathy, cardiovascular disease, increased intracranial pressure, neurological disorders, and spinal deformities.

Anaesthetic Procedure: Patients underwent a preoperative assessment, including history, clinical examination, and relevant investigations. After securing IV access, preloading with Ringer's lactate (10 ml/kg) was performed. Baseline vitals were recorded. Spinal anaesthesia was administered at the L3-L4 interspace using a 25G Quincke's needle under aseptic conditions, and patients were positioned supine post-injection with oxygen supplementation (4 L/min).

Monitoring & Assessments: Hemodynamic parameters (HR, BP, SpO_2), sensory and motor block characteristics, and intraoperative/postoperative complications were recorded at predefined intervals. Sensory block onset was assessed using the hot/cold swab method, while motor block was evaluated using the Modified Bromage Scale.

Pain Assessment and Rescue Analgesia: Postoperative pain was assessed using the Visual Analog Scale (VAS). Patients were assessed at 0,10,20,30,60 and 180 minutes postoperatively. Rescue analgesia was given when VAS score was more than 4.

Outcome Measures: Primary outcomes included sensory and motor block onset, duration, and postoperative analgesia. Secondary outcomes were hemodynamic stability and adverse effects such as nausea, vomiting, hypotension, bradycardia, respiratory depression, shivering, and urinary retention.

Statistical Analysis: All data were recorded and statistical analysis was done using SPSS 24.0. and GraphPad Prism version 5. For qualitative data, the Chi-square test was employed as a test of significance. The independent t test was employed to assess the mean difference between two quantitative variables and two qualitative variables, respectively.

3. Results & Observations

A total of 120 patients were included in the study. They were randomly allocated into equal groups: Group-D (Dexmedetomidine) and Group-F (Fentanyl) - with 60 patients in each group. Computer-generated randomization ensured unbiased group allocation. Following completion of the study, an intergroup analysis was performed using the student's t-test and Chi square test to compare the two groups, yielding the following results. The data was presented as range, mean, and standard deviation (SD). A p-value < 0.05 was considered statistically significant.

Table 1: Distribution of Mean Age (Yrs)

		Number	Mean	SD	Minimum	Maximum	Median	p-value
Age (Yrs)	**Group-D**	60	41.6000	11.1571	20.0000	60.0000	42.0000	0.1894
	Group-F	60	44.4333	12.3293	22.0000	60.0000	43.0000	**(Not Significant)**

Table 2: Sex Distribution in Both Groups

Gender	Group D (n, %)	Group F (n, %)
Female	18(30%)	18(30%)
Male	42(70%)	42(70%)
Total	60(100%)	60(100%)

Table 3: Comparison of Mean Height (Cm)

		Number	Mean	SD	Minimum	Maximum	Median	p-value
Ht (Cm)	Group-D	60	162.8833	6.1784	148.0000	174.0000	163.0000	0.9895
	Group-F	60	162.9000	7.5615	149.0000	178.0000	164.0000	**(Not Significant)**

Table 4: Comparison of Mean Weight (Kg)

		Number	Mean	SD	Minimum	Maximum	Median	p-value
Wt. (Kg)	Group-D	60	62.9667	6.7797	48.0000	87.0000	62.0000	0.6241
	Group-F	60	63.6500	8.3703	42.0000	85.0000	64.0000	(Not Significant)

Table 5: Comparison of Mean Pre-operative Sensory Block (PSB) (min)

		Number	Mean	SD	Minimum	Maximum	Median	p-value
PSB (min)	Group-D	60	1.4975	.3221	0.7500	2.5000	1.5000	<0.0001
	Group-F	60	2.4767	.5104	1.2000	4.0000	2.5000	**(Significant)**

Table 6: Comparison of Mean Pre-operative Motor Block (PMB)

		Number	Modified Bromage Scale	Mean	SD	Minimum	Maximum	Median	p-value
PMB (min)	Group-D	60	4.862	1.9933	.6722	1.0000	5.0000	1.9000	<0.0001
	Group-F	60	4.126	3.2217	.9292	2.0000	6.0000	3.0000	**(Significant)**

Table 7: Comparison of Mean Duration of motor block (min):

		Number	Mean	SD	Minimum	Maximum	Median	p-value
Duration of motor block (min)	Group-D	60	359.3333	34.3431	310.0000	456.0000	348.0000	<0.0001
	Group-F	60	265.7167	28.4737	226.0000	348.0000	260.0000	**(Significant)**

Table 8: Comparison of Mean Systolic Blood Pressure (SBP)

		Number	Mean	SD	Minimum	Maximum	Median	p-value
BSBP	Group-D	60	134.4500	12.8925	107.0000	168.0000	136.0000	0.4227
	Group-F	60	136.4167	13.8678	110.0000	172.0000	138.0000	
SBP2	Group-D	60	123.6500	15.2202	92.0000	160.0000	124.5000	0.8434
	Group-F	60	123.0667	17.0053	83.0000	165.0000	119.5000	
SBP4	Group-D	60	111.7333	14.6679	78.0000	141.0000	108.0000	0.1882
	Group-F	60	115.6000	17.2324	82.0000	156.0000	114.5000	
SBP6	Group-D	60	107.1000	15.0589	80.0000	135.0000	109.0000	0.0091
	Group-F	60	114.3500	14.8824	80.0000	146.0000	114.5000	
SBP8	Group-D	60	107.2833	15.8404	80.0000	134.0000	107.0000	0.0001
	Group-F	60	118.3833	14.5627	76.0000	150.0000	120.5000	
SBP13	Group-D	60	108.3833	14.8622	82.0000	134.0000	112.5000	<0.0001
	Group-F	60	123.1500	12.8760	89.0000	144.0000	126.5000	
SBP18	Group-D	60	110.9333	13.3517	80.0000	136.0000	112.0000	<0.0001
	Group-F	60	124.7333	12.4545	94.0000	146.0000	126.5000	
SBP23	Group-D	60	114.2833	12.6090	86.0000	133.0000	115.5000	0.0001
	Group-F	60	123.5833	11.8769	96.0000	154.0000	124.0000	
SBP33	Group-D	60	119.6167	10.9469	90.0000	151.0000	120.0000	0.0257
	Group-F	60	124.0333	10.4638	101.0000	142.0000	128.0000	
MSBP	Group-D	60	115.2704	10.8664	95.3333	136.1111	116.3889	0.0004
	Group-F	60	122.5907	11.1205	93.7778	142.1111	123.3333	

Table 9: Comparison of Mean Diastolic Blood Pressure (DBP)

		Number	Mean	SD	Minimum	Maximum	Median	p-value
BDBP	Group-D	60	83.9333	7.6709	64.0000	98.0000	85.0000	0.1885
	Group-F	60	85.9500	8.9791	62.0000	99.0000	86.0000	
DBP2	Group-D	60	74.8833	10.3401	56.0000	98.0000	74.5000	0.7672
	Group-F	60	75.5000	12.3364	48.0000	102.0000	76.0000	
DBP4	Group-D	60	66.8000	10.7417	42.0000	90.0000	65.0000	0.0319
	Group-F	60	71.5667	13.1862	46.0000	104.0000	68.5000	
DBP6	Group-D	60	64.6167	12.2046	40.0000	84.0000	65.0000	0.0020
	Group-F	60	71.5167	11.7249	42.0000	94.0000	71.0000	
DBP8	Group-D	60	64.7000	12.1882	42.0000	83.0000	68.0000	<0.0001
	Group-F	60	74.2333	12.1144	40.0000	93.0000	76.0000	
DBP13	Group-D	60	65.7667	12.6697	44.0000	88.0000	65.5000	<0.0001
	Group-F	60	76.4667	10.6810	50.0000	92.0000	78.0000	
DBP18	Group-D	60	67.4167	10.0815	42.0000	88.0000	68.0000	<0.0001
	Group-F	60	76.9167	9.6941	54.0000	94.0000	77.5000	
DBP23	Group-D	60	69.2167	10.2165	48.0000	88.0000	68.5000	0.0047
	Group-F	60	74.3833	9.4297	56.0000	94.0000	74.0000	
DBP33	Group-D	60	73.5667	7.9796	58.0000	89.0000	73.0000	0.2847
	Group-F	60	75.1000	7.6462	58.0000	88.0000	77.0000	
MDBP	Group-D	60	70.1000	8.4141	55.0000	85.8889	71.9444	0.0004
	Group-F	60	75.7370	8.3876	55.4444	90.8889	77.0556	

Table 10: Comparison of Mean Heart Rate

		Number	Mean	SD	Minimum	Maximum	Median	p-value
BHR	Group-D	60	80.7500	11.3833	60.0000	112.0000	79.5000	0.6005
	Group-F	60	82.0667	15.7382	58.0000	126.0000	82.0000	
HR2	Group-D	60	77.9500	15.9941	52.0000	116.0000	72.0000	0.1100
	Group-F	60	82.8333	17.2048	56.0000	133.0000	80.0000	
HR4	Group-D	60	72.8000	17.8010	46.0000	119.0000	71.0000	0.1115
	Group-F	60	77.8167	16.4404	50.0000	120.0000	76.5000	
HR6	Group-D	60	67.9833	17.2081	42.0000	108.0000	69.0000	0.0131
	Group-F	60	75.5000	15.4245	46.0000	103.0000	74.0000	
HR8	Group-D	60	66.6500	16.0843	44.0000	101.0000	64.5000	0.0563
	Group-F	60	71.9333	13.8624	50.0000	106.0000	71.0000	
HR13	Group-D	60	65.6500	13.3503	45.0000	104.0000	67.0000	0.0240
	Group-F	60	71.1167	12.8407	47.0000	104.0000	68.0000	
HR18	Group-D	60	67.1667	11.9875	51.0000	100.0000	65.5000	0.0189

	Group-F	60	72.5167	12.6162	48.0000	112.0000	70.0000	
HR23	Group-D	60	68.3500	12.3451	52.0000	100.0000	68.5000	0.1087
	Group-F	60	72.0333	12.6169	51.0000	116.0000	69.0000	
HR33	Group-D	60	70.1833	11.7740	52.0000	97.0000	69.0000	0.2685
	Group-F	60	72.5833	11.8726	57.0000	120.0000	69.0000	
MHR	Group-D	60	70.8315	12.4789	54.1111	104.3333	69.6667	0.0497
	Group-F	60	75.3778	12.6388	57.4444	108.6667	74.2222	

Table 11: Comparison of Mean Time for RESCUE ANALGESIA

		Number	Mean	SD	Minimum	Maximum	Median	p-value
Time For Rescue Analgesia	Group-D	60	408.8333	45.2305	298.0000	540.0000	400.0000	<0.0001 **Significant**
	Group-F	60	286.8814	30.0964	240.0000	360.0000	280.0000	

4. Discussion

Subarachnoid block is widely used for lower limb procedures, and adjuvants like opioids (Fentanyl) and α2-agonists (Dexmedetomidine) enhance its efficacy. These adjuvants reduce the required anaesthetic dose, lower adverse effects, and minimize rescue analgesia needs while maintaining hemodynamic stability and facilitating early ambulation.

This study compared intrathecal Dexmedetomidine (5 µg) and Fentanyl (25 µg) as adjuvants to 0.5% hyperbaric Levobupivacaine in 120 patients undergoing infra-umbilical surgeries. Demographic parameters (age, sex, height, weight) and surgical duration were statistically similar between groups, ensuring comparability.

Sensory block onset was significantly faster in Group D (1.50 ± 0.32 min) than Group F (2.48 ± 0.51 min) ($p<0.0001$), consistent with findings by **Rahimzadeh et al [5]. and Gupta K et al [6].** Motor block onset was also quicker in Group D (1.99 ± 0.67 min) than Group F (3.22 ± 0.93 min) ($p<0.0001$), corroborating studies by **Paul et al (2017) [7] and Bhure & Jagtap (2019) [8].** The duration of motor block was significantly longer in Group D (359.33 ± 34.34 min) than Group F (265.71 ± 28.47 min) ($p<0.0001$).

Systolic and diastolic blood pressure, mean arterial pressure, and heart rate were significantly different at multiple intraoperative time points ($p<0.0001$), aligning with **Bhure & Jagtap (2019) [8], Ramesh Koppal et al. [9], and Goel et al [10].**

The mean time for rescue analgesia was significantly longer in Group D (408.83 ± 45.23 min) than Group F (286.88 ± 30.09 min) ($p<0.0001$), indicating superior analgesic efficacy of Dexmedetomidine. This concurs with **Nayak et al. (2019) [11], Paul et al. (2017) [7], and Gupta K et al [6].** VAS scores remained 0 at 10, 20, 30, and 60 minutes in both groups.

Nausea, vomiting, bradycardia, and hypotension were statistically insignificant between groups, aligning with previous research.

This study confirms that Dexmedetomidine provides faster sensory and motor onset, prolonged analgesia, and improved hemodynamic stability compared to Fentanyl, supporting its use as an effective intrathecal adjuvant.

5. Limitations of the Study

- The sample size was only 120 cases. Study with a larger number of patients (sample) the observations may vary.
- Being a single centric study, regional variations has not been evaluated.
- The study was carried out in a tertiary care hospital, so hospital bias cannot be ruled out.

6. Conclusion

This study establishes Dexmedetomidine as a superior adjuvant to intrathecal Levobupivacaine compared to Fentanyl. It's faster onset, prolonged sensory and motor blockade, and opioid-sparing benefits make it a viable option for infra-umbilical surgeries. The minimal hemodynamic instability further supports its safety and efficacy, suggesting its broader application in regional anaesthesia

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Nil

Conflicts of Interest
There are no conflicts of interest.

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