



An Evidence Based Examination and Description of the Side Effect Profile of Sugammadex (Bridion) a Cyclodextrin Molecule: Quality Improvement Project

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OBJECTIVE

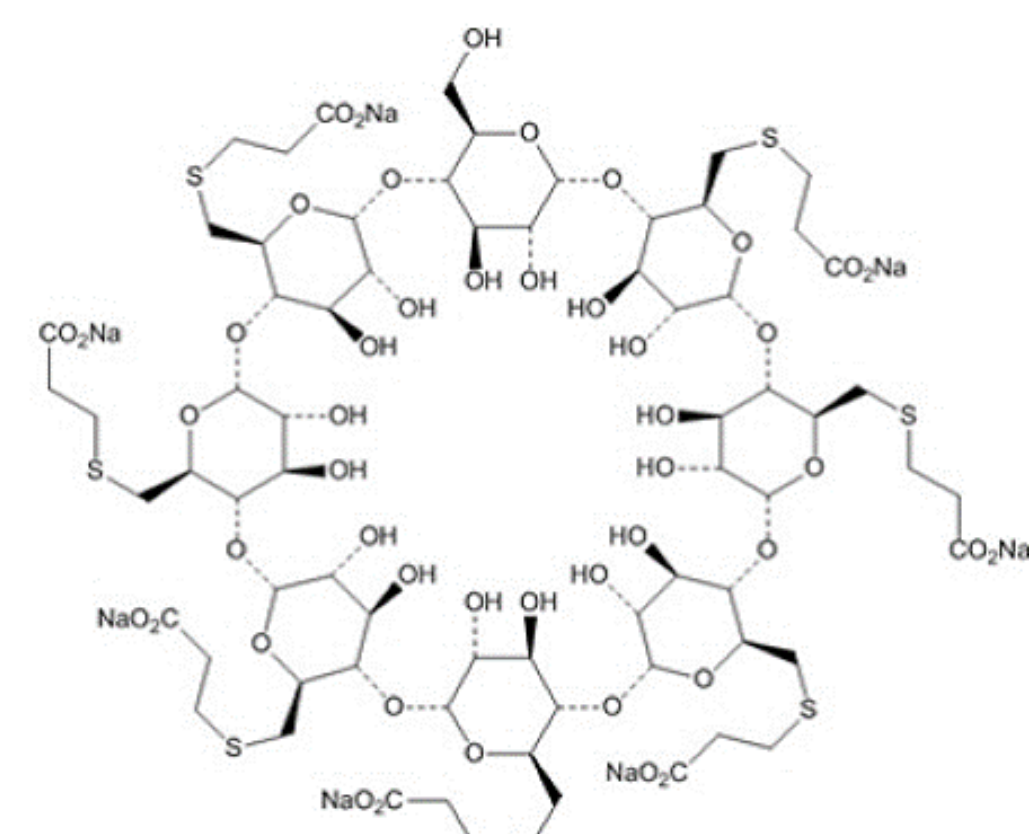
- To examine current evidence and analyze the etiology of the adverse reactions of Sugammadex (Bridion)
- The goal was to evaluate knowledge deficits, among nurse anesthesia students, and develop a teaching tool to improve the delivery of care based on practice recommendations.

INTRODUCTION

- Sugammadex is used for the reversal of aminosteroidal neuromuscular blocking agents such as rocuronium or vecuronium.
- While there are many benefits of using Sugammadex, the development of potentially life-threatening side effects such as severe hypotension, QT interval prolongation, and severe bradycardia have been reported
- Clinicians have hypothesized that the cause of life-threatening bradycardia and hypotension advancing into cardiac arrest after Sugammadex administration may be caused by an increased amount of free Sugammadex in plasma molecules, presence of underlying heart diseases, an excessive dose, and coronary spasms

METHODS

- A total of 20 participants were surveyed for this Quality Improvement project
- The participants were current Union University seniors in the BSN-DNP nurse anesthesia track program. They were selected because they use Sugammadex during their clinical rotations and will likely use this medication in their future practice
- The questions that were provided through SurveyMonkey were developed in response to the research conducted about the side effect profile of Sugammadex and their clinical relevance to the participants' current clinical experience using this drug
- Databases included: ScienceDirect, Medline, PubMed
- Search terms: Sugammadex, bradycardia, side-effects



REVIEW OF LITERATURE

History: The use of Sugammadex (Bridion) was approved by the U.S. Food and Drug Administration (FDA) on December 15, 2015, for the reversal of aminosteroidal neuromuscular blocking agents Rocuronium and Vecuronium for patients who received these neuromuscular blocking agents during surgery. Europe was the first to approve the use of Sugammadex in 2008, but there was a delay by the U.S. FDA due to concerns of the safety profile. Despite safety concerns, Sugammadex has successfully entered the pharmaceutical market in the United States and several studies have demonstrated its efficacy and safety although potential risks still prevail.

Mechanism of Action: Sugammadex is a selective neuromuscular relaxant blocking agent with a gamma-cyclodextrin structure that consists of oligosaccharides that are linked around a central cavity. After administering Sugammadex, aminosteroidal neuromuscular blocking agents rocuronium and vecuronium becomes entrapped within the central cavity. The entrapment results in neutralizing the neuromuscular relaxants and decreasing their plasma level. This creates a concentration gradient between the neuromuscular end plate and plasma. The formation of this concentration gradient causes displacement of the muscle relaxant from the neuromuscular end plate back into the plasma which results in even more neutralization of the remaining relaxant. This explains the rapid reversal effect of Sugammadex.

Serious Adverse Effects: The underlying mechanism of the serious side effect profile developed after the administration of Sugammadex is still unknown.

Treatment Recommendations: The recommended treatment for bradycardia associated with Sugammadex is an anticholinergic such as atropine. The initial dose of atropine is 0.5 mg which may be repeated every 3-5 minutes up to 3 mg or 6 doses. Glycopyrrolate (0.2- 0.4 mg) can be administered to treat patients with mild bradycardia without hypotension. Adding ephedrine or phenylephrine to increase the patient's blood pressure may be an option for Sugammadex induced hypotension. If severe bradycardia is sustained and accompanied by hypotension leading to cardiac arrest, epinephrine is recommended. The recommended dose is 1mg epinephrine IV given every 3-5 minutes.

Practice Recommendations:

• Sugammadex (Bridion) dose:

4mg/kg (deep block): If spontaneous recovery of the twitch response has reached 1-2 post-tetanic counts (PTCs) and there are no twitch responses to train-of-four (TOF) stimulation following rocuronium or vecuronium blockade.

2 mg/kg (moderate block): If spontaneous recovery has reached the reappearance of the 2nd twitch in response to TOF stimulation

16 mg/kg: Reversal within 3 minutes of rocuronium dose

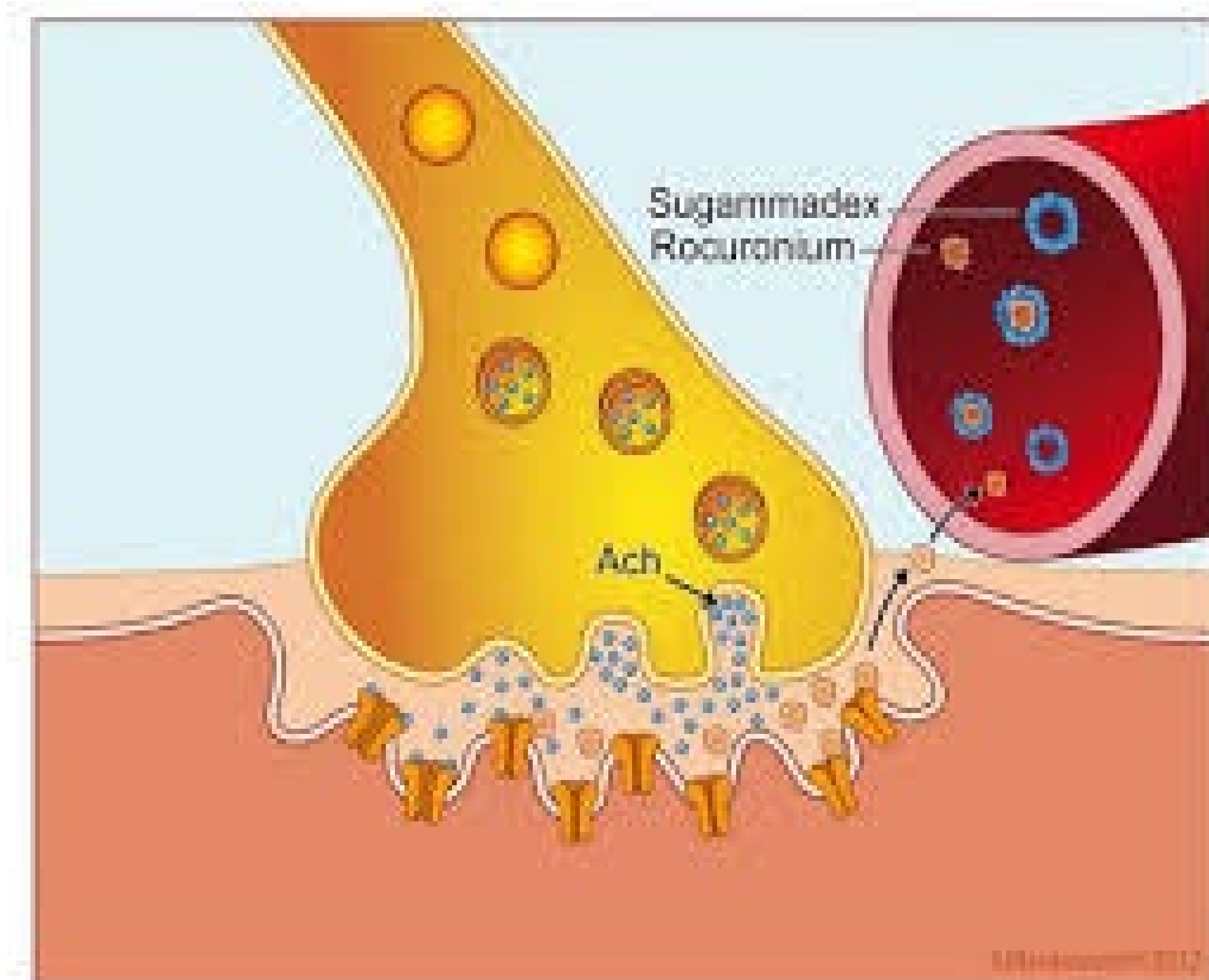
- Use only the optimal dose of Sugammadex for the desired effect
 - Dosing should be based on the depth of the neuromuscular blockade. Doses outside of the optimal range create potential risks for adverse reactions
- Preparation for a possible bradycardic episode is advised
 - Ensure that medications are readily available to treat bradycardia in the event that an episode does occur after drug administration. The patient should have electrocardiogram monitors in place during and after Sugammadex administration.
- Use neuromuscular monitoring instead of empirical dosing
 - Empirical dosing is likely to result in excessive or inadequate dosing of Sugammadex which can be detrimental to patient safety
- It is recommended that patients are closely monitored for hemodynamic changes during and after reversal
- Recognition of preoperative heart conditions is important
 - History of a preexisting heart conditions may be a possible mechanism of bradycardia after Sugammadex administration
- Give Sugammadex as a slow IV push

RESULTS

- This Quality Improvement Project aligns with the goal of nurse anesthetists to provide safe anesthesia to every patient.
- Based on the findings from the survey, participants agreed that the information provided was understandable and relevant to their clinical experience. They also agreed that after reviewing the attached informational sheet, they would be able to recognize and treat possible adverse reactions that may occur after Sugammadex administration, in accordance with practice recommendations.

CONCLUSION

- A comprehensive understanding of the properties, advantages, and limitations of this drug is crucial for patient safety
- This quality improvement project is clinically significant to nurse anesthesia students because students are now able to recognize rare, but possible serious adverse reactions caused by Sugammadex. If this rare event were to occur, treatment recommendations were provided. To decrease its occurrence, practice recommendations were also provided.
- More research and future trials are urgently needed to obtain more information about the serious adverse effects of Sugammadex



REFERENCES

Available Upon Request