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Development of a Propofol Administration Protocol for Soy or Egg-Allergic Patients

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Introduction to the Problem

The incidence of food allergies in the United States is increasing, raising concerns about potential allergic reactions between drugs formulated with substances derived from foods (Jackson, Howie, & Akinbami, 2013). Propofol is the most frequently administered intravenous agent for anesthesia, and its preparation commonly contains a lipid emulsification of soybean oil, glycerol, egg lecithin, and an antimicrobial agent (Baker & Naguib, 2005; Sommerfield et al., 2019). The use of this formulation has been blamed for allergic and anaphylactic reactions in patients with allergies to egg or soy, but the evidence is conflicting (Asserhoj, Mosbech, Kroigaard, & Garvey, 2016; Hofer, McCarthy, Buck, & Hendrick, 2003; Tashkandi, 2010). Manufacturers for propofol, such as Fresenius Kabi and Hospira, include food allergies to eggs or soy as a contraindication to propofol administration. However, the American Academy of Allergy, Asthma, and Immunology; whose mission is to advance knowledge and improve patient care for those with allergies, suggests that patients with a soy or egg allergy can receive propofol without any special precautions (Pongdee, 2019). These differing statements and the lack of confirmatory data lead to clinician uncertainty and avoidance of propofol without conclusive evidence.

There are currently no widely accepted practice protocols or guidelines regarding the administration of propofol in patients allergic to eggs or soy. Therefore, the purpose of this project was to develop and implement a practice protocol for patients requiring sedation with the intended use of propofol who state they have food allergies to egg or soy at a regional medical center in central Illinois. Given the prevalent use of propofol by anesthesia providers and the

increased occurrence of food allergies, the development of a practice protocol for individuals with soy or egg allergies is important and provides clinical relevance for this project.

Literature Review

Few studies evaluate the use of propofol on egg or soy allergic individuals. Among current evidence, there is inconsistent information about the safety of propofol for patients with allergies to egg or soy due to its lipid emulsification. Two case reports linked an anaphylactic reaction from propofol to a patient's diagnosis of food allergies (Hofer et al., 2013; Tashkandi, 2010). These case reports lacked allergy testing to confirm propofol's emulsification as the cause of the allergic reaction, and the reaction was attributed to propofol only due to the time-based connection following administration and the patient's documented food allergies (Hofer et al., 2003; Tashkandi, 2010). The patient in the report submitted by Hofer, McCarthy, Buck, and Hendrick (2003), however, experienced respiratory compromise before propofol administration, had a history of reactive airway disease, and also was administered rocuronium, a muscle relaxant. Muscle relaxants are the most common cause of anaphylaxis during anesthesia and conceivably a more likely cause of the reaction than propofol (Mills, Sice, & Ford, 2013).

Seven retrospective studies suggested that propofol is safe for most patients with food allergies (Asserhoj et al., 2016; Lambert, Wadams, Freeman, & Maffei, 2011; Mehta et al., 2017; Molina-Infante et al., 2014; Murphy, Campbell, Baines, & Mehr, 2011; Sommerfield et al., 2019; Wiskin, Smith, Wan, Nally, & Shah, 2015). There remains a concern about safety for individuals who have a history of anaphylaxis following food consumption (Murphy et al., 2011). A patient in the study performed by Murphy, Campbell, Baines, and Mehr (2011), had a history of egg anaphylaxis and experienced a non-anaphylactic immediate allergic reaction after propofol administration. It was not determined if the patient had an allergic reaction to propofol

or the lipid vehicle because allergy testing to the 10% intralipid was not performed. Another patient in this study also had a history of egg anaphylaxis and did not react to propofol (Murphy et al., 2011). Four patients in a study that was performed by Lambert, Wadams, Freeman, and Maffei (2011), had a history of egg anaphylaxis. There were no reported cases of an allergic or anaphylactic reaction in these four patients or the other 55 children exposed to propofol (Lambert et al., 2011).

Overall, there is no clear evidence that anaphylactic or allergic reactions to propofol are related to egg or soy allergy. There also is no significant relationship between egg allergy and severe allergic reactions to propofol. Studies showing patients tolerating propofol administration despite an allergy to egg or soy, suggests that propofol administration is safe in these patients. The evidence suggesting avoidance of propofol in these patients is weak and often lacked appropriate allergy testing postoperatively. Choosing alternatives to propofol is not evidence-based and may lead to worse health outcomes and avoidance of the best treatment.

Project Methods

Despite the increase in food allergies and the frequent use of propofol, there were no practice protocols or guidelines available for the administration of propofol to patients with food allergies at a regional medical center in central Illinois. There was, however, an incident reporting system that flagged propofol administration to patients with a documented egg or soy allergy. Due to this lack of guidance and the non-evidence-based incident reporting system, a Quality Improvement project was conducted that involved the development and implementation of a practice protocol for the administration of propofol to patients with food allergies, particularly to eggs or soy.

The purpose of this project was to increase the knowledge of the anesthesia providers, enabling them to make informed, evidence-based decisions, reduce unnecessary variations in anesthetic practice, and improve quality of care by adopting this propofol administration protocol into their practice. The protocol was created in collaboration with clinical stakeholders and provided recommendations based on the comprehensive literature review; the recommendation of the American Academy of Allergy, Asthma, and Immunology; and additional current evidence-based practice. The protocol was an algorithm that included questions to ask patients with a history of food allergies to egg and soy. Based on the responses about the patient's clinical history and ability to eat foods that contain egg or soy, propofol administration is recommended with either no special precautions or with precautions to treat the possibility of a mild allergic reaction. The protocol recommends propofol administration to all patients, even if they had a history of anaphylactic reactions following the ingestion of egg or soy.

Once key stakeholders approved the protocol, an educational presentation was provided to staff members, followed by a brief survey. The survey contained 15 questions with 14 questions requiring a yes, no, or not sure response that measured participants' understanding of propofol and food allergies and also perceptions of the acceptability of the new protocol. The last question was an open-ended question asking participants to identify any concerns or recommendations about the presentation or new protocol.

Ten participants, including eight certified registered nurse anesthetists, one anesthesiologist, and one pharmacist, attended the presentation and completed the survey. All of the participants present were appropriate and important to the implementation of this practice protocol.

Evaluation

The results of the survey indicated that the educational presentation increased the staff's knowledge of the manufacturing of propofol and the diagnosis of food allergies. Responses indicated that, before the intervention, only 80% of participants knew that most allergenic proteins in eggs are limited to the egg whites. All participants recognized that soy and egg are part of the lipid vehicle in propofol, however, only 70% acknowledged they knew egg lecithin was derived from egg yolk. Prior to the presentation, 70% of the participants knew the soybean oil present in propofol was refined and unlikely to contain significant quantities of allergenic particles. Fifty percent of participants reported knowing before the presentation that the pharmaceutical processing of egg lecithin eliminates or significantly alters the proteins that could cause an allergic reaction.

The results of the survey also revealed a slight increase in the staff's knowledge following the educational presentation on the implementation of the protocol. However, staff continued to indicate uncertainty about the administration of propofol to patients with a history of anaphylaxis following egg or soy ingestion. Before the presentation, 30% of participants stated they based their decision to administer propofol on the patient's ability to tolerate baked or processed goods. Following the presentation, 90% of participants stated they would administer propofol to patients who are unable to tolerate baked goods due to allergic symptoms. Before the presentation, 90% said they did not routinely avoid propofol in patients allergic to egg or soy. After the presentation, only 40% said they would administer propofol to patients with a history of anaphylaxis following egg or soy ingestion, 50% said they would not administer propofol to these patients, and 10% said they were not sure. The developed protocol recommends propofol administration to all patients, even with a history of egg or soy anaphylaxis. The protocol

informs the providers that in these patients, a special precaution to treat the possibility of a mild allergic reaction is reasonable.

Participants did not explain why they would avoid propofol in patients with a history of egg or soy anaphylaxis. Avoidance may be due to the limited number of studies, to propofol manufacturers listing allergies to egg or soy as a contraindication, or to limited time to educate the participants about pharmaceutical processing and pathology of food allergies. It would have been beneficial to have a response section in the survey that allowed participants to explain why they would avoid propofol.

There are some limitations of this project related to the survey. There was only one survey, it was instructed to be completed after the presentation, and participants self-reported their perception of their knowledge before and after the presentation. A pre-survey containing questions about participants' current practice of propofol administration to patients with egg or soy allergies could have been developed and collected before the presentation. A post-survey containing questions to evaluate if the presentation caused the participants to develop a practice change due to the information provided could also have been developed. After reviewing the responses, it was determined that including an 'if no, briefly explain' section would have facilitated information about why providers may not administer propofol to patients with a history of anaphylaxis to egg or soy.

Impact on Practice

This project helped to educate the key stakeholders at the host facility on current evidence concerning the administration of propofol to patients with food allergies. This education encouraged them to implement a newly developed propofol administration protocol for patients with allergies to egg and soy. The findings of this project indicated an increase in

knowledge and application after implementation of an educational program, which included a PowerPoint presentation, a clinical practice protocol, and a post-educational survey.

Even though some anesthesia providers at this facility remain reluctant to administer propofol to patients with a history of egg or soy anaphylaxis, they are more receptive to administering propofol to patients who can not tolerate eating baked or processed goods. The participants who decide to implement the developed protocol and administer propofol to all patients may be able to inform other participants and staff members who were not present about their outcomes from this implementation.

Additional research studies on propofol administration to patients with a history of anaphylaxis after ingestion of egg or soy will provide additional evidence and lead to more detailed data. Appropriate postoperative allergy testing should be performed for patients who experienced an allergic response following anesthesia administration to determine if the response was due to propofol itself or the lipid vehicle. Support from major anesthesia organizations about the use of propofol in food allergic patients will also lead to less clinician uncertainty.

Conclusion

In conclusion, evidence suggests that propofol is safe for patients with an allergy to egg or soy, even for those with a history of anaphylaxis (Asserhoj et al., 2016; Lambert et al., 2011; Mehta et al., 2017; Molina-Infante et al., 2014; Murphy et al., 2011; Sommerfield et al., 2019; Wiskin et al., 2015). The evidence recommending avoidance of propofol in these patients is weak and often based upon anecdotal information and not appropriate postoperative allergy testing (Hofer et al., 2003; Tashkandi, 2010). If an anesthesia provider chooses to avoid propofol because their patient has a history of anaphylaxis following ingestion, they may be adversely affecting the care of their patient by using a medication with more severe side effects. Propofol is

preferred over other anesthetic agents due to its rapid effects on the brain, quick metabolic clearance, and minimal side effects (Garcia, Whalin, & Sebel, 2013; Nagelhout, 2014).