

NCT02914119

Use of Neuromuscular Blocking Agents and Neuromuscular Monitoring in 7 Danish Teaching Hospitals

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## **2.1 Primary objective**

To assess the frequency of use of objective neuromuscular monitoring with acceleromyography in 7 Danish anaesthesia departments, using 18 months of retrospectively collected data from the Anaesthesia Information Management System (AIMS).

## **Secondary objectives**

To assess the incidence of residual neuromuscular blockade, the frequency and timing of reversal of the neuromuscular blockade with sugammadex or neostigmine, and the association between hypoxemic events and use of neuromuscular monitoring.

### **2.1.1 Clinical hypotheses**

We hypothesize that objective neuromuscular monitoring is applied in 80% of cases involving a non-depolarizing NMBA (with or without succinylcholine) and 50% of cases involving only succinylcholine.

## **Perspectives**

Unlike in the U.S. and many European countries, most Danish operating rooms are equipped with objective neuromuscular monitoring. However, it is not known to which degree the equipment is actually being used, which will be investigated in this study. Moreover, the study will serve as a baseline study for a future interventional study with the aim of increasing the use of objective neuromuscular monitoring.

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Neuromuscular blocking agents (NMBAs) are used in general anaesthesia to facilitate endotracheal intubation and improve surgical conditions. Postoperative residual neuromuscular blockade occurs if the effects of the NMBA have not subsided or been sufficiently reversed when the patient is awakened.<sup>1</sup> Residual neuromuscular blockade is associated with both subjective complaints such as general fatigue, double vision and difficulty of speech, as well as increased risk of respiratory complications and prolonged length of stay in the post-anaesthesia care unit (PACU).<sup>2-4</sup> A peripheral nerve stimulator applied intra-operatively allows for assessment of the degree of neuromuscular blockade.<sup>5</sup> Objective neuromuscular monitoring, combining the peripheral nerve stimulator with measuring the response to nerve stimulation by means of e.g. acceleromyography, allows for more precise determination of the depth of neuromuscular blockade. The use of objective neuromuscular monitoring may prevent or reduce the incidence of residual neuromuscular blockade.<sup>6</sup> Routine use of objective neuromuscular monitoring is recommended whenever administering intermediate-acting, i.e. non-depolarizing, NMBAs.<sup>7-9</sup> We have showed

that patients receiving short-acting NMBAs also risk experiencing being awake while paralysed, especially if not monitored with a nerve stimulator.<sup>10 11</sup> Hence, it has recently been recommended that objective neuromuscular monitoring should be applied whenever any type of NMBA is administered.<sup>12</sup> In a Danish survey from 2005, 43% of anaesthetists replied that they always use neuromuscular monitoring when administering an NMBA.<sup>13</sup> However, the actual frequency of application of neuromuscular monitoring and the incidence of residual neuromuscular blockade is not known.

The study is a cross-sectional study with data from anaesthesia departments of seven Danish teaching hospitals in the Zealand Region of Denmark. The departments use the same objective neuromuscular monitoring device integrated in the anaesthesia machine (Philips MP70 NMT module (acceleromyography)) and the same AIMS (Metavision Anaesthesia (iMDsoft , Germany)).

### **Eligibility**

We will include all patients who received general anaesthesia with neuromuscular blockade in the 18 months up until the time of data collection. Patients, who are eligible more than once, i.e. undergoing general anaesthesia on more than one occasion, will be included in the analyses as a case for every general anaesthetic received.

### **Primary outcomes**

- Proportion of cases involving a non-depolarizing NMBA (with or without succinylcholine) where objective neuromuscular monitoring is applied.
- Proportion of cases involving only succinylcholine where objective neuromuscular monitoring is applied.

The primary outcome is split in cases with non-depolarizing NMBAs and cases with succinylcholine only, as the types of NMBAs are typically used in different clinical situations, i.e. for non-emergent tracheal intubation and rapid sequence induction, respectively.

### **Secondary outcomes**

- Median of last recorded TOF ratio before tracheal extubation or removal of supraglottic airway device in patients receiving a non-depolarizing NMBA.
- Proportion of cases involving a non-depolarizing NMBA receiving sugammadex or neostigmine, respectively.
- Proportion of cases involving a non-depolarizing NMBA receiving more than one administration of a reversal agent.
- Timing of NMBA reversal with sugammadex or neostigmine, respectively, according to an ordinal scale (neostigmine: TOF count 0, 1, 2, 3, [TOC count 4 to TOF ratio 0.9], TOF ratio  $\geq 0.9$ ) (sugammadex: PTC 0, PTC 1 to 15, TOF 0, 1, 2, 3 [TOC count 4 to TOF ratio 0.9], TOF ratio  $\geq 0.9$ ).
- Proportion of cases receiving an NMBA before tracheal intubation.
- Proportion of cases involving a non-depolarizing NMBA in which neuromuscular monitoring was applied before tracheal intubation.
- Time from tracheal extubation or removal of supraglottic airway device to discharge from PACU in cases involving a non-depolarizing NMBA with and without neuromuscular monitoring, respectively.

- Proportion of cases involving a non-depolarizing NMBA with mild oxygen desaturation (<90%) in the time between tracheal extubation or removal of supraglottic airway device and discharge from PACU with and without neuromuscular monitoring, respectively.
- Proportion of cases involving a non-depolarizing NMBA with severe oxygen desaturation (<80%) in the time between tracheal extubation or removal of supraglottic airway device and discharge from PACU with and without neuromuscular monitoring, respectively.

All outcomes will be reported both as total and for each department separately, as well as for 3-month periods.

### **Data collection**

Data are recorded in the AIMS in two ways: automatically or manually by the anaesthetist. Automatically recorded data include respiratory parameters like peripheral oxygen saturation as well as TOF data. Manually entered data include type and dose of intravenously administered medication and time of tracheal extubation. TOF data are recorded automatically when the neuromuscular monitoring module is activated. The AIMS saves automatically recorded TOF data every minute, that is, even though the neuromuscular monitoring module may be set to measure a TOF value every 12 s, data will only be stored once every minute. To ensure that the reported TOF values at tracheal extubation are not erroneously measured due to e.g. lack of fixation of the patient's hand or movements caused by the surgical personnel, we will collect the last five TOF values before tracheal extubation and use the highest value. In cases with desaturation, the electronic anaesthesia chart including the anaesthetist's comments will be reviewed to confirm the event.