



Original Contribution

Incidence of complications in the post-anesthesia care unit and associated healthcare utilization in patients undergoing non-cardiac surgery requiring neuromuscular blockade 2005–2013: A single center study☆



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ABSTRACT

Study objective: The use of neuromuscular blockade agents (NMBA), had been associated with significant residual post-operative paralysis and morbidity. There is a lack of clinical evidence on incidence of postoperative complications within the post-anesthesia care unit (PACU) in patients exposed to intraoperative NMBA's. This study aims to estimate the incidence of post-operative complications associated with use of NMBAs and assessing its association with healthcare resource utilization.

Design: Retrospective cohort

Setting: Post-anesthesia care unit in tertiary care center

Patients: Adults having non-cardiac surgery and receiving NMBAs between April-2005 and December-2013

Measurements: We assessed: 1) incidences of major and minor PACU complications, 2) incidence of any postoperative complication in patients receiving a NMBA reversal (neostigmine) vs. without. 3) We secondarily assessed the relationship between PACU complications and use of healthcare resources.

Main results: The incidence of any major complications was 2.1% and that of any minor complication was 35.2%. ICU admission rate was 1.3% in patients without any complications, versus 5.2% in patients with any minor and 30.6% in patients with any major complication. ICU length of stay was prolonged in patients with any major (52.1 ± 203 h), compared to patients with any minor (6.2 ± 64 h) and with no complications (1.7 ± 28 h). Patients who received a NMBA and neostigmine, compared to without neostigmine, had a lower incidence of any major complication (1.7% vs. 6.05%), rate of re-intubation (0.8% vs. 4.6%) and unplanned ICU admission (0.8% vs. 3.2%).

Conclusions: This study documents that incidence of major PACU complications after non-cardiac surgery was 2.1%, with the most frequent complications being re-intubation and ICU admission. Patients receiving NMBA reversal were at a lower risk of re-intubation and unplanned ICU admission, justifying routine use of reversals. Complete NMBA reversals are crucial in reducing preventable patient harm and healthcare utilization.

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1. Introduction

General anesthesia is generally considered to be safe, which is largely due to advancements in patients monitoring and pharmaceuticals during the last decades. Despite the great advancements in perioperative anesthesia, complications in the post-anesthesia care unit (PACU) remain common. Major complications in the PACU are generally rare, but even minor complications significantly contribute to increased

morbidity and mortality leading to increased healthcare costs. A U.S. prospective study published in 1992 investigated complications in 18,473 consecutive patients entering a PACU at a university teaching hospital [1]. Using a standardized collection form, the incidence of all PACU complications combined was 23.7% [1]. According to the U.S. Closed Claims Database, postoperative complications in the PACU account for 7.1% of all anesthesia related malpractice claims and are more likely to be associated with serious outcomes, including death and brain damage.

Neuromuscular blockade agents (NMBA) are frequently utilized in patients undergoing general anesthesia for surgery. Full reversal of the action of NMBAs is essential to safe recovery in the PACU, but is sometimes incomplete [2]. More than sixty years ago, patients exposed to neuromuscular blockade agents (NMBA) intraoperatively were reported to have a six-fold increase in perioperative mortality [3]. Since then, newer NMBAs with better hemodynamic profiles and more reliable onset and recovery have been developed. As a result, long-acting NMBAs have largely been abandoned from clinical practice in favor of intermediate-acting NMBAs. Despite this change in clinical practice, postoperative complications remain common and are frequently attributed to residual neuromuscular blockade [4,5]. The incidence of residual NMB in the PACU was previously reported to range between 3.5 and 64% [6].

The overall incidences of postoperative complications in the PACU in recent years remain largely unknown. Furthermore, whether exposure to NMBA and subsequent reversal contributes to postoperative complications in the PACU remains controversial. Our goal was thus to investigate the incidence of complications in the PACU in a tertiary care institution. A subset of the primary goal was to estimate the incidence of complications in patients receiving NMBA reversal at the end of surgery versus no reversal. Secondly, we wanted to assess the association of any complication in the PACU and impact of healthcare resources including rate of admission to ICU, ICU and in-hospital length of stay, and discharge destination.

2. Methods

With approval of the Institutional Review Board and waived informed consent, we retrospectively analyzed all patients undergoing elective non-cardiac surgery between April 2005 and December 2013 and requiring neuromuscular blockade at the Cleveland Clinic, Main Campus, Cleveland, Ohio. Data were obtained from the Cleveland Clinic Perioperative Health Documentation System (PHDS), an electronic medical record-based registry of non-cardiac surgery. Cleveland Clinic uses electronic medical anesthesia records. The PHDS functions as a quality assurance and improvement tool for the Anesthesiology Institute as well as the source for clinical research and contains the full anesthetic record of each patient. Additionally, several other resources feed into the PHDS registry. Baseline information from preoperative assessments, laboratory values and tests as well as administrative information is recorded. Postoperatively numerous assessments and variables acquired in the PACU are incorporated as well as hospital discharge data. Unique identifiers allow for data consistency and the addition of data from pharmacy logs as well as the Blood bank and our Laboratory. This manuscript was prepared according to the STROBE guidelines.

3. Quality control

Events of interest were carefully defined in discussed with Cleveland Clinic investigators and our statistical programmers. Both PHDS and clarity registries accurately reflect the electronic medical record. Both teams are experienced using SQL queries to extract data from the databases. The data were tested multiple times and statistical programmers cross-checked check both sources using various statistical methods. The investigators and research fellows manually checked critical events against the original records to assure data integrity. And finally, a

committee evaluated all available electronic and paper records of the patients to confirm the status before adjudicating potential complications.

The primary goal was to estimate the incidence of any complication in the post anesthesia care unit (PACU) in patients receiving NMBA. Complications were categorized into major (including myocardial infarction, cardiac arrest, pulmonary aspiration, stroke, unplanned admission to ICU, return to OR and re-intubation) or minor (hypotension, hypertension, hypoxemia, bronchospasm, prolonged neuromuscular blockade, nausea and vomiting, hypo/hyperglycemia, hypo/hyperkalemia, hypernatremia, and bradycardia). Definitions of complications are presented in Table 1.

A part of the primary goal was to estimate the incidence of any postoperative complication in patients receiving neuromuscular blockade and reversal medication (neostigmine) at the end of surgery vs. patients not receiving any reversal medication.

Our second goal was to assess the relationship between having any postoperative complication and associated healthcare resource use including rate of admission to ICU, ICU and in-hospital length of stay, and discharge destination.

All data were pulled from the Cleveland Clinic Perioperative Health Documentation System.

4. Statistical analysis

For our primary goal we estimated the incidence of having any major event (versus no major complication) using the exact binomial method. For our secondary goal we simply described healthcare resources in the form of length of ICU and hospital length of stay associated with postoperative events among patients receiving an NMBA. This was done univariably (ignoring measured confounding variables) and after 1:1 propensity score matching those with and without a major event on baseline and surgical parameters.

Our achieved sample size of 128,886 surgeries allowed us to estimate the primary outcome, the incidence of any major complications, with a high degree of precision. This precision is evidenced by our 95% confidence interval width of 202 to 218 events (surgeries with at least 1 major event) per 10,000 surgeries. Similar precision was available for each component of the primary outcome. SAS statistical software (Carey, NC) was used for all analyses.

5. Results

During the study period, 251,247 surgeries on 164,240 non-cardiac patients were performed. 182,343 (72.6%) of the surgeries on 129,822 (79.0%) patients received any NMBA during surgery. 136,634 (74.9%) surgeries were directly admitted to the PACU after surgery. We removed surgeries with prolonged stay at the PACU exceeding 10 h (N = 6805) and those with missing demographic or surgical procedures (N = 943). The final study therefore included 128,886 surgeries on 99,280 patients. The average PACU stay was 3.5 ± 1.8 h.

5.1. Goal 1

The observed incidence of any major complication was 2701 out of 128,886 surgeries (Incidence per 10,000 surgeries: 210). The individual major complications are summarized in Table 2. The major finding is, that re-intubation and unplanned admission to the ICU are the most frequent major complications in the PACU.

The observed incidence of any minor complication 45,375 out of 128,886 surgeries (incidence per 10,000 surgeries: 3521). Individual minor complications are summarized in Table 3. The major finding is, that Hypertension and Nausea and Vomiting are the most frequent minor complications.

Further, we assessed incidences of postoperative complications among patients with NMBA reversal vs. without. The major finding is

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