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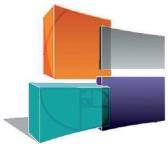

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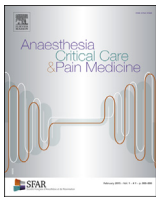

Original Article

Comparison of the TOF-Scan™ acceleromyograph to TOF-Watch SX™: Influence of calibration

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ABSTRACT

Introduction: Quantitative neuromuscular monitoring is now widely recommended during anesthesia using neuromuscular blocking agents to prevent postoperative residual paralysis and its related complications. We compared the TOF-Watch SX™ accelerometer requiring initial calibration to the TOF-Scan™, a new accelerometer with a preset stimulation intensity of 50 mA not necessitating calibration.
Study design: This pilot, prospective, observational study included adults undergoing general anesthesia with endotracheal intubation and muscle relaxation, having both arms free during surgery. Accelerometers were set up randomly on each arm. Anesthesia was started with remifentanil and propofol before an intubation dose of atracurium or rocuronium. Train of four stimulation was performed every 15 s. Differences between measures were tested using Student's *t*-test and agreement assessed by Bland and Altman analysis.
Results: Thirty-two patients were included. During onset, a mean bias of −26 seconds with a limit of agreement from −172 to +119 seconds was observed between TOF-Watch SX™ and TOF-Scan™ to obtain 0 response to TOF. During recovery, TOF-Scan™ showed a significantly later recovery from 1 response to T4/T1 > 10%, but a bias of 0 minute and limits of agreement from −4 to +4 minutes for T4/T1 > 90% (NS).
Conclusion: These results suggest a poor agreement between the calibrated TOF-Watch SX™ and the fix intensity TOF-Scan™ for onset and early recovery of relaxation (i.e. deep neuromuscular blockade) but a good agreement for recovery to TOF 90%. Data are not interchangeable between the devices, but both can be useful to detect residual paralysis.

1. Introduction

Quantitative or objective monitoring of neuromuscular blockade for patients under general anesthesia necessitating muscle relaxants is now widely recommended. It is as useful to optimize the time of intubation [1], than to adjust the level of paralysis during surgery and finally to confirm full recovery of neuromuscular blockade before extubation whether or not pharmacological reversal is used [2]. Several studies have demonstrated a decreased incidence of postoperative residual paralysis [3–5] in the presence of quantitative neuromuscular monitoring. By identifying clearly the patients who need reversal, it also avoided systematically and sometimes useless reversal [6] that has been recently shown to have additional morbidity [7].

However, quantitative monitoring is still not a standard of care since recent studies estimated that around 50% of anaesthetists in France [8], as in Europe and up to 70% in US did not use routinely a quantitative monitoring of neuromuscular blockade agent (NMBA) [9].

Several factors have been proposed to understand this gap between evidence based medicine and clinical practice. Practitioners have been described as busy and hurried, always concerned about starting the next case [10]; they are convinced of having never seen a case of residual paralysis in their own practice [9]. Also, they often need to share a quantitative monitor between 2 or 3 operating rooms [9]. Therefore, a larger use of quantitative NMBA monitors may depend on how quick and easy they are to install, and the need for an initial calibration may impair this ergonomic concern.

Calibration of the acceleromyographic device to adjust the supramaximal intensity of current to each patient sensitivity

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before muscle relaxant injection has been recommended by experts at least for scientific purposes [11], but is debated in routine practice [12,13]. It might not be necessary to detect residual paralysis if a train of four ratio of at least 1.0 is targeted [14]. In the other hand, bypass of calibration may encourage the use of monitoring by both saving time during the busy step of induction, and allowing monitoring in a patient already paralyzed.

Recently, a new acceleromyography monitor became commercially available (TOF-Scan™, IdMed) which proposes a fixed, non-calibrated, current intensity adjustable by the user.

This study was designed to investigate the agreement between a calibrated acceleromyograph, TOF-Watch SX™ (Alsevia) and the non-calibrated TOF-Scan™ (IdMed) during onset, maintenance and recovery of neuromuscular blockade.

2. Patients and methods

This prospective, open-labeled, non-randomized, and observational study was approved by our hospital's ethical committee (ref: 2013-A00967-38) and informed consent was obtained from each patient. During a 6-months period, adult patients with American Society of Anesthesiologists physical status I–III, aged 25–78 years, scheduled to undergo elective surgery with general anesthesia and orotracheal intubation and both arms in abduction were included by only one investigator. Exclusion criteria were rapid sequence induction, age less than 18, pregnancy, allergy to neuromuscular blocking agent, history or presumed difficult ventilation or intubation. After insertion of an intravenous line and installation of standard monitoring combining EKG, pulse oximetry, and non-invasive blood pressure, the patient was placed in a supine position for surgery, the forelimbs were extended passively, the antibrachiums supported along its length in a horizontal position, and the carpus taped to the operating table. Devices were placed in both arms randomly.

Anesthesia was initiated with remifentanil target controlled infusion (TCI) followed by propofol, 2.0–3.0 mg/kg.

After loss of consciousness, the TOF-Watch SX™ was calibrated using the CAL2 function: the device starts stimulating with a series of single twitches at a maximum intensity of 60 mA and adjusts the gain at 100%. Then, the stimulating intensity is reduced in steps of 5 mA until the detected answer is below 90% of the initial stimulation response (for example at 35 mA). Thereafter, the current is set at the next higher step (in the example: 40 mA) increased by 10% (e.g. 44 mA) and called "supramaximal stimulation". The current intensity used by TOF-Watch SX™ to produce supramaximal acceleration was recorded for each patient. At the same time, the TOF-Scan™ was initiated with a non-calibrated intensity of stimulation fixed at 50 mA for all patients.

Thereafter, 0.5 mg/kg of atracurium or 0.6 mg/kg of rocuronium was injected and TOF was measured every 15 s by both TOF-Watch SX™ and TOF-Scan™ until obtaining 0 response at the train of four (TOF) before tracheal intubation. During surgery, anesthesia was maintained with inhalational agent, and remifentanil administered in TCI mode (Base Primea, Fresenius). Ventilation was controlled, and end-tidal carbon dioxide tension ($ETCO_2$) was maintained between 32 and 36 mmHg. Repeated boluses or intravenous infusion of neuromuscular blockade agent was administered to maintain train of four responses between 0 and 2 if necessary for surgery.

At the end of surgery, neostigmine in combination with atropine or sugammadex was used for reversal if a residual blockade was diagnosed at the discretion of the anaesthetist. In the absence of residual paralysis (defined by T4/T1 > 90% in both devices), extubation was performed accordingly in conjunction with other clinical parameters such as awakening.

2.1. Data recording and analysis

The following data were recorded:

- at onset, times, in s, to obtain T4/T1 (train of four ratio) < 90%, < 50%, < 10%, and TOF (train of four) < 4, TOF = 0;
- at recovery of blockade, times (min), to obtain 1, 2, 3, 4 response at the train of four and then T4/T1 > 10%, 25%, 40%, 70%, 75%, 90%.

Results are expressed as mean (M ± SD). For the estimation of an agreement between the calibrated and the non-calibrated measurements, a Bland–Altman analysis was performed with the calculation of bias and limits of agreement, and precision. Time difference between two acceleromyographs at every step of onset and recovery were compared with Student test. Differences were considered significant when $P < 0.05$. Finally, we calculated mean of absolute value of relative differences during 3 periods (onset, recovery and all the surgery) with their confidence interval (CI) and used a Student test to test the null hypothesis that the absolute value of relative differences was more than 20% (defined as the limit of an acceptable clinical time difference between both devices). All analyses were performed using the software Microsoft Excel 2010.

3. Results

Thirty-eight patients were included in the study; 6 were excluded from data analysis due to change of position during surgery, error message delivered by TOF-Watch SX™, unplanned difficult intubation, severe hypotension or incomplete data. Finally, 32 patients (ASA I–III) were included for data analysis; 16 of these were women.

The demographical characteristics were as follows: age 72 ± 16 years; body mass index 25 ± 4 $kg{\cdot}m^{-2}$; duration of surgery 179 ± 113 min. Surgery was abdominal, gynecologic, or head and neck.

Atracurium was used in 27 patients and rocuronium in 5 patients. Nine patients had a single injection of NMBA for intubation, 6 received some additional doses and 17 had continuous intravenous infusion. In 24 patients, a pharmacological reversal was administered (22 with neostigmine and atropine and 2 with Sugammadex) before emergence from anesthesia.

The mean supramaximal stimulation current for the TOF-Watch SX™ was 55 ± 8 mA while the stimulation current was preset at 50 mA for the TOF-Scan™. The stimulation current was different between two devices in 29 of 32 patients (23 patients had a higher intensity with TOF-Watch SX™ i.e. > 50 mA, 6 patients had a lower intensity).

During onset of neuromuscular blockade, there were no significant difference between the devices for time to obtain T4/T1 < 90%, < 50%, < 10%, TOF < 4, and TOF = 0 (Figs. 1 and 2).

During recovery of neuromuscular blockade, significant differences were noticed between devices for both deep and moderate blockade (Fig. 3):

- TOF-Scan™ showed later recovery from deep neuromuscular blockade (recovery of 1, 2, 3, 4 responses of train of four and T4/T1 > 10%, $P < 0.05$);
- then TOF-Scan™ estimated a slightly shorter delay to achieve T4/T1 > 70% and T4/T1 > 75% ($P < 0.05$);
- finally, no difference was found between the two devices for full recovery of neuromuscular blockade (T4/T1 > 90%, $P > 0.05$).

Bland and Altman analysis for deep neuromuscular blockade (for example TOF = 3 responses) showed a bias (mean) of 5.3 minutes, with an upper/lower limit of agreement of [−10.9;