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

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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±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). 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. 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.

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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.[1] 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.[2]

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 anesthesia.[3] 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 co-morbidities. 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).\[^{[4]}\]

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.\[^{[5]}\]

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.

Exubation 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.

Exubating 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.\[^{[6]}\]

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.\[^{[7]}\]

Dexmedetomidine is the new alpha-2 agonist having eight-times more affinity for alpha-2 adrenoceptors 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.\[^{[8]}\]

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 \(\frac{1}{2}\) 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**

| Surgical Procedure | Group A | Group B | Group C |
|--------------------|---------|---------|---------|
| (n=50)             | B-C     | A-B     |
| ENT surgery        |         |         |
| 2.40               | 2.40    | 2.14    |
| Plastic surgery    | 14.0    | 14.0    | 12.0    |
| 10.00              | 0.00    | 0.00    | 2.40    |
| Orthopedic surgery | 10.00   | 5.00    | 4.00    |
| Surgical oncology  | 14.0    | 14.0    | 4.00    |
| 10.00              | 1.00    | 5.00    | 4.00    |
| Surgical gastro-enterologist | | | |
| 14.00              | 1.00    | 1.00    | 2.40    |
| General surgery    | 14.0    | 14.0    |
| 1.00               | 1.00    | 1.00    |
| Neurosurgery/spine surgery | | | |
| 14.00              | 1.00    | 1.00    |
| Urology            | 5.00    | 5.00    |
| 5.00               | 5.00    | 5.00    |

**Rate Pressure Product**

Within the group changes:
In group A, baseline RPP was 9858.02±1425.82, which was increased to 14836.6±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 increase 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%.

Between group A & group C there was statistically significant increase in RPP in group A, while in group B there was statistically significant decrease in RPP. Changes in RPP between group A & group C was statistically significant form 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 1: Showing type of Surgical Procedure among the groups.**

| Surgical Procedure | Group A | Group B | Group C |
|--------------------|---------|---------|---------|
| (n=50)             | B-C     | A-B     |         |
| ENT surgery        |         |         |
| Plastic surgery    | 14.0    | 12.0    |
| Orthopedic surgery | 10.00   | 5.00    |
| Surgical oncology  | 14.0    | 4.00    |
| Gastro-enterologist | 1.00    | 1.00    |
| General surgery    | 1.00    | 1.00    |
| Neurosurgery/spine surgery | | | |
| Urology            | 5.00    | 5.00    |

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

| Group | Over all P value | Pair wise significance |
|-------|------------------|-----------------------|
| Group A | 0.166           | 0.558                 |
| Group B | 0.001           | 0.000                 |
| Group C | 0.000           | 0.000                 |

**Pre-induction**

9858.02±1425.82

**Reversal**

11718.78±1729.39*

**Extubation**

14836.6±3165.20*

**2 min**

15384.1±2562.96* 8

**4 min**

15573.2±2137.71* 1

**6 min**

15161.5±2137.81* 1

**8 min**

13983.76±2571.26* 1

**10 min**

12803.06±1987.46* 1

**15 min**

11896.8±1806.62* 1

**25 min**

11223.48±1573.32* 1

**30 min**

10366.6±1268.96 1

**60 min**

10109.62±1186.91 1

**90 min**

9801.30±1289.29 1

**120 min**

9101.12±1285.34 1

**P <0.05 is statistically significant for between the groups.**

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**

| Time (min) | Ramsay Sedation score | Group A | Group B | Group C | Over all P value | A-B | A-C | B-C |
|-----------|-----------------------|--------|--------|--------|------------------|-----|-----|-----|
| 15        | 1.64±0.56             | 2.22±0.42 | 2.34±0.56 | <0.001 | 0.000 | 0.000 | 0.088 |
| 20        | 1.80±0.40             | 2.22±0.42 | 2.34±0.56 | <0.001 | 0.000 | 0.000 | 0.403 |
| 25        | 1.92±0.27             | 2.08±0.34 | 2.16±0.42 | 0.003  | 0.062 | 0.002 | 0.491 |
| 30        | 2.00±0.00             | 2.04±0.20 | 2.04±0.20 | 0.363  | 0.433 | 0.433 | 1.000 |
| 60        | 1.96±0.20             | 2.02±0.14 | 2.00±0.00 | 0.097+ | 0.086 | 0.331 | 0.757 |
| 90        | 1.92±0.27             | 1.98±0.25 | 2.00±0.00 | 0.151  | 0.339 | 0.146 | 0.886 |
| 120       | 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.

**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.

**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 tympanomastoidoplasty 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.[9] RecepAksu et al.[10] Wang BS et al.[11] G. Turan et al.[12] BarkhaBindu et al and D. Jain et al.[13,14] 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.

References

1. Asai T, Koga K, Vaughan RS. Respiratory complications associated with tracheal intubation and extubation.British Journal of Anaesthesia 1998; 80: 767–75.
2. Abdy S. An audit of airway problems in the recovery room. Anaesthesia 1999; 54: 372–5.
3. Peskett MJ. Clinical indicators and other complications in the recovery room or postanaesthetic care unit.Anaesthesia1999;54: 1143–9.3.
4. Rose DK, Cohen MM, Wigglesworth DF, DeBoer DP. Critical respiratory events in the postanaesthesia care unit. Patient,surgical, and anesthetic factors. Anesthesiology 1994;81: 410–8.4
5. Mhyre JM, Riesner MN, Polley LS, Naughton NN. A series of anesthesia-related maternal deaths in Michigan, 1985-2003. Anesthesiology 2007;106: 1096–104.5
6. Auroy Y, Benhamou D, Péquignot F, Bovet M, Jouglé E, Lienhart A. Mortality related to anaesthesia in France: analysis of deathsrelated to airflow complications. Anaesthesia2009;64: 366–70.
7. Lewis G. The Confidential Enquiry into Maternal and Child Health (CEMACH). Saving Mothers’ Lives: Reviewing Maternal Deaths to make Motherhood Safer—2003–2005. The Seventh Report on Confidential Enquiries into Maternal Deaths in the United Kingdom.London: CEMACH, 2007.7.
8. Asai T, Koga K, Vaughan RS. Respiratory complications associated with tracheal intubation and extubation. British Journal of Anaesthesia 1998; 80: 767–75.
9. Nishina K, Mikawa K, Maekawa N, Obara H. Fentanyl attenuates cardiovascular responses to tracheal extubation. Acta Anaesthesiol Scand 1995 ; 39: 85-89.
10. RecepAksu, Aynur Akin, CihangirBiçer, AliyeEsmaoğlu, ZeynepTosun, AdemBoyaci. Comparison of the effects of dexmedetomidine versus fentanyl on airway reflexes and hemodynamic responses to tracheal extubation during rhinoplasty: A double-blind, randomized, controlled study. Current Therapeutic Research - June 2009 (Vol. 70, Issue 3, Pages 209-220.
11. Wang BS, Yu JB, Wang F, Zhang L, Zhang Y, Li SQ, ZhonghuaEri Bi Yan HouTou Jing Wai KeZaZhi. “Effect of dexmedetomidine on stress responses during extubation in patients undergoing uvulopalatopharyngoplasty”. 2012 Jun; 47(6):498-501.
12. Turan G, Ozgulerkin A, Turan C, Dincer E, Yuksel G. Advantageous effects of dexmedetomidine on haemodynamic and recovery responses during extubation for intracranial surgery. Eur J Anaesthesiol 2008;25:816-20.
13. Bindu B, Pasupuleti S, Gowd UP, Gorre V, Murthy RR, Laxmi M B. A double blind, randomized, controlled trial to study the effect of dexmedetomidine on hemodynamic and recovery responses during tracheal extubation. J AnaesthesiolClinPharmacol 2013;29:162-7
14. D. Jain, R. Khan, M. Maroof: Effect Of Dexmedetomidine On Stress Response To Extubation. The Internet Journal of Anesthesiology. 2009 Volume 21 Number 1

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