

The Feasibility of Endotracheal Intubation with Subcutaneous Dissociative Conscious Sedation versus General Anesthesia: A Prospective Randomized Trial

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ABSTRACT

Despite outstanding improvements in anesthesia techniques and anesthetics, difficult airway is still a dilemma and is accompanied by morbidity and mortality. The aim of this study is to compare the feasibility of endotracheal intubation with the traditional method of general anesthesia by using muscle relaxants, and “sDCS” (Subcutaneous Dissociative Conscious Sedation) which has been recently reported as an efficient method of anesthesia with the capability of maintaining spontaneous ventilation and providing an appropriate situation for laryngoscopy and endotracheal intubation. **Material and Methods:** This randomized clinical trial was conducted on 100 patients who were scheduled for elective laparotomy. Patients were randomly divided into two groups: group A and group B. In group A, patients underwent general anesthesia with thiopental sodium and relaxant. In group B, patients underwent “subcutaneous Dissociative Conscious Sedation” and received low dose subcutaneous ketamine and intravenous narcotic with no relaxant. The feasibility of direct laryngoscopy and tracheal intubation, hemodynamic changes, desaturation ($SpO_2 < 90\%$), patient cooperation, patient comfort, hallucination, nausea and vomiting, nystagmus and salivation were evaluated in two groups. Adverse events including apnea and need for positive pressure mask ventilation, additional dose of fentanyl were recorded in group B. The anesthesiologist who performed the procedure was asked about the patient calmness and cooperation during the procedure and the feasibility of laryngoscopy and tracheal intubation. The incidence of nausea and vomiting in post-operative care unit was recorded too. **Results:** Hemodynamic variables were comparable in two groups. No event of irreversible respiratory depression, desaturation, need for positive pressure ventilation and hallucination was observed in group B. All patients were cooperative and obedient during the laryngoscopy and tracheal intubation. The incidence of nausea was not statistically significant. The anesthesiologist was satisfied by the quality of patient’s cooperation for laryngoscopy in both groups. **Conclusion:** Subcutaneous dissociative conscious sedation is comparable with general anesthesia to provide desirable situation for laryngoscopy and tracheal intubation.

KEYWORDS

Difficult Airway; Ketamine; Laryngoscopy; Subcutaneous Dissociative Conscious Sedation; Tracheal Intubation

1. Introduction

Laryngoscopy and tracheal intubation are evaluated as painful procedures and in the presence of inadequate anesthesia result in sympathetic overactivity and considerable increase in heart rate and blood pressure [1,2].

General anesthesia using intravenous anesthetics with or without neuromuscular blocking agents is commonly used to facilitate laryngoscopy and tracheal intubation and reducing sympathetic overactivity [2]. Induction doses of most hypnotics and intravenous anesthetics are accompanied by a period of respiratory depression, and in the case of difficult airway, the necessity to maintain

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spontaneous ventilation restricts using intravenous anesthetics and neuromuscular blocking agents [2-4]. Airway regional blocks as a simple and acceptable method for awake tracheal intubation provide appropriate situation for maintaining spontaneous ventilation and patient cooperation during the procedure [5].

Despite the advantages mentioned above, unfavorable effects such as bleeding, nerve damage, intravenous injection of local anesthetic, elimination of highly effective airway protective reflexes and the absence of enough access to anatomical landmarks and neck and upper airway pathologies such as obesity, tumors and burns encourage anesthesiologists to find safe alternatives to general anesthesia and airway regional blocks [5-7]. Different methods have been recommended to provide adequate sedation and desirable situation for awake endotracheal intubation and respiratory depression is a common concerning complication of these experienced methods [8-16]. The variety of these experienced methods indicates the importance of respiratory depression in patients with predicted difficult airway and the necessity of substitution of an alternative respiratory preserving method of anesthesia instead of traditional methods.

Subcutaneous dissociative conscious sedation/anesthesia which is defined as “using subcutaneous injection of sub anesthetic doses of ketamine in conjunction with intravenous narcotics” is a recently introduced alternative method of respiratory preserving characteristic [17-20].

The aim of this study is to compare general anesthesia and subcutaneous dissociative conscious sedation and evaluation of the adequacy of “sDCS” for laryngoscopy and tracheal intubation as an alternative to general anesthesia in compromised airway.

2. Material and Methods

Our prospective study enrolled 100 patients ASA class I, who were scheduled for elective laparotomy. Patients were randomly assigned into two groups of 50 patients. The study was approved by ethics committee of Tehran University of Medical Sciences. An informed written consent was obtained from the patients.

Exclusion criteria included predicted difficult intubation, history of coronary artery disease, psychological disorders, increased ICP and history of drug abuse.

Direct laryngoscopy and tracheal intubation performed by the same anesthesiologist for all patients by a Macintosh Laryngoscope. Heart rate and blood pressure was recorded before laryngoscopy and on the second and fifth minutes after laryngoscopy.

Noninvasive monitoring including noninvasive blood pressure, pulse oximetry, heart rate and 3 leads ECG was established before anesthesia. Vital signs were recorded in 5 minutes intervals throughout the anesthesia.

The nurse who recorded all data was not informed about the methods of anesthesia in both groups and blinding was applied in collecting the data, also the patient was not informed exactly which method of anesthesia would be employed for him and he had ethical consent about either of each methods defined for him.

Patients were randomly assigned into two groups: A and B. Allocation was done by using block randomization.

Patients were pre oxygenated in both groups.

Technique of anesthesia

In group A patients received 2 µg/kg fentanyl and 0.1 mg/kg morphine sulfate as premedication. General anesthesia was induced by 5 mg/kg Na-thiopental and 0.6 mg/kg atracurium. Laryngoscopy and tracheal intubation was performed after 3 minutes.

In group B “Dissociative Conscious Sedation” was induced by 2 µg/kg fentanyl and 0.1 mg/kg morphine sulfate intravenously and 0.6 mg/kg ketamine subcutaneously. Tongue and pharynx were anesthetized topically by 1 - 2 ml lidocaine spray (4%). Spontaneous ventilation was supplemented by O₂ through face mask. 10 minutes after subcutaneous injection of ketamine and achieving a desirable level of conscious sedation, patients were asked to open their mouth, then laryngoscopy and intubation was performed.

The desirable level of conscious sedation is defined as “an arouseable patient with proper response to verbal commands”.

Additional dose of 50 - 100 µg fentanyl was administered if the patient was not cooperative enough for first try tracheal intubation.

Increased systolic blood pressure more than 20% and/or exceeded 170 mmHg, was controlled by incremental doses of TNG 50 µg IV until the systolic blood pressure reached 140 mmHg.

Patients in two groups were evaluated for the feasibility of direct laryngoscopy and tracheal intubation, hemodynamic changes, desaturation (SpO₂ < 90%), patient cooperation, patient comfort, nausea and vomiting, hallucination, nystagmus and salivation (need for aspiration before laryngoscopy).

Adverse events including apnea, need for positive pressure mask ventilation, additional dose of fentanyl, nystagmus and hallucination were recorded in group B.

The anesthesiologist who performed the procedure was asked about the patients’ calmness and cooperation during the procedure and feasibility of laryngoscopy and intubation.

The incidence of nausea and vomiting in post-operative cares unit was recorded too.

The day after the surgery when the patients were fully awake and in stable condition they were asked about re-

calling the events during laryngoscopy and intubation.

Statistical analysis

The sample size was estimated using $\alpha = 0.05$ and power = 0.80. Data analysis was performed using SPSS Version 16. *P* value less than 0.05 was considered significant. T test and chi square test were used for quantitative and qualitative data analysis respectively.

3. Results

Demographic data were similar in two groups. The mean age of the patients was 28.23 ± 6.05 in group A and 26.32 ± 8.43 in group B (Table 1). All the patients were intubated successfully in both groups.

Hemodynamic variables (heart rate and blood pressure) were comparable in two groups (Table 2).

There was no event of irreversible respiratory depression, desaturation, need for positive pressure ventilation and hallucination in group B. All the patients were cooperative and obedient during the laryngoscopy in this group. Mild nystagmus was detected in 5 patients in group B. Reversible apnea was detected in 4 patients in group B which was reversed by asking the patients to breathe. In group B one patient needed additional dose of fentanyl and laryngoscopy was performed on the second attempt. The incidence of nausea and vomiting were similar in two groups (Table 2). There was no incidence of

recall about the events of laryngoscopy and intubation in group B. The operator was satisfied by the quality of patient’s preparation for laryngoscopy in both groups (Table 2).

Mild nystagmus was detected in 5 patients in group B. That was improved completely in recovery room.

Increase in heart rate more than 20% from the base line was recorded during the intubation in 3 patients in group A and 5 patients in group B that was not statistically significant.

Increase in blood pressure more than 20% from the base line was recorded during the intubation in 2 patients in group A and 3 patients in group B, which was not statistically significant.

The incidence of nausea was 3 in group A and 5 in group B that was not statistically significant.

The incidence of vomiting was 2 in group A and 4 in group B that was not statistically significant.

There was no report of recall about the events of laryngoscopy and intubation in group B. The operator anesthesiologist was satisfied by the quality of patient’s preparation for laryngoscopy in both group, but he mentioned that muscle relaxation facilitated the procedure in group A significantly better in all cases.

4. Discussion

Laryngoscopy and tracheal intubation are evaluated as painful procedures and in the presence of inadequate anesthesia result in sympathetic overactivity and considerable increase in heart rate and blood pressure [1,2]. General anesthesia using intravenous anesthetics with or without neuromuscular blocking agents is commonly used to facilitate laryngoscopy and tracheal intubation and reducing sympathetic over activity [2]. Induction doses of most hypnotics and intravenous anesthetics are accompanied by a period of respiratory depression and in the case of difficult airway the necessity to maintain spontaneous ventilation restricts using intravenous anesthetics and neuromuscular blocking agents [2-4]. Airway regional blocks as simple and accepted methods for awake tracheal intubation provide appropriate situation for maintaining spontaneous ventilation and patient cooperation during the procedure [5]. Despite the advantages mentioned above unfavorable effects such as bleeding, nerve damage, intravenous injection of local anesthetic, elimination of highly effective airway protective reflexes and the absence of enough access to anatomical landmarks and neck and upper airway pathologies such as obesity, tumors and burns encourage anesthesiologists to design safe alternatives to general anesthesia and airway regional blocks [5-7].

Different methods have been recommended to provide adequate sedation and desirable situation for awake en-

Table 1. The incidence of recorded parameters with difference in both groups.

variables	Group A	Group B	p-value
Mean age	28.23 ± 6.05	26.32 ± 8.43	0.2
Male/Female	21/29	26/24	0.7

* p < 0.05: significant.

Table 2. The incidence of recorded parameters with difference in both groups.

Variables	Group A %	Group B %	p-value
Mild Nystagmus*	0	10	0.09
Irreversible apnea	100	0	0.001
Reversible apnea*	0	8	0.008
Patient’s cooperation	0	100	0.001
Increased HR > 20%	6	10	0.5
Increased BP > 20%	4	6	0.3
Nausea	6	10	0.5
Vomiting	4	8	0.3

* p < 0.05: significant. *Mild nystagmus in these patients was completely improved till post-operative period and induced no visual disturbance. *All patients in group B breathe on command when they were asked to breathe.

dotracheal intubation and respiratory depression is a common concerning complication of these experienced methods [8-16].

Subcutaneous dissociative conscious sedation which is defined as “using subcutaneous injection of sub anesthetic doses of ketamine in conjunction with intravenous narcotics” [17-20] is a recently introduced method of conscious sedation [17-20]. It should be in mind that topical anesthesia of larynx with lidocaine spray is an inseparable component of sDCS while using in airway manipulation.

Ketamine an antagonist of N-methyl-D-aspartate glutamate receptor is the unique hypnotic agent with simultaneous properties of analgesia, amnesia and hypnosis [22]. This agent can be used by different routes of administration such as intravenous, oral, rectal and subcutaneous [21]. Preserving airway protective reflexes while maintaining spontaneous ventilation is a unique characteristic of subcutaneous administration of ketamine [21,22]. Our study showed preserved airway protective reflexes in all patients who underwent sDCS. Recent studies have shown the considerable effect of sub anesthetic doses of ketamine to enhance the analgesic properties of narcotics in control of both acute and chronic pain [23-28]. Major side effects of ketamine are psychomimetic effects, increased salivation and excitatory cardiovascular effects. Low plasma level of this anesthetic agent (<150 ng/ml) achieved by rectal and subcutaneous administration subsides the adverse effects of the drug and provides desirable level of analgesia and amnesia [18,21]. Combination of ketamine with narcotics (sDCS) enhances the pain relieving effect of narcotics considerably. Stimulant effect of ketamine on respiration, especially in the presence of increased end tidal P_{CO_2} [29,30] are behind the low rate of narcotic related respiratory depression. Outstanding analgesia and amnesia along with low rate and reversible characteristic of respiratory depression with sDCS provide desirable situation acquired during awake laryngoscopy and tracheal intubation.

According to our previous reports of DCS using low dose ketamine in combination to narcotics is a safe alternative to general anesthesia in patients with poor physical condition [17] and is comparable or even superior to airway regional blocks in compromised airway [18-20].

This study showed the capability of subcutaneous dissociative conscious sedation in providing desirable situation for laryngoscopy and tracheal intubation.

5. Conclusion

Subcutaneous dissociative conscious sedation is comparable with general anesthesia to provide desirable situation for laryngoscopy and tracheal intubation.

Contributions

MJJ designed and conducted the study. Editing of the manuscript and final approval was carried out by MJJ. S.SH carried out data collection and manuscript writing. JZ carried out statistical measurement and data analysis. All authors read and approved the final manuscript.

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