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Research article

Does sugammadex facilitate recovery after outpatient tonsillectomy in children?

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KEYWORDS

Sugammadex;
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Abstract *Introduction:* Sugammadex is an efficient reversal agent at any time, after neuromuscular blockade. It provides complete reversal for light or deep block facilitating rapid airway control and decreases anesthesia recovery period in outpatient surgeries in children.
Patient and methods: After ethical committee approval, informed consent and sample size calculation, 70 patients planned for outpatient total bilateral tonsillectomy were divided randomly into 2 groups. Group S (n = 35) received 2 mg/kg sugammadex to reversing NMB achieved by rocuronium. Group N (n = 35) received 0.05 mg/kg neostigmine and atropine sulfate 0.01 mg/kg, and extubation time (time from administration of reversal agent to time of extubation), train-of-four ratio, time to reach train-of-four >0.9, and side effects were recorded.
Results: There was no significant difference in demographic variables. TOF ratio after reversing was a statistically less in group S than in group N ($p < 0.05$). The time when TOF rate exceeded 0.9 and extubation time were less in group S than in group N with significant difference ($p < 0.05$). No adverse effect was recorded in both groups.
Conclusions: Sugammadex has created a novel rapid, effective and reliable retrieval from NMB with rocuronium in children undergoing tonsillectomy with no side effects.

1. Introduction

Tonsillectomy and adenoidectomy in considered one of the most frequent surgeries carried out all over the world. Healthy children undergoing such procedure may be associated with considerable morbidity and death rate [1]. The anesthetic technique use neuromuscular blockers associated with higher complications than other techniques without them. This is due to the development of postoperative residual neuromuscular block, affecting ventilation, airway patency, and hypoxia [2]. The reversal of NMBs is done by acetyl-cholinesterase inhibitors (neostigmine, edrophonium, or pyridostigmine). Undesirable side effects of cholinesterase inhibitors (bradycardia, hypersalivation and bronchoconstriction) can avoided by muscarinic antagonists as atropine. However, side effects of muscarinic antagonists such as blurring of vision, mouth dryness, and increase in heart rate may occur. Cholinesterase inhibitors have difficulty in reversing deeper muscular paralysis [3]. Because of their mechanism of action is based upon the action

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of acetylcholine on motor end plate. At deep neuromuscular blockade, NMBA is present at the motor end plate, but the maximum increase in the amount of acetylcholine to compete with NMBA is expressed [3]. Neostigmine is the most potent and selective cholinesterase inhibitors and not selective as it stimulates both nicotinic and muscarinic systems. Atropine is used to avoid the concomitant side effects [4].

Sugammadex eliminates the effect of steroid formed non-depolarizing muscle relaxants through binding to them. The first study on sugammadex in volunteers is published in 2005 [5]. Sugammadex is an alternative reversal agent to NMB, which was executed by cholinesterase inhibitor. Postoperative residual NMB action and the muscarinic adverse effects are not present with sugammadex, when used to reverse rocuronium induced NMB [6].

Rapid action of Sugammadex attributed to the mechanism of action differs from other reversal agents [7]. More pediatric studies are needed for certification of its use in variety of patients needed to increase the knowledge about the safety and effective use of sugammadex [8]. So we aim to present our use of sugammadex regarding dose and in side effects in the pediatrics. Sugammadex has been used to reverse moderate NMB in various studies and shown very good recovery of motor power [9,10]. Compared with neostigmine administration (0.05 mg/kg), sugammadex recovery time was approximately 13 times faster [11].

2. Materials and methods

This prospective randomized single blind clinical trial in which the participant and their guardian did not know the drug used, was conducted at Zagazig University Hospital, between June 2015 and December 2015, after approval of our hospital ethical committee and written informed consent was obtained from parents or guardian of **70** children.

2.1. The aim of the study

Our aim was to compare the efficacy of sugammadex and neostigmine on reversing neuromuscular blockade in pediatric patients undergoing outpatient tonsillectomy. The primary outcome was to measure the train-of-four ratio after reversing neuromuscular blockers. The secondary outcome is extubation time.

2.2. Rationale

The use of neuromuscular blockers in children was associated with higher complications due to the development of postoperative residual neuromuscular block, affecting ventilation, airway patency, and hypoxia, side effects of cholinesterase inhibitors (bradycardia, hypersalivation and bronchoconstriction) and muscarinic antagonists such as blurring of vision, mouth dryness, and increase in heart rate.

2.3. Randomization

Allocation of subject in one arm of study was done by using physical method (coin): head for one group and tail for the other, until one group is completed, after that all randomly selected subjects will automatically be allocated to the remaining group (randomization with balance).

Seventy healthy children (2–10 years) scheduled for total bilateral tonsillectomy were included in this study, exclusion criteria such as parent refusal, age less than 2 years or more than 10 years, difficult intubation, any neuromuscular disease, any metabolic disorder, known drug hypersensitivity, kidney impairment, liver impairment, congenital heart disease and history of malignant hyperthermia were not included.

Patients received no premedication, when they attended operating theater; basic monitoring was carried out by the following: ECG (HR), blood pressure cuff to record (MAP), and capnography and SpO_2 values. An intravenous cannula was inserted in peripheral vein of the upper limb. Anesthesia was started with fentanyl (1 mice/kg) analgesia, propofol (1–2 mg/kg) and rocuronium (0.6 mg/kg) for intubation. Ventilation was provided by facemask with 100% and their neuromuscular block was monitored in other limb using the TOF-Watch® SX (Organon, Dublin, Ireland), by stimulation of the ulnar nerve and activity of the adductor pollicis muscle. Two electrodes were positioned near the wrist and the ulnar nerve till recovery to a TOF ratio of 0.9 and then maintained with isoflurane.

Neuromuscular blocking effect was monitored clinically by increase in respiration frequency and disruption to respiration curve, and with the onset of muscular movements. Another bolus dose of rocuronium, 0.2 mg/kg, was injected during surgery. At end of procedure isoflurane was discontinued and TOF monitoring started. On the reappearance of **T2** in ***1st group (Group N)***, patients received reversal by neostigmine (0.05 m/kg) and atropine sulfate 0.01 mg/kg according to body weight. In ***2nd group (Group S):*** reversal was by 2.0 mg/kg sugammadex.

Two anesthesiologists were available during procedure: one was in charge of anesthesia (induction, tracheal intubation, reversal of muscle relaxant, extubation and recovery), while the other was in charge of recording all variables. In both groups **the primary outcome** was to evaluate recovery time from neostigmine or sugammadex administration until recovery of the TOF ratio to 0.9% was recorded and **the secondary outcome** extubation time from reversal from NMB to extubation was recorded.

Adverse effects such as bradycardia, hypotension, arrhythmia, nausea, vomiting, rash, or postoperative recurrence of neuromuscular blockade were recorded and patients' oxygen saturation and breathing in the recovery area were monitored for at least 2 h.

2.4. Statistical analysis

Sample Size: In study by Kara et al. 2014, TOF ratio at extubation was 76.95 ± 31 in Neostigmine group versus 96.35 ± 21.34 in Sugammadex group, at a power analysis of β-error = 0.8 and α-error = 0.05, and 35 patients per study group were needed as the appropriate sample size to find significance difference between the studied drugs.

Continuous variables were checked for normality by using Shapiro-Wilk test. Mann Whitney *U* test was used to compare two groups of non-normally distributed data. Percent of categorical variables were compared using the Pearson's Chi-square test. All tests were two sided. $p < 0.05$ was considered