

# The Sedation Score (Ramsay Sedation Score) and Recovery Profile (Modified Aldrete's Score) in Fentanyl, Dexmedetomidine and Placebo Groups

Liyakhat Ali<sup>1</sup>, Shrinivas TR<sup>2</sup>

<sup>1</sup>Assistant Professor, Department of Anesthesiology, GIMS, Kalaburgi, Karnataka, <sup>2</sup>Associate Professor, Department of Anesthesiology, KIMS, Koppal, Karnataka

## Abstract

**Background:** Extubation and emergence from general anesthesia is a stressful event which is a less addressed clinical entity. Problems associated with extubation, recovery, and emergences are more common than problems at intubation. Reports from the UK suggest that respiratory complications are common at extubation and during recovery. Death or brain injury was more common in claims associated with extubation and recovery than those occurring at the time of induction of anesthesia. **Subjects and Methods:** The Consolidated Standards of Reporting Trials (CONSORT) recommendations for reporting randomized, control clinical trials were followed. After obtaining hospital ethics committee approval, a prospective randomized controlled study was done to compare fentanyl, dexmedetomidine and placebo in attenuating of hemodynamic stress response during extubation and emergence from general anaesthesia; in 150 patients with 50 patients in each of 3 groups. **Results:** Sedation score at 15 min in group A was  $1.64 \pm 0.56$ , in group B sedation score was  $2.36 \pm 0.53$ . Among group A & B, there was statistically significant difference at 15, 20 and at 120 minutes following extubation ( $p < 0.050$ ). At remaining interval of observation there was no statistically significant difference ( $p > 0.050$ ). Recovery score at 15 min following extubation in group A, B, C were  $13.28 \pm 0.50$ ,  $13.78 \pm 0.46$ ,  $13.78 \pm 0.42$  respectively. **Conclusion:** There was statistically significant difference in recovery score among the groups ( $p < 0.001$ ) at 15, 20, 25 minutes of study period. But clinically recovery score were nearly similar in all 3 groups.

**Keywords:** The Sedation Score, Recovery Profile, Fentanyl.

**Corresponding Author:** Dr. Shrinivas TR, Associate Professor, Department of Anesthesiology, KIMS, Koppal, Karnataka.

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## Introduction

Endotracheal intubation is over all accepted as "gold standard of securing airway and providing adequate ventilation". Direct laryngoscopy and endotracheal intubation is almost always associated with haemodynamic changes due to reflex sympathetic activity caused by stimulation of epipharyngeal and laryngo-pharyngeal structures. In 1940, Reid and Brace first described hemodynamic response to laryngoscopy and intubation. There are lot of clinical studies, techniques and drugs which have dealt with attenuation of this stress response.<sup>[1]</sup>

Tracheal extubation is a critical step during emergence from general anaesthesia. It is not simply a reversal of the process of intubation because conditions are often less favorable than at the start of anaesthesia. At extubation, there is a transition from a controlled to an uncontrolled situation. Anatomical and physiological changes, compounded by time pressures and other constraints, contribute to a situation that can be more challenging for the anaesthesiologist than tracheal intubation. Extubation can result in a significant number of problems with serious consequences, including hypoxic brain injury and death.<sup>[2]</sup>

Extubation and emergence from general anaesthesia is a stressful event which is a less addressed clinical entity. Problems associated with extubation, recovery, and emergences are more common than problems at intubation. Reports from the UK suggest that respiratory complications are common at extubation and during recovery. Death or brain injury was more common in claims associated with extubation and recovery than those occurring at the time of induction of anaesthesia. But tracheal extubation and emergence from anaesthesia have generated less interest than intubation.

The pressor response, which is part of a huge spectrum of stress response, results from increase in sympathetic and sympathoadrenal activity, as evidenced by increased plasma catecholamine concentrations in patients undergoing surgery under general anaesthesia.<sup>[3]</sup>

The period of emergence from general anaesthesia and tracheal extubation is a hyper dynamic state in which increased oxygen consumption, catecholamine secretion, tachycardia and hypertension is observed. Emergence pressor response usually lasts for approximately 5-30 min depending on surgical procedure, duration and patient's comorbidities. The peak rise in the pulse rate and blood pressure is usually transient, variable and unpredictable.

Usually these changes which are well tolerated by healthy individuals may be deleterious in patients with hypertension, coronary artery disease or intracranial hypertension.

Emergence from general anaesthesia entails set of adverse clinical events like hypoxia (e.g.atelectasis) ,upper airway obstruction (e.g., edema, residual anesthetic), vocal fold-related obstruction (e.g., vocal cord paralysis),tracheal obstruction(e.g.,subglottic edema), bronchospasm, aspiration, hypertension, increased intracranial pressure, increased pulmonary artery pressure, increased bronchial stump pressure (e.g., after pulmonary resection),increased ocular pressure, increased abdominal wall pressure (e.g., risk of wound dehiscence).<sup>[4]</sup>

Certain neurosurgical procedures like craniotomy for traumatic brain injury, intracranial mass excision, vascular malformation, aneurysmal surgeries, trans-sphenoidal pituitary surgery and ophthalmic surgeries like open globe injury repair demand stress free extubation and smooth emergence. Arterial hypertension should be avoided because it can contribute to intracranial bleeding and increased edema formation. In the face of a poorly auto regulating cerebral vasculature, hypertension results in elevation of ICP.<sup>[5]</sup>

Much of the concern with coughing and straining has a similar basis. The sudden increases in intrathoracic pressure as seen during coughing and straining results in transient increases in cerebral arterial and venous pressure causing elevation of intracranial pressure, bleeding, cerebral edema .

Extubation under deep anaesthesia decreases cardiovascular stimulation and reduces the incidence of coughing and straining on the tube. However, the incidence of respiratory complications has been found to be greater after extubation under deep anaesthesia, regardless of the type of operation. A small number of studies involving children show a greater incidence of upper airway complications with awake extubation as a result of increased airway reactivity.

Extubating an awake patient is usually associated with bucking (coughing on the tube). This causes sympathetic stimulation which also increases the heart rate, arterial blood pressure, central venous pressure, intracranial pressure and intraocular pressure leading to increased oxygen consumption hypoxia in extubated patient. Such responses are potentially hazardous in cases of increased intracranial pressure, intracranial vascular anomalies, open-globe injuries, ophthalmologic surgery, or in cases in which increased intra-abdominal pressure could lead to abdominal dehiscence. Therefore the prevention of postoperative sympathetic response is very critical for high risk patients in order to maintain haemodynamic stability and to reduce the post-operative morbidity.<sup>[6]</sup>

Different pharmacological approaches and techniques have been utilized in an attempt to attenuate these emergence haemodynamic stress response including fentanyl, clonidine, esmolol and lignocaine (xylocard). Search is still on to find out an ideal drug which attenuates all the hemodynamic alterations (neural, hormonal and immunological) in response to airway manipulation without delaying recovery and causing any adverse events (sedation, respiratory depression, hypotension etc).

Fentanyl is a phenylpiperidine derivative synthetic opioid agonist with a high affinity for  $\mu$  receptors. It has high lipid solubility and thus rapidly distributed in the tissues. A bolus

dose of intra-venous (IV) dose fentanyl given before extubation attenuates the cardiovascular changes associated with tracheal extubation and emergence without prolonging the recovery.

Alpha agonist like clonidine has been used extensively for attenuation of sympathoadrenal stimulation caused by tracheal intubation and surgery.<sup>[7]</sup>Dexmedetomidine is the new alpha-2 agonist having eight-times more affinity for alpha-2 adrenoreceptors as compared to clonidine, and is known to decrease the plasma catecholamine levels and also suppresses the release of catecholamine. Dexmedetomidine has sedative, analgesic, sympatholytic, and anxiolytic effects that blunt many of the cardiovascular responses in the perioperative period. It reduces the requirements for volatile anesthetics, sedatives and analgesics without causing significant respiratory depression.<sup>[8]</sup>

Though studies have shown the efficacy of individual drugs and compared with different drugs, there are few studies which have compared fentanyl, dexmedetomidine with control group for attenuation of stress response during extubation and emergence from general anaesthesia in an ideal anaesthetic condition, using depth of anaesthesia monitors (entropy) and neuromuscular monitors (TOF). There are only a few clinical studies which have assessed extubation quality, sedation score and recovery scores post-operatively in patients. This study compares the efficacy of these two drugs to control group in attenuation of stress response during emergence.

## **Subjects and Methods**

The Consolidated Standards of Reporting Trials (CONSORT) recommendations for reporting randomized, control clinical trials were followed. After obtaining hospital ethics committee approval, a prospective randomized controlled study was done to compare fentanyl, dexmedetomidine and placebo in attenuating of hemodynamic stress response during extubation and emergence from general anaesthesia; in 150 patients with 50 patients in each of 3 groups.

### **Inclusion Criteria**

Patients were randomly allotted to each of study group, based on a computer generated random number table using Microsoft excel. 150 patients with 50 in each group of ASA (American Society of Anaesthesiologists) physical status I & II patients aged between 18-55 years undergoing elective surgical procedures, lasting between 1 and ½ hour to 4 hour, under general anesthesia requiring endotracheal intubation were enrolled for study.

### **Exclusion criteria**

Patients with following condition were excluded from study. Pregnant women, patients with bronchial asthma, Chronic Obstructive Pulmonary Diseases (COPD), ischemic heart diseases, hypertension, chronic renal disease, and patient with deranged liver function, cirrhosis. Patients with difficult airway, obesity, psychiatric illness etc. Patients coming for Surgeries on neck, oral cavity were also excluded from the study.

**Pre-anaesthetic assessment:**

All the patients undergoing planned elective surgery were assessed as per the routine preoperative protocol. Preoperative investigations like hemoglobin and complete blood count, blood sugar level, blood urea, serum creatinine level, Serum electrolytes, electrocardiogram (age > 40 yrs) and Chest X-ray (in chronic smokers) were ordered depending on patient characteristics' and surgery planned

All the patients were randomized in to 3 groups of 50 each, named as

**Group A:** Receiving 0.9% normal saline.

**Group B:** Receiving IV fentanyl.

**Group C:** Receiving IV dexmedetomidine.

**Results**

**Table 1: Showing type of Surgical Procedure among the groups.**

Surgical Procedure	Group A (n=50)		Group B (n=50)		Group C (n=50)	
	No	%	No	%	No	%
1. ENT surgery	2	4.0	2	4.0	7	14.0
2. Plastic surgery	7	14.0	7	14.0	10	20.0
3. Orthopedic surgery	0	0.0	0	0.0	2	4.0
4. Surgical oncology	5	10.0	5	10.0	4	8.0
5. Surgical gastro-enterology	7	14.0	7	14.0	4	8.0
6. OBG	15	30.0	15	30.0	13	26.0
7. General surgery	5	10.0	5	10.0	5	10.0
8. Neurosurgery/spine surgery	7	14.0	7	14.0	4	8.0
9. Urology	2	4.0	2	4.0	1	2.0

**Rate Pressure Product**

**Within the group changes:**

In group A, baseline RPP was 9858.02±1425.82, which was increased to 14836.64±3165.20 at extubation representing a rise of 4978.62±1739.38 (> 50%). Maximum RPP value was recorded at 15573.20±2137.71 representing a rise of 5715.18 ± 398.33 (> 50 %). There was statistically significant rise in RPP from extubation to 25 minutes (p<0.03), then it gradually decreased to remain below baseline value at 120

min, where it was 10111.22±1285.34.

In group B baseline RPP was 10212.12±1509.32 at extubation it raised to 11069.24±2275.56 which was highest recorded and was statistically not significant. There was statistically significant decrease in RPP from 15 minutes to 90 minutes of observation.

In group C baseline RPP was 10510.74±2124.23 at extubation it was 9579.70±1813.31 which was highest calculated after induction which was statistically not significant (p>0.003). There was statistically significant decrease in RPP from 4 minutes to 120 minutes after extubation.

**Between the group changes:**

Baseline Rate Pressure Product (RPP) in group A was 9858.02±1425.82, in group B 10212.12±1509.32, and in group C it was 10510.74±2124.23. There was no statistically significant difference with respect baseline RPP among 3 groups studied (p=0.166). When groups A, B & C were compared, there was statistically significant changes in RPP throughout study period (p<0.050).

Between group A and group B there was statistically significant rise in RPP in group A from extubation till 90 minutes (p<0.003) of study period. At extubation increase in RPP in group A (control group) was significantly high (> 50 %) while in group B increase in RPP was just around 8%.

When group A is compared with group C, there was statistically significant increase in RPP in group A, while in group C there was statistically significant decrease in RPP. Changes in RPP between group A & group C was statistically significant from extubation (p=0.000) till the end of study (120 min p=0.000). Rise in RPP which was the product of HR & SBP was better controlled in group C (Dexmedetomidine) than group A (control group).

Statistically significant difference in RPP was noticed between group B & group C at various points from extubation to 60 minutes of study period (p < 0.05), except at 10 min, where there was no statistically significant difference (p=0.781). Among two groups rise in RPP was better controlled in group C (Dexmedetomidine) than group B (fentanyl group).

**Table 2: Comparison of Rate Pressure Product (RPP) RPP=HR × SBP of three groups studied**

	Group A	Group B	Group C	Over all P value	Pair wise significance		
					A-B	A-C	B-C
Pre-induction	9858.02±1425.82	10212.12±1509.32	10510.74±2124.23	0.166	0.558	0.141	0.660
Reversal	11718.78±1729.39*	9623.54±2290.22	8721.00±1648.62*	<0.001	0.000	0.000	0.051
Extubation	14836.64±3165.20*	11069.24±2275.56	9579.70±1813.31	<0.001	0.000	0.000	0.009
2 min	15384.14±2562.96*	10886.40±2112.30	9310.48±1544.33	<0.001	0.000	0.000	0.001
4 min	15573.20±2137.71*	10643.80±1876.74	8966.96±1420.84*	<0.001	0.000	0.000	0.000
6 min	15161.52±1843.17*	10071.14±1641.62	8655.64±1308.83*	<0.001	0.000	0.000	0.000
8 min	13983.76±2571.26*	9857.46±1622.38	8242.28±1098.90*	<0.001	0.000	0.000	0.000
10 min	13548.50±2067.95*	9568.44±1491.88	8227.26±1032.16*	<0.001	0.005	0.000	0.781
15 min	12803.06±1987.46*	9345.82±1815.05*	7603.22±859.46*	<0.001	0.000	0.000	0.000
20 min	11896.84±1806.62*	9099.62±1606.88*	7572.32±884.03*	<0.001	0.000	0.000	0.000
25 min	11223.48±1573.32*	9081.78±1581.31*	7821.44±994.50*	<0.001	0.000	0.000	0.000
30 min	10366.68±1268.96	9176.66±1479.40*	8168.56±1001.63*	<0.001	0.000	0.000	0.000
60 min	10109.62±1186.91	9442.64±1515.43*	8469.10±986.42*	<0.001	0.023	0.000	0.000
90 min	9801.50±1289.29	9395.46±1503.61*	8817.92±912.95*	0.001	0.244	0.000	0.060
120 min	10111.22±1285.34	9402.14±1596.52	8973.70±1020.00*	<0.001	0.022	0.000	0.240

P < 0.05 is statistically significant for between the groups analysis, pair wise significance is shown in blue colour.

\* P < 0.003 after Bonferroni's correction for within the group analysis.

To summarize changes in RPP, there was statistically significant difference at various points (p< 0.05) between

groups studied. In Group A there was significant rise in RPP while in group C there was significant fall in the RPP. Changes in RPP value was adequately controlled in group C (dexmedetomidine group) followed by group B (fentanyl group). While in group A (control group) RPP was significantly high.

**Comparison of Ramsay Sedation score**

**Table 3: Comparison of Ramsay Sedation score (Total score 6) of three groups studied**

Ramsay Sedation score	Group A	Group B	Group C	Over all P value	Pair wise significance		
					A-B	A-C	B-C
15 min	1.64±0.56	2.36±0.53	2.62±0.73	<0.001	0.000	0.000	0.088
20 min	1.80±0.40	2.22±0.42	2.34±0.56	<0.001	0.000	0.000	0.403
25 min	1.92±0.27	2.08±0.34	2.16±0.42	0.003	0.062	0.002	0.491
30 min	2.00±0.00	2.04±0.20	2.04±0.20	0.363	0.433	0.433	1.000
60 min	1.96±0.20	2.02±0.14	2.00±0.00	0.097+	0.086	0.331	0.757
90 min	1.92±0.27	1.98±0.25	2.00±0.00	0.151	0.339	0.148	0.886
120 min	1.76±0.43	1.94±0.31	1.98±0.14	0.002	0.015	0.002	0.805

In group C, sedation score at 15 min was 2.62±0.73, in group A it was 1.64±0.56. There was statistically significant difference between group A & group C at 15, 20, 25 and at 120 minutes following extubation (p<0.050). At remaining interval sedation score were similar.

Sedation score were similar at various points of observation between group B and group C. There was no statistical significance difference between group B & C (p>0.050).

To summarize there was statistically significant difference (p<0.050) among the groups studied with respect to Ramsay sedation score at 15, 20, 25 and at 120 minutes after extubation. Higher the score value means more was the sedation. Sedation score was higher in group C & group B in comparison to group A. In other words patients in group C and group B were relatively more sedated than group A (Control group). Patients in group A were slightly anxious and agitated towards the end of study (120 min) than group B & C, who were quite and calm. But clinically there was no significant difference among the groups and no group required any active clinical intervention apart from routine monitoring.

**Aldrete's Recovery Score**

There are 7 parameters to be assessed while assigning the score. Points 0, 1, 2 were given against these parameters. Total score was 14. Patients were assessed against all the seven parameters at 15, 20, 25, 30, 60, 90,120 minutes following extubation.

Recovery score at 15 min following extubation in group A, B, C were 13.28±0.50, 13.78±0.46, 13.78±0.42 respectively. There was statistically significant difference in recovery score among the groups (p<0.001) at 15, 20, 25 minutes of study period. But clinically recovery score were nearly similar in all 3 groups.

**Table 4: Comparison of Aldrete's Recovery Score (Total 14) of three groups studied.**

Recovery Score (Total 14)	Group A	Group B	Group C	P value
15 min	13.28±0.50	13.78±0.46	13.78±0.42	<0.001
20 min	13.34±0.56	13.84±0.37	13.90±0.30	<0.001
25 min	13.64±0.60	13.94±0.24	13.92±0.27	<0.001
30 min	13.90±0.30	13.96±0.20	13.96±0.20	0.350
60 min	13.92±0.27	13.96±0.20	13.98±0.14	0.355

**Between the groups' changes:**

Sedation score at 15 min in group A was 1.64±0.56, in group B sedation score was 2.36±0.53. Among group A & B, there was statistically significant difference at 15, 20 and at 120 minutes following extubation (p<0.050). At remaining interval of observation there was no statistically significant difference (p>0.050).

90 min	13.90±0.30	13.90±0.30	13.94±0.24	0.718
120 min	13.76±0.48	13.86±0.35	13.92±0.27	0.103

**Use of post-operative analgesics**

Patients with extensive surgeries and relatively longer duration of surgery had post-operative pain near the end of observation (120 min). We have used analgesics like fortwin, diclofenac sodium, fentanyl and sometimes pethidine to treat moderate to severe post-operative pain.

**Table 5: Table showing use of post-operative analgesics in three groups.**

Use of post-operative Analgesics (i.v)	Group A		Group B		Group C	
	No (n=50)	%	No (n=50)	%	No (n=50)	%
No	36	72.0	44	88.0	43	86.0
Yes	14	28.0	6	12.0	7	14.0
Fortwin	9	18.0	3	6.0	7	14.0
Pethidine	0	0.0	1	2.0	0	0.0
Fentanyl	4	8.0	1	2.0	0	0.0
Diclofenac sodium	1	2.0	1	2.0	0	0.0

Patients in group A had moderate to severe pain and required analgesics, 6 (12%) patients in group B required analgesics while in group C 7(14%) patients studied required analgesics. There was no statistical significance among the groups A, B and C with respect to use of post-operative analgesics (P=0.076).

**Discussion**

In our study, we used entropy and TOF monitors to have ideal anaesthetic depth and muscle relaxation intra-operatively and at the time of extubation. By use of these monitors, adequate drug doses were used and we were able to objectively measure the patient recovery from anaesthesia. Clinical errors which could influence the outcome of our study were minimized.

Entropy values intra-operatively in groups A, B and C were maintained between 40-60. There was a statistically significant difference among the groups at extubation (p<0.050). But it was of no clinical significance as all



patients woke up similarly in all 3 groups and no clinical intervention was required. TOF Ratio was similar in all three groups intra-operatively and at the time of reversal and extubation.

To assess and compare the quality of extubation among the study groups, we have used 5-point extubation quality scale. Quality of extubation bears direct relation to haemodynamic changes during emergence. Quality of extubation was said to be good if there was no coughing, bucking or any complication. Scale 1 signifies smooth extubation while scale 5 signifies poor quality of extubation.

In our study there was statistically ( $p < 0.001$ ) and clinically significant difference among the groups A, B, C groups with respect to extubation quality scale. 54% & 16% of patients in dexmedetomidine group and fentanyl group were extubated with extubation quality scale of 1, while no patient in normal saline group were extubated with scale of 1. Dexmedetomidine group had smoother extubation quality than fentanyl group. Extubation quality in control group was relatively poor compared to other groups and one patient in control group (Normal saline), who underwent tympano-mastoidoplasty had laryngospasm following extubation.

In our study we found that there was statistically significant difference ( $p < 0.050$ ) among the groups A, B & C with respect to Ramsay sedation score at 15, 20, 25 and at 120 minutes after extubation. Patients in dexmedetomidine group (C) and Fentanyl group (B) were little more sedated than group A (Control group). Patients in group A were slightly anxious and agitated towards the end of study (120 min) than group B & C (patients were calm). Despite statistical difference, clinically there was no significant difference among the groups and no group required any active clinical intervention for excessive sedation apart from routine monitoring.

To assess the effect of study drug on post-operative recovery, we used Aldrete's recovery score. In our study there was a statistically significant difference ( $p < 0.001$ ) in recovery score, following extubation among the 3 groups at 15, 20, 25 minutes after extubation. However after first half an hour following extubation, clinically recovery score were nearly similar in all 3 groups. All the patients irrespective of their group had a good recovery and discharged from post anaesthesia care unit uneventfully.

Our study results co-relates well with the findings of studies by Nishina et al,<sup>[9]</sup> RecepAksu et al,<sup>[10]</sup> Wang BS et al,<sup>[11]</sup> G. Turan et al,<sup>[12]</sup> BarkhaBindu et al and D. Jain et al.<sup>[13,14]</sup> Patients in dexmedetomidine group were haemodynamically stable; extubation quality was good; there was no delay in

recovery in comparison to normal saline group.

## Conclusion

Sedation score and recovery profile are comparable among the groups.

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