Comparison of the TOF-Cuff® monitor with electromyography and acceleromyography during recovery from neuromuscular block

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Editor—The TOF-Cuff® (RGB Medical Devices, Madrid, Spain) is a new neuromuscular monitoring device that consists of a modified blood pressure cuff with two electrodes on the inside. It overcomes some of the disadvantages of other neuromuscular monitoring devices. For instance, the TOF-Cuff can be used during surgical procedures where the arms need to be adducted alongside the patient’s body, as the measurements do not require a free-moving thumb. However, the TOF-Cuff has thus far only been compared with mechanomyography (MMG). We aim to provide additional validation by has thus far only been compared with mechanomyography (MMG). We aim to provide additional validation by comparing it with electromyography (EMG; EMG-NMT module of the TOF-Watch SX with Hand Adapter; Organon, Oss, The Netherlands).

We present the combined data of two independent research protocols, both conducted from January to May 2018 at the Radboud University Medical Centre (Nijmegen, The Netherlands; TOF-Cuff vs AMG) and Leiden University Medical Centre (Leiden, The Netherlands; TOF-Cuff vs EMG). Both protocols had a non-interventional design. Consequently, all anaesthetic procedures were left at the discretion of the attending anaesthesiologist. Normothermia was maintained.

The TOF-Cuff was placed with the electrodes at the medial bicipital groove on one of either upper arm (non-randomised). The EMG and AMG devices were connected to the ipsi- and contralateral extremity, respectively. For AMG, the preload Hand Adapter and fingers were fixated using adhesive tape, allowing the thumb to move freely. After induction of anaesthesia, but before administration of rocuronium, devices were administered. To avoid underestimating bias in the last part of the recovery phase, paired data were discarded after one of the TOF-Cuff and TOF-Watch SX with Hand Adapter reached a normalised TOF ratio of 1.0 because ultimately both devices will return to a TOF ratio of 1.0. Data were recorded every 30–60 s during spontaneous recovery from neuromuscular block and normalised for baseline TOF ratio. Data acquisition ceased when sugammadex was administered. To avoid underestimating bias in the last part of the recovery phase, paired data were discarded after one of the devices reached a normalised TOF ratio of 1.0 because ultimately both devices will return to a TOF ratio of 1.0. Data were stored in electronic case record forms (Castor EDC, CIWIT B.V., www.castoredc.com).

A total of 310 paired measurements were analysed. Subject characteristics were not significantly different between the two groups. The mean induction dose of rocuronium was 44.3 mg (standard deviation = 7.5) in Nijmegen and 45.6 mg (5.0) in Leiden. One subject was excluded because stable baseline measurements by TOF-watch SX could not be established. Three subjects were excluded because sugammadex was given early in the recovery phase resulting in insufficient data. All four subjects were replaced. Only sugammadex was used as reversal agent. Data were analysed using a modified...
Bland–Altman analysis for repeated measurements. The bias [95% confidence interval (CI)] for the TOF-ratio range of 0–1 was 0.28 (0.20–0.37) and 0.30 (0.24–0.37) for TOF-Cuff minus EMG and TOF-Cuff minus AMG, respectively, with wide limits of agreement (LoA; Fig. 1). For TOF-ratio range of 0.8–1, bias was 0.31 (0.20–0.42) and 0.38 (0.29–0.48). The average time of recovery (95% CI) until a normalised TOF ratio >0.9 was 24.0 (10.9–37.1) min (EMG) and 25.3 (11.6–39.0) min (AMG) longer than with TOF-Cuff. Our study is the first to compare the TOF-Cuff with EMG and AMG. Two other studies used MMG as reference method and, similar to our data, both found that recovery from neuromuscular block measured by TOF-Cuff preceded MMG. They did, however, find a much smaller bias. Rodiera and colleagues found a bias of −0.04 (MMG minus TOF-Cuff, 95% CI −0.06 to −0.02, LoA −0.21 to 0.12) for a TOF ratio >0.70 in 40 adults and 20 children. Veiga Ruiz and colleagues included 32 adults and calculated a bias of 0.047 (TOF-Cuff minus MMG) by comparing TOF-Cuff TOF ratio >0.7 with MMG TOF ratio >0.9. However, we contend that this is not a sound comparison. Additionally, neostigmine or sugammadex was routinely used and earlier recovery from block than peripheral muscles central muscles such as the diaphragm have a faster onset and earlier recovery from block than peripheral muscles such as the adductor pollicis and upper airway muscles.

Consequently, even shallow levels of residual block in these muscles attenuate upper airway patency and inhibit protective airway reflexes.

Because there is a time lag between the recovery from neuromuscular block at the upper arm and AMG and EMG at the adductor pollicis, the latter devices are more appropriate to exclude the presence of residual neuromuscular block. Measurement of block at the upper arm could be a better estimate of block at central muscles such as the diaphragm and vocal cords. This opens interesting opportunities for future studies. In addition, the behaviour of the TOF-Cuff in the situation were neuromuscular reversal agents are routinely administered deserves further attention. Our data indicate that measurement of neuromuscular block at the muscles of the upper arm using the TOF-Cuff cannot be used interchangeably with measurements at the adductor pollicis using EMG or AMG. Recovery to a normalised TOF ratio of >0.9 took on average 25 min longer with EMG or AMG compared with the TOF-Cuff. Therefore, EMG and AMG are more appropriate to exclude residual neuromuscular block.

Authors’ contributions
Study design: PK, MB, CK-B, AD. Data collection: PK, MB, HJE, GH. Measurements: HJE, GH, CM, AD. Statistical analysis: PK, MB, HJE, EO, GH. Interpretation of data: GH, PK, CM, MB, AD. Writing of the manuscript: PK, MB. Revision of the manuscript: HJE, CK-B, GJS, EO, GH, CM, AD. Discussed the results and contributed to the final manuscript: all authors.

Declarations of interest
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References

Why we scan the barcodes of anaesthetic medications

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Editor—In their editorial comment on our article¹ describing an anaesthesia medication safety bundle, Grigg and Litman² expressed some reservations about scanning of barcodes on vial and syringe labels. We would like to clarify our perspective on scanning barcodes.

We agree completely that prefilled, prelabelled medication syringes are highly desirable. Drawing medications from vials into syringes is a task that arguably could be better accomplished in a pharmacy clean room or a commercial compounding facility than on an anaesthesia cart top. However, there are several real-world problems with the proposal to replace all vials with prefilled syringes. Although many anaesthesia medications are available from commercial compounding facilities, many other anaesthesia medications are not. To name just a few examples, etomidate, vasopressin, protamine, and sugammadex are not currently available to us in prefilled syringes. Moreover, because of frequent shortages, prefilled syringes of anaesthesia medications may not be consistently available, forcing the use of vials as a substitute, which is now a distressingly common problem. Some hospital pharmacies are able to prepare prefilled syringes in their clean rooms, but clean room capacity is often a rate-limiting resource. The cost of prefilled syringes can be problematic, as discussed in our recent article on the economics of prefilled syringes.³ Finally, concerns have been expressed about the quality control and sterility of i.v. medications prepared by commercial compounding facilities (e.g. see https://www.pharmedium.com/company/news/phar-medium-services-llc-expands-voluntary-nationwide-recall-additional-lots-compounded-sterile-products-within-expiry-due-lack-sterility-assurance).⁴,⁵ In the USA, these facilities generally do not operate under the same regulatory oversight as the pharmaceutical companies that manufacture the drugs in the first place. For the foreseeable future, it is highly likely that most anaesthesia providers will continue to prepare at least some of their medications from vials.

The Codonics™ vial label barcode scanner and syringe label printer that we described in our article was associated with a reduced incidence of vial swap error.¹ It is important to note that our providers do not regard the Codonics machine as inefficient or as complicating their workflow. In fact, providers at the University of Washington Medical Center regard the Codonics machine as a labour-saving device that improves workflow. Because of this, virtually all of the syringe labels in our practice meet The Joint Commission and other standards; in this unit, there are no improperly labelled or unlabelled syringes.⁶,⁷ Moreover, this level of labelling compliance was achieved with minimal training and no special encouragement or incentives for our providers. In a randomised comparison of the multi-faceted Safersleep™ system (that uses barcodes) with conventional methods for checking medication administration (while utilising an automated anaesthesia record), time spent on medication preparation and administration was slightly increased (by ~2 min per case), whereas the time spent on recordkeeping was almost halved (from a mean of ~20 min—~10 min), and more time was spent on observing the patient.⁸ Again, this suggests a net facilitation of process, rather than the addition of ‘an inefficient layer’.

Barcode scanning is not a new technology, but this does not mean that it is not useful. Because we have barcode scanners for identifying providers’ identification badges as an integral part of our anaesthesia information management system (AIMS), there is minimal additional cost of using these scanners to scan syringe labels.⁷ A hand-held, corded