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Prospective Double Blinded Randomized Control Study, Comparing the Intrathecal Efficacy of Adjuvants Like Fentanyl 25mcg, Dexmeditomedine 10mcg with Low Dose 0.42% Hyperbaric Levobupivacaine (4.2mg) in Patients Coming for Elective Anorectal Surgeries

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ABSTRACT

Anorectal surgeries, typically performed in ambulatory settings, often result in postoperative challenges such as prolonged pain, leg immobility, urinary retention, and hemodynamic disturbances. Regional anesthesia, specifically saddle block anesthesia, using low doses of local anesthetics with adjuvants like opioids and alpha-2 agonists, can extend analgesia while minimizing these complications. This study aimed to compared the effects of intrathecal administration of Dexmedetomidine and Fentanyl with 0.42% hyperbaric Levobupivacaine on sensory and motor block onset and duration, hemodynamic stability, postoperative analgesia, and adverse effects. Conducted between November 2023 and June 2024 , 240 patients undergoing elective anorectal surgeries were randomly divided into three groups: one receiving Levobupivacaine with Dexmedetomidine (Group D), another with Fentanyl (Group F), and a control group (Group C) receiving Levobupivacaine without additives. Results indicated that Group D had a slower onset of sensory block compared to Group F but a significantly prolonged duration of analgesia (314.54 minutes for Group D vs. 200.98 minutes for Group F and 185.71 minutes for Group C). Sensory regression times were longest in Group D, the time for first voiding of urine was delayed, particularly in Group D (242.56 minutes) compared to Group F (135.90 minutes) and Group C (100.25 minutes). Hemodynamic parameters, including heart rate, blood pressure, and mean arterial pressure, remained stable across all groups. Overall, the study concluded that using low-dose hyperbaric Levobupivacaine with adjuvants such as Dexmedetomidine or Fentanyl provides prolonged postoperative analgesia, minimal motor

INTRODUCTION

Spinal anesthesia is widely regarded as the most commonly used technique for perianal surgeries due to its ease of administration, cost-effectiveness, and ability to provide adequate surgical anesthesia. However, a significant challenge associated with spinal anesthesia, especially when using only local anesthetics, is the short duration of action. This results in the need for early analgesic intervention in the postoperative period to manage pain effectively. Postoperative pain control is critical, as inadequate management can lead to increased discomfort, prolonged recovery, and higher medical costs [1,2].

Various adjuvants have been used alongside local anesthetics to prolong the duration of postoperative analgesia and improve intraoperative pain management. These adjuvants are particularly beneficial in avoiding intraoperative visceral and somatic pain. Recently, α-2 adrenoreceptor agonists, such as Clonidine and Dexmedetomidine, and opioids like Fentanyl have gained popularity as adjuvants due to their sedative and analgesic properties. They provide high-quality intraoperative pain control, prolonged postoperative analgesia, and minimal hemodynamic side effects [3,4].

Dexmedetomidine, a highly selective α2 adrenergic receptor agonist, is widely used as an adjuvant in subarachnoid blocks for various surgical procedures, including anorectal, orthopedic, urolo gical, and lower abdominal surgeries. It is a S-enantiomer of Medetomidine, known for its high α2/α1 selectivity ratio (1620:1) compared to Clonidine (220:1), making it a potent choice for enhancing spinal anesthesia. Dexmedetomidine exerts its analgesic effects at both the spinal and supraspinal levels, prolonging the duration of sensory and motor blockade. It achieves this by binding to presynaptic C-fibers and postsynaptic dorsal horn neurons, which

reduces pain transmission. Moreover, Dexmedetomidine has been shown to attenuate the body's stress response to surgery and anesthesia, contributing to better patient outcomes [5,6].

Fentanyl, a synthetic opioid, is a potent lipophilic μ-opioid receptor agonist, estimated to be 80 times more potent than morphine. This potency is largely due to its high lipophilicity, which allows it to penetrate the central nervous system more effectively. Fentanyl is commonly administered intrathecally in doses of 10–30 mcg, providing rapid onset and a short duration of action (4–6 hours) with minimal cephalic spread, making it less likely to cause delayed respiratory depression compared to other opioids. When used intrathecally, Fentanyl selectively decreases nociceptive input from Aδ and C fibers without affecting dorsal root axons or somatosensory evoked potentials. This makes Fentanyl an ideal adjuvant for enhancing spinal anesthesia, providing good-quality anesthesia, and reducing the need for early postoperative analgesic supplementation [7].

Levobupivacaine, the pure Senantiomer of racemic Bupivacaine, has a more favorable safety profile, particularly with respect to its effects on the cardiovascular and central nervous systems. It has been used in both hyperbaric and isobaric forms for anorectal surgeries. While hyperbaric local anesthetics are more commonly used in spinal anesthesia, they can lead to side effects such as hypotension and excessively high levels of spinal block. These effects can be minimized by using lower doses of local anesthetics. Saddle block anesthesia, a selective form of spinal anesthesia, is often employed for perianal surgeries as it targets the sacrococcygeal nerve roots with a small bolus of hyperbaric local anesthetic. This technique allows for effective anesthesia with reduced risk of complications [8,9].

Adjuvants like Fentanyl and Dexmedetomidine are often added to local anesthetics to enhance sensory blockade and reduce the dose of the local anesthetic required. This combination results in improved intraoperative pain control and prolonged postoperative analgesia without causing significant motor blockade or hemodynamic instability [10].

The aim of this prospective study is to compare the efficacy of Dexmedetomidine (10 mcg) and Fentanyl (25 mcg) as adjuvants when administered intrathecally with a low dose of 0.42% hyperbaric Levobupivacaine (4.2 mg) for perianal surgeries. The study will evaluate the onset and duration of sensory and motor blocks, the hemodynamic effects, postoperative analgesia, and any adverse effects associated with each adjuvant. By examining these parameters, this study seeks to determine the optimal combination of local anesthetic and adjuvant for providing effective anesthesia and prolonged postoperative pain relief, with minimal side effects [11].

The combination of low-dose hyperbaric Levobupivacaine with intrathecal Dexmedetomidine or Fentanyl is a promising approach for providing high-quality anesthesia for perianal surgeries. Both adjuvants have shown the potential to extend the duration of sensory blockade, enhance postoperative analgesia, and maintain stable hemodynamic parameters, while minimizing motor blockade. This study aims to further explore and compare the efficacy of these adjuvants in clinical practice, offering valuable insights into optimizing anesthesia techniques for improved patient outcomes [12,13].

The objective of this study is to compare the effects of Dexmedetomidine and Fentanyl as adjuvants to 0.42% hyperbaric Levobupivacaine administered intrathecally, focusing on the onset and duration of sensory and motor blocks, postoperative analgesia, and hemodynamic stability. Primary outcomes include the onset of sensory blockade, presence of motor block, duration of analgesia, maximum sensory block, and the time for two-segment regression. Secondary outcomes assess hemodynamic changes and potential side effects such as hypotension, bradycardia, sedation, pruritus, nausea, vomiting, urinary retention, dizziness, and blurred vision. The study aims to identify the most effective adjuvant for prolonged analgesia with minimal adverse effects.

MATERIAL AND METHODS

This prospective observational study was conducted at the Department of ANORECTAL SURGERIES, ESIC MC PGIMSR & Model Hospital, Rajajinagar from November 2023 to June 2024. Ethical approval has been obtained from the Ethical Approval Committee of ESIC MC PGIMSR & Model Hospital, Rajajinagar.

Study Population:

The study population was randomly divided into three groups: Group D received 4.2 mg of 0.42% hyperbaric Levobupivacaine with 10 μg of Dexmedetomidine; Group F received the same dose of Levobupivacaine with 25 μg of Fentanyl; Group C received Levobupivacaine without any additives. Inclusion criteria were patients aged 18-60 years, ASA class I or II, scheduled for elective anorectal surgeries. Patients with comorbidities, allergies to anesthetics, ASA class III-V, emergency cases, BMI over 30 kg/m², or contraindications for spinal anesthesia were excluded.

Data Analysis:

Data was collected from patients aged 18-60 years, classified as ASA class I and II, who were scheduled for elective anorectal surgeries without any comorbid conditions. The participants were randomly divided into three groups, with each group consisting of 80 patients. Group D received 4.2 mg of 0.42% hyperbaric Levob-upivacaine with 10 μg of Dexmedetomidine, Group F received the same dose of Levobupivacaine with 25 μg of Fentanyl, and Group C received 4.2 mg of Levobupivacaine with 0.5 ml of normal saline. A preoperative assessment was conducted the day before surgery, and written informed consent was obtained. Patients were premedicated with Ranitidine and Alpraz-

olam and received intravenous fluids before anesthesia. Monitoring included pulse, SPO2, ECG, and NIBP using a multi-channel monitor. A subarachnoid block was performed at the L3-L4 interspace using a 25G Quincke's spinal needle, and after confirming clear cerebrospinal fluid flow, the appropriate anesthetic was injected. Patients remained seated for five minutes post-injection.

RESULT

The study involved 240 patients scheduled for elective anorectal surgeries under saddle block anesthesia. They were divided into three groups of 80: Group D received 4.2 mg of hyperbaric Levobupivacaine (0.42%) with 10 µg Dexmedetomidine, Group F received the same dose of Levobupivacaine with 25 µg Fentanyl, and Group C received Levobupivacaine without any additives.

Demographically, the patients' ages ranged from 18 to 60 with no significant age differences across the groups. Themean ages were 29.91 years for Group D, 30.10 for Group F, and 30.15 for Group C, showing homogeneity in age distribution (p=0.694). Gender distribution was also balanced across the groups, with 46.3% female and 53.8% male patients in each group (p=1).

Regarding physical characteristics, there were no significant differences in weight, height, or BMI between the groups. The mean weight was around 63 kg across all groups, with a standard deviation of 4.87-5.72 kg. Heights averaged about 166 cm, and BMI values were consistent at approximately 22.78-22.92 kg/m², indicating no statistical significance in these measurements ($p > 0.5$ for all). The groups were well-matched in terms of these key demographic and physical factors, ensuring a reliable comparison of anesthesia outcomes.

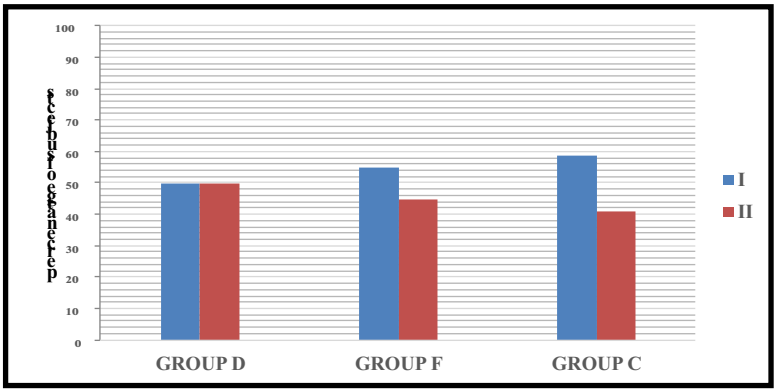

Figure 1: Graph Showing Distribution of the Subject According to ASA and Group

The mean total duration of surgery across the three groups was similar, with Group D averaging 25.51 minutes, Group F at 24.80 minutes, and Group C at 24.93 minutes. The differences in surgery duration among the groups were not statistically significant (p=0.387), indicating that the type of anesthesia used did not impact the length of the procedures.

Table 1: Comparison of Time for onset of Sensory Block, Time for Maximal Level of Sensory Block, Time for Two Segment Sensory Regression, Total Duration of Analgesia and time for Rescue Analgesia Among all three Groups

Group		Mean ± Std. Deviation (in mins)	P value
Time for onset of Sensory Block	D	2.41±0.724	<0.001
	F	2.01±0.464	
	C	3.80±1.141	
Time for maximal level of sensory block	D	4.58±0.823	<0.001
	F	4.01±1.611	
	C	4.88±0.333	
Time for Two segment sensory regression	D	47.34±9.480	<0.001
	F	37.04±7.836	
	C	32.00±5.634	
Total duration of analgesia	D	314.99±54.719	<0.001
	F	200.99±17.916	
	C	185.71±9.096	
Time for Rescue Analgesia	D	366.38±53.427	<0.001
	F	241.60±24.420	
	C	216.44±14.760	

The study shows significant differences in sensory block onset, regression, and analgesia duration among the three groups. Group F had the fastest sensory block onset (2.01 min), followed by Group D (2.41 min), and Group C (4.01 min) ($p<0.001$). Group D had the longest total duration of analgesia (314.99 min), followed by Group F (200.99 min) and Group C (185.71 min) ($p<0.001$). Group D also had the longest time to rescue analgesia (366.58 min), compared to Group F (241.60 min) and Group C (216.44 min) ($p<0.001$). These differences were statistically. significant, with Group D showing the most prolonged effects

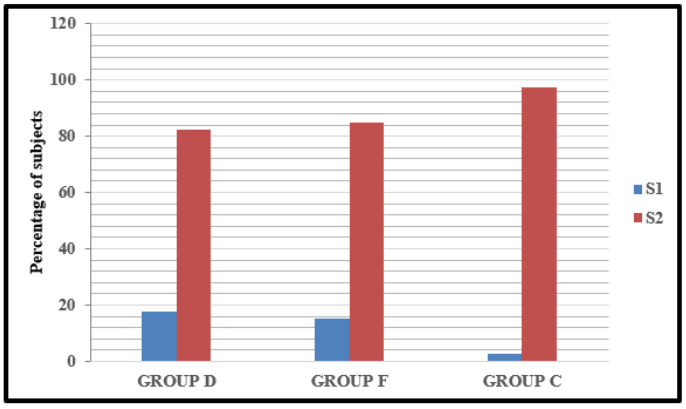

Figure 2: Graph Showing Distribution of the Subject According to Maximal Level of Sensory Block and Group

Table 2: Comparison of Mean Heart Rate at Various Interval Among all the three Group

	Group	Mean	Std. Deviation	P value
Basal	D	88.06	10.857	.071
	F	85.33	9.387	
	C	84.68	9.136	
0min	D	88.06	10.857	.071
	F	85.33	9.387	
	C	84.68	9.136	
2min	D	87.59	10.692	.093
	F	85.48	9.027	
	C	84.34	8.767	
4min	D	87.93	9.912	.089
	F	85.49	8.815	
	C	84.90	8.765	
6min	D	87.54	11.026	.153
	F	85.40	8.511	
	C	84.76	8.610	
8min	D	87.56	10.751	.135
	F	85.31	8.990	
	C	84.70	8.575	
10min	D	87.56	10.751	.135
	F	85.31	8.990	
	C	84.70	8.575	
15min	D	87.20	8.834	.143
	F	85.14	8.837	
	C	84.58	8.827	
20min	D	86.83	8.506	.187
	F	85.16	8.489	
	C	84.41	8.501	
30min	D	87.51	9.306	.150
	F	85.25	8.322	
	C	85.14	8.322	
40min	D	87.56	8.734	.144
	F	85.29	8.451	
	C	85.21	8.456	
50min	D	87.85	8.265	.062
	F	85.20	8.373	
	C	85.11	8.274	
60min	D	87.85	8.265	.062
	F	85.20	8.373	
	C	85.11	8.274	
75min	D	87.85	8.265	.062
	F	85.20	8.373	
	C	85.11	8.274	
90min	D	88.08	7.843	.066
	F	85.58	8.144	
	C	85.39	8.259	

The study compared systolic (SBP), diastolic (DBP), and mean arterial pressure (MAP) across three groups at various intervals, finding no statistically significant differences in any of these measures. Systolic, diastolic, and MAP readings were comparable between Group D, Group F, and Group C. Similarly, oxygen saturation (SPO2) levels were consistent and statistically similar among the groups throughout the monitoring period. The stability of these parameters indicates no major hemodynamic variations among the groups.

Table 3: Time for 1st Void of Urine

	Group	Mean	Std Deviation	P value
Time for 1 st Void of Urine	D	242.56	36.826	<0.001
	F	135.90	10.935	
	C	100.25	13.485	

Table 4: Distribution of the Subject According to Modified RAMSAY Sedation Score and Group

RSC	Group			Total
	D	F	C	
1	4	8	7	19
	5.0%	10.0%	8.8%	7.9%
2	76	72	73	221
	95.0%	90.0%	91.3%	92.1%
Total	80	80	80	240
	100.0%	100.0%	100.0%	100.0%

Table 5: Distribution of the Subject According to Surgeon Satisfaction Among the Groups

Surgeon satisfact	Group			Total
	D	F	C	
Excellent	74	73	58	205
	92.5%	91.3%	72.5%	85.4%
Good	6	7	22	35
	7.5%	8.8%	27.5%	14.6%
Fair	0	0	0	0
	0%	0%	0%	0%
Poor	0	0	0	0
	0%	0%	0%	0%
Total	80	80	80	240
	100.0%	100.0%	100.0%	100.0%

Table 6: Distribution of the Subject According to Patient Satisfaction Among the Groups

Patient Satisfaction	Group D		Group F		Group C	
	No	%	No	%	No	%
Excellent	58	72.5	58	72.5	53	66.6
Good	13	16.25	11	13.75	9	11.25
Fair	9	11.25	11	13.75	18	23.3
Poor	0	0.0	0	0.0	0	0.0
Total	80	100.0	80	100.0	80	100.0

Patient satisfaction was rated as excellent in 72.5% of patients in Groups D and F, and 66.6% in Group C. Good satisfaction was observed in 16.25% of Group D, 13.75% of Group F, and 11.25% of Group C. Fair satisfaction was reported in 11.25% of Group D, 13.75% of Group F, and 23.3% of Group C. The differences in satisfaction levels between the groups were statistically insignificant (p=0. 676).

DISCUSSION

Saddle spinal block is widely recognized as a primary anesthetic technique for perianal surgeries in adults. Utilizing a low dose of intrathecal hyperbaric local anesthetic in the sitting position effectively limits sympathetic block, enabling patients to ambulate early postoperatively. Despite its benefits, a low dose of hyperbaric local anesthetic used alone does not extend postoperative analgesia, making it particularly suitable for outpatient perianal procedures where it facilitates early mobilization without pain or residual anesthesia complications. Various intrathecal adjuvants have been employed to enhance anesthetic quality and prolong analgesia. This study aims to evaluate the reliability and efficacy of saddle block utilizing a low dose of hyperbaric Levobupivacaine (4.2 mg, 0.42%) combined with Fentanyl (25 mcg) and Dexmedetomidine (10 mcg) for perianal surgeries, focusing on their impacts on sensory block onset, postoperative analgesia, voiding effects, the timing of rescue analgesia, and overall patient and surgeon satisfaction [14,15].

The choice of saddle spinal block over traditional spinal block is driven by its advantages, including effective .

intraoperative and postoperative analgesia, early mobilization, minimal hemodynamic side effects, and reduced postoperative opioid consumption. Levobupivacaine hydrochloride, a pure S (-) enantiomer of racemic Bupivacaine, is associated with fewer cardiovascular and central nervous system effects than its predecessor, owing to the lower affinity of the S (-) isomer for inactivated cardiac sodium channels. This reduced cardiotoxicity renders Levobupivacaine an appealing alternative to racemic Bupivacaine. Both hyperbaric and isobaric Levobupivacaine have been used in anorectal surgeries, but sufficient data comparing their efficacy remains sparse. To minimize the potential for hemodynamic side effects often associated with hyperbaric solutions, the study employs lower doses of local anesthetics [16,17]

Dexmedetomidine stands out for its anxiolytic and opioid-sparing properties, alongside its minimal impact on respiratory depression, making it a valuable asset in anesthesia and intensive care settings. Its analgesic effects are mediated through α2 receptor interaction and have been shown to prolong anesthesia when used as an adjuvant with local anesthetics for various nerve blocks. Although the neurotoxicity associated with Dexmedetomidine remains uncertain, reports of potential demyelination have emerged, particularly with epidural injections. However, other studies indicate a neuroprotective effect against cerebral ischemia. Overall, human studies on perineural Dexmedetomidine do not suggest significant neurological deficits, yet safety data regarding its neuraxial and perineural administration remain limited [18].

An optimal anesthetic technique is expected to yield excellent surgical conditions, rapid recovery, early discharge, minimal postoperative side effects, and high satisfaction rates for both patients and surgeons, all while maintaining high-quality analgesia and cost-effective anesthetic services. Selective spinal anesthesia utilizing minimal effective local anesthetic doses for specific surgeries, such as perianal procedures, is increasingly popular due to its effectiveness. The saddle block, allowing for early mobilization without pain or complications, combined with the addition of adjuvants like Dexmedetomidine and Fentanyl, extends postoperative analgesia while minimizing hemodynamic complications. Given that anal surgeries are minor and necessitate minimal motor block for early mobility, the application of lower local anesthetic doses, supplemented with adjuvants, enhances patient satisfaction outcomes our study aims to confirm [19,20].

Saddle anesthesia is a selective spinal technique delivering a direct small bolus of hyperbaric local anesthetic toward the S4-S5 and coccygeal nerve roots. Previous research on saddle blocks has indicated varying low doses of hyperbaric Bupivacaine (1.5 to 4 mg) for minor perianal surgeries, with a determination by Roshidi et al. that the effective dose for saddle block is 1.9 mg. The reliability, short duration, and excellent satisfaction reported in these studies underscore the technique's value. By incorporating adjuvants such as Fentanyl (25 mcg) and Dexmedetomidine (10 mcg), our study anticipates improved sensory block effects and reduced local anesthetic requirements [21].

The demographic data collected in the study showed comparable age, sex, weight, height, BMI, and surgical duration across the three groups, with no statistically significant differences in these parameters. Specifically, the mean surgical durations in Group D, Group F, and Group C were 25.51±4.186, 24.80±3.066, and 24.93±3.055 minutes, respectively, with a P value of 0.387 indicating no significant variation [22].

In terms of sensory block onset, Group D exhibited a sensory onset time of 2.41±0.724 minutes, Group F showed 2.01±0.464 minutes, and Group C presented 3.80±1.141 minutes, resulting in a statistically significant P value of <0.001. Group F achieved the earliest onset compared to Groups D and C, confirming previous studies on hyperbaric Levobupivacaine's effectiveness. The time for maximal sensory block was similarly analyzed, with Group D reaching this point at 4.58±0.823 minutes, Group F at 4.01±1.611 minutes, and Group C at 4.88±0.33 minutes, again with a statistically significant result (P<0.001).

Time for two-segment sensory regression varied among the groups, with Group D at 47.34±9.480 minutes, Group F at 37.04±7.836 minutes, and Group C at 32.00±5.634 minutes, all showing statistical significance (P<0.001). Total analgesia duration was longest in Group D at 314.99±54.719 minutes, followed by Group F at 200.99±17.916 minutes and Group C at 185.71±9.096 minutes, also statistically significant (P<0.001). The time for rescue analgesia was greatest in Group D (366.38±53.427 minutes), highlighting the advantages of adding adjuvants.

Motor block was absent in all three groups, attributable to the low dose of hyperbaric Levobupivacaine. Hemodynamic parameters, including systolic and diastolic blood pressure and heart rates, did not show significant differences pre- and post-surgery among the groups, likely due to the minimized doses of local anesthetics. Additionally, the time for the first void of urine post-surgery showed significant differences: Group D at 242.56±36.826 minutes, Group F at 135.90±10.935 minutes, and Group C at 100.25±13.485 minutes, with a P value <0.001 [23].

Regarding adverse effects, the study observed no significant issues like bradycardia, hypotension, nausea, or vomiting across the groups. While some instances of pruritus and shivering were noted in Group F, these effects were minimal and align with findings from previous research. The RAMSAY sedation scores indicated that a small percentage of patients in each group exhibited anxiety, with most being calm and quiet [24].

Overall, the study underscores the effectiveness and safety of using low-dose hyperbaric Levobupivacaine com--

bined with adjuvants like Fentanyl and Dexmedetomidine in saddle spinal blocks for perianal surgeries, supporting early mobilization and enhanced patient satis-faction while minimizing complications [25].

CONCLUSION

Saddle spinal block is a widely used anesthesia technique for perianal surgeries in adults, utilizing low doses of hyperbaric local anesthetics to limit sympathetic block and facilitate early mobilization. While it does not prolong analgesia when used alone, the study demonstrates the efficacy of combining Dexmedetomidine (10 mcg) and Fentanyl (25 mcg) with hyperbaric Levobupivacaine (4.2 mg). This combination achieves rapid onset of sensory block, prolongs postoperative analgesia, maintains stable hemodynamic parameters, and allows for early mobilization, making it ideal for outpatient procedures.

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