A Comparative Study of Hemodynamic Stability in Patients Having Impaired Ejection Fraction Undergoing Lower Limb Surgery in Regional Nerve Block Versus Epidural Block

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Abstract: ***Background**: Heart failure (HF), a syndrome resulting from structural and functional myocardial abnormalities, is characterized by compromised ventricular filling or ejection, leading to symptoms such as dyspnea and peripheral edema. Patients with low left ventricular ejection fraction (LVEF) undergoing surgery are at increased risk for perioperative complications. Hemodynamic management in such patients, particularly with regional anesthesia techniques, is crucial to reduce intraoperative and postoperative risks. **Aim & Objectives**: This study aimed to compare the hemodynamic stability, pain control, and complications in patients with impaired ejection fraction undergoing lower limb surgery under regional nerve block versus epidural block. **Materials & Methods**: A randomized, controlled trial was conducted in the Department of Anesthesia at MLN Medical College, Prayagraj. A total of 88 patients with LVEF <45%, aged 60–92 years, were randomized into two groups: Group A (epidural block) and Group B (regional nerve block). Baseline characteristics, including age, gender, and hemodynamic parameters, were comparable between the groups. Hemodynamic variables, pain scores (VAS and Bromage scores), and incidence of complications were recorded during surgery. **Results**: The duration of surgery did not differ significantly between groups. Patients in Group A had significantly lower pain scores (VAS: 0.59±0.54; Bromage: 0.77±0.68) compared to Group B (VAS: 2.55±0.76; Bromage: 2.48±0.55). Hemodynamic parameters, including heart rate, systolic, and diastolic blood pressures, remained stable across both groups. However, Group A reported higher incidences of bradycardia (15.9% vs. 0.0%) and hypotension (20.5% vs. 0.0%) compared to Group B. Conversely, a significantly higher proportion of Group B patients experienced pain (38.6% vs. 0.0%). **Conclusion**: Both techniques provided comparable intraoperative hemodynamic stability. However, regional nerve block resulted in higher pain incidence, while epidural block was associated with increased rates of hypotension and bradycardia. Individualized anesthetic planning is essential to optimize outcomes in this patient population.***

Keywords: Heart failure, Low ejection fraction, Regional nerve block, Epidural block, Hemodynamic stability, Lower limb surgery, Perioperative complications, Pain management

1. Introduction

Heart failure (HF) is a clinical syndrome arising from structural and functional myocardial abnormalities, leading to compromised ventricular filling or ejection of blood [1,2,3]. Clinically, HF is manifested by a combination of symptoms such as dyspnea, orthopnea, and peripheral edema, along with signs like elevated jugular venous pressure and pulmonary congestion, often attributable to underlying cardiac structural or functional deficits [4]. These abnormalities culminate in reduced cardiac output and/or increased intracardiac pressures.

Since the late 20th century, the prevalence of heart failure has increased significantly, presenting substantial challenges not only in terms of mortality and morbidity but also in the broader context of healthcare infrastructure and financial burdens on patients and healthcare systems alike [5,6,7]

When considering patients with low left ventricular ejection fraction (LVEF) undergoing surgery, these concerns become particularly pronounced. The reduced cardiac reserve in these patients increases the risk of intraoperative and postoperative complications, making it imperative to optimize hemodynamic stability and nutritional status preoperatively. anesthesiologists and surgical teams must carefully consider the patient's NYHA classification and associated biochemical markers to tailor perioperative management strategies that minimize the risk of adverse outcomes [8,9,10].

Regional nerve block, which typically includes peripheral nerve blocks such as femoral or sciatic nerve blocks, offers the advantage of targeted anesthesia with minimal systemic effects. This method is hypothesized to provide superior hemodynamic stability in patients with impaired ejection fraction, as it avoids the significant sympathetic blockade associated with central neuraxial techniques. The localized nature of regional nerve blocks may reduce the risk of hypotension and bradycardia, which are common concerns in this patient demographic [11].

Conversely, epidural anesthesia, while offering effective analgesia and muscle relaxation, exerts a more profound impact on the autonomic nervous system. The sympathectomy induced by epidural block can lead to marked hypotension, particularly in patients with preexisting cardiovascular compromise. This hypotension may necessitate the use of vasopressors or fluid resuscitation, potentially exacerbating the strain on a heart already functioning at a reduced capacity [8].

Clinical studies have demonstrated varying outcomes, with some suggesting that regional nerve blocks may confer a hemodynamic advantage in this population, reducing the incidence of intraoperative hypotension and the need for vasopressors. However, other studies highlight the efficacy of epidural blocks in providing stable hemodynamics when meticulously managed, underscoring the importance of individualized anesthetic planning [1,2].

The comparison of hemodynamic stability in patients with impaired ejection raction undergoing lower limb surgery under regional nerve block versus epidural block is a critical area of investigation, given the cardiovascular vulnerabilities inherent in this patient population. Hemodynamic stability, defined as the maintenance of adequate blood pressure, cardiac output, and tissue perfusion, is particularly challenging to achieve in patients with reduced ejection fraction due to their compromised cardiac reserve [1,2]. The present study was conducted with the aim to compare nerve block versus epidural block in patients with impaired ejection fraction undergoing lower limb surgery.

2. Aims and Objectives

Aim

- A comparative study between hemodynamic stability in patients having impaired ejection fraction undergoing lower limb surgery in regional nerve block verses epidural block

Objectives

- To compare the effects of regional nerve block and epidural block on hemodynamic stability in patients having impaired ejection fraction undergoing lower limb surgery.
- To evaluate the efficacy of regional nerve block and epidural blockin patients having impaired ejection fraction undergoing lower limb surgery.
- To compare the pain scores in impaired ejection fraction patients undergoing diabetic lower limb surgery regional nerve block or epidural block.

3. Materials and Methods

Study settings:
The study was conducted in Department of Anaesthesiology, MLN Medical College, Prayagraj

Study duration:
One year

Study design:
Hospital based Prospective Randomized controlled study

Sample Size:
The sample size was calculated by

$$n=Z^2P(1-P)/d^2$$

where,

- n = sample size,
- Z = Z statistic for a level of confidence, for the level of confidence of 95%, which is conventional, Z value is 1.96.
- P = expected prevalence or proportion (in proportion of one; if 2.5%, P = 0.025),
- d = precision (in proportion of one; if 5%, d = 0.05).

n=$1.96 \times 1.96 \times 0.10 \times 0.90/0.05^2$
n=37.45

Inclusion Criteria:

- Ejection fraction <45% patients scheduled to undergo lower limb surgeries
- Patients with ASA grade I-III
- Patients of either sex aged 18-65 years

Exclusion criteria

- Patients not giving consent
- Ejection fraction >45% and <35 %
- Local infection at site of block
- H/o allergy to study medications
- Patients taking α agonist / antagonist regular pain medication
- Morbid obesity
- Pregnancy

Methodology:
A computer system was be used for randomization by creating a list of number each number referred to one of the two groups Group A (Epidural block) and Group B (Regional nerve block)

Group A: A 20-G epidural catheter had been inserted into the epidural space at the L3-L4 interspace under completely aseptic conditions with an 18-G Tuohy needle using a loss-of-resistance technique. A volume of 12 ml of bupivacaine HCl 0.5%, together with fentanyl (50 µg), was injected into the epidural space as an initial dose 5 minutes after the injection of 4 ml lidocaine 2% with epinephrine 1:200,000 (5 mcg/ml) as a test dose. After the first injection, 6 ml of bupivacaine HCl 0.5% was injected hourly as a bolus through the epidural catheter. At the end of the surgery, 10 ml of bupivacaine HCl 0.25% was injected through the epidural catheter before it was removed.

Group B: Femoral, sciatic, and obturator nerve blocks were performed using the neurostimulation technique with isolated 21-G needles of 12 cm length connected to a peripheral nerve stimulator (Vygon) and started at 1.5 mA with a frequency of 2 Hz.

An inguinal paravascular approach was chosen to block the femoral nerve. The patient was positioned face down. The anterior superior iliac spine and the pubic tuberosity were connected by a line, and the femoral artery was palpated along this line. One to two centimeters below the inguinal ligament and 1 to 2 centimeters laterally, the needle was inserted. It was then advanced slightly cephalad, and the reflux of blood into the clear connecting tube was closely observed with repeated aspiration. The femoral nerve was localized by eliciting quadriceps contractions (the dancing patella) at a current level below 0.5 mA. After negative aspiration, 20 ml of bupivacaine 0.375% was slowly administered to this site.

The standard Labat method was used to block the sciatic nerve. The patient was placed in the Sims position with the dependent surgical side to the side. The dependent lower extremity was supported by the operating extremity, which was flexed 90 degrees at the knee and 45 degrees at the hip.

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Skin markers were used to identify and mark the greater trochanter, sacral hiatus, and posterior superior iliac spine. The greater trochanter and the posterior superior iliac spine were marked with a skin marker. This line was divided into two halves. A third line was drawn between the greater trochanter and the sacral hiatus, and a vertical line was drawn 3-5 cm from its center to the needle insertion site. The nerve, approximately 6-8 cm deep, was located by placing the needle perpendicular to the skin. The sciatic nerve was identified by inducing foot movements (dorsiflexion or plantar flexion) below 0.5 mA, and 25 ml of bupivacaine 0.375% was administered.

The obturator canal was reached after the needle was inserted at an angle of 30 degrees to the skin in a cephalad direction, 2 cm caudal and lateral to the pubic tubercle. Once the obturator canal was reached, contraction of the adductor muscles of the thigh was achieved with a current of less than 0.5 mA, and then 10 ml of bupivacaine 0.375% was injected.

The sensory level of the epidural block in Group A was measured by the absence of pinprick pain at five-minute intervals for 40 minutes after the block was completed. After the cessation of the epidural block, motor block was assessed every 5 minutes for 40 minutes using the Bromage scale. After completion of nerve blocks in Group B, assessments were made every five minutes for an additional 40 minutes. The sciatic nerve (plantar), femoral nerve (anterior thigh), and obturator nerve (medial thigh) regions were assessed for sensory loss of pinprick sensation. The femoral nerve, obturator nerve, common peroneal nerve, and tibial nerve, as well as dorsiflexion and plantar flexion of the foot, and the Bromage scale were tested to assess motor block.

Both the Bromage scale and the visual analogue score were used to assess the onset and quality of regional blockade in both groups. If the onset of anesthesia occurred within 40 minutes and was adequate for the entire procedure (visual analogue score of 0 in determining dermatomes to be blocked for the procedure and achievement of a Bromage score of ≥2), the blockade was considered successful. If the blockade did not work, general anesthesia was induced.

After each procedure, arterial blood pressure and heart rate were recorded every five minutes. If needed, ephedrine 10 mg was administered to treat hypotension (systolic blood pressure ≤100 mmHg or a decrease of more than 30% from baseline). Patient and surgeon satisfaction with the anesthetic procedures was assessed using a two-point scale, with 1 representing "satisfactory" and 2 representing "unsatisfactory" (necessitating another anesthetic procedure).

After surgery, patients were observed and assessed at 1, 2, 4, 6, 12, and 24 hours for the occurrence of problems such as vomiting or urinary retention, and for the time to request the first analgesic.

Statistical Analysis

The data will be expressed as mean +_standard deviation (SD) or median, range and percentage as appropriate. All the categorical data will be compare by using chi square test. Continuous variables in two groups will be compared by t-test. The p-value <0.05 will be considered as significant. The statistical analysis will be done using SPSS 21.0 version (Chicago, Inc., USA) windows software.

4. Results and Discussions

4.1 Results

Table 1: Group-wise distribution of the study population

SN	Group	Treatment Modality	No.	%
1	Group A	Epidural Block	44	50.0
2	Group B	Regional Nerve Block	44	50.0

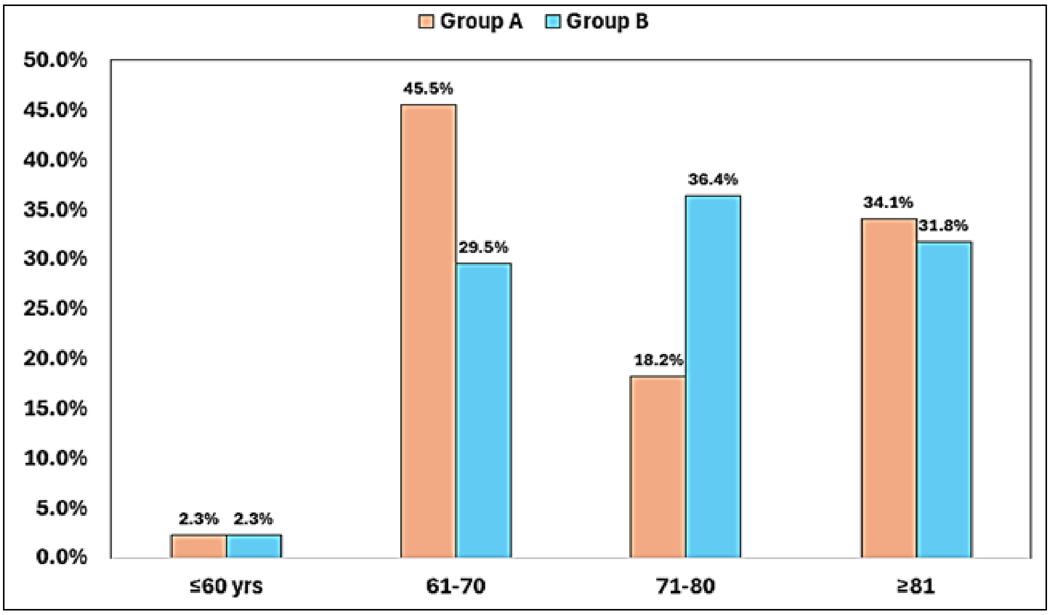

Figure 1: Intergroup comparison of Age

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Table 2: Intergroup comparison of Age

SN	Age Group (years)	Group A (n=44)		Group B (n=44)	
		No.	%	No.	%
1	≤60 yrs	1	2.3	1	2.3
2	61-70	20	45.5	13	29.5
3	71-80	8	18.2	16	36.4
4	≥81	15	34.1	14	31.8
$\chi 2$=4.186 (df=3); p=0.242					
Student's t-test		Mean	SD	Mean	SD
		74.27	9.83	76.20	7.78
		t= -1.022; p=0.310			

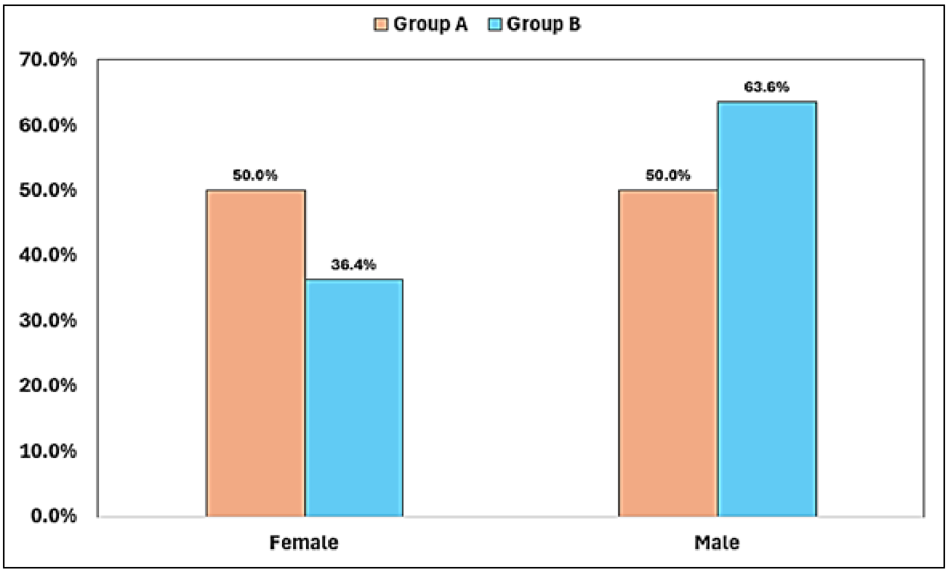

Figure 2: Intergroup comparison of Gender

Table 3: Intergroup comparison of Gender

SN	Gender	Group A (n=44)		Group B (n=44)	
		No.	%	No.	%
1	Female	22	50.0	16	36.4
2	Male	22	50.0	28	63.6
χ^2=1.667; p=0.197					

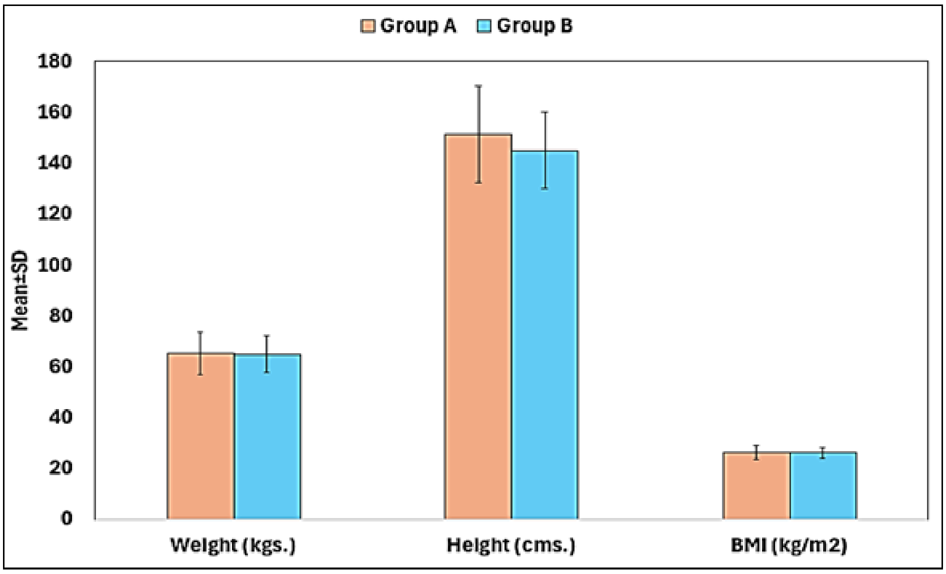

Figure 3: Intergroup comparison of Anthropometric Parameters

Table 4: Intergroup comparison of Anthropometric Parameters

SN	Parameter	Group A (n=44)		Group B (n=44)		Student's t-test	
		Mean	SD	Mean	SD	t	p
1	Weight (kgs.)	65.1	8.3	64.8	7.2	0.137	0.891
2	Height (cms.)	151.3	18.9	145.1	15.1	1.705	0.092
3	BMI (kg/m^2)	26.2	2.6	26.1	2.2	0.269	0.789

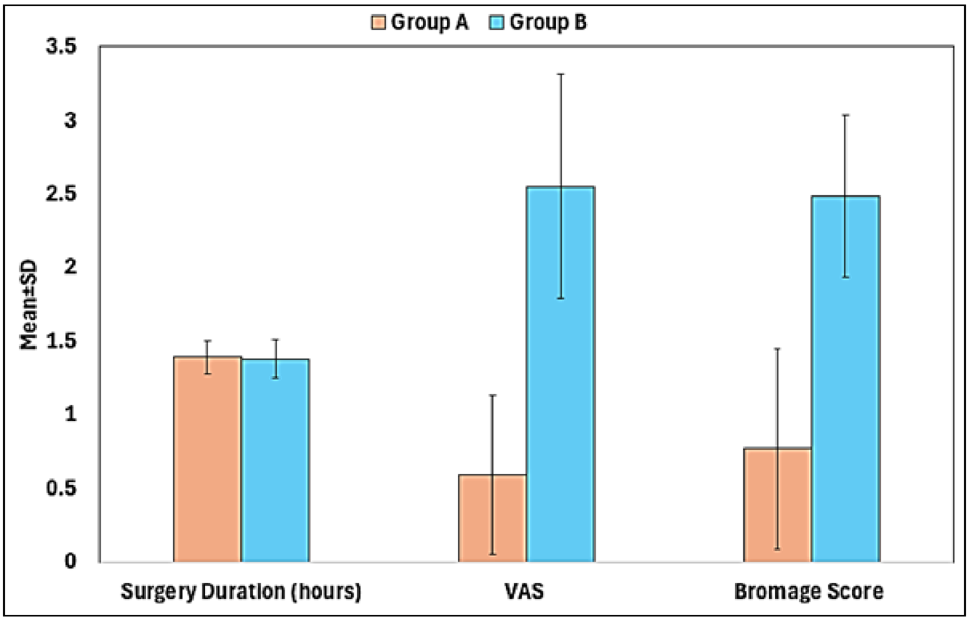

Figure 4: Intergroup comparison of Intra-op Findings

Table 5: Intergroup comparison of Intra-op Findings

SN	Findings	Group A (n=44)		Group B (n=44)		Student's t-test	
		Mean	SD	Mean	SD	T	P
1	Surgery Duration (mins.)	83.36	6.82	82.77	7.99	0.373	0.710
2	ASA Grade	3.00	0.0	3.00	0.0	-	-
3	VAS	0.59	0.54	2.55	0.76	-13.875	<0.001
4	Bromage Score	0.77	0.68	2.48	0.55	-12.965	<0.001

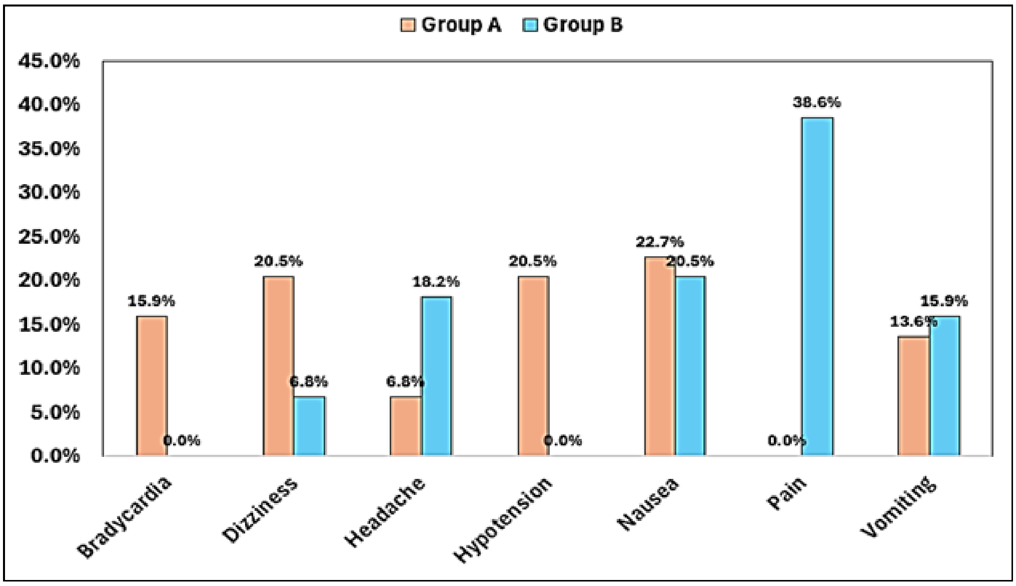

Figure 5: Intergroup comparison of Intra-op Findings

Table 6: Intergroup comparison of Heart-rate (in bpm) at different observation intervals

SN	Interval	Group A (n=44)		Group B (n=44)		Student's t-test	
		Mean	SD	Mean	SD	T	p
1	Baseline	70.89	4.18	72.55	5.21	-1.647	0.103
2	5 min	71.30	10.75	74.52	6.53	-1.946	0.055
3	10 min	74.48	13.33	77.43	6.11	-1.702	0.092
4	15 min	76.89	13.03	76.16	9.40	-1.337	0.185
5	30 min	77.75	5.93	77.77	4.94	0.300	0.765
6	45 min	76.18	7.09	78.91	5.67	-0.020	0.984
7	60 min	78.55	6.13	79.98	6.11	-1.992	0.051
8	75 min	82.95	5.73	83.70	5.03	-1.097	0.276
9	90 min	70.89	4.18	72.55	5.21	-0.652	0.516

Table 7: Intergroup comparison of Systolic Blood Pressure (in mmHg) at different observation intervals

SN	Interval	Group A (n=44)		Group B (n=44)		Student's t-test	
		Mean	SD	Mean	SD	't'	p
1	Baseline	119.75	7.90	119.98	6.71	-0.144	0.886
2	5 min	118.09	6.36	120.32	4.96	-1.832	0.070
3	10 min	119.75	4.23	120.77	6.06	-0.344	0.127
4	15 min	122.64	5.69	124.39	5.41	-0.897	0.678
5	30 min	123.70	7.75	123.89	4.79	-0.132	0.895
6	45 min	123.95	6.29	124.86	6.88	-0.647	0.520
7	60 min	122.05	7.10	123.89	6.03	-1.823	0.056
8	75 min	126.95	5.47	126.61	6.30	0.271	0.787
9	90 min	125.32	4.89	126.66	5.25	-0.144	0.886

Table 8: Intergroup comparison of Diastolic Blood Pressure at different observation intervals

SN	Interval	Group A (n=44)		Group B (n=44)		Student's t-test	
		Mean	SD	Mean	SD	T	p
1	Baseline	74.23	5.02	76.45	5.89	-1.345	0.182
2	5 min	80.31	4.28	81.41	4.68	-0.352	0.749
3	10 min	82.55	17.00	84.32	4.91	-0.867	0.350
4	15 min	77.20	7.51	78.75	4.79	-1.151	0.253
5	30 min	78.45	5.40	80.55	4.72	-1.935	0.056
6	45 min	78.36	7.93	80.86	4.82	-1.787	0.077
7	60 min	81.61	4.73	81.89	6.49	-0.225	0.822
8	75 min	82.32	4.48	83.07	5.40	-0.709	0.480
9	90 min	74.23	5.02	76.45	5.89	-1.345	0.182

Table 9: Intergroup comparison of post-op complications

SN	Interval	Group A (n=44)		Group B (n=44)		Chi-sq test	
		No.	%	No.	%	$\chi 2$	'p'
1	Bradycardia	7	15.9	0	0.00	7.604	0.005
2	Dizziness	9	20.5	3	6.8	3.476	0.062
3	Headache	3	6.8	8	18.2	2.597	0.107
4	Hypotension	9	20.5	0	0.00	10.025	0.001
5	Nausea	10	22.7	9	20.5	0.067	0.795
6	Pain	0	0.00	17	38.6	21.070	<0.001
7	Vomiting	6	13.6	7	15.9	0.090	0.763

4.2 Discussions

The findings of the current study share similarities when compared to most contemporary studies. Like Sanatkar et al. (2013, 2014) and Mutahar et al. (2016), the current study observed hemodynamic stability in patients undergoing spinal anesthesia, particularly those with low ejection fraction (EF < 40%). Both studies reported no significant hypotension or vasopressor needs during or after spinal anesthesia, suggesting that low-dose spinal blocks with local anesthetics can safely preserve hemodynamic parameters in high-risk patients.

The current study aligns with the findings of Shamim et al. (2018) and Mulugeta et al. (2020), which also observed that peripheral nerve blocks or spinal anesthesia provide effective anesthesia without adverse cardiovascular events in patients with reduced cardiac output or multi-organ dysfunction. Both studies concluded that these anesthetic methods are safe alternatives for lower limb surgeries in high-risk populations.

Similar to Bansal et al. (2016) and Shamim et al. (2018), the current study found that postoperative analgesia was adequately managed without intraoperative pain complaints. These studies consistently demonstrated that both peripheral nerve blocks and spinal anesthesia provide satisfactory pain relief during lower limb surgeries, reducing the need for systemic analgesics.

Like Hakim (2020) and Fu et al. (2021), the current study reported minimal use of vasopressors during spinal anesthesia. This reinforces the finding that neuraxial anesthesia techniques, particularly with low-dose local anesthetics, contribute to maintaining stable hemodynamic conditions without requiring significant pharmacological support.

Both the current study and many contemporary studies employed low-dose local anesthetics (e.g., bupivacaine) and opioids (e.g., sufentanil) during spinal blocks. The use of such low doses is crucial in maintaining hemodynamic stability, particularly in patients with compromised cardiac function. This similarity in dosing protocols contributes to the observed hemodynamic stability across studies.

Similar patient populations with reduced ejection fraction or coronary artery disease were included in both the current and contemporary studies, which led to consistent findings related to cardiovascular safety during spinal or peripheral nerve block anesthesia.

While contemporary studies like Sanatkar et al. (2013) and Sanatkar et al. (2014) reported decreases in mean arterial pressure (13%-20%) during spinal anesthesia, the current study did not observe significant hypotension. This could be attributed to differences in patient populations, anesthetic techniques, or monitoring protocols. For instance, the lower baseline mean arterial pressure in the contemporary studies may have predisposed their subjects to more pronounced decreases in blood pressure, whereas the current study might have included patients with better preoperative optimization.

The current study focused solely on spinal anesthesia, whereas some contemporary studies like Bansal et al. (2016) and Jung et al. (2021) evaluated peripheral nerve blocks (e.g., femoral and sciatic nerve blocks). Although both techniques provided effective anesthesia and pain control, nerve blocks were shown to have additional benefits such as reduced hemodynamic fluctuation and prolonged postoperative analgesia, which were not specifically emphasized in the current study.

The current study did not specify the duration of postoperative analgesia, unlike Bansal et al. (2016) and Hakim (2020), who found prolonged analgesic effects (up to 12-13 hours) with combined peripheral nerve blocks or sequential spinal-epidural anesthesia. The absence of prolonged postoperative analgesia in the current study might stem from the exclusive use of spinal anesthesia without adjunct analgesic techniques (e.g., fentanyl or nerve blocks).

Mamatkulov et al. (2021) and Fu et al. (2021) specifically studied patients with low ejection fraction (≤35%) undergoing peripheral nerve blocks for lower limb surgery. They found no conversion to general anesthesia and minimal postoperative complications, a point not emphasized in the current study, which involved only spinal anesthesia. The use of peripheral nerve blocks in contemporary studies might have been favored for patients with severe cardiac impairment due to their minimal impact on hemodynamics compared to spinal anesthesia.

The differences in outcomes, particularly in hemodynamic stability and postoperative analgesia, can be attributed to the type of anesthesia used. Peripheral nerve blocks, as seen in Bansal et al. (2016) and Shamim et al. (2018), provided longer-lasting analgesia and better hemodynamic control compared to spinal anesthesia. This divergence is likely due to the localized effects of nerve blocks, which do not affect systemic circulation as significantly as spinal blocks.

The design of contemporary studies, including the use of case-control designs or larger sample sizes, as seen in Fu et al. (2021) and Mamatkulov et al. (2021), might explain differences in hemodynamic and analgesic outcomes. These studies often used more refined techniques, such as ultrasound-guided blocks, which were not employed in the current study.

The higher rate of hypotension reported in Sanatkar et al. (2013) could be linked to their inclusion of patients with more severe baseline cardiac dysfunction, leading to greater susceptibility to blood pressure changes during anesthesia. In contrast, the current study might have excluded patients with such extreme comorbidities, contributing to the absence of significant hypotension.

In conclusion, the current study's findings largely align with contemporary research regarding the safety and efficacy of spinal anesthesia in patients with low cardiac output. However, variations in anesthetic techniques and patient characteristics contribute to differences in hemodynamic outcomes and postoperative analgesia duration.

5. Conclusion

The present study was conducted at the Department of Anesthesia, MLN medical college, Prayagraj with the aim to compare the hemodynamic stability, stability and complications in patients having impaired ejection fraction undergoing lower limb surgery in regional nerve block verses epidural block. For this, 88 patients with Ejection Fraction <45% aged between 60 & 92 years of age (Mean age: 75.24±8.87 years), 56.8%males & all with ASA Grade III with were screened for the inclusion and exclusion criteria and included in the study after taking informed consent. All the included patients were then randomised using the computer- generated tables, Group A underwent surgery under Epidural Block; Group B underwent surgery under Regional Nerve Block. All baseline characteristics like age, gender, Anthropometric data & Hemodynamic parameters did not differ significantly between the groups.

Key findings of the study were as follows:
1) Duration of surgery did not differ significantly between the two groups.
2) Patients in Group A exhibited significantly lower pain measured by VAS & Bromage Score as compared to those in Group B (0.59±0.54 vs. 2.55±0.76; 0.77±0.68 vs. 2.48±0.55, respectively).
3) At none of the observation intervals from baseline to 90 mins during surgery, Heart rate, Systolic Blood Pressure and Diastolic Blood pressure differed significantly between the two groups.
4) A significantly higher proportion of cases in Group A as compared to Group B reported incidence of Bradycardia (15.9% vs. 0.0%), Hypotension (20.5% vs. 0.0%).
5) A significantly higher incidence of Pain was observed in Group B as compared to Group A (38.6% vs. 0.0%).
6) Incidence of other complications like Dizziness, Headache, Nausea and Vomiting were comparable between the two groups.

The two techniques were comparable in terms of hemodynamic management intra-operatively, while Pain was reported by a higher proportion of cases in Group B, while Hypotension and bradycardia were reported in higher proportion of cases in Group A.

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