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The Role of Sugammadex in Managing Rocuronium-Induced Anaphylaxis: A Case Report and Review of the Literature

Marouane Jidal*, Youssef Halhoul, Yasser Ouatab, Hassan Kraitiss, Abderrahman Elwali, Mustapha Bensghir

Department of Anesthesiology and Intensive Care Unit, Mohammed V Military Hospital, Rabat, Morocco
Email: *marouane.j96@gmail.com

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Abstract

Background: Anaphylactic shock induced by neuromuscular blocking agents is a rare complication, but it accounts for 50% to 70% of perioperative anaphylactic shocks. Although not yet officially recommended, Sugammadex is increasingly being used in the therapeutic arsenal for anaphylactic shock induced by rocuronium. **Case Presentation**: We report the case of a 46-year-old North African female who experienced grade III anaphylactic shock during a laparoscopic cholecystectomy. Despite standard resuscitation, significant improvement was only observed after administering 1000 mg of Sugammadex. The surgery was completed without further NMBAs, and the patient was stable postoperatively. **Methods:** A PubMed and Scopus search adhering to Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines was performed to include studies reporting patients with an anaphylactic reaction to rocuronium treated with Sugammadex. **Results:** The search yielded 12 cases of patients with an anaphylactic reaction to rocuronium treated with Sugammadex. All studies were case reports (Level IV of evidence). Different characteristics of these cases are described, including age, time between injection of rocuronium and start of anaphylaxis, the dose of Sugammadex and-ministred and clinical response. **Conclusion:** This case, aligned with other reports, suggests Sugammadex's potential efficacy in such cases, though controlled studies are challenging due to the rarity of these reactions. Therefore, Sugammadex should not replace established resuscitation protocols.

Keywords

Anaphylactic Shock, Rocuronium, Sugammadex, Case Report

1. Introduction

Perioperative anaphylactic shock is a rare but concerning complication among anesthesiologists. Its incidence varies between countries and is estimated between 1/250 and 1/18,600 anesthesia cases, with a clear female predominance [1]. This wide variation in reported incidence likely reflects differences in national pharmacovigilance systems, diagnostic criteria, exposure to anesthetic agents, reporting practices, and patient populations. Neuromuscular blocking agents (NMBAs) account for 50% to 70% of allergic reactions observed during the perioperative period, followed by latex and antibiotics, with succinylcholine and rocuronium being the most frequently implicated neuromuscular blockers [2]. Sugammadex is a reversal agent used to neutralize the effects of non-depolarizing steroidal neuromuscular blockers (rocuronium and vecuronium). Recently, several clinical cases [3]-[13] have highlighted the potential efficacy of this molecule in cases of anaphylactic shock induced by rocuronium refractory to catecholamines.

The present article reports a new case of anaphylactic shock to rocuronium refractory to catecholamines that responded favorably to Sugammadex; furthermore, a comprehensive systematic review of the literature of the use of Sugammadex in managing refractory shock induced by rocuronium is performed.

2. Methods

2.1. Study Selection

A comprehensive literature search of PubMed and Scopus was performed in accordance with the PRISMA 2020 (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines. In addition, a search was performed on Google Scholar to identify articles not reported in PubMed or Scopus. The search for publications was undertaken using the following keywords: "anaphylactic shock," "rocuronium," and "Sugammadex." The search extended to all available English-language articles from 2010 to May 2023. All included articles were case reports, and according to the Oxford Centre for Evidence-Based Medicine table, they were labeled as Level IV studies.

2.2. Inclusion and Exclusion Criteria

Cases were included in the final review only if the article showed adequate clinical and biological information. The following studies were excluded: literature reviews, animal studies, correspondence or letters, articles not available in full text, articles reporting an anaphylactic reaction to Suggamadex, and articles with incomplete clinical information. Titles and abstracts were initially reviewed to identify articles with positive exclusion criteria.

2.3. Data Extraction

Extraction data was performed from eligible cases. Specific information was obtained from eligible articles. Collected data included age, history of allergic reactions, type of surgery, anaphylactic reaction grade, time between injection of rocu-

ronium and start of anaphylaxis, time between the start of anaphylaxis and injection of Sugammadex, dose of Sugammadex andministred, clinical response and finally confirmation test. Not all articles provided information about each item; therefore, a comparative analysis was limited by the nature and the limited number of the source data.

3. Results

3.1. Case Presentation

M.F. A 46-year-old north african female patient was scheduled for laparoscopic cholecystectomy due to gallstones. Her medical history included well-controlled hypothyroidism on Levothyroxine and cesarean section under spinal anesthesia without notable allergic events. She had no known drug, food, or other allergies, including cosmetics.

Preoperative evaluation revealed a patient in good general condition, weighing 64 kg with a BMI of 22 $kg.m^{-2}$, blood pressure at 120/80 mmHg, heart rate at 86 bpm, SpO_2 at 99%, and good exercise tolerance with a functional capacity > 4 METs. Additionally, the anesthesia assessment found good venous access and no criteria indicating difficult ventilation or intubation.

Premedication consisted of 75 mg of hydroxyzine the night before and the morning of the procedure. Perioperative monitoring data, which included a three-lead EKG, continuous SpO_2, and non-invasive blood pressure measurements every minute, were systematically recorded on the monitor and documented in the anesthesia record.

After establishing an 18 G IV canula, the patient was pre-oxygenated and received 500 ml of 0.9% normal saline. Anesthesia induction involved 170 mg of propofol, 20 mg of 2% lidocaine, and 200 µg of fentanyl. Following loss of consciousness, 40 mg of rocuronium was administered, and orotracheal intubation was performed two minutes later. Maintenance anesthesia was achieved with 2% sevoflurane. Notably, the patient did not receive antibiotic prophylaxis as this was a straightforward laparoscopic cholecystectomy.

Five minutes after induction, the patient developed a rash on her chest and limbs, followed rapidly by a drop in blood pressure to 75/39 mmHg without desaturation or increased airway pressures. After rapidly excluding obstructive or cardiogenic shock through pleuro-pulmonary and cardiac ultrasound, which showed no pneumothorax, right heart dysfunction, and indicated good contractility, grade III anaphylactic shock (Ring and Messner classification) was promptly suspected. The management included halting halogenated agents, administering 1 L of 0.9% normal saline, giving five 100 µg boluses of adrenaline, and initiating a continuous adrenaline infusion at 0.05 µg/kg/min via another IV line in the opposite arm.

Due to the lack of significant hemodynamic improvement, a decision was made to antagonize the NMBAs with a rescue dose of 1000 mg of Sugammadex, administered nine minutes after the onset of symptoms. One minute later, there was an improvement in hemodynamic parameters and the rash resolved (**Figure 1**).

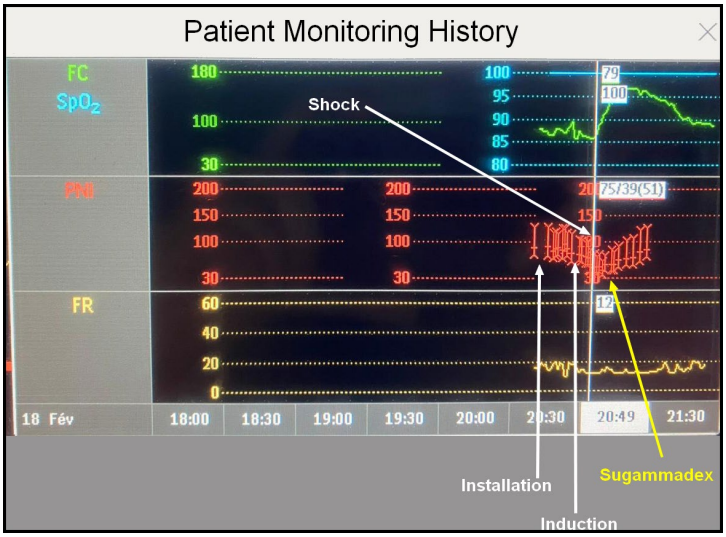

Figure 1. Patient monitoring history.

Invasive blood pressure monitoring via an arterial catheter was performed, fluid resuscitation continued with normal saline, adrenaline support was gradually reduced, and a blood sample was obtained.

The decision to proceed with the surgery without NMBAs was made in consultation with the surgical team, using propofol for maintenance in a TIVA approach. Hemodynamic parameters remained stable without vasopressor support throughout the surgery, and the patient was extubated 30 minutes post-surgery and transferred to the ICU for 24-hour observation.

The patient was informed of the anesthetic incident. Given the positive serum tryptase and histamine levels (anti-AQ IgE testing was unavailable at our hospital), she was referred to an allergy-anesthesia consultation one month later. All drugs used during anesthesia (propofol, fentanyl, lidocaine, rocuronium) were tested; only the skin tests for rocuronium were positive (those for succinylcholine and atracurium were negative).

3.2. Systematic Review

The literature search yielded 334 articles. After removal of duplicates, the title and abstract of 247 articles were screened, and based on exclusion criteria, 232 articles were eliminated. After this initial filter, 15 articles were assessed for eligibility, of which 4 were excluded for different reasons. Thus, 11 articles with a total of 11 patients were eligible for analysis (Figure 2).

Table 1 summarizes the characteristics of these 11 cases in addition to our own case, totaling 12 patients.

Table 2 shows the characteristics of these patients with suspected anaphylactic reaction to rocuronium treated with Sugammadex.

Most patients were female (83%) with a median age of 56 years. The onset of the anaphylactic reaction had a median time of 2 minutes, with 75% of the reactions classified as Type III. Regarding the administered dose of sugammadex, the

median dose was 450 mg. Finally, the outcome was favorable in 100% of cases, with a median response time of 2 minutes.

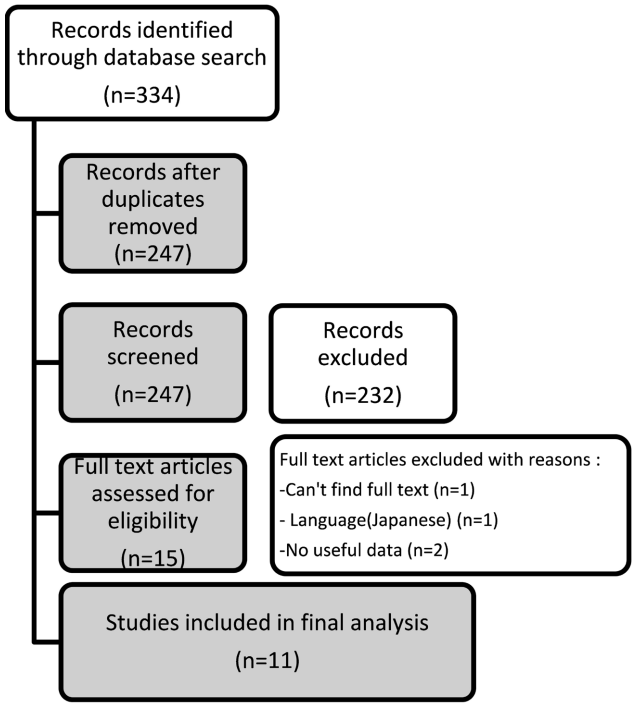

Figure 2. Flow chart of the literature search strategy and article selection for screening and analysis.

Table 1. Descriptive characteristics of the study population.

Variables	Value N: 12
Age (in years)[1]	56 [47; 62]
Gender[2]	
Male	2 (17)
Female	10 (83)
Anaphylactic reaction grade[2]	
II	1 (8)
III	9 (75)
IV	2 (17)
Start of anaphylaxis (min)[1]	2 [0.1; 5]
Shock-Sugammadex period (min)[1]	20 [14; 30]
Dose rocuronium (mg)[1]	50 [41; 50]
Dose Sugammadex (mg[1])	450 [200; 775]
Outcome[2]	
Favourable	12 (100)
Response time (min)[1]	2 [1; 3]

[1]expressed as median [interquartile range]; [2]expressed as headcount (percentage).

Table 2. Descriptive characteristics of the study population.

Cases	Patients	Surgery	Anaphylactic reaction grade	Start of anaphylaxis	Schock-Sugam madex period (min)	Dose rocuronium (mg)	Dose Sugammadex (mg)	Clinical response		Confirmation test
								Time	Outcome	
McDonnell *et al.* (2011) [3]	Woman, 33 yo, prior surgeries without allergy reports	Diagnostic abdominalaparoscopic procedure	Grade IV	30 sec	23	30	500	45 sec	Favourable	Tryptase + Skin test +
Funell *et al.* (2011) [8]	Woman 47 yo, previous allergic reaction to cotrimoxazole	Laparoscopic cholecystectomy	Grade III	Immediate	60	50	400	2,5 min	Favourable	Tryptase + Skin test +
Badaoui *et al.* (2012) [6]	Woman, 52 yo, prior surgeries without allergy reports	Laparoscopic rectal cancer surgery	Grade III	2 min	20	50	1000	5 min	Favourable	Tryptase + Skin test +
Timbó Barbosa *et al.* (2012) [9]	Woman, 62 yo, prior surgeries without allergy reports	Cranial epidural hematoma evacuation	Grade III	Immediate	5	45	700	2 min	Favourable	-
Motamed *et al.* (2012) [5]	Woman, 61 yo	Bone cementoplasty	Grade III	5 min	20	27	180	3min	Favourable	Tryptase +
Raft *et al.* (2012) [4]	Woman, 51 yo	Umbilical hernia repair	Grade III	2 min	18	50	2000	Few sec	Favourable	Tryptase + Skin test +
Kawano *et al.* (2012) [10]	Woman 62 yo, no prior surgeries	Modified radical mastectomy	Grade II	Immediate	30	20	200	«Shortly afterward»	Favourable	-
Sirieix *et al.* (2014) [7]	Woman, 60 yo, prior surgeries without allergy reports	Biliopancreactic endoscopic US	Grade III	3 min	10	50	600	35 min	Favourable	Tryptase + Skin test +
Itziar De La Cruz *et al.* (2019) [11]	Man 36 yo,	Laparotomy for blunt abdominal truama	Grade III	Immediate	-	80	280	2 min	Favourable	Tryptase + Skin test +
Sun-Min Kim *et al.* (2020) [12]	Woman, 72 yo, prior surgeries without allergy reports	Decompressive lumbar laminectomy	Grade III	10 min	30	50	200	«Shortly thereafter»	Favourable	Skin test +
Sheng-Kai Hung *et al.* (2022) [13]	Man, 68 yo, prior surgeries without allergy reports	Robotic-assisted radical prostatectomy	Grade IV	20 min	60	60	200	«Shortly thereafter»	Favourable	Skin test +
Our study	Woman, 46 yo	Laparoscopic cholecystectomy	Grade III	5 min	9	50	1000	1 min	Favourable	Tryptase + Skin test +

4. Discussion

Since the publication of the clinical case reported by McDonnell *et al.* [3], which represents the first illustration of the potential benefit of Sugammadex administration in cases of anaphylactic reaction refractory to catecholamines induced by rocuronium, several publications [4]-[13] have reported similar observations. Our case report therefore falls in line with these findings. And like all these reported cases, ours also raises the question of the pathophysiology of Sugammadex during anaphylactic shock. NMBAs carry two antigenic motifs (quaternary ammoniums [NH_4^+]) recognized by specific IgE, making their allergenic potential more likely by binding two IgE molecules [14].

Additionally, immediate IgE-mediated hypersensitivity reactions have been reported during the first exposure to an NMBA, suggesting sensitization to a common allergenic determinant, such as substances containing quaternary ammoniums or tertiary amines found in many products, including cosmetics and disinfectants [15]. Several studies are investigating this relationship, including one conducted among hairdressers [16]. Another hypothesis involves exposure to pholcodine, an opioid antitussive. After the withdrawal of pholcodine-based cough syrups in Norway, there was a reduction in IgE-mediated HSR cases to NMBAs and a decrease in anti-quaternary ammonium antibodies in the population [17].

Avoiding exposure to the antigen is recommended in managing anaphylactic shock, but this is difficult once the drug is administered intravenously. Sugammadex is a cyclodextrin capable of specifically and stably encapsulating rocuronium molecules [18]. This binding could mask the antigenic determinants, rapidly and significantly reducing the antigenic load and interaction with IgE. The hypothesis for Sugammadex's efficacy might involve the prolonged release of newly formed anaphylaxis mediators sustained by high antigen concentrations [3] [4]. Reducing antigen concentration post-Sugammadex administration could stop de novo mediator synthesis, allowing cardiovascular recovery. Notably, while some reports [4] [6] [9] describe the use of high "rescue doses" of Sugammadex, the median dose in our systematic review was 450 mg, lower than typical rescue regimens. This observation suggests that the effect may not be strictly dose-dependent, and that other factors—such as timing of administration, severity of the reaction, and individual variability—likely influence clinical response.

However, *in vitro*, Sugammadex does not reduce CD263 expression, a basophil activation marker, in rocuronium-allergic subjects [19]. Furthermore, the specific IgE responsible for the allergic reaction might be polyclonal and/or recognize various antigenic determinants on the molecule's surface, which could be masked by the rocuronium-Sugammadex complex or remain accessible [20] [21]. Thus, Sugammadex's efficacy could vary. One case report [22], published only as a correspondence and therefore excluded according to our predefined criteria (which required full case reports), described no clear reversal of anaphylactic shock signs to rocuronium after sugammadex injection.

Indeed, given the small sample size of our review and the fact that the literature

only reports cases where reversal was favorable, it is very difficult to establish logistic regression models to identify factors influencing the success or failure of sugammadex use in the management of rocuronium-induced anaphylactic shock. Therefore, we encourage the publication of cases where the use of sugammadex resulted in a failure to reverse the shock.

Thus, despite 100% of the cases in our review achieving anaphylactic shock reversal following sugammadex administration, establishing a direct causal link remains impossible. To overcome this limitation, the establishment of national and international registries for perioperative adverse drug events would be essential to systematically capture both successful and unsuccessful interventions, thereby reducing publication bias and improving the quality of evidence.

Additionally, several cases of immediate hypersensitivity reactions have been reported following Sugammadex administration. In Japan, the risk of anaphylactic shock to Sugammadex is estimated at 1/34,483 uses [23] [24].

To conclude, an allergy to NMBAs also raises the question of the anesthetic technique to be used for any future surgery. If the surgical procedure can be performed under regional anesthesia, this technique should, of course, be preferred. When surgery does not require muscle relaxation, tracheal intubation can be easily performed without muscle relaxants. In the context of a patient allergic to an NMBA, the best drug combination would be propofol (2.5 mg/kg), alfentanil (>30 μg/kg), and lidocaine (1 - 2 mg/kg), providing intubation conditions comparable to those obtained with thiopental and succinylcholine [25] [26].

The issue becomes more complex if the surgery requires a certain degree of intraoperative muscle relaxation. The simplest solution is probably to use higher concentrations of halogenated agents. All halogenated agents share the ability to produce some degree of muscle relaxation, with the myorelaxant properties of isoflurane being the most studied [25].

However, with the advent of allergology-anesthesia consultations, skin testing, the gold standard, allows for the diagnosis of NMBA allergy. If the administered NMBA tests positive, cross-sensitivity to other NMBAs is assessed during the same consultation. This process provides clear and safe guidance for anesthesiologists in choosing an NMBA for future anesthesia by suggesting the one with a negative skin test. Several clinical cases and case series [19] [24] [27] confirm the good tolerance of the NMBA with a negative test.

5. Conclusion

The effectiveness of a high dose of sugammadex in the treatment of rocuronium-induced anaphylactic shock after the failure of traditional resuscitation methods has been reported. However, given the rarity of published cases (particularly the lack of reports on non-responders as highlighted in our systematic review), conducting controlled clinical studies is challenging. At present, the use of sugammadex in this context remains off-label and not approved, mainly due to the absence of randomized controlled trial data. Moreover, the underlying pathophysi-

ological mechanisms behind this beneficial effect remain poorly understood. Therefore, the use of sugammadex in this context should not replace resuscitation performed in accordance with established guidelines.

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Ethics Approval and Consent to Participate

We gained the written informed consent of the patient to use her clinical information and photographic material for the publication.

Conflicts of Interest

The authors declare no competing interests.

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