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Review Article

CLINICAL PRACTICE

Sugammadex and neuromuscular disease: a systematic review with assessment of reporting quality and content validity

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Abstract

Background: Efficacy and safety of sugammadex for the reversal of neuromuscular blocking agents (NMBAs) in patients with neuromuscular diseases remains unclear. We summarised the available evidence and evaluated the quality of data reporting and the validity of published reports.

Methods: We searched for reports (any design) on the usage of sugammadex (any regimen) for the reversal of an NMBA in patients (any age) with any neuromuscular disease. We used a modified CARE checklist (maximum score 23) to assess the quality of data reporting and an original specific validity checklist (maximum score 41) that was developed through a Delphi process.

Results: We retrieved 126 observational reports (386 patients). Most dealt with myasthenia gravis patients receiving rocuronium. The train-of-four ratio returned to ≥0.9 in 258 of 265 (97.4%) patients in whom neuromonitoring was used. Adverse events occurred in 14 of 332 (4.2%) patients in whom adverse events were reported as present or absent. In 90 case reports, the median score of the 23-point CARE checklist was 13.5 (inter-quartile range [IQR] 11–16). In all 126 reports, the median score of the 41-point validity checklist was 23 (IQR 20–27). Scores were positively correlated.

Conclusions: These uncontrolled observations (of mainly low to moderate quality and validity) do not allow confident assessment of the efficacy and safety of sugammadex for the reversal of NMBAs in patients with neuromuscular diseases. Reporting of observational data should follow established guidelines, include specific information to ensure validity, and emphasise what the new data add to current knowledge.

Systematic Review Protocol: PROSPERO 2019 (CRD42019119924).

Keywords: case report; efficacy; neuromuscular block; neuromuscular disease; quality; rocuronium; safety; sugammadex

Editor's key points

- Patients with neuromuscular comorbidities are at risk of postoperative complications when receiving neuromuscular blocking agents. Sugammadex could be a solution, but supporting evidence remains scarce.
- In 126 reports (90 case reports), 2.6% of patients receiving sugammadex for the reversal of a neuromuscular blocking agent failed to achieve a train-of-four ratio ≥0.90 and 4.2% experienced an adverse event. Quality of data reporting and validity of the reports ranged from low to moderate.
- Further case reports should adhere to reporting guidelines to improve the relevance of the publication.

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The prevalence of neuromuscular diseases ranges from 100 to 300 per 100 000 persons and is increasing as survival improves.[1,2] Consequently, it is not uncommon to encounter these patients in daily anaesthesiology practice. When performing general anaesthesia, using a neuromuscular blocking agent (NMBA) facilitates tracheal intubation and may improve surgical conditions.[3–7] Patients with neuromuscular comorbidity, should they receive an NMBA during anaesthesia, are at a particularly high risk of residual neuromuscular block in the postoperative period. Sugammadex, a γ-cyclodextrin, forms complexes with steroidal NMBAs, blocking their action, and does not interfere with acetylcholine at the neuromuscular junction. It then may be a compelling option for the reversal of a neuromuscular block in patients with neuromuscular comorbidities who received a steroidal NMBA. Unfortunately, prospective clinical studies focusing on the safety of NMBAs usually exclude patients with neuromuscular diseases.[8–11]

A qualitative systematic review published in 2019, including 43 observational studies, mainly case reports, reported on the use of sugammadex in adults with neuromuscular comorbidities receiving an NMBA.[12] The authors reported not only on the successful reversal of rocuronium with sugammadex in these patients but also on adverse reactions and instances of inadequate reversal despite the administration of sugammadex. The reports provided only limited knowledge on optimal dosing and timing of administration of sugammadex, and the authors did not assess the validity of the analysed observational reports or the quality of data reporting.

Since the abovementioned systematic review, additional, potentially relevant case reports have been published. Therefore, our systematic review had two objectives: firstly, to update and to summarise the available evidence on the efficacy and safety of sugammadex in patients with neuromuscular comorbidities receiving an NMBA, and secondly, to evaluate the validity of the published reports and the quality of data reporting.

Methods

The study protocol was published in the international prospective register of systematic review Prospero (PROSPERO 2019 CRD42019119924).[13]

Eligibility criteria

We included research articles (any design) reporting on patients of any age, with any disease affecting the CNS, motor neurones, nerves, neuromuscular junction, or muscles, and who were undergoing surgery under general anaesthesia using an aminosteroid NMBA (rocuronium or vecuronium, any regimen), and receiving sugammadex (any regimen) for the reversal of the neuromuscular block. We did not consider narrative reviews or conference abstracts.

Information sources

We searched PubMed, Embase, Cochrane, and SciELO databases, last update March 14, 2024. Additional references were searched from the bibliographies of retrieved articles. We contacted the authors of the included reports for clarification when necessary.

Search strategy

We developed a search strategy with the help of a librarian at the Faculty of Medicine of the University of Geneva, Geneva, Switzerland. The search strategy was highly sensitive in order not to miss any reports. We developed a search equation and translated it manually for each database searched (Supplementary material 1).

Selection process

Two authors (AS and GK) independently screened titles and abstracts of retrieved references that met our inclusion criteria. We used the Rayyan web app for the study selection process.[14] Any disagreement regarding inclusion was solved through discussion with a third author (NE).

Data collection process

The data were extracted from each included article by one author (AS) and recorded in a Microsoft® Excel (version 16.81, Microsoft Corp., Redmond, WA, USA) spreadsheet designed for this study. Extracted variables were checked by GK, and disagreements were resolved with NE.

Data items

All items extracted are listed in Supplementary material 2. We categorised the diseases into five classes according to the descending steps of neuromuscular transmission: CNS, upper or lower motor neurone, peripheral nerve, neuromuscular junction (myasthenia gravis), or muscle.

Quality of data reporting and validity of reports

Quality of data reporting: CARE guidelines

As the majority of the retrieved studies were case reports, we focused on this group of reports and used the 2013 CARE guidelines proposed by the EQUATOR network for the assessment of the quality of data reporting.[15] We attributed one point for each item, except for section 8, points 10b, 10c, and 12, as they were irrelevant in the perioperative context. The maximum score was thus 23.

Validity of reports: Delphi process

To evaluate the validity of the reports (i.e. the quality of the content of the reports from the perspective of the clinical usefulness and completeness of the information provided), we developed a specific checklist with the help of selected NMBA experts following a Delphi process. The first version of the checklist included 33 items that we considered compulsory for the description of a valid report on the usage of an NMBA. This list was submitted to nine international NMBA experts. Eight of them answered and suggested additional potentially useful items. If at least four experts mentioned an item, it was added to the second version of the checklist, which was then sent back to the expert panel for validation. Our final checklist included 41 items. As we attributed one point for each item, the maximum score was 41. A detailed description of the Delphi process and a list of the included items is provided in Supplementary material 3.

Efficacy and safety measures

Efficacy was assessed based on the available data on the return to a train-of-four ratio (TOFr) ≥0.9. We extracted all adverse events reported.

Synthesis methods

All data are described as reported in the original articles. Items are summarised either as numbers (%) of all reports or as numbers (%) of all patients, and as medians and inter-quartile ranges, computed with IBM Corporation® SPSS Statistics (version 29.0.2), as deemed adequate based on the extracted data. For reports describing more than one patient, the validity checklist score of the report was computed as the mean score of each individual patient.

Results

Study selection

Our search strategy identified 1072 studies, of which 210 were double hits (Fig. 1). We screened 862 papers, excluded 25 because of languages we could not translate (21 in Japanese, three in Turkish, and one in Russian), added two references identified from the bibliographies of retrieved articles, and finally included 126 reports.

Characteristics of the included reports

Of the 126 included reports, 90 (71%) were published as 'case reports', 30 (24%) were case reports published as letters to the editor or in the correspondence sections of the journals, five (4%) were case series, and one (0.8%) was a prospective cohort study. The countries of origin of all reports are listed in Supplementary material 4. The total number of patients analysed was 386. Reports included 1 to 117 patients. The number of reports and cumulative number of patients published per year are presented in Figure 2. Compared with the previously published systematic review,[12] we included 83 additional reports with data from 192 additional patients. A detailed description of the included studies is provided in Supplementary Table S1.

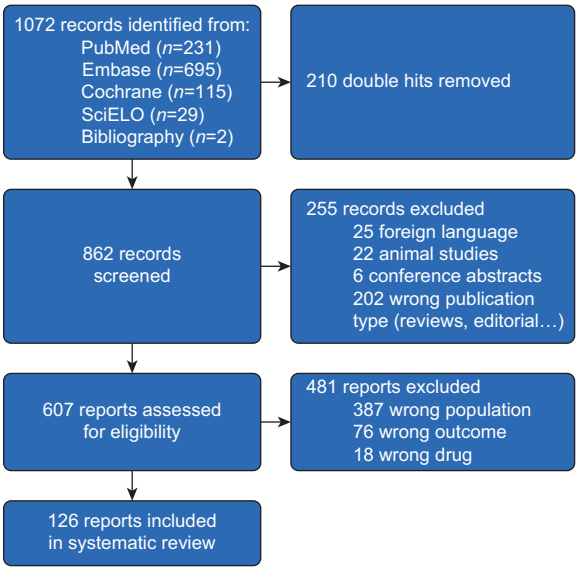

Fig 1. Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) flow diagram.

Characteristics of patients

Of the 386 patients, 152 were men, 204 were women, and for 30, no information was reported on sex. Their age ranged from 3 weeks to 87 yr. The patients suffered from myasthenia gravis (290), muscle diseases (44), CNS diseases (23), motor neurone diseases (24), and peripheral nerve disease (5). ASA scores were reported for 242 patients (62.7%) in 21 reports. Surgeries performed on these patients included endocrinology (*n*=226, 58.5%), visceral surgery (*n*=50, 13%), otorhinolaryngology surgery (*n*=28, 7.3%), or thoracic surgery (*n*=11, 2.8%).

Anaesthesia and surgery management

All patients underwent general anaesthesia with an NMBA. A total of 234 and 146 patients received i.v. and inhalation anaesthesia, respectively. Information on anaesthesia was lacking for six patients.[16,17,18,19,20] Rocuronium was used in 376 patients and vecuronium in nine. For one patient, no information on the NMBA used was provided.[18] Sugammadex regimens ranged from 1 to 17 $mg \cdot kg^{-1}$. The neuromuscular monitor used was described in 337 patients (87%), and the motor unit used for neuromonitoring was reported in 308 patients (79.8%). Baseline TOFr was reported in 52 patients (13.5%). After surgery, 171 patients (44.3%) were transferred to an intensive care unit, 76 (19.7%) to a postinterventional care unit, five (1.3%) to a regular ward, and four (1%) to an intermediate care unit. No information was provided for 130 patients (33.7%).

Results of individual studies and synthesis

Primary outcome

Efficacy. A TOFr was reported in 265 patients (68.7%). Of those, a postoperative TOFr ≥0.9 was not achieved in seven (2.6%) patients. In two of these seven patients, the TOFr was 88% and 86% at extubation,[21,22] in three, the TOFr further improved

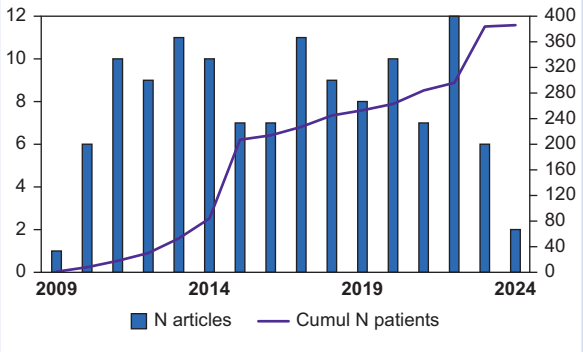

Fig 2. Number of reports and cumulative number of patients published per year. Year 2024 included until March 14.

after subsequent administration of neostigmine,[23,24,25] in one, the TOFr returned to the pre-curarisation value which was 65% only,[26] and in one, the post-tetanic count was 6.[27]

Safety. Safety endpoints were reported as present or absent in 332 (86%) patients. Adverse events occurred in 14 patients (4.2%), four requiring reintubation. Two of them were diagnosed with a postoperative myasthenic crisis.[18,28] One was described having an unstable breathing, and one suffered from undiagnosed myasthenia gravis at the time of surgery and had a respiratory arrest 2.5 h after the end of surgery.[29,30] One patient was described with a postoperative myasthenic crisis but did not require reintubation,[25] and three had myasthenic crisis at postoperative day 1, 2, and 9.[30] For the other six, one developed anaphylaxis that was attributed to sugammadex by the authors,[31] two had symptoms compatible with exacerbation of myasthenia gravis,[17,32] one had a suspicion of residual effect of sevoflurane,[33] one suffered from a recurarisation that was corrected, before extubation, with an additional dose of sugammadex,[34] and one had a persistent neuromuscular block not attributed to rocuronium by the authors.[27]

Secondary outcomes

Quality of data reporting: modified CARE checklist. The median score of all 90 case reports was 13.5 (IQR 11–16). For case reports published before 2013 (i.e. before the publication of the CARE guidelines), the median score was 15.5 (IQR 14.25–17.75), and for those published after 2013, it was 13 (IQR 10.75–16). There was a visual negative trend over the years (Fig. 3).

Validity checklist. The median score of all 126 included articles was 23 (IQR 20–27). The median score was not different between reports reported as case reports (23.5), as letters to the editor, or correspondence (23). There was also a visual negative trend over the years (Fig. 4).

Correlation between checklists. There was a positive correlation between the scores of the modified CARE and the validity checklist (Fig. 5).

Conflict of interest. Of 126 reports, 13 (10.3%) included at least one author who reported a conflict of interest (COI) related to sugammadex, 81 (64.3%) reported that none of the authors had any COI, and 32 (25.4%) did not report on presence or absence of COI. None of the papers in which authors declared COI reported on any adverse events, whereas complications were reported in reports where authors explicitly declared the absence of COI (9) or did not report the absence or presence of COI (2).

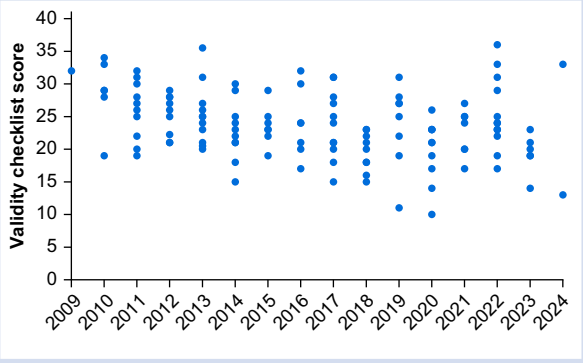

Fig 4. Evolution of the scores over time. Each dot represents one of 126 reports. Year 2024 included until March 14.

Discussion

The retrieved reports confirmed previous observations on the efficacy of sugammadex in patients with neuromuscular diseases receiving a steroidal NMBA,[12] with a reported failure rate for the reversal of the neuromuscular block (TOFr <0.9) of only 2.6% (seven of 265 patients). These results emphasise the importance of careful monitoring of the neuromuscular function when administering an NMBA, even when using sugammadex. No report suggested a complete failure of the reversal of the neuromuscular block with sugammadex.

Despite a systematic and exhaustive search of the literature, we retrieved uncontrolled observations only, mostly case reports or small case series, and the reports were of limited validity and quality of data reporting. The preponderance of uncontrolled observations in this specific setting is not surprising given the low prevalence of the diseases studied and that NMBAs are usually avoided in such populations.[35] This may explain why high-quality data from large controlled trials are lacking. For the 15-yr period studied, we found relevant

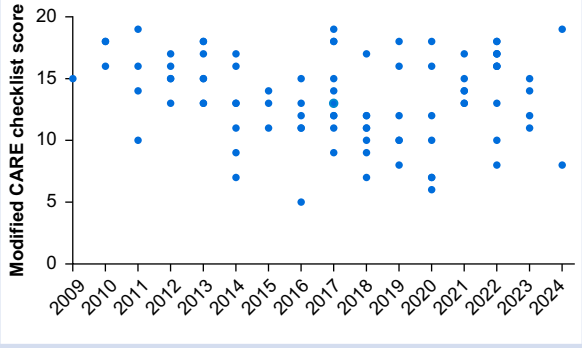

Fig 3. Evolution of the scores over time. Each dot represents one of 90 case reports. Year 2024 included until March 14.

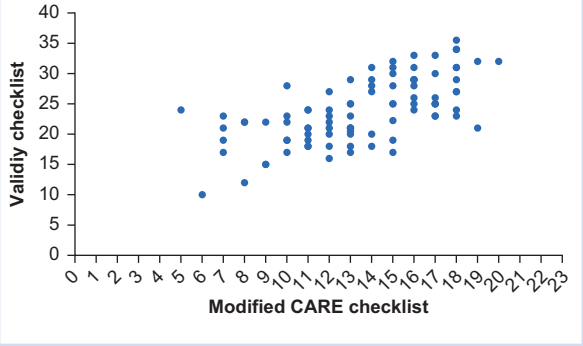

Fig 5. Correlation between the scores. Each dot represents one of 90 case reports.

data of 386 patients only. Sometimes, uncontrolled observations may be the best clinicians get to guide decision-making. However, the low validity and the low quality of data reporting of most of these observational reports further limit their informative value.

To evaluate the quality of data reporting, we used the CARE checklist for the case reports and an original checklist specifically developed for this analysis, for all the included reports. There were three main results. Firstly, the checklists were positively correlated, suggesting that reports that followed general reporting guidelines also tended to report more relevant data. Although a causal association between the two checklists remains uncertain, publishers should actively promote the use of reporting guidelines as they may also improve the validity of observational reports. Secondly, there was no improvement in the quality of data reporting over time despite the publication of the CARE guidelines. Inadequate adherence to the CARE guidelines has been reported before.[36] And finally, there seemed to be a negative trend over time of the scores of both checklists, suggesting that the quality and validity of relevant information provided in the reports has been decreasing. It is important to note that our validity checklist, developed in collaboration with eight specialists in the field, has not been externally validated and was developed for the purpose of this specific review.

We found 30 case reports published as letters to the editor or in a correspondence section. Journal editors may limit the inclusion of case reports as complete reports because they are cited less often, negatively affecting a journal's impact factor.[37] However, when published as letters or correspondences, authors of case reports cannot fully adhere to the CARE recommendations, which include, for example, an abstract, and this is likely to have a detrimental impact on the quality of data reporting and the relevance and validity of the provided information. Uncontrolled observations, such as case reports, are at the bottom of the evidence pyramid. However, they may help reveal new diseases, describe the clinical management of rare diseases, or establish plans for further research. Also, case reports may have a significant educational value.[38–41] Consequently, case reports must be wholly and correctly reported.

All included articles were published in peer-reviewed journals. Nonetheless, in some reports, relevant information was lacking. For example, in this very 'anaesthesia-centred' topic, the ASA score for categorising the risk of perioperative complications was reported in only 16.7% of the reports. When studying the efficacy of NMBAs and their reversal, the most prominent tool is neuromuscular monitoring. However, neuromuscular monitoring was often insufficiently recorded, described as 'visual',[42] or not performed at all.[43] In one patient, even the NMBA was not described.[18] Reasons for these obvious omissions remain unclear.

In 25% of the reports, there were no COI disclosure statements from authors and a COI was reported in 10.3% of the included studies. These numbers are similar to those found in the literature,[44] and the insufficient description of COI has been previously reported for the anaesthesiology literature.[45] Even if no conclusion can be drawn from the limited sample size of the present study, it is interesting to note that no complication was reported in papers where authors declared a COI. The impact of industry sponsorship on the reporting of favourable and unfavourable outcomes in published studies has been described.[46–48]

The previously published systematic review included 43 reports with data from 193 patients.[12] The authors excluded children and described the main results qualitatively by classifying the reports according to different disease families. Our analyses were based on an exhaustive search of reports of patients of any age and with any neuromuscular disease. We assembled all the available data in a numerical and comprehensive way and summarised information on quality of data reporting and validity of the reports. Although our analyses eventually included more than three times the number of reports and data of twice more patients than the previously published systematic review, we were unable to provide more insights into the efficacy and harm of the reversal of the neuromuscular blocking effect of an NMBA with sugammadex in patients with neuromuscular diseases. There was no evidence of an improvement in the quality of data reporting or in the validity of the reports over time. For many of these new observational reports, it remained unclear what their added value was, and why they were published at all.

Since 2009, approximately eight reports on this topic have been published annually, with few new information. This raises the question as to whether the publication of additional case reports on the successful reversal of NMBAs with sugammadex is beneficial. It appears unlikely that such observational and uncontrolled reports would significantly improve current knowledge.

Conclusions

Our study highlights the difficulty of answering a simple clinical question based on solid evidence in managing a population suffering from a rare disease. The quality of the available evidence does not allow the conclusion that sugammadex is efficacious or safe in this context. Nonetheless, the convincing biochemical mechanism of the interaction between sugammadex and steroidal NMBAs, the almost unanimous reports of success of reversal, and the minimal number of reports of adverse events support the administration of a steroidal NMBA in this population, as long as the NMBA is used in combination with careful quantitative neuromuscular monitoring. Authors of further observational reports should concentrate on new insights, include all relevant information to ensure their report's validity, and follow established guidelines of data reporting. Editors should ensure that authors publish observational reports that satisfy confirmed criteria of validity and quality of data reporting.

Authors' contributions

Conceptualisation: all authors
Assessed the eligibility of the studies: AS, GKB
Data extraction: AS, GKB
Data analysis: AS, NE
Writing the original draft: AS
Supervision: MT, NE
Review, editing, and validation of the manuscript: all authors

Declaration of interest

The authors declare that they have no conflicts of interest.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.bja.2024.05.015.

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