ORIGINAL ARTICLE

Conditions of endotracheal intubation with and without muscle relaxant in children

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ABSTRACT

Aim To compare intubation conditions and hemodynamic response of two induction regimens, with or without muscle relaxant using a combination of either fentanyl and propofol or propofol and suxamethonium.

Methods A total of 80 children aged 4-12 years were enrolled in a prospective randomized double-blinded study. Children were randomly allocated in two equal groups. In group F induction was done with fentanyl and propofol, while propofol and suxamethonium were used in group S. Intubation conditions were assessed using Copenhagen Consensus Score (CCS), based on ease of laryngoscopy, position of vocal cords, degree of coughing, jaw relaxation and limb movements. Systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP) and heart rate (HR) were observed at preinduction, postinduction and postintubation at 1, 3 and 5 minute.

Results Clinically acceptable CCS was found in 95% of patients in group F versus 100% in group S. Intubation conditions were excellent in 85%, good in 10% and poor in 5% of patients in group F. In the group F, signifficantly lower SBP and MAP postinduction and postintubation at 1 and 3 minute, and lower DBP postinduction and postintubation at 1 minute ($p<0.05$) was found comparing to group S. In group S, significantly higher postinduction and postintubation HR at 1 minute was found comparing to group F ($p<0.05$).

Conclusion Induction combination fentanyl-propofol provide acceptable intubation conditions comparable with suxamethonium in children. This induction regimen ensures better hemodynamic stability associated with endotracheal intubation. It could be recommended for intubation when muscle relaxants are not indicated.

Key words: pediatric anesthesia, fentanyl, propofol, neuromuscular block, suxamethonium

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INTRODUCTION

Endotracheal intubation (ETI) is the best way to ensure secure patient's airway and to maintain control of adequate respiration during general anesthesia. In pediatric patients, a safe and gentle intubation is crucial. Children have a faster respiratory frequency, decreased FRC and decreased compliance. The oxygen consumption is higher, but respiratory reserve is low in children. All those factors may increase the risk of hemoglobin desaturation during short periods of apnea (1).

Neuromuscular blocking agents (NMBD), depolarizing or non-depolarizing were introduced in clinical practice to facilitate laryngoscopy and ETI in 1942. Depolarizing muscle relaxants act as acetylcholyne receptor agonists, whereas non depolarizing muscle relaxants function as competitive antagonists (2). The NMBD require special attention in pediatric anesthesia because their effects in children may differ from those in adults. Average doses of NMBD in children are used on mg/kg, but it is important to know that children have more extrajunctional receptors in skeletal muscles so they are more prone to risk of prolonged neuromuscular blockade (3).

Suxamethonium has been preferred agent for ETI for many years. Its advantages include faster onset of reliable muscle relaxation (30-40“) and spontaneous and short reversal duration of action, typically less than 10 minutes (4). A recommended dose is 1 mg/kg. However, suxamethonium has potential and harmful side-effects such as malignant hyperthermia, hyperkalemia, bradycardia, cardiac arrest, increased intraocular and intracranial pressures, rhabdomyolysis and masseter muscle spasm (5). In patients with low cholinesterase activity or genetically aberrant enzyme, it can induce prolonged paralysis (6). It is contraindicated in burns and caution should be used in patients with neuromuscular disorders (7). There is a risk of anaphylaxis too (8). The clinicians were motivated to find an alternative to suxamethonium in pediatric anesthesia because of its side effects. At the same time, several changes have occurred that have reduced or avoided long acting muscle relaxant for short surgical procedures (9). The most common indications for not using NMBD in children include the risk for malignant hyperthermia and postoperative nausea and vomiting, brief radiologic or painful procedures when rapid recovery is needed (MRI, bone marrow aspiration, gastrointestinal endoscopy), frequent repeated anesthesia, neurosurgical procedures to assist with control of intracranial pressure and for cerebral metabolic protection, surgical intervention in which muscle relaxation is not necessary (10). Rajan et al. recommended ETI without muscle relaxants in children undergoing cleft surgery and keeping them spontaneously breathing while securing the airway (11).

A combination of induction of hypnotic agent and some of the opioid agents such as fentanyl, alfentanil or sufentanil without the use of muscle relaxant, was recommended by many investigators for safe and successful ETI (12,13). Pharmacokinetics and pharmacodynamics of fentanyl have shown to blunt pressor response to laryngoscopy and intubation 5-7 min after administration (14). Fentanyl may be a suitable agent for ETI (15). Propofol as an induction agent has shown better intubation conditions than thiopental at the first point, better jaw relaxation and attenuation of laryngeal reflex (16). All previous studies recorded very different results depending on the protocol used (various drugs for premedication, different opioid agents, the combinations of different doses of propofol and opioids, different chronology of application of intravenous agents), and consequently the best study design and investigators consensus have not been found yet.

In this study, we hypothesized that the combination of propofol 3mg/kg and fentanyl 3 μg/kg can be a useful alternative to suxamethonium and provide good conditions for ETI in children. The aim of this study was to compare intubation conditions with suxamethonium as muscle relaxant that achieves optimal ETI versus induction of anesthesia with fentanyl and propofol, as well as to compare hemodynamic response of ETI with suxamethonium versus fentanyl and propofol.

PATIENTS AND METHODS

Patients and study design

This prospective randomized, double-blind clinical study was carried out in the Department of Anesthesiology and Intensive Care Unit at the Cantonal Hospital in Zenica. The study took place over the period of three months, between February and May 2016. The study protocol was

approved by the Ethics Committee of the Cantonal Hospital in Zenica. After obtaining written informed consent of the patients' parents, 80 children were enrolled in the study. All children underwent ETI for various routine elective surgical procedures in the supine position.

Inclusion criteria were children aged 4-12 years without predictive signs of difficult intubation, and grade I and II according to physical status classification system of the American Society of Anesthesiologists (ASA) (17).-

Exclusion criteria were history of cold, patients with cardiopulmonary, neuromuscular, renal or hepatic disease, potentially difficult intubation, neurosurgical and ophthalmic operations, history of allergy to any of study drugs, emergency surgery, patients with increased risk of aspiration and patients with abnormalities of the upper airway (tumor, polyps, inflammation).

A careful preanesthetic visit was conducted the day before surgery. Patients' pulse rate, blood pressure, respiratory rate, EKG and other relevant clinical signs and symptoms were noted by detailed history and clinical examination.

Patients were allocated randomly into two induction groups of 40 patients: Group S (control group) included the patients in which anesthesia induction and ETI were performed with suxamethonium and propofol, and group F (study group) included the patients in which anesthesia induction and ETI were performed with fentanyl and propofol. Patients were randomized by a physician not involved in the study, using closed envelopes technique.

In the preanesthesia room, an intravenous cannula of 22G or 24G was inserted to all patients. In the operation room, standard clinical monitoring was performed: pulse oximetry, noninvasive arterial blood pressure, the electrocardiogram and capnography.

Methods

After the start of infusion fluids in a dose of 10 mL/kg, the same premedication was given to both patient groups: midazolam 0.05 mg/kg and atropine 0.01 mg/kg intravenously, 5 minutes prior induction.

Patients in the S (control) group were preoxygenated by facial mask for 3-5 minutes. Five minutes after premedication, patients were induced by propofol 3mg/kg over a period of 30 seconds followed by suxamethonium 1mg/kg; ETI was performed 60 seconds later.

Patients in the group F (study group) received five minutes after premedication fentanyl intravenously over 30 seconds. Because it takes 5-7 minutes for fentanyl to equillibrate plasma and brain concentrations we waited for five minutes after giving fentanyl solution and then the children received propofol 3mg/kg over the period of 30 seconds; 2% lidocaine 0.2 mg/kg was added to propofol to avoid pain of propofol solution. After administration of fentanyl patients were observed for the development of unconsciousness, apnea and oxygen desaturation and 100% oxygen was administrated by facial mask; ETI was performed 60 seconds after hypnotic doses of propofol. When trachea could not be intubated because of muscle spasm, coughing or excessive movements, iterative bolus of propofol 1mg/kg was administered in both patient groups. If ETI was not successful after two attempts, suxamethonium 1mg/kg was given to complete intubation.

In both groups, ETI was performed by a single experienced anesthesiologist not involved in the anesthetic regimen and blinded to the drugs used in the study**.** Pediatric laryngoscope with Macintosh blade was used for laryngoscopy (Macintosh blade 2, Teleflex/Rüsh, Germany). Trachea was intubated with an appropriate size cuffed tracheal tube. The patients were ventilated with 100% oxygen by facial mask before intubation. After intubation, balanced anesthesia was maintained as necessary for each case. Mechanical ventilation was done with a tidal volume of 8-10 mL/kg and the rate of 20-25 respirations per minute. End tidal carbon dioxide was maintained 30-35 mmHg.

Assessment of quality of intubation conditions

The quality of intubation condition was assessed by using The Copenhagen Consensus Conference score (CCS) (18). The qualitative scoring system was proposed by the consensus conference on Good Clinical Research Practice in Pharmacodynamic Studies of Neuromuscular Blocking agents. The score includes five variables: jaw relaxation (relaxed, ↑tone or rigid), ease of laryngoscopy (easy, slight resistance, impossible), position and movements of vocal cords (open, moving, closed), limb movements (none, slight,

severe) and coughing (none, ≤2, >2 cough). Each of these variables were graded as excellent, good or poor. The intubation conditions were labeled as excellent if all variables were excellent, good if all variables were good or excellent, poor if any variable was poor. Excellent and good intubation conditions are considered as a clinically acceptable intubation condition score. Poor intubation condition is taken as clinically unacceptable score.

Assessment of hemodynamic response of ETI

The following hemodynamic monitoring was made: pulse oximetry by BCI international, measurements of heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP) and mean arterial pressure (MAP). Each of these variables were noted at the following time points. The baseline values (t_0) were taken for preinduction measurements at 1 minute after the administration of atropine, postinduction measurements (t_i) immediately after the administration of induction drugs, and postintubation measurements at 1 (t_1), 3 (t_3), 5 (t_5) minutes after intubation.

Statistical analysis

Sample size was estimated using sample size calculator software with 95% confidence interval and power of 80%. The $p< 0.05$ was considered as statistically significant. Pearson's Chi-Squared test was used to compare of the categorical variables. The change in continuous parameters and its statistical significance was tested by applying Levene's Test for Equality of Variances and T-test for Equality of Means. The results was expressed us means, standard deviation and percentage.

RESULTS

There was no significant difference between demographic data of two patient groups: age, gender, body weight, ASA grade and type surgery.

Statistical analysis of the overall CCS

The CCS was clinically acceptable in 38 (95%) children and unacceptable in 2 (5%) children, in group F, versus clinically acceptable CCS in 40 (100%) children in group S (p=0.152).

Intubation conditions were excellent in 34 (85%), good in four (10%) and poor in two (5%) children in group F versus excellent in 39 (97.5%) children and good in one (2.5%) child in S group. Easy laryngoscopy was noted in 38 (95%) and fair in two (5%) patients in F group versus all 40 (100%) patients in S group. Vocal cords were opened in 35 (87.5%), moved in three (7.5%) and closed in two (5%) patients in group F versus opened in 39 (97.5%) and moved in one (2.5%) patient in S group. Cough was not recorded in 38 (95%), ≤2 cough in one (2.5%) and >2 cough in one (2.5%) child in group F, versus no cough in all 40 (100%) patients in S group. Jaw relaxation was noted as relaxed in 38 (95%) and higher tone in two (5%) children in group F. The same result was noted in group S. Limb movements were not recorded in the any group. The ETI was performed in the first attempt in 38 (95%) children and the second one in two (5%) children. Both of them belonged to group F and they had poor intubation conditions and unacceptable overall CCS. One child had more than two cough and iterative bolus dose of 1mg/kg propofol was administered to facilitate intubation. In another case, the child had closed vocal cords and suxsamethonium 1 mg/kg was given to achieve intubation. There were no children with laryngospasm, bronchospasm, chest rigidity, hypoxia, difficult mask ventilation, postoperative nausea and vomiting, prolonged respiratory depression or any others complications (Table 1).

Table 1 . Comparison of Copenhagen Consensus Scoring (CCS) system variables

Parameter	Patient group	No (%) of patients according to the CCS			p
		Easy	**Fair**	**Impossible**	
Laryngoscopy	Fentanyl	38 (95)	2 (5)	0	
	Suxamethonium	40 (100)	0	0	0.152
		Opened	**Moving**	**Closed**	
Vocal cords position and movements	Fentanyl	35 (87.5)	3 (7.5)	2 (2.5)	
	Suxamethonium	39 (97.5)	1 (2.5)	0	0.20
		None	**≤2 cough**	**> 2 cough**	
Cough	Fentanyl	38 (95)	1 (2.5)	1 (2.5)	
	Suxamethonium	40 (100)	0	0	0.359
		Relaxed	**↑ Tone**	**Rigid**	
Jaw relaxation	Fentanyl	38 (95)	2 (5)	0	
	Suxamethonium	38 (95)	2 (5)	0	1.000
		None	**Slight**	**Severe**	
Limb movement	Fentanyl	40 (100)	0	0	
	Suxamethonium	40 (100)	0	0	1.000
		Exellent	**Good**	**Poor**	
CCS	Fentanyl	34 (85)	4 (10)	2 (5)	
	Suxamethonium	39 (97.5)	1 (2.5)	0	0.126
		Acceptablee	**Unacceptable**		
Overall CCS assessment	Fentanyl	38 (95)	2 (5)		
	Suxamethonium	40 (100)	0 (0)		0.152

Results of hemodynamic changes during intubation

Statistically significant differences were not recorded between the mean basal values of all observed hemodynamic parameters.

Significant decrease of the SBP mean was noticed for postinduction (10.4%) and postintubation at 1 (8.96%) and 3 (6.8%) minute in group F ($p<0.05$). In the S group, SBP showed a slight increase from the base line to other time points, but there was not statistical significance.

A significant decrease of the DBP was noted for postinduction (19.8%) and postintubation at 1 (12.4%) minute in group F ($p<0.05$). Increase of the mean DBP was not statistically significant in the group S.

Statistically significant decrease of the MAP was noticed in the group F ($p<0.05$) at postinduction (19.9%) and postintubation at 1 minute (11.4%) and 3 minute (5.3%). In the group S an increase of the MAP was noticed but with no statistical significance.

The mean HR was not significantly changed during ETI in the group F. In the group S, a statistically significant increase at postinduction (11.8%) and postintubation at 1 minute (9%) was found.

The hemodynamic conditions were much better controlled in the study group. Data recorded a statistically significant decrease of the SBP, DBP, MAP postinduction and postintubation at 1 and 3 minute. Bradycardia, hypotension or other hemodynamic complications did not occur (Table 2).

The mean SpO_2 was excellent (100%) in both groups, without significant changes during the study.

Table 2. Comparison of hemodynamic parameters changes at various time intervals

Parameter*	Patient group		p
	Fentanyl (Mean)	**Suxamethonium** (Mean)	
SBP			
SBP0	111.50	115.05	0.164
SBPi	95.45	121.45	0.000
SBP1	100.85	119.88	0.000
SBP3	104.73	114.08	0.009
SBP5	106.48	112.03	0.061
DBP			
DBP0	67.08	67.65	0.780
DBPi	53.80	73.30	0.000
DBP1	58.73	71.10	0.000
DBP3	63.53	69.93	0.062
DBP5	64.45	66.95	0.401
MAP			
MAP0	82.30	83.18	0.683
MAPi	66.08	89.38	0.000
MAP1	73.95	88.08	0.000
MAP3	78.03	83.93	0.057
MAP5	80.93	82.00	0.713
HR			
HR0	109.85	110.40	0.882
HRi	107.30	123.20	0.000
HR1	110.08	120.30	0.004
HR3	116.95	118.68	0.584
HR5	116.50	119.65	0.338

*SBP, Systolic blood pressure; DBP, Diastolic blood pressure; MAP, mean arterial pressure; HR, heart rate; X0, basal value (preinduction); Xi, after induction; X1, 1 min postintubation; X3, 3 min postintubation; X5, 5 min postintubation;

DISCUSSION

The present study investigated intubation conditions and hemodynamic responses for ETI with and without the use of muscle relaxants in children. Our results suggest that the combination of the propofol 3mg/kg and fentanyl 3µg/kg provided clinically acceptable CCS for ETI in 95% patients and better hemodynamic stability compared with the standard combination of the propofol- suxamethonium in healthy premedicated children.

The ETI intubation without muscle relaxants has been often investigated during the last 25 years. In 1992, following a report on cardiac arrest, the USA Food and–Drug administration recommended to use the suxamethonium only for emergency and rapid sequence intubation in children (19). Suxamethonium creates the best intubation conditions and has superior acting to rocuronium (20). However, the mentioned adverse effects are not acceptable in the current anesthesia practice (21).

The NMBD have slow onset and prolonged action which is not useful in short surgical procedures and rapid sequence induction. Studies of ETI without muscle relaxants have focused on intubation conditions, hemodynamic responses, intraocular and intracranial pressure (22). The advance of shorter acting opioid agents in combination with propofol has been used successfully for ETI. Keaveny et al. was one of the earlier investigators who approved that propofol 2.5 mg/kg could provide acceptable intubation conditions in 95% of patients without muscle relaxant application (23). Propofol causes profound respiratory depression and apnea, induces depression of upper airway reflexes and recovery is more rapid and pleasant than thiopental. 1% lidocaine is used to minimize propofol injection pain, which is unlikely in children (24). But propofol used alone could not achieve optimal intubation conditions (25).

Additional administration of opioids or lidocaine improved intubation conditions. Lidocaine used as adjuvant attenuates intraocular pressure response, cough and hemodynamic changes to ETI (26). Va-

rious opioids like fentanyl, remifentanil, sufentanil improved intubation conditions and blunted hemodynamic response to laryngoscopy and ETI (27).

Naziri et al. concluded that the combination of remifentanil and propofol provided acceptable intubation conditions and better hemodynamic response than suxamethonium in children (28). Adamus et al. founded that 0.4μg/kg sufentanil and 2 mg/kg propofol combination provided acceptable intubation conditions in 97% patients (29).

Fentanyl, which we used in the present study, has a rapid onset, short duration and effective abolishing pressure response to ETI. Both bradycardia and postoperative pain less frequently appeared with fentanyl than remifentanil (30). The combination of propofol and fentanyl for ETI without muscle relaxant was evaluated for different occasions, like cesarean sections, for pediatric fiberoptic intubation and for patients with myasthenia gravis (31-33).

Induction dose of fentanyl suppressed, while the dose of 6 μg/kg completely abolished pressure response for ETI (34). Large doses of fentanyl can lead to muscular rigidity, bradycardia, nausea, vomiting or postoperative respiratory depression (35). For these reasons, we chosed a smaller dose of fentanyl, 3 μg/kg, and we did not record any adverse effects. Fentanyl provides more consistent attenuation pressor response than lidocaine (36).

The investigators evaluated various doses of propofol. Gupta reported that a dose of 3-3.5 mg/kg of propofol produced acceptable intubation conditions and hemodynamic stability (37). Propofol dose of 3μg/kg with 2 μg/kg fentanyl and 1.5 mg/kg of lidocaine achieved acceptable intubation conditions and attenuation stress response. It seems that the addition of lidocaine allowed to use smaller dose of fentanyl (38).

Based on the results of previous studies, we used 3μg/kg of fentanyl 5 minutes before application of 3 mg/kg of propofol. Our results have shown clinically acceptable CCS in 95% cases in fentanyl group. We avoided muscular rigidity and respiratory incidents using lower dose and slow injection of fentanyl (39) and sedation with midazolam (40). Midazolam in premedication caused very similar basal hemodynamic values, but during the study we observed better control stress response in fentanyl group.

Our study has some specific points. We used lower doses of fentanyl without any topical anesthetic in order to avoid cough reflex. Antiemetic drugs, medication to alert pressor response to ETI, and inhalation induction agents were not used. Similarly to our results, Shaik and Bellagalli reported acceptable CCS in 95% of patients in fentanyl group and 100% in suxamethonium group (41). Shah observed the actual response of propofol and fentanyl, without premedication and recoded acceptable conditions for ETI in 87% of patients (42). Contrary to our results, Leitaut et al combined a lower dose of propofol of 2.5 mg/kg 3 minutes after application of 3 μg/kg of fentanyl, and they reported clinically acceptable CCS in only 35% of patients (43). Other investigators also found that combination of low dose fentanyl with propofol provided poor intubation conditions (44,45).

Different results between the studies are a consequence of different protocols which they used. Anesthesiologists have to formulate optimal combination of drugs concerning doses of different agents and their proper timing, **a** relaxant-free technique for ETI (46). Authors analyzed incidence of laryngeal injuries related to relaxant free-technique. Some of them did not find a difference between the approach with and without muscle relaxant (47,48). Combes et al. reported that ETI without muscle relaxants increased difficult intubation (49). In our study, we did not have any case of difficult intubation.

Our study has some limitations. Obtained results refer only to healthy children. Inclusion of the children with higher ASA grade or younger than 4 year might be required to optimize the induction protocol. Furthermore, airway damage related to the approach with and without muscle relaxant was not observed.

In conclusion, the combination of 3μgr/kg of fentanyl and 3mg/kg of propofol ensures clinically acceptable Consensus Copenhagen Score in 95% of patients for endotracheal intubation in premedicated and healthy children and provide better hemodynamic conditions than the combination propofol-suxamethonium. This method could be used effectively and safely in children when muscle relaxants are not indicated.

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Uvjeti za endotrahealnu intubaciju sa i bez mišićnog relaksanta kod djece

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SAŽETAK

Cilj Usporediti intubacijske uvjete i hemodinamski odgovor kod dva indukcijska protokola, sa i bez primjene mišićnog relaksanta, koristeći kombinaciju fentanila i propofola ili propofola i suksametonija.

Metode Osamdeset djece, u dobi od 4 do 12 godina, uključeni su u prospektivnu, randomiziranu, dvostruko slijepu studiju. Djeca su randomizacijom podijeljena u dvije jednake grupe. U grupi F indukcija je izvedena fentanilom i propofolom, dok su propofol i suksametonij korišteni u grupi S. Intubacijski uvjeti procijenjeni su Kopenhagenskim konsenzus-skorom (CCS), koji se zasniva na lakoći laringoskopije, položaju glasnica, stepenu kašlja, relaksaciji vilice i pokretima usana. Sistolni krvni pritisak (SBP), dijastolni krvni pritisak (DBP), srednji arterijski pritisak (MAP) i srčana frekvencija (HR) praćeni su prije indukcije, poslije indukcije i poslije intubacije u 1, 3. i 5. minuti.

Rezultati Klinički prihvatljiv CCS zabilježen je u 95% pacijenata u grupi F, a 100% u grupi S. Intubacijski uvjeti bili su odlični u 85%, dobri u 10% i loši u 5% pacijenata u grupi F. U grupi F zabilježen je statistički značajno niži SBP i MAP poslije indukcije i poslije intubacije u 1. i 3. minuti i niži DBP poslije indukcije i poslije intubacije u 1. minuti u odnosu na grupu S ($p<0,05$). U grupi S zabilježen je statistički značajno veći HR poslije indukcije i poslije intubacije u 1. minuti u odnosu na grupu F ($p<0,05$).

Zaključak Indukcijska kombinacija fentanil-propofol osigurava prihvatljive uvjete za intubaciju, usporedive sa suksametonijem kod djece. Ovaj indukcijski protokol osigurava bolju hemodinamsku stabilnost pridruženu endotrahealnoj intubaciji. Može se preporučiti za intubaciju kada mišićni relaksanti nisu indicirani.

Ključne riječi: pedijatrijska anestezija, fentanil, propofol, neuromišićni blok, suksametonij