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Original Article

Comparison of Hemodynamic Responses of Pregabalin plus Fentanyl and Fentanyl Alone After Endotracheal Intubation in Lumbar Spine Surgery: A Double-Blind, Randomized Clinical Trial

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Background: Endotracheal intubation increases heart rate and blood pressure. The aim of this study was to compare the haemodynamic response following tracheal intubation between pregabalin plus fentanyl and fentanyl alone in lumbar spine surgery.

Materials and Methods: In this double-blind clinical trial, 80 patients aged 20–65 years who were candidates for spine surgery were randomly divided into two equal groups. Before tracheal intubation, the first group received fentanyl (F), while the second group received pregabalin plus fentanyl (P). Variables including systolic blood pressure, diastolic blood pressure, heart rate at different time points, and the mean postoperative pain score based on the Numerical Rating Scale were recorded.

Results: The mean age in the F group was 46.98 ± 8.91 years, compared with 45.43 ± 12.49 years in the P group. Repeated-measures ANOVA showed a significant group effect for mean systolic blood pressure at different time points (P = 0.001). Mean diastolic blood pressure also demonstrated a significant group effect between the two groups (P = 0.002). The mean heart rate one minute after induction of anaesthesia was significantly higher in the F group than in the P group (P < 0.001). The mean pain score was 5.88 in the F group and 4.98 in the P group, with no statistically significant difference between groups (P = 0.313).,

Conclusion: The findings of this study indicate that haemodynamic changes following tracheal intubation were less pronounced in the pregabalin plus fentanyl group than in the fentanyl alone group.

Keywords: Hemodynamic response, Pregabalin, Fentanyl, Tracheal intubation, Lumbar spine surgery

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Introduction

Tracheal intubation can cause undesirable responses in the cardiovascular system, such as increases in heart rate and blood pressure, as well as in the respiratory system (e.g. bronchospasm). These changes typically peak one to two minutes after the onset of laryngoscopy and return to baseline levels within five minutes. Although such transient changes are generally well tolerated in healthy individuals, they may be problematic in susceptible patients, particularly those with systemic hypertension, coronary artery disease, abdominal or intracranial aneurysms, and recent myocardial infarction, potentially leading to adverse outcomes such as myocardial ischaemia and cerebral haemorrhage.

Various drugs, including vasodilators, adrenergic receptor blockers, and calcium channel blockers, have been used to attenuate these unwanted haemodynamic responses. A common approach is the administration of a short-acting opioid, such as fentanyl, and intravenous lidocaine before laryngoscopy. Propofol or sodium thiopental are commonly used for the induction of anaesthesia. However, the combination of these agents with fentanyl may increase the risk of side effects, including cardiovascular and respiratory depression, hypotension, and apnoea during anaesthetic induction.

Spine surgeries are increasingly performed in both paediatric and adult populations, presenting multiple challenges for anaesthesiologists. Many of these patients have comorbidities such as severe cardiovascular and respiratory failure, making haemodynamic management particularly demanding. In addition, the surgical procedure itself, with associated blood loss, prolonged anaesthesia, and postoperative pain, places further stress on the cardiovascular system. Factors such as the timing of awakening and extubation, duration of stay in the recovery unit, and postoperative side effects including pain, nausea, vomiting, and dizziness are important, as they influence recovery and may affect surgical outcomes, including haematoma formation or surgical failure.

Pregabalin, a gamma-aminobutyric acid (GABA) analogue, exerts analgesic, anticonvulsant, and anxiolytic effects by reducing glutamate synthesis. Its reported side effects include dizziness, insomnia, peripheral oedema, and dry mouth. Previous studies have shown that a single oral dose of pregabalin administered one to two hours before induction of anaesthesia can reduce changes in blood pressure and heart rate during and after laryngoscopy and endotracheal intubation.

Fentanyl is a synthetic opioid with an analgesic potency several times greater than that of heroin. It is primarily used as a pre-anaesthetic medication and sedative in the operating theatre and is widely employed for anaesthesia and pain management. Fentanyl is approximately 75–125 times more potent than morphine, with an onset of action of 2–3 minutes and a duration of 30–60 minutes, and it has no amnestic effect. It is administered intravenously at a dose of 0.5–1 μg/kg over three minutes and may be repeated every two minutes to achieve the desired effect, with a maximum dose of 5 μg/kg. Reported side effects include reductions in diastolic blood pressure, decreased arterial oxygen saturation, nausea, and vomiting; however, the most significant adverse effect is respiratory depression, which is exacerbated by the concurrent use of sedative agents.

Although previous studies have demonstrated the beneficial effects of pregabalin, the available evidence remains limited. Therefore, the present study was conducted to compare the haemodynamic responses of pregabalin combined with fentanyl versus fentanyl alone following tracheal intubation in patients undergoing lumbar spine surgery.

Materials and methods

Study Design and Patient Selection

This randomised, double-blind clinical trial was conducted from December 2020 to January 2022 on patients scheduled for elective lumbar spine surgery at Ayatollah Rouhani Hospital in Babol.

Inclusion and Exclusion Criteria

Patients were included if they were aged 20–65 years, classified as American Society of Anesthesiologists (ASA) physical status I or II, scheduled for lumbar spine surgery, had no history of hypertension, and were not taking antihypertensive

medications. Exclusion criteria included age under 20 or over 65 years, ASA class ≥ III, bradycardia, systolic blood pressure < 90 mmHg, opioid addiction, difficult intubation, hypertension, use of antihypertensive drugs, and surgical procedures lasting longer than three hours.

The study was approved by the Ethics Committee of Babol University of Medical Sciences (Code: IR.MUBABOL.HRI.REC.1400.128) and registered in the Iranian Registry of Clinical Trials (IRCT) under the number IRCT20111010007752N12. Written informed consent was obtained from all participants.

Initially, the study was designed to compare pregabalin alone with fentanyl alone. However, due to unfavourable haemodynamic conditions observed in the first few patients in the pregabalin-only group, the study protocol was modified to an add-on design. Consequently, both groups received fentanyl; one group (P) additionally received pregabalin, while the other group (F) received a placebo.

Randomization and Blinding

After obtaining written informed consent, patients were randomly assigned to one of two groups, the pregabalin plus fentanyl group (P) or the fentanyl-only group (F), with 40 patients allocated to each group. Randomisation was performed using permuted blocks of size four, with each block consisting of random combinations of two allocations to group A (pregabalin) and two to group B (placebo). The random sequence was generated by a statistician.

Capsules containing pregabalin and placebo were prepared to be identical in shape, size, and appearance and were placed in identical containers, each labelled with a three-digit code. Upon enrolment, one container was assigned to each patient, and the corresponding code was recorded in the patient's file. The allocation codes were disclosed only after completion of the study.

This study was conducted in a double-blind manner; patients, the attending anaesthesiologist, and the anaesthesia assistant responsible for data collection were all unaware of the treatment allocation.

The intervention group (P) received a single oral capsule of pregabalin 75 mg eight hours before surgery. The control group (F) received an oral placebo capsule eight hours before surgery.

Anaesthetic Procedure

Both groups received fentanyl at a dose of 1 µg/kg administered over 10 minutes before tracheal intubation. All patients were given 2 mg of intravenous midazolam prior to intubation. Anaesthesia was induced in all patients with propofol 2 mg/kg. Atracurium 0.5 mg/kg was used as a muscle relaxant in both groups, followed by tracheal intubation. Anaesthesia was maintained with a mixture of 50% O_2 and N_2O and 1.2% isoflurane under controlled ventilation. In addition, both groups received morphine 0.01 mg/kg before skin incision.

Data Collection and Outcomes

The primary outcomes were systolic blood pressure, diastolic blood pressure, mean arterial pressure, and heart rate. These variables were recorded at baseline, before induction of anaesthesia, after induction, and at 1, 3, 5, and 10 minutes following tracheal intubation. The secondary outcome was postoperative pain, assessed using the Visual Analogue Scale (VAS). After admission to the recovery room, pain was measured every 15 minutes until discharge from recovery. On the VAS, a score of 0 indicated no pain, 5 indicated moderate pain, and 10 indicated severe pain.

Statistical Analysis

The sample size was calculated based on a previous study, with a significance level (α) of 0.05 and a statistical power of 80%. A minimum sample size of 22 patients per group was required. Statistical analysis was performed using SPSS software, version 22. Descriptive statistics, the chi-square test, independent t-test, Mann–Whitney U test, and Kaplan–Meier analysis were used as appropriate. A p-value of < 0.05 was considered statistically significant.

Results

In this research, 80 patients were enrolled **(Figure 1).**

Patient Characteristics

No significant differences were observed in the demographic characteristics between the two groups ($P > 0.05$), indicating that the groups were homogeneous in this regard. The mean pain score was 5.88 in the fentanyl group (F) and 4.98 in the pregabalin plus fentanyl group (P), with no statistically significant

difference between the groups (P = 0.313). The mean age was 46.98 ± 8.91 years in group F and 45.43 ± 12.49 years in group P. The mean body mass index (BMI) was 34.7 ± 1.30 kg/m² in group F and 35.0 ± 1.34 kg/m² in group P (**Table 1**).

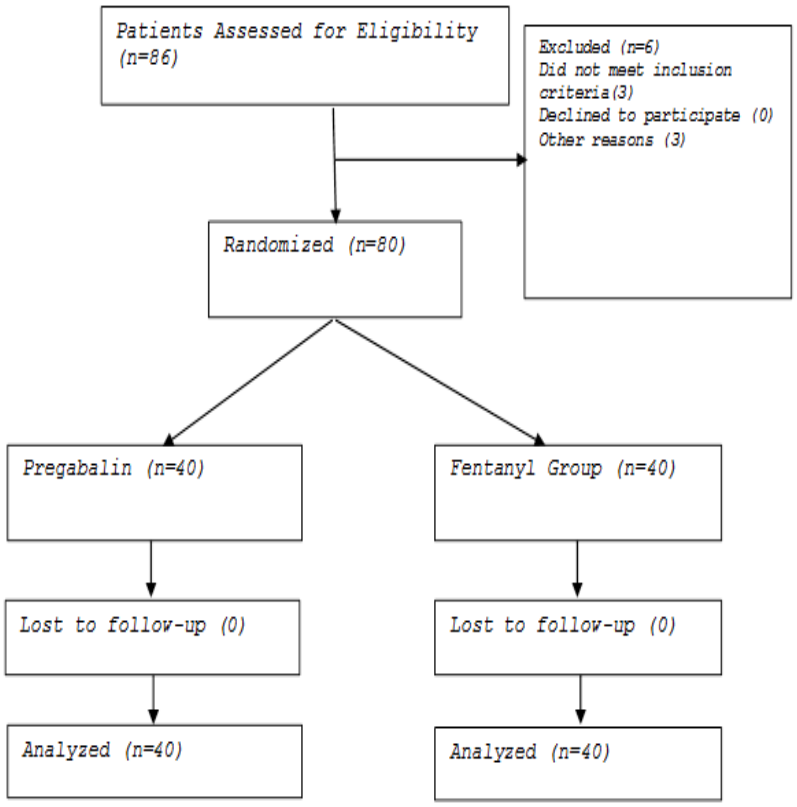

Fig 1. Flowchart of patients participating in the clinical Trial

Table 1: Demographic Characteristics and Pain Scores of Subjects in the Two Groups

Group		Fentanyl percentage frequency	Pregabalin percentage frequency	P
Gender				
Gender	Male	16(40)	19 (47.5)	0.625
	Female	24(60)	21 (52.5)	
History of Disease	ASA Class I	34 (85)	35 (87.5)	0.99
	ASA Class II, Type 2 Diabetes	6 (15)	5 (12.5)	
Age (M±SD)		46.98 ± 8.91	45.43 ± 12.49	0.525
Body Mass Index (M±SD)		34.7 ± 1.30	35.0 ± 1.34	0.313
Pain Score		5.88 ± 0.79	4.98 ± 0.94	0.313

According to the results presented in Table 1, no statistically significant difference was observed in the demographic characteristics between the two groups (P>0.05); thus, the groups were considered homogeneous at baseline.

Medication and Haemodynamics

Analysis of mean heart rate at different time points using repeated-measures ANOVA showed that the overall group effect was not statistically significant (P = 0.517) (**Figure 2**).

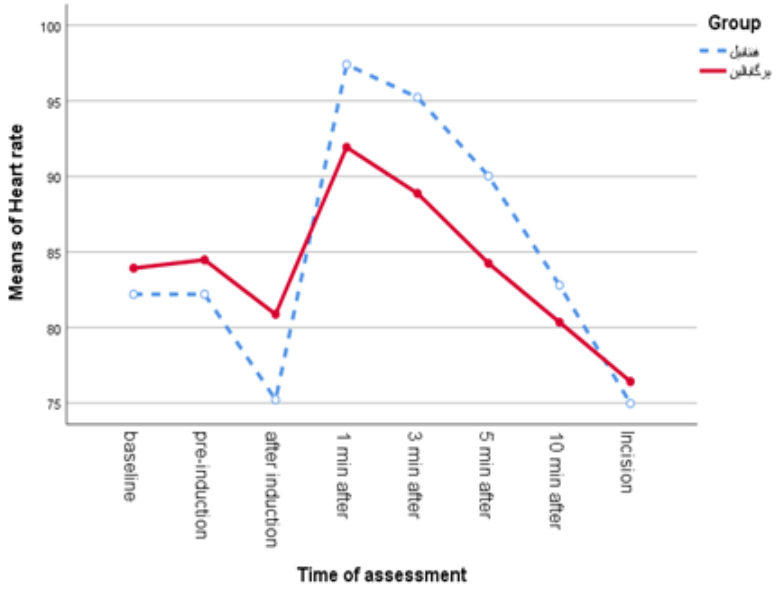

Fig 2. Mean Heart Rate at Different Times in the Two Study Groups .

The mean heart rate at one minute after induction increased significantly more in the fentanyl group than in the pregabalin group (effect size = 0.625, P < 0.001) (**Figure 3**).

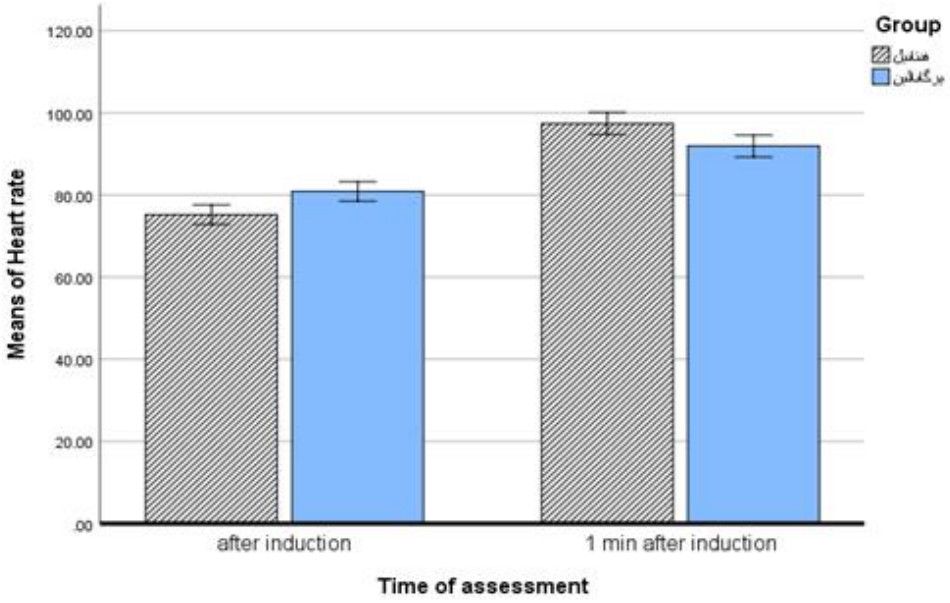

Fig 3. Mean Heart Rate at Post-Induction and One-Minute Post-Induction in Two Study Groups .

Repeated - measures ANOVA indicated that the group effect on mean diastolic blood pressure across different time points was statistically significant (effect size = 0.114, P = 0.002) (**Table 2**).

Table 2. Comparison of Mean Arterial Pressure (MAP) at Different Time Points in Two Grou

diastolic blood pressure	Group	Mean	MD
Start of sedation	Fentanyl	75.65	6.22
	Pregabalin	73.27	2.9
Preinduction	Fentanyl	75.65	6.22
	Pregabalin	80.05	5.79
After induction	Fentanyl	60.62	3.95
	Pregabalin	71.72	6.15
1 min after intubation	Fentanyl	86.1	7.12
	Pregabalin	84.97	7.11
3 min after intubation	Fentanyl	82.45	7.80
	Pregabalin	82.3	6.26
5 min after intubation	Fentanyl	76.4	6.84
	Pregabalin	78.47	6.21
10 min after intubation	Fentanyl	66.27	5.53
	Pregabalin	73.32	6.23
Skin incision	Fentanyl	57.92	3.90
	Pregabalin	67.72	6.38

According to the results presented in **Table 3**, the mean diastolic blood pressure at one minute after induction increased significantly more in the fentanyl group than in the pregabalin group (effect size = 0.585, P < 0.001). Repeated-measures ANOVA demonstrated that the group effect on mean systolic blood pressure across different time points, including one minute after induction, was statistically significant (effect size = 0.122, P = 0.001) (**Table 4**, **Figure 4**).

Table 3. Mean Arterial Blood Pressure After and One Minute After Induction in the Two Study Groups

Mean Arterial Pressure	Group	Mean	MD
Start of sedation	Fentanyl	126.78	7.47
	Pregabalin	129.18	5.84
Preinduction	Fentanyl	126.77	7.47
	Pregabalin	135.22	9.67
After induction	Fentanyl	110.75	5.03
	Pregabalin	126.8	9.89
1 min after intubation	Fentanyl	142.95	8.18
	Pregabalin	138.8	10.75
3 min after intubation	Fentanyl	139.45	8.08
	Pregabalin	136.57	9.96
5 min after intubation	Fentanyl	129.85	7.64
	Pregabalin	131.57	9.35
10 min after intubation	Fentanyl	116.67	6.77
	Pregabalin	126.25	9.24
Skin incision	Fentanyl	105.35	6.53
	Pregabalin	120.82	9.11

Table 4. Mean Systolic Blood Pressure at Different Times in the Two Study Groups

systolic blood pressure	Group	Mean	MD
Start of sedation	Fentanyl	126.78	7.47
	Pregabalin	129.18	5.84
Preinduction	Fentanyl	126.77	7.47
	Pregabalin	135.22	9.67
After induction	Fentanyl	110.75	5/03
	Pregabalin	126.8	9.89
1 min after intubation	Fentanyl	142.95	8.18
	Pregabalin	138.8	10.75
3 min after intubation	Fentanyl	139.45	8.08
	Pregabalin	136.57	9.96
5 min after intubation	Fentanyl	129.85	7.64
	Pregabalin	131.57	9.35
10 min after intubation	Fentanyl	116.67	6.77
	Pregabalin	126.25	9.24
Skin incision	Fentanyl	105.35	6.53
	Pregabalin	120.82	9.11

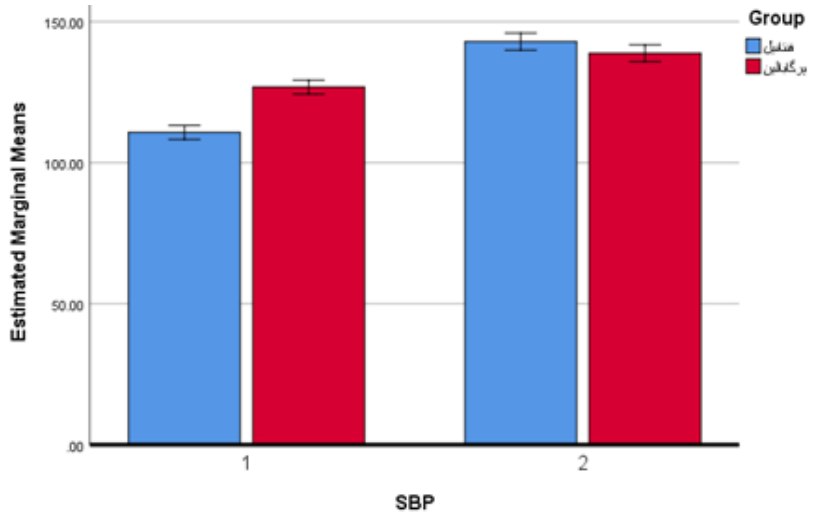

Fig 4. Mean Systolic Blood Pressure After and One Minute After Induction in the Two Study Groups

Discussion

This study aimed to compare the haemodynamic effects of fentanyl alone with those of pregabalin combined with fentanyl following tracheal intubation in patients undergoing elective lumbar spine surgery. The mean systolic blood pressure, diastolic blood pressure, and mean arterial pressure at different time points were consistently lower in the pregabalin plus fentanyl group than in the fentanyl- only group. A study by T. Murari *et al.* compared oral clonidine with oral pregabalin for attenuation of the stress response in patients undergoing elective surgery. They reported that mean heart rate and diastolic blood pressure were significantly lower in the clonidine group, whereas postoperative analgesia was superior in the pregabalin group. In the present study, the mean pain score was also lower in the pregabalin group, which is consistent with their findings. Moreover, the results reported by Murari *et al.* regarding the effectiveness of pregabalin

in reducing haemodynamic changes are in agreement with the findings of our study.

Conversely, Rathore *et al.* reported that clonidine was more effective than pregabalin in suppressing haemodynamic responses, including heart rate and blood pressure, following tracheal intubation. This contrasts with the results of the present study, in which the increase in heart rate was significantly less pronounced in the pregabalin group than in the fentanyl-only group. Similarly, our findings differ from those of Dhanya *et al.*, who demonstrated that pregabalin significantly reduced heart rate and mean arterial pressure at 1, 3, 5, and 10 minutes after laryngoscopy. These discrepancies may be attributable to differences in sample size, study design, or the anaesthetic and analgesic regimens used.

The results of the present study are consistent with those reported by Mahoori *et al.*, who compared gabapentin and pregabalin as premedication agents and found that increases in heart rate and blood pressure following tracheal intubation were significantly lower in both groups compared with controls, without significant adverse effects.

One limitation of this study was the lack of assessment of sedation levels, postoperative complications, and opioid requirements in the recovery room, which may limit the interpretation of the broader clinical effects of pregabalin

Conclusion

The results of the present study demonstrated that the mean heart rate, systolic blood pressure, diastolic blood pressure, and mean arterial pressure at one minute after induction were significantly lower in the pregabalin plus fentanyl group compared with the fentanyl-only group. These findings indicate that the addition of pregabalin was more effective in attenuating the haemodynamic response to tracheal intubation.

Limitations

This study has several limitations. First, the relatively small sample size may limit the generalisability of the findings. Second, the dose of pregabalin and the duration of its administration were low, which may have acted as confounding factors and potentially underestimated its full effect. Third, comparing an active drug combination with a non-drug control (placebo plus fentanyl) may not represent the most robust comparative design. Finally, individual differences in patients' sensitivity and response to pain could have influenced pain scores, introducing variability in the questionnaire-based assessment.

Suggestions

For patients undergoing lumbar spine surgery, the administration of pregabalin as a premedication in combination with fentanyl may be recommended to improve haemodynamic stability following tracheal intubation and to aid in postoperative pain control. Given the favourable haemodynamic profile observed in this study, pregabalin may represent a useful adjunct in anaesthetic premedication protocols for this patient population. Further research is recommended to evaluate the role of pregabalin in providing sedation and analgesia in other surgical procedures. In addition, future studies should investigate different dosing regimens and determine the optimal timing of preoperative pregabalin administration to maximise its clinical benefits.

Declaration

Acknowledgments

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Author Contributions

The main concept and design of the study were developed by Dr Parviz Amri. Data collection was carried out by Dr Reza Rojaii. Statistical analysis was performed by Dr Hoda Shirafkan. Data analysis and interpretation were conducted by Dr Shahram Seifi. All authors contributed to drafting and revising the manuscript and approved the final version for publication.

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