Original Article

Intraoperative electromyographic monitoring in children using a novel pediatric sensor

ABSTRACT

Background: Train-of-four (TOF) monitoring is essential in optimizing perioperative outcomes as a means to assess the depth of neuromuscular blockade and confirm recovery following the administration of neuromuscular blocking agents (NMBAs). Quantitative TOF monitoring has been limited in infants and children primarily due to lack of effective equipment. The current study evaluates a novel electromyography (EMG)-based TOF monitor with a recently developed pediatric-sized self-adhesive sensor in infants and children.

Methods: Consented pediatric patients undergoing inpatient surgery requiring the administration of NMBAs were enrolled. The EMG electrode was placed along the ulnar nerve on the volar aspect of the distal forearm. The muscle action potentials from the adductor pollicis muscle were recorded throughout surgery at 20-second intervals. Data from the monitor's built-in memory card were later retrieved and analyzed.

Results: The final study cohort included 51 patients who ranged in age from 0.2 to 7.9 years and in weight from 4.2 to 36.0 kilograms. Thirty patients weighed less than 15 kgs. Supramaximal stimulus current intensity (mA) at a pulse width of 200 μsec was 30 mA in 8%; 40 mA in 29%; 50 mA in 16%; and 60 mA in 20% of the patients. Supramaximal stimulus current intensity (mA) at a pulse width of 300 μsec was 50 mA in 4%; 60 mA in 24%. The muscle action potential baseline amplitude was 8.7 ± 3.3 mV and recovered to 7.2 ± 3.7 mV after antagonism of neuromuscular blockade. The average baseline TOF ratio was 100 ± 3% and recovered to 98 ± 7% after antagonism of neuromuscular blockade. No technical issues were noted with application of the sensor or subsequent use of the monitor.

Conclusion: Neuromuscular monitoring can be performed intraoperatively in pediatric patients who are less than 8 years of age using a novel commercially available EMG-based monitor with a recently developed pediatric sensor. The novel sensor allows use of an EMG-based monitor in infants and children in whom acceleromyography or subjective (visual) observation of the TOF response may not be feasible. Automatic detection of neuromuscular stimulating parameters (supramaximal current intensity level, baseline amplitude of the muscle action potential) was feasible in pediatric patients of all sizes including those weighing less than 15 kilograms or when there was limited access to the extremity being monitored.

Key words: Laparoscopic surgery, neuromuscular blockade, neuromuscular blocking agents, train-of-four monitoring

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Introduction

During intraoperative anesthetic care, neuromuscular blocking agents (NMBAs) are administered to provide skeletal muscle relaxation for endotracheal intubation, ensure a motionless patient, and provide surgical relaxation. Monitoring the response of the train-of-four (TOF) following the administration of NMBAs remains an essential component to guide the timing of redosing and document the efficacy of reversal of neuromuscular blockade.[1,2] Responses to TOF stimulation may be evaluated subjectively (qualitatively) with direct visual observation and counting of the muscle twitches following stimulation with a peripheral nerve stimulator (PNS), objectively (quantitatively) by measuring the number of twitches in the TOF sequence (TOF count or TOFC), or by measuring the twitch height of the first TOF twitch (T1), the height of the 4th twitch (T4), and calculating their ratio (T4/T1, or TOF ratio, TOFR).[3] Quantitative technology for TOF monitoring includes mechanomyography, acceleromyography, or electromyography-based (EMG) devices. Given the potential for inaccuracies with visual inspection when using qualitative monitoring, there has been increased use of quantitative devices during intraoperative care of adults.[4-6]

However, there remains limited clinical data with quantitative TOF monitoring in infants and children. Furthermore, the majority of pediatric anesthesiology practitioners may not even monitor TOF responses subjectively during the administration of NMBAs.[7] This practice has the potential to impact clinical outcomes as clinical trials have demonstrated that the incidence of residual neuromuscular blockade may be as high as 48.2%.[8,9] Although there has been increased use of quantitative TOF monitoring in adults, it appears that this practice change has not occurred in infants and children. Commonly cited reasons for lack of monitoring include lack of reliable monitors especially in smaller pediatric patients; clinical productivity metrics with the impetus for efficiency; challenges with calibration of existing acceleromyographic monitors for use in smaller patients; limited clinical exposure to new TOF monitoring technologies such as EMG-based devices; and lack of clinical standards regarding NMBA administration and monitoring in the pediatric population.[9,10] One example of this is that the recently-published guidelines for neuromuscular monitoring from the American Society of Anesthesiologists and the European Society of Anesthesia and Intensive Care did not address monitoring in pediatric-aged patients. Additionally, use of quantitative monitoring technology that requires the measurement of muscle movement can generally only be used when the target muscle (typically, the adductor pollicis muscle of the thumb) can move freely. The latter is not feasible when the arm is at the patient's side or inaccessible under the surgical drapes, which may occur during minimally invasive laparoscopic and other surgical procedures.[11-13]

This limitation does not apply to the novel EMG-based neuromuscular monitors as these devices measure the evoked muscle action potentials without the need for measurement of muscle movement.[11-13] EMG-based devices measure the TOF responses from the amplitude of the individual EMG responses (compound muscle action potentials, cMAPs). To date, there are limited data regarding the use of EMG-based TOF monitors in pediatric patients. We previously evaluated a commercially available adult EMG-based monitor (TetraGraph™, Senzime BV, Uppsala, Sweden) and adult electrode array (TetraSens™) in 100 pediatric patients with an average age of 11 years, weighing 20-60 kilograms, and undergoing inpatient surgical procedures.[14] Automatic detection of neuromuscular stimulating parameters (supramaximal current intensity level and baseline amplitude of the muscle action potential) was feasible. The quantitative EMG-based TOF monitor functioned well allowing for effective monitoring of neuromuscular blockade and reversal. No difference was noted in the efficacy of the device when the arm was not visible or was at the patient's side (during laparoscopic surgery). In our previous study, we limited the study cohort to patients weighing ≥20 kilograms due to the size limitations of the adult-developed electrode array (TetraSens™). The primary objective of the current study was to evaluate the feasibility of TOF monitoring using the novel pediatric sensor (TetraSens Pediatric) with the TetraGraph™ in a similar yet smaller and younger cohort of pediatric patients presenting for surgical procedures requiring the administration of a NMBA.

Methods

Study design and study population: This study was approved by the Institutional Review Board of Nationwide Children's Hospital, Columbus, Ohio (IRB#: STUDY00001075). Date of approval for modification of study protocol to use the pediatric sensor was February 2022. The study was registered at clinicaltrials.gov (NCTINCT04475250). Eligibility for the study was limited to pediatric patients less than 8 years of age presenting for a surgical procedure that included the administration of a NMBA. Patients with peripheral neurologic, myopathic, or neuropathic diseases, peripheral edema, or those in whom one of the upper extremities or hands could not be used for TOF monitoring, such as a surgical procedure involving that limb, were not eligible for inclusion. Patients who met eligibility requirements were

identified on the day of surgery in the preoperative holding area. Written informed consent was obtained from a parent or legal guardian.

Intraoperative anesthesia management, including the type of anesthesia, specific anesthetic agents used, the choice of NMBA, its dose and the reversal agent, was at the discretion of the attending pediatric anesthesiologist. Anesthesia providers were not blinded to the use of the monitor, the TOF ratio, and the count displayed on the TetraGraph™ EMG monitor. Anesthesia providers were asked to follow their routine clinical practices including placement of a PNS and visual determination of TOF responses as needed to guide the dosing of NMBAs during the procedure. According to our usual institutional clinical practices, rocuronium was primarily used for neuromuscular blockade and sugammadex for reversal.

The TetraGraph™ is a commercially available, EMG-based TOF monitor. It provides electrical stimulation over a peripheral nerve and then directly measures the amplitude (muscle action potential) of the evoked responses of the innervated muscle, providing a quantitative measurement of the muscle response to the stimulus. Measurement and quantification of the EMG response eliminates the subjective evaluation that is required with visual observation of the twitches. Clinical studies have also demonstrated that the quantitative measurements with the TetraGraph™ provide a more sensitive and reproducible measure of the degree of neuromuscular blockade and recovery than visual using a PNS.[12,13] The TetraGraph™ is FDA approved for use in adults. After evaluation and review by our IRB, it was labelled as a non-significant risk study for pediatric use.

For the purpose of our study, the patient was transported to the operating room and anesthesia was induced by the inhalation of sevoflurane. Following this, the skin was prepped with an alcohol swab and the sensor was placed. The pediatric sensor or recording electrodes (TetraSens™ Pediatric) was placed on the palmar surface of the adductor pollicis muscle and its insertion on the medial aspect of the proximal phalanx of the thumb. The stimulating electrodes were placed along the ulnar nerve on the volar surface of the forearm [Figure 1]. After the sensor was placed on the patient, the electrodes were connected using the cord to the TetraGraph™. The device automatically determines the stimulating current necessary for maximal muscle contraction, to ensure consistent recruitment of all muscle fibers [Figure 2].

Outcomes and statistical analysis: The primary endpoint evaluated the efficacy and feasibility of using the TetraGraph™ EMG monitor in pediatric patients less than 8 years of age. The device recorded the TOF ratio, the TOF counts, post-tetanic count (PTC), and responses during maintenance of block and block recovery following the administration of sugammadex. Data were recorded throughout surgery at 20-second intervals until tracheal extubation. Data from the device's digital memory card were retrieved and analyzed. As a secondary aim, we also compared data from patients who weighed more than 15 kilograms to those who weighed ≤15 kilograms. In this smaller cohort, we evaluated the efficacy of the device in recording and displaying the TOF data throughout the surgical procedure by measuring the number of failures of reporting neuromuscular data among the cohort.

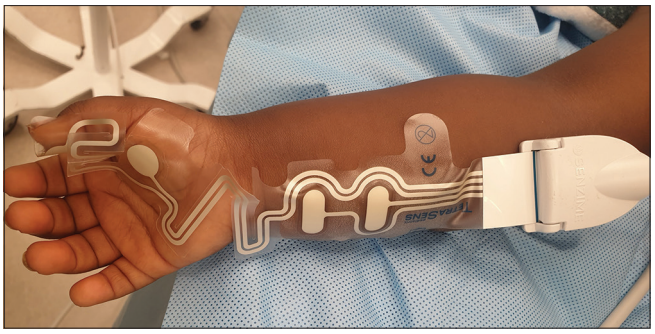

Figure 1: The Tetragraph™ electromyograph monitor with the pediatric recording electrodes (TetraSens™) attached to the palmar surface of the adductor pollicis muscle and its insertion on the medial aspect of the proximal phalanx of the thumb. The stimulating electrodes were placed along the ulnar nerve on the volar surface of the forearm

Continuous variables were summarized as mean (IQR) and categorical variables as percentages. We used descriptive statistics and a non-paired *t* test to compare the characteristics of neuromuscular monitoring with the TetraGraph™ between the two cohorts of patients based on weight (more than 15 kilograms versus ≤15 kilograms). All analyses were conducted using the Statistical Package for the Social Sciences (SPSS) software for Windows, version 26.0 (IBM Corp., Armonk, NY).

Results

A total of 65 patients were enrolled in the study. Of these patients, data were lost from 13 following installation of a hardware update, and one patient was excluded due to age being outside the intended age range of the current study. The remaining study cohort of 51 patients ranged in age from 0.2 to 7.9 years (mean 3.2 ± 2.6 years) and in weight from 4.2 to 36.0 kilograms (mean 14.2 ± 7.0 kg). The weight distribution is listed in Table 1. Table 2 summarizes the characteristics of neuromuscular monitoring using the TetraGraph™ EMG with a pediatric sensor in the entire study cohort of 51 pediatric patients. Automatic detection of supramaximal stimulus (current amplitude in mA required to initiate a maximal single muscle twitch plus 30%) was

obtained in 86% of patients. Supramaximal stimulus current intensity (mA) at a pulse width of 200 μsec was 30 mA in 8%; 40 mA in 29%; 50 mA in 16%; and 60 mA in 20% of the patients. Supramaximal stimulus current intensity (mA) at a pulse width of 300 μsec was 50 mA in 4%; 60 mA in 24%. The muscle action potential mean baseline amplitude was 8.7 ± 3.3 mV. The average baseline TOF ratio was 100 ± 3%. Complete data for neuromuscular recording (baseline to recovery including fade in the TOFR from baseline) were obtained in 78% of the patients. Due to the administration of a NMBA prior to sensor placement and monitor initiation, baseline data were not obtained from 22% of the patients. After antagonism of neuromuscular blockade, the baseline amplitude recovered to a mean of 7.2 ± 3.7 mV, and the TOF ratio recovered to a mean of 98 ± 7%. No technical issues were noted with application of the sensor or subsequent use of the monitor even in patients weighing less than 10 kilograms.

Table 1: Weight distribution of the study cohort (*n*=51)

Weight group (kilograms)	Number of patients
0 to less than 10	16
10 to less than 20	25
20 to less than 30	9
30 to less than 40	1

Table 2: EMG monitoring in entire cohort and patients based on weight groups

Parameter	Entire cohort (*n*=51)	≤15 kilograms (*n*=30)	More than 15 kilograms (*n*=21)
Baseline TOFr (%)	100±3	100±3*	101±3
Recovered TOFr (%)	98±7	96±9*	100±5
Baseline amplitude (mV)	8.7±3.3	8.0±2.9*	9.5±3.7
Recovered amplitude (mV)	7.2±3.7	5.6±2.7^{+}	8.9±3.7

Data are listed as the mean±SD. EMG=electromyography; TOFr=train-of-four ratio; SD=standard deviation; mV=millivolts; *P=NS compared to more than 15 kg cohort. $^{+}$P=0.006 compared to more than 15 kg cohort

Figure 2: Photograph of the Tetragraph™ showing the four EMG twitches obtained and the demonstration of the train-of-four ratio (TOFr%)

We also separately analyzed TOF responses based on weight, dividing the study cohort of 51 patients in those who weighed ≤15 kilograms (n = 30) and those who weighed more than 15 kilograms (n = 21). No difference in the efficacy of the monitor was noted based on the patient's weight [Table 2]. There were no differences in baseline TOFr (%), the recovered TOFr (%), and the baseline amplitude between the two weight groups. The recovered amplitude was lower in patients who weighed ≤15 kilograms (7.2 ± 3.7 mV in the entire cohort, 5.6 ± 2.7 mV in the lower weight cohort, and 8.9 ± 3.7 mV in patients who weighed more than 15 kilograms).

Discussion

The current prospective study assessed neuromuscular monitoring using the EMG-based TetraGraph™ and a novel pediatric array (TetraSens™ Pediatric) in a cohort of patients who were less than 8 years of age and undergoing inpatient surgical procedures in a large tertiary care children's hospital [Figures 2 and 3]. Clinically useful information regarding the degree of neuromuscular blockade and recovery was obtained from the majority of patients. Although the TetraGraph™ has been used in both adults and older children, the current study included a total of 30 patients who weighed ≤15 kilograms, and 16 who weighed less than 10 kilograms, a group previously thought not to be amenable to consistently successful quantitative neuromuscular monitoring.[12-14] The application of this technology in infants and children has been facilitated by the availability of a pediatric-sized sensor. One difference that we did note in the two weight groups was that there was a difference in the recovered amplitude, which was statistically less in patients ≤15 kilograms. If this is a clinically significant finding, it may relate to differences accounted for by maturation of neuromuscular transmission, which have been noted previously when evaluating TOF using acceleromyography with a force displacement transducer.[15]

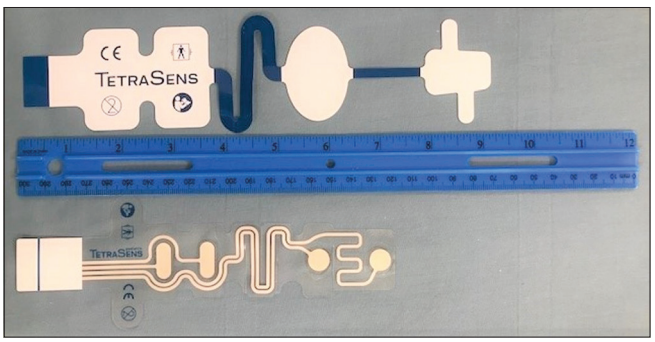

Figure 3: Photograph of the adult and pediatric version of the TetraSens™ self-adhesive sensor. The adult sensor measures approximately 9 inches in length compared to 7 inches for the pediatric sensor

Many of the patients in the current cohort were positioned for the surgical procedure in such a way that access to the extremity being monitoring was not feasible, demonstrating another advantage of EMG-based monitoring. Acceleromyography requires that the target muscle (usually the thumb) moves freely (to measure the responses) or be seen (to assess subjectively). This requirement may limit its use in procedures where the patient's arms are restricted by surgical drapes or not freely visible. The risk of postoperative residual NMB has been shown to be 5-fold higher when a PNS and the supramaximal current is not determined.[16] Another confounding characteristic that has been noted with acceleromyography is that the baseline TOF ratio may be >100%.[17-19] With a falsely elevated baseline, the recovering TOF ratio must be normalized to the starting baseline ratio to avoid inaccuracies in assessing reversal and the degree of residual neuromuscular block. This inaccuracy has not been noted with EMG-based technology such as the TetraGraph™. When compared to visual monitoring, the TetraGraph™ evaluates fade by calculating the TOF ratio, thus allowing for intraoperative titration of additional doses of NMBAs as well as documentation of effective antagonism (TOF ratio >0.90). This should facilitate the prevention of residual paralysis and its clinical consequences.[8,20] However, residual neuromuscular blockade was not assessed in the post-anesthesia care unit (PACU) as part of the current study. As such, conclusions regarding the potential for residual blockade and its clinical impact cannot be drawn.

In conclusion, although developed initially for use in adults with an adult-sized sensor, our preliminary data suggest that with the use of the novel pediatric sensor, the TetraGraph™ EMG monitor can be used in infants and children, even those who weigh less than 10 kilograms. Nerve stimulation parameters and clinical responses were consistent with those reported in adults. EMG-based technology does not require visual observation or free motion of the stimulated muscle group, thereby allowing the technology to be used for surgical procedures with restricted access to the extremity being monitored including laparoscopic and robotic techniques. The feasibility of using this monitor in pediatric patients should allow prospective clinical studies comparing EMG-based monitoring to other quantitative methods of measuring neuromuscular blockade.

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Conflicts of interest

There are no conflicts of interest.

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