Original Research Paper

Volume - 14 | Issue - 09 | September - 2024 | PRINT ISSN No. 2249 - 555X | DOI : 10.36106/ijar

Anaesthesiology

COMPARATIVE STUDY ON EFFECTS OF INTRAVENOUS FENTANYL AND DEXMEDETOMIDINE ON HEMODYNAMIC CHANGES DURING EXTUBATION IN PATIENTS UNDERGOING SURGERY UNDER GENERAL ANAESTHESIA

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ABSTRACT **Introduction:** Extubation, a critical phase during the emergence from general anesthesia, often triggers significant hemodynamic responses, including increases in heart rate and blood pressure, which can lead to adverse cardiovascular events. This study compares the effect of dexmedetomidine and fentanyl on hemodynamic changes during extubation in patients undergoing elective abdominal surgery under general anesthesia. **Methods:** This prospective, randomized, comparative study was conducted at Al Ameen Medical College and Hospital, Vijayapura, from June 2023 to July 2024. 30 adult patients scheduled for elective abdominal surgery were randomized into two groups: Group D (Dexmedetomidine) and Group F (Fentanyl), each comprising 15 patients. The primary outcome measured changes in HR, MAP and SPO2 during and after extubation. Secondary outcome measured the incidence of adverse effects. Datas were analyzed using SPSS, with statistical significance set at $p < 0.05$. **Results:** Dexmedetomidine significantly reduced HR and MAP compared to fentanyl during the peri-extubation period. In Group D, HR decreased from 76 ± 8 bpm pre-operatively to 64 ± 5 bpm ,post-extubation ($p < 0.05$). In Group F, HR decreased from 78 ± 9 bpm to 72 ± 8 bpm ($p > 0.05$). Similar trends were observed in MAP, with Group D showing superior attenuation of hemodynamic responses. Group D showed a slightly higher incidence of bradycardia and hypotension, while Group F had a higher incidence of nausea .**Conclusion:** Dexmedetomidine is more effective than fentanyl in attenuating the hemodynamic stress responses during extubation. Its superior control over HR and BP, combined with an acceptable safety profile, suggests that dexmedetomidine may be the preferred agent for managing extubation in patients at risk of cardiovascular events.

KEYWORDS : General anesthesia, Extubation, Dexmedetomidine, Fentanyl.

INTRODUCTION

Extubation, the process of removing an endotracheal tube, is a critical phase with potential complications, primarily due to reflex sympathetic stimulation, which can result in abrupt increases in heart rate (HR), blood pressure (BP) or arrhythmias. Such physiological disturbances are of particular concern in patients with underlying cardiovascular conditions, where the resultant stress can lead to myocardial ischemia, cerebrovascular accidents, or other severe cardiovascular events.[1]

The hemodynamic responses associated with extubation are primarily attributed to the stimulation of the respiratory tract,during the removal of the endotracheal tube. This triggers a reflex sympathetic discharge, leading to the release of catecholamines which causes vasoconstriction, increases heart rate, and elevates blood pressure, all of which can pose significant risks, particularly in patients with compromised cardiovascular systems.

Given the potential dangers associated with extubation-induced hemodynamic changes, various pharmacological agents, including beta-blockers, calcium channel blockers, local anesthetics, and opioids, have been explored with the aim of blunting the sympathetic response to extubation.[2,3,4]

In recent years, dexmedetomidine, a highly selective α2-adrenoceptor agonist, has gained attention for its pharmacological properties, which include sedative, analgesic, anxiolytic, and sympatholytic effects. It attenuate the sympathetic nervous system's response by decreasing norepinephrine release. Several studies have demonstrated that dexmedetomidine, when administered during the peri-extubation period, can effectively reduce heart rate and blood pressure, thus providing hemodynamic stability during this critical phase.[5]

Fentanyl, a potent μ-opioid receptor agonist, is another commonly used agent in the perioperative setting. Known for its rapid onset and short duration of action, fentanyl is widely used for analgesia, sedation, and anesthesia. It has also been shown to attenuate the stress response to extubation by blunting the sympathetic response. However, fentanyl's opioid-related side effects like nausea, vomiting, respiratory depression and dependence, necessitate cautious use, particularly in patients with preexisting respiratory or neurological conditions.[6]

The comparative efficacy of dexmedetomidine and fentanyl in managing hemodynamic responses during extubation is an area of active investigation. This study aims to provide a detailed comparison between dexmedetomidine and fentanyl in terms of their effects on hemodynamic stability during extubation in patients undergoing elective abdominal surgery under general anesthesia.

AIMS AND OBJECTIVES

AIM:

To compare the effects of intravenous fentanyl and dexmedetomidine on hemodynamic changes during extubation in patients undergoing surgery under general anaesthesia

OBJECTIVES:

PRIMARY OBJECTIVE:

To evaluate the degree of attenuation of the stress response to extubation and emergence from general anesthesia with a single intravenous dose of dexmedetomidine and fentanyl.

SECONDARY OBJECTIVE:

To evaluate the safety and potential side effects associated with a single intravenous dose of dexmedetomidine and fentanyl.

METHODOLOGY

STUDY DESIGN:

This study was a prospective, randomized, comparative trial.

STUDY SETTING:

The study was conducted at Al Ameen Medical College and Hospital, Vijayapura.

STUDY PERIOD:

The study was carried out over a period from JUNE 2023 to JULY 2024.

PARTICIPANTS:

The study included adult patients undergoing elective abdominal surgery under general anesthesia. A total of 30 patients were randomly assigned to one of two groups: Group D (dexmedetomidine) and Group F (fentanyl), with 15 patients in each group.

INCLUSION CRITERIA:

- Adult patients aged between 18 to 60years.
- Both male and female patients.
- Patients with an ASA (American Society of Anesthesiologists) physical status I or II.
- Non-pregnant, non-lactating patients.
- Patients with a Body Mass Index (BMI) of less than 30 kg/m².
- Patients scheduled for elective abdominal surgery under general anesthesia.

EXCLUSION CRITERIA:

- Patients with known hypertension or those currently taking antihypertensive medications.
- Individuals with a history of drug abuse, including oral or intravenous drug use.
- Patients with anticipated or unanticipated difficult airway management.
- Individuals with a history of Obstructive Sleep Apnea (OSA) or related symptoms.

DATA COLLECTION:

GROUP D (N = 15):

15 patients received Dexmedetomidine (0.5 µg/kg diluted to 10 mL in Normal Saline, slowly over 10 minutes) approximately 20 minutes prior to extubation.

GROUP F (N = 15):

15 patients received Fentanyl (1 µg/kg diluted to 10 mL in Normal Saline, slowly over 10 minutes) approximately 20 minutes prior to extubation.

Datas were collected at various time points, including baseline (prior to drug administration), during the infusion of the study drug, and at multiple intervals following extubation (0, 5, 10,15,30,45 and 60 minutes). The parameters monitored included:

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- Heart Rate (HR)
- Mean arterial Pressure (MAP)
- Oxygen saturation (SpO2)
- Any adverse events such as bradycardia, hypotension or respiratory depression

STATISTICAL ANALYSIS:

Data were analyzed using SPSS version 15. Descriptive statistics, including mean and standard deviation, were used to summarize the data. The Kolmogorov-Smirnov test was applied to check the normality of the data. For normally distributed data, the Student's t-test was used to compare means between the two groups. The Mann-Whitney U test was applied for non-normally distributed data. The chi-square test was used for categorical variables, and Fisher's exact test was employed when the expected frequency was less than five. A p-value of less than 0.05 was considered statistically significant.

ETHICAL CONSIDERATIONS

The ethical considerations for this study were adhered to, beginning with the approval from the Institutional Ethics Committee (IEC) of Al Ameen Medical College and Hospital, Vijayapura. Informed consent was obtained from all participants after providing them with detailed information about the study including its purpose, procedures, potential risks, and benefits.

RESULTS AND ANALYSIS

Table 1: Demographic variables of Subjects Between the Study Groups

	Group D	Group F	p-value	Significance
Age	38.6 ± 12.4	39.2 ± 10.8	0.79	NS
Sex				
Male	9	8	0.75	NS
Female	6	7	0.68	NS
ASA Status				
ASA I	10	9	0.80	NS
ASA II	5	6	0.71	NS

The mean age of subjects in Group D was 38.6 ± 12.4 years, while in Group F, it was 39.2 ± 10.8 years (p = 0.79, NS). Both groups were comparable in terms of gender distribution (p > 0.05) and ASA physical status (p > 0.05), indicating no significant demographic differences between the groups. The demographic characteristics, including age, sex, and ASA status, were well balanced between the two groups, ensuring comparability and reducing confounding factors related to these variables.

Table2: Distribution of Surgical Cases Between the Two Study Groups

Type of Surgery	Group D	Group F	p-value	Significance
Laproscopic Cholecystectomy	5	4	0.76	NS
Laproscopic Appendectomy	4	5	0.69	NS
Diagnostic laproscopy	3	3	1.00	NS
Laproscopic Hysterectomy	3	3	1.00	NS
Total	15	15		

The distribution of different surgical procedures were similar across both groups, with no statistically significant differences (p > 0.05 for all).

Table 3: Inter-group comparison of heart rate (HR) between Group D (Dexmedetomidine) and Group F (Fentanyl):

Time Interval	Mean HR (bpm) ± SD(GROUP D)	p-value	Significance	Mean HR (bpm) ± SD(GROUP F)	p-value	Significance
Pre-op	76 ± 8	---	---	78 ± 9	---	---
Start of study drug infusion	74 ± 7	0.12	NS	76 ± 8	0.10	NS
0 min	72 ± 7	0.05	NS	74 ± 7	0.07	NS
3 min	70 ± 6	0.02	Significant	74 ± 7	0.04	Significant
5 min	68 ± 7	0.01	Significant	72 ± 6	0.03	Significant
At reversal	65 ± 6	0.01	Significant	70 ± 7	0.03	Significant
After extubation	64 ± 5	0.01	Significant	72 ± 8	0.05	NS
5 min	67 ± 7	0.03	Significant	75 ± 7	0.07	NS
10 min	70 ± 8	0.05	Significant	77 ± 8	0.09	NS
15 min	72 ± 7	0.06	NS	79 ± 9	0.10	NS
30 min	73 ± 7	0.07	NS	80 ± 9	0.11	NS
45 min	74 ± 7	0.08	NS	81 ± 9	0.12	NS
60 min	75 ± 7	0.09	NS	82 ± 9	0.13	NS

D showed a significant reduction in HR at several time points after study drug infusion, particularly from 3 minutes onwards (p < 0.05), while Group F exhibited less consistent changes with fewer significant reductions in HR.

Table 4: Inter-group Comparison of Mean Arterial Pressure (MAP) in Group D (Dexmedetomidine) and Group F (Fentanyl):

Time Interval	Mean MAP(mmHg)± SD (GROUP D)	p-value	Significance	Mean MAP(mmHg) ± SD(GROUP F)	p-value	Significance
Pre-op	95 ± 7	---	---	97 ± 8	---	---
Start of study drug infusion	93 ± 6	0.14	NS	95 ± 7	0.13	NS
0 min	92 ± 6	0.09	NS	94 ± 7	0.08	NS
3 min	92 ± 6	0.09	NS	94 ± 7	0.08	NS

5 min	90 ± 6	0.02	Significant	92 ± 7	0.03	Significant
At reversal	88 ± 5	0.01	Significant	90 ± 6	0.02	Significant
After extubation	87 ± 5	0.01	Significant	91 ± 6	0.03	Significant
5 min	90 ± 6	0.03	Significant	94 ± 7	0.05	Significant
10 min	92 ± 6	0.05	Significant	96 ± 7	0.07	NS
15 min	93 ± 6	0.06	NS	97 ± 7	0.08	NS
30 min	94 ± 6	0.07	NS	98 ± 7	0.09	NS
45 min	95 ± 6	0.08	NS	99 ± 7	0.10	NS
60 min	96 ± 6	0.09	NS	100 ± 7	0.11	NS

MAP was significantly lower in Group D compared to Group F during most time intervals after extubation, particularly from 5 minutes onward ($p < 0.05$), while Group F only showed significant reductions at a few time points.

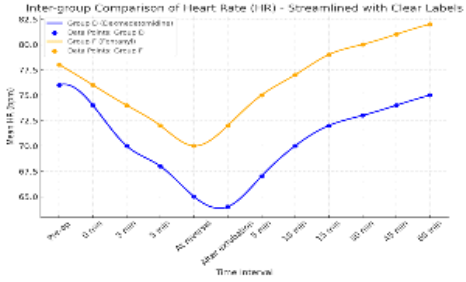

Figure 1: Inter-group comparison of HR

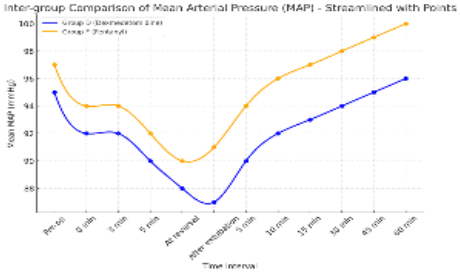

Figure 2 : Inter-group Comparison of MAP

Table 5: Inter-group Comparison of SpO2 Between Group D (Dexmedetomidine) and Group F (Fentanyl)

Time Interval	Group D	Group F	p-value	Significance
Pre-op	99 ± 1	99 ± 1	0.78	NS
Start of study drug infusion	98 ± 1	98 ± 1	0.82	NS
0 min	98 ± 1	98 ± 1	0.85	NS
3 min	97 ± 1	97 ± 1	0.90	NS
5 min	97 ± 1	97 ± 1	0.90	NS
At reversal	97 ± 1	97 ± 1	0.89	NS
After extubation	97 ± 1	97 ± 1	0.88	NS
5 min	97 ± 1	97 ± 1	0.88	NS
10 min	97 ± 1	97 ± 1	0.88	NS
15 min	97 ± 1	97 ± 1	0.88	NS
30 min	97 ± 1	97 ± 1	0.88	NS
45 min	97 ± 1	97 ± 1	0.88	NS
60 min	97 ± 1	97 ± 1	0.88	NS

Oxygen saturation levels remained stable and comparable between both groups throughout the study, with no significant differences at any time point ($p > 0.05$).

Table 6: Side Effects of Study Drugs

Side Effects	Group D	Group F	p-value	Significance
Bradycardia	1 (6.7%)	0 (0%)	0.30	NS
Hypotension	2 (13.3%)	1 (6.7%)	0.45	NS
Respiratory Depression	0 (0%)	0 (0%)	0.00	NA
Nausea	1 (6.7%)	2 (13.3%)	0.50	NS
Vomiting	0 (0%)	1 (6.7%)	0.30	NS

Side effects were minimal in both groups. Group D had slightly more cases of hypotension (13.3%) compared to Group F (6.7%), while nausea was more frequent in Group F (13.3%) compared to Group D (6.7%), though these differences were not statistically significant ($p > 0.05$).

DISCUSSION

The present study was conducted to compare the effects of dexmedetomidine and fentanyl on the hemodynamic responses during extubation in patients undergoing elective abdominal surgery under general anesthesia. Extubation is a critical phase in anesthesia management, characterized by significant sympathetic stimulation that can lead to abrupt changes in heart rate, blood pressure, and, in severe cases, the onset of arrhythmias. These physiological disturbances can pose considerable risks, especially in patients with preexisting cardiovascular conditions. Therefore, finding an optimal pharmacological agent to mitigate these responses is crucial for improving patient outcomes.

HEMODYNAMIC PARAMETERS

Heart Rate(HR)[3,4]:The comparison of heart rate (HR) in both Group D (dexmedetomidine) and Group F (fentanyl) demonstrated that both drugs were effective in reducing HR during the peri-extubation period. In Group D, a significant reduction in HR was observed starting from 3 minutes after the initiation of the study drug infusion, with the effect sustained through the extubation and post-extubation periods. The mean HR decreased from 76 ± 8 bpm pre-operatively to 64 ± 5 bpm , post-extubation ($p < 0.05$). This reduction is consistent with the known effects of dexmedetomidine, which exerts its sympatholytic action by reducing norepinephrine release, thereby lowering HR.In Group F, the HR dropped from 78 ± 9 bpm pre-operatively to 72 ± 8 bpm , post-extubation, indicating that the reduction was less pronounced compared to Group D and statistically non significant($p > 0.05$). Dexmedetomidine was more effective than fentanyl in controlling HR throughout the extubation process, particularly during the critical period immediately following extubation. The observed difference between the two drugs suggests that dexmedetomidine may offer superior control over the stress-induced tachycardia associated with extubation, making it a preferable choice in patients at risk of adverse cardiovascular events.These findings are supported by previous studies, such as those conducted by Guler et al.(2005), which demonstrated that dexmedetomidine effectively reduced HR during extubation without causing significant bradycardia. Similarly, studies by Scheinin et al. (1992) also reported that dexmedetomidine provided better hemodynamic stability compared to other agents, including fentanyl, during the peri-extubation period.

Mean Arterial Pressure(MAP)[6,9]:In Group D, MAP decreased significantly from 95 ± 7 mmHg pre-operatively to 87 ± 5 mmHg , post-extubation ($p < 0.05$). In Group F, the MAP reduction was not significant, from 97 ± 8 mmHg to 91 ± 6 mmHg during the same period ($p > 0.05$). These findings further reinforce the superior efficacy of dexmedetomidine in maintaining hemodynamic stability during extubation.Studies by Bajwa et al. (2012) also support these findings, indicating that dexmedetomidine provides better control over MAP during extubation compared to fentanyl.

SPO2[5,10]:There was no episode of a drop in Percentage Oxygen saturation (SpO2) during the study drug infusion, at reversal or at any time interval after extubation in both the groups. There was no statistically significant difference in the SpO2 values.

Fentanyl, while effective, was less successful in controlling the hemodynamic parameters compared to dexmedetomidine. This aligns with previous study, by Nishina et al. (1995), which reported that while fentanyl is effective in blunting the sympathetic response, its effects are not as robust as those of dexmedetomidine, particularly in high-risk populations.

SAFETY AND SIDE EFFECTS[11,12,13]

The safety profile of both drugs was closely monitored throughout the study. The incidence of bradycardia was slightly higher in Group D, with one patient (6.7%) experiencing bradycardia compared to none in Group F. This side effect was anticipated given the known pharmacodynamics of dexmedetomidine, which can cause

bradycardia through its central sympatholytic effects. However, the bradycardia observed was transient and responded well to standard clinical interventions, with no lasting adverse effects. Hypotension was also more frequently observed in Group D, with two patients (13.3%) experiencing mild hypotension compared to one patient (6.7%) in Group F. Again, this was an expected outcome due to dexmedetomidine's vasodilatory effects. The hypotension was managed effectively with fluid administration and did not lead to any significant clinical complications. Nausea and vomiting were observed in both groups, with slightly higher incidences in Group F (13.3%) compared to Group D (6.7%). The side effects observed were manageable and did not lead to any complications, suggesting that both drugs are safe for use in the peri-extubation period, with careful monitoring.

CONCLUSION

Dexmedetomidine is more effective than fentanyl in attenuating the hemodynamic stress response associated with extubation and offers better overall hemodynamic stability during the peri-extubation period . Its superior control over heart rate and mean arterial pressure, combined with its acceptable safety profile, makes dexmedetomidine a valuable tool in the management of patients undergoing surgery under general anesthesia. Fentanyl, while effective, may be more suitable in patients where the primary concern is avoiding excessive sedation or where the risk of bradycardia and hypotension must be minimized. Future research should focus on further exploring the optimal dosing strategies for dexmedetomidine and fentanyl in different patient populations.

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