



Philips Intellivue NMT module: precision and performance improvements to meet the clinical requirements of neuromuscular block management

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Abstract

The variability or inaccuracy of acceleromyographic measurements could interfere with the interpretation of the train-of-four (TOF) ratio during neuromuscular block (NMB) recovery. This study evaluated the precision and performance of the Philips Intellivue NMT module (NMT) before (part 1) and after (part 2) several technical upgrades (i.e., firmware upgrade, new cable, and hand adapter) that were recently available. Two cohorts of 30 patients who were scheduled to undergo rhino/septoplasty under general anesthesia were included in the study. TOF ratios were recorded simultaneously every 15 s on both hands with the NMT and a TOF-Watch SX installed inside a SL TOF-Tube (TWX). Before rocuronium was administered and once final responses were stabilized, the average of the four successive measurements that determined the baselines and repeatability coefficients were compared using a z test. Simultaneous measurements were recorded at different NMB stages: onset, depth of NMB after intubation, when TWX recovered TOF count 2, TOF ratios 0.5 and 0.9, and when NMT recovered TOF ratio 0.9. The results were compared using a Student t test; $p < 0.05$ was considered significant. The NMT repeatability coefficients obtained in part 1 were significantly higher than with the TWX, they were significantly lower in part 2. Initially, the NMT significantly overestimated NMB recovery at every stage. Conversely, in the second part of the study, no difference reached statistical significance. With the recent upgrades and the new hand adapter, the NMT provided similar results compared with the TWX. Their implementation should be recommended in clinical practice.

Keywords Neuromuscular transmission monitoring · Acceleromyography · Train-of-four ratio · Residual paralysis

1 Introduction

Quantitative neuromuscular transmission monitoring (NMTM) is useful to manage the depth of neuromuscular blockade (NMB) during general anesthesia. In every patient, it determines the individual onset time before tracheal intubation. It also provides the clinician with post-tetanic count (PTC) and train-of-four (TOF) count to maintain the NMB

at the proper depth according to the surgical need (deep or moderate NMB, respectively) [1, 2]. Finally, quantitative NMTM is a definitely recommended method to reduce the risk of residual NMB at the time of tracheal extubation [3, 4]. Using the adductor pollicis force measurement with mecanomyography (MMG), numerous studies have determined a minimum recovery threshold of TOF ratio 0.9 to ensure the patient's safety. Under that level, as soon as the TOF ratio decreases to 0.8, pharyngeal dysfunction predisposes to upper airway obstruction, impaired ability to swallow, and critical respiratory events [5–7].

Among other techniques, acceleromyography (AMG) has been developed to provide the clinician with a simple quantitative NMTM [8]. It has been demonstrated to be a valuable measurement tool in clinical practice [9]. However, the results obtained using devices provided by the industry are not always credible and may vary considerably to such a degree that clinicians choose to disregard them,

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unfortunately [10]. Calibration of the initial measurement and normalization (initial T4/T1 ratio $\times$ 90/100) to refer the TOF ratios obtained during recovery to the baseline control ratio have been proposed to improve this issue [11, 12].

In October 2012, Philips Healthcare launched a new device using AMG to integrate their monitoring station: the Philips Intellivue NMT monitor (Royal Philips Electronics, Amsterdam, The Netherlands). However, an important inter-measurement variability was demonstrated in clinical practice that could impair its reliability [13]. NMT firmware improvements (865383 NMT Module firmware FW A.00.10), including both the noise detection and the calibration process, were implemented in most centers in July 2013. Furthermore, in July 2017, Philips introduced a new cable (989803174581, CE 0123) and a dedicated accelerometer hand adapter (reference code 989803199211 Intellivue NMT-Hand Adapter).

The goal of this dual study was to evaluate this new device in the clinical setting before (part 1) and after (part 2) all the different upgrades recently available. In the first part of the study, we tested the hypothesis that the inter-measurement variability obtained with the initial Philips NMT monitor could distort the determination of the TOF ratio 0.9 recovery thresholds and impair the patient's safety at the time of tracheal extubation. Then, in a second cohort of patients enrolled after obtaining the upgrades and the Intellivue NMT-Hand adapter, we tested the hypothesis that these would improve any problem encountered in part 1.

The data provided by the new device were compared to those provided by the TOF-Watch SX (Alvesia Pharma, France) installed inside the SL TOF-Tube. The latter combination, also using AMG, has been demonstrated to provide clinically comparable measurements with those obtained with MMG, especially during NMB recovery [14].

Compared simultaneously on both hands of the same patient during nasal surgery, the primary outcome measure was the performance (the agreement) of the measurements provided by the two techniques at different stages of the NMB and particularly when they recovered TOF ratio 0.9. The secondary outcome measures were the TOF ratio's initial and final baselines and their repeatability coefficients to compare the precision of both devices.

2 Materials and methods

2.1 The Philips Intellivue NMT module

This NMTM was designed to be integrated exclusively into the Philips anesthesia Intellivue station. The peripheral cable provided the ulnar nerve stimulation through two robust grabbers fixed on standard cutaneous electrodes, and a three-dimensional (3D) piezoelectric sensor provided

AMG measurements of the thumb movements in every direction. The module software allowed the anesthetist to configure the nerve stimulation patterns. The current results and their trends were recorded and displayed on the monitor screen. According to the device manual, no specific installation of the hand was required until the availability of the hand adapter (an elastic piece of silicon placed between the thumb and the forefinger), which included a place to insert the AMG transducer.

2.2 Patient management

The two consecutive study protocols were approved by the Institutional Ethical Committee (CHU UCL Namur, Yvoir, Belgium, OM 050 Prof. P. Evrard, under registration numbers 160/2016 B039201630750 and 69/2017 B039201732792) and included in the Australian and New Zealand Clinical Trials Registry (ACTRN12617000625370 and ACTRN12617001151325), respectively.

After obtaining written informed consent from all participants, 30 patients with American Society of Anesthesiologists (ASA) grades I–II (aged 18–80 years), who were scheduled to undergo rhinoplasty or rhinoseptoplasty under general anesthesia, were included in both consecutive parts of the study. The exclusion criteria were pregnant or breastfeeding women, patients with renal or hepatic insufficiency, patients with neurological disorders, and any patient with a suspected allergy to the drugs used in the protocol or receiving medications that could interfere with neuromuscular transmission. The patient's height, weight, age, and sex were recorded in the protocol, as was their dominant hand (left or right) to define the population investigated.

All patients received alprazolam 0.5 mg 60 min before arriving in the operating theatre. They were conventionally monitored with a pulse oximeter, a three-lead electrocardiogram, and a non-invasive blood pressure scheduled in automatic mode at 5-min intervals. An intravenous catheter was inserted into their forearm for crystalloid infusion (side at random). Neuromuscular monitoring was set up according to a specific protocol.

Anesthesia was induced with continuous intravenous infusion of remifentanyl 0.25 μ g/kg/min and continuous infusion of propofol 1% to obtain a theoretical plasma concentration of 3–6 μ g/mL (Diprifuor Cardinal Health, Basinstoke, UK). Lidocaine 1 mg/kg was given as an intravenous bolus. After loss of consciousness, manual ventilation was provided during NMTM calibration and the measurement of the initial baseline. Then, rocuronium 0.5 mg/kg was administered. Non-invasive automatic blood pressure measurement was suspended during the neuromuscular onset so as not to limit the distribution of the rocuronium in either of the two arms. Onset time was recorded when the TOF count reached zero with both monitors and tracheal intubation was

performed. Automatic non-invasive blood pressure measurement was reactivated. Mechanical ventilation (closed circuit, 40% oxygen in air) maintained end-tidal CO₂ within the normal range. Anesthesia was maintained with the continuous intravenous administration of remifentanyl 0.15 µg/kg/min and propofol with a target plasma concentration of 2–4 µg/mL. Blankets prevented heat loss from the body, and the oropharyngeal temperature was kept stable.

2.3 Neuromuscular transmission monitoring

All recordings were performed during general anesthesia. The skin was cleaned with diethylether, and two electrodes (E152, IMMED Benelux, Brussels, Belgium) were placed above the ulnar nerve on each wrist. The AMG transducers were taped on the thumbs' pulp. Both arms were positioned alongside the body on soft padding to protect nerve structures. In the first part of the study, the arm with the Philips Intellivue NMT module was left free of any specific installation as it was recommended in its user manual, yet avoiding any direct compression on the thumb. In the second part of the study, the Intellivue NMT-Hand Adapter including the AMG transducer was placed between the thumb and the first finger. The other hand with the TOF-Watch SX was inserted and held inside the SL TOF-Tube. Both techniques were allocated on both sides at random.

Individual supra-maximal stimulation and initial calibration were obtained using each device's internal automatic sequence, and the current intensity was recorded. Four consecutive TOF stimulations were applied at 15-s intervals, and the T4/T1 ratios were recorded prior to rocuronium administration to determine the initial baseline. We calculated 90% of the mean value to determine the normalized TOF ratio 0.9 recovery threshold for each monitoring module using the following formula: normalised TOF ratio 0.9 = sum of 4 TOF ratio $\times$ 9/40 with a result rounded up.

Consecutive TOF stimulations every 15 s monitored the onset of the NMB. After tracheal intubation and mechanical ventilation settings, a PTC was determined simultaneously using each monitor. After a period of 3 min, TOF stimulations were applied again every 15 s on both hands throughout the study period to record the NMB spontaneous recovery until a final stable baseline was achieved.

Different clinically relevant stages of NMB were simultaneously recorded on each monitor during the induction and recovery, as follows:

- Onset of the NMB: time in seconds from rocuronium administration to TOF count 0
- PTC (0–20): measurement of the actual depth of a deep NMB
- TOF count 2: measurement of a moderate degree of NMB. When the TOF-Watch SX first reached a TOF

count 2 or greater, four consecutive measurements were recorded on both monitors.

- TOF ratio 0.5: during the recovery phase, four consecutive measurements were recorded on each monitor as soon as the TOF-Watch SX reached TOF ratio 0.5 or greater.
- TOF ratio 0.9 (primary outcome measure): the time to recover a TOF ratio 0.9 was recorded on each monitor. Four consecutive measurements were recorded on both monitors as soon as each of them recovered TOF ratio 0.9 or greater.
- Normalized TOF ratio 0.9 (90% of the initial baseline): the time to recover a normalized TOF ratio 0.9 was recorded on each monitor. Four consecutive measurements were recorded on both monitors as soon as each of them reached the normalized TOF ratio 0.9.

Then, to accelerate NMB final recovery, 100 mg of sugammadex was administered. After 3 min, the last four consecutive measurements were recorded to determine the TOF ratio final baselines. The investigation did not interfere with intra- and postoperative care.

2.4 Statistical analysis and sample determination

The precision assessment relied on the comparison of the measurements' variability. Initial TOF ratios were recorded with four successive measurements before rocuronium was administered. Repeatability coefficients, calculated as $1.96\sqrt{2SD}$ [1], were determined for the Philips NMT module and the TOF-Watch SX and compared using a *z* test; a low factor indicated little variability between consecutive measurements. The same comparative analysis was conducted once a final baseline was stabilized. The Philips NMT repeatability coefficients obtained during parts 1 and 2 were also compared *p* < 0.05 was considered significant.

The performance of the Philips NMT module was compared to the TOF-Watch SX installed inside the SL TOF-Tube. At the different NMB stages (PTC, TOF count 2, TOF ratio 0.5, TOF ratio 0.9, and normalized TOF ratio 0.9), four consecutive measurements were recorded simultaneously on both devices when the value concerned was reached with the TOF-Watch SX, and also when the TOF ratio 0.9 (raw and normalized) was reached with the Philips NMT module. These results were compared using a Student *t* test; *p* < 0.05 was considered significant.

The sample size determination was considered in light of recovery of the TOF ratio 0.9, the critical safety threshold for tracheal extubation. An intermeasurement variability [standard deviation (SD)] of more than 17.5% was observed on a pre-series with the Philips NMT module [13]. Based on a paired *t* test with a risk α of 0.05, a sample size of 30 patients allowed a power of 95% to detect a 10% difference

Table 1 Population

Population	Part 1 (n = 30)	Part 2 (n = 30)
Gender (M%)	55%	50%
Age (y.o.)	44.2 ± 14.1	40.9 ± 15.7
Weight (kg)	82.9 ± 16.3	72.9 ± 15.8
Height (cm)	173.3 ± 11.1	172.4 ± 9.5
Right hand dominant	97%	87%

between the Philips NMT module and the TOF Watch SX. This difference would have a significant clinical implication, as the recovery of TOF ratio 0.8 has been demonstrated to be insufficient when compared to 0.9 [4, 5].

The statistical analyses were carried out with SPSS® 15.0 statistical software (SPSS Inc., Chicago, Ill) and G*Power 3 [15].

3 Results

Thirty patients were included in both parts of the study. The population characteristics are presented in Table 1.

During the two consecutive parts of the study, the Philips NMT module was set on the dominant hand in 52% and 53%, respectively. The calibration process was successful in all cases with the TOF Watch SX. The Philips NMT module completed the calibration process in 42% and 100% in the two parts of the study, respectively. The nerve stimulation intensity was 55 ± 6 and 54 ± 9 mA for the TOF Watch SX, and 52 ± 5 and 47 ± 13 mA for the Philips NMT module in both parts of the study.

The results of the initial and final TOF ratio baselines with both methods are provided in Table 2. The repeatability coefficients obtained in the first part of the study with the Philips NMT module were significantly higher than with the TOF Watch SX installed inside the SL TOF-Tube. The situation improved with the new Intellivue NMT-Hand Adapter in the second part of the study; the difference between initial baselines was no longer significant. The NMT repeatability coefficients were significantly lower in part 2 compared with part 1 (initial baseline $p < 0.001$ and final baseline $p = 0.015$).

The comparisons of the data provided by both methods at the different stages of the NMB are provided in Table 3. In the first part, the Philips NMT module significantly overestimated NMB recovery at every stage. When the Philips NMT

Table 2 Precision assessment

	Part 1			Part 2		
	TWX	NMT	p	TWX	NMT	p
TOFr initial (%)	109.01 ± 9.24	114.12 ± 12.90		107.89 ± 11.38	114.61 ± 12.21	
C repeatability	17.09 ± 6.04	37.45 ± 13.24	<0.001	17.24 ± 6.10	20.75 ± 7.34	0.082
TOFr final (%)	108.91 ± 9.37	116.45 ± 11.62		106.83 ± 6.84	109.78 ± 6.62	
C repeatability	10.47 ± 3.70	23.38 ± 8.26	<0.001	13.60 ± 4.81	18.01 ± 6.36	0.009

TWX TOF-Watch SX installed inside the SL TOF-Tube, NMT Philips Intellivue NMT module, including firmware improvements, a new cable and a hand adapter in part 2. Train-of-four ratio (TOFr) is expressed in %. All results as mean ± SD

Table 3 Performance assessment

	Part 1			Part 2		
	TWX	NMT	p	TWX	NMT	p
Onset time (s)	146.10 ± 38.57	137.77 ± 40.50	0.247	165.33 ± 62.93	158.37 ± 67.46	0.610
PTC (n)	3.10 ± 5.67	6.00 ± 7.44	0.003	4.83 ± 6.57	5.90 ± 7.48	0.470
TWX TOFc 2 (n)	2.00 ± 0.11	2.81 ± 1.31	0.002	1.91 ± 0.34	1.64 ± 1.35	0.315
TWX TOFr 50 (%)	53.83 ± 4.99	66.62 ± 17.62	<0.001	53.59 ± 5.11	50.94 ± 13.42	0.307
TWX TOFr 90 (%)	91.82 ± 2.20	103.47 ± 15.17	0.001	90.86 ± 3.23	90.27 ± 15.87	0.846
NMT TOFr 0.9 (%)	78.26 ± 12.54	92.68 ± 3.50	<0.001	87.11 ± 12.40	91.17 ± 3.66	0.092
TWX TOFr N 0.9 (%)	98.64 ± 8.22	105.54 ± 15.53	0.020	96.88 ± 11.04	93.08 ± 16.33	0.194
NMT TOFr N 0.9 (%)	86.60 ± 10.87	103.93 ± 11.17	<0.001	97.07 ± 12.03	100.74 ± 10.74	0.155

TWX TOF-Watch SX installed inside the SL TOF-Tube, NMT Philips Intellivue NMT module, including firmware improvements, a new cable and a hand adapter in part 2. Onset time is expressed in minutes, post-tetanic count (PTC) and TOF count (TOFc) as a count, train-of-four ratio (TOFr) in %, normalized (N). All results as mean ± SD

module passed the TOF ratio 0.9 thresholds, the TOF Watch SX stated only 0.78 on average. The bilateral normalization did not improve this > 10% difference. The delay between both devices to reach the TOF ratio 0.9 was 5 ± 7.5 min. Conversely, in the second part of the study, no difference reached statistical significance.

4 Discussion

The main finding of this study is that the Philips Intellivue NMT monitor initially provided in 2013 significantly overestimated all stages of NMB recovery compared with a TOF-Watch SX installed inside a SL TOF-Tube. Different technical upgrades including calibration and the introduction of a dedicated hand adapter in 2017 improved the performance of the device and removed all contralateral differences (see Table 3).

Quantitative NMTM is definitely recommended to manage the depth of NMB [2] to facilitate tracheal intubation [16], to improve specific surgical conditions [17], and to pass the threshold of TOF ratio 0.9 before tracheal extubation [3, 4]. Even a slight degree of residual paralysis may have significant clinical consequences [6, 7]. Then, it is crucial to use valuable monitors that can stand these clinical requirements to ensure adequate intraoperative NMB management. AMG has been shown to be a valuable tool for clinical practice [9]. The TOF-Watch SX monitor was the established standard of AMG monitors [1] and was successfully compared to MMG under specific hand installation conditions [14, 18]. The Philips Intellivue NMT monitor used the same measurement method and demonstrated in this study several issues in recording accurate and reliable AMG data in clinical practice. The solutions available to improve data collection and interpretation are discussed.

The Philips Intellivue NMT monitor demonstrated an important range of the initial and final measurements (baseline TOF ratios) during the first part of the study. The precision of four consecutive measurements was expressed as repeatability coefficients (see Table 2) [1]. Using the same device to collect baseline TOF ratios in clinical practice, Stouffs et al. previously demonstrated a significant improvement of the repeatability coefficient from 51.5 to 34.6 when proceeding to the NMT calibration [13]. Actually, without calibration, the responses to TOF stimulation could be small enough to interfere with the proper calculation of a TOF count or ratio and could not be reliable [19]. A further improvement from 37.5 to 17.2 was demonstrated in the second part of this study when using a hand adapter. As previously published, the addition of an elastic preload to the thumb had no effect on the average control TOF ratio, but reduced the range of the responses [20].

The average baseline TOF ratios were all greater than unity (see Table 2). This reverse fade is a common issue with AMG (the first response is smaller than the following) because the thumb is not starting from the same point after consecutive contractions [21]. This situation is only partly improved with an elastic preload that favors that the thumb returned to its initial position after each response; but, values of 1.05–1.15 are still commonly observed [22, 23]. Consequently, AMG tended to overestimate the NMB recovery when compared with MMG, and both techniques are not interchangeable. It has been suggested to recover TOF ratio 1.0 to rule out low degrees of residual paralysis or to refer the TOF ratios obtained during recovery to the baseline control ratio (normalization) to improve the agreement of AMG versus MMG [24]. In this study, the normalization process did not improve the agreement between both AMG devices, which was finally achieved after Philips NMT firmware improvement of the calibration and noise detection, and the addition of a hand adapter and a new cable.

The results provided by this study may differ from other trials. It aimed to investigate the problems encountered in clinical conditions when using the NMT in the simplest way—with the arms alongside the body without any specific installation, as suggested by the Philips manual. In part 1 before the upgrades, we demonstrated frequent calibration errors, a wide inter-measurement variability, and a significant difference between the data provided by the two AMG devices. Arm-to-arm variations have been demonstrated previously [25], a difference of more than 10% on average was considered here as clinically relevant at the time of tracheal extubation. This difference disappeared in the second part of the study.

The major weakness of this study was the clinical setting of the method, which differed slightly from Good Clinical Practice in Pharmacodynamic Studies [1]. Based on a previous comparison with MMG [14], the TOF-Watch SX installed in a SL TOF-Tube was substituted as the reference in this daily practice conditions' study. Actually, it was our goal to highlight the issues of possibly unreliable data obtained in routine clinical conditions and the solutions implemented by Philips to provide the clinician with a valuable tool to manage intraoperative NMB.

In conclusion, the different upgrades introduced until 2017 (including calibration and a dedicated hand adapter) significantly improved the precision of the Philips Intellivue NMT monitor and reduced all differences observed with the TOF-Watch SX during NMB recovery. All users should confirm their implementation in clinical practice to meet the requirements of NMB management.

Compliance with ethical standards

Conflict of interest Dubois PE perceived grants from Merck Belgium for publications in the field of neuromuscular transmission monitoring development and honorarium for lectures but, as all co-authors, has no conflict of interest with the present study.

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