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Propofol administration is safe in adult eosinophilic esophagitis patients sensitized to egg, soy, or peanut

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Abstract

Background: Sedation might improve tolerability and adherence to endoscopic procedures in patients with eosinophilic esophagitis (EoE). Propofol administration is often contraindicated in patients with hypersensitivity to egg, soy, or peanut.
Objective: To investigate the safety of propofol administration for procedural sedation in EoE patients sensitized/allergic to egg, soy, peanut.
Methods: A retrospective observational study in adult EoE patients undergoing esophagogastroduodenoscopy with propofol sedation was conducted between January 2009 and March 2013. Food-specific serum IgE and skin prick tests for egg, soy, peanut, and cross-reactant foods were performed in all patients.
Results: Sixty EoE adult patients, mostly on food elimination diets (91%), were evaluated (age: 28 years (14–56), male gender (90%)). Atopy was present in 88% of patients, being the most prevalent comorbidities rhinoconjunctivitis (78%) and asthma (67%). Fifty-two patients (86%) were sensitized to either egg, soy, or peanut. Eighteen patients (28%) had a history of allergic reactions to egg, legumes, and nuts and strictly avoided these foods. A total of 404 upper endoscopies were performed under propofol sedation. No allergic adverse events were reported, except a transient bronchospasm after orotracheal intubation in an asthmatic adolescent receiving multiple drugs for anesthesia, in whom no sensitization to either propofol or its lipid vehicle was confirmed.
Conclusions: Propofol was safely administered for procedural sedation in a large series of adult EoE patients multisensitized to egg, soy, peanut, showing one-third clinical allergy to these foods.

Propofol (2,6-diisopropylphenol) has gained popularity as an agent for both induction and maintenance of anesthesia. Its use has expanded worldwide over the last decade from solely an anesthetic agent to one of the most preferred sedative–hypnotic agent drugs in the intensive care unit and outpatients procedures, by either anesthesiologists and, lately, nonanesthesiologists (1). Propofol-related anaphylactoid reactions in the early 1980s across Europe, mostly related to the surfactant 'Cremophor EL' (2), promptly changed to a different lipid solvent. This fatty emulsified formulation, which is the current mainstay of propofol delivery, contains egg lecithin (12 mg/ml) and soybean oil (100 mg/ml). This emulsion was specifically designed to avoid allergic reactions in egg- or soy-allergic patients, considering that soybean oil is highly refined with almost nonallergenic content after the refining process and egg lecithin comes from egg yolk, being the most allergenic proteins contained in egg white (3). Over the last 25 years, several cases of anaphylaxis or allergic adverse events after propofol administration have been reported (4–20), presumably related in most cases to cross-reactivity with food allergies.

Abbreviations
EoE, eosinophilic esophagitis; SFED, six-food elimination diet; SPT, skin prick test.

For this reason, propofol is usually contraindicated in patients with known hypersensitivity to egg and soy, and some other hypersensitivities include legume and peanut, which may show cross-reactivity with soy (21–24). However, there is still disagreement on this matter, and the Association of Anaesthetists of Great Britain and Ireland has recently claimed that there is no evidence to avoid propofol in egg- or soy-allergic patients; in fact, egg allergy is not included in warning labels in the UK (25). Up to now, only an 11-year retrospective series has addressed the rate of allergic reactions after propofol administration in 28 egg-allergic children (documented by positive skin prick test (SPT) to egg white), two of them with a history of egg anaphylaxis (26). Upon 43 propofol administrations, only one allergic reaction was observed in a child with previous egg anaphylaxis. There are no available data in adults regarding this issue.

Eosinophilic esophagitis (EoE) is an increasingly recognized chronic immune-/antigen-mediated, food allergy-associated, inflammatory esophageal disorder (27). Concomitant atopic diseases, such as asthma, atopic dermatitis, allergic rhinitis/sinusitis, and food allergies, are common (50–80%) in pediatric and adult EoE patients (28). Food allergens have been identified as major contributors to the pathogenesis of EoE, and recent reports on children (29, 30) and adults (31, 32) have highlighted the effectiveness of empirical six-food elimination diet (SFED). However, this dietary approach requires multiple upper endoscopies after reintroduction of each alimentary group to identify causative foods. In this regard, propofol sedation might improve patient tolerability and adherence to further endoscopic procedures, but the safety of propofol in EoE patients, usually multisensitized to food allergens, has not been addressed yet. As such, the goal of this study was to assess the safety of propofol sedation for upper endoscopy in adult EoE patients either allergic or sensitized to egg, soy, legume, or peanut, or their respective cross-reactive allergens.

Material and methods

This was a retrospective observational study, conducted in two secondary referral hospitals, which gather large cumulative experience on EoE in Spain, from January 2009 to March 2013. All patients gave their written informed consent for endoscopy and procedural sedation, and the investigations were conducted according to the principles expressed in the Declaration of Helsinki. Approval from ethics and research committee before reviewing patient records was obtained.

Study population

Adult EoE patients, defined by age older than 14 years, with dysphagia and/or food impaction and persistent esophageal eosinophilia (>15 eo/HPF) on high-dose proton pump inhibitor therapy (omeprazole 40 mg b.i.d), according to the current guidelines (27), who underwent at least one upper gastrointestinal endoscopy under propofol sedation, were included. Patients with a previous history of immediate allergic reaction after egg, soy, or legume–peanut intake were not excluded.

Propofol administration

In patients undergoing propofol sedation supervised by an endoscopist, all upper gastrointestinal endoscopies were performed according to a standard protocol. All patients were given supplemental oxygen (2 l/min) through nasal cannula and monitored by electrocardiogram, pulse oximetry, heart rate, and blood pressure monitoring. All patients had an intravenous line with continuously running normal saline infused by gravity. In every endoscopy suite, an emergency set for mask ventilation and emergency drugs was always immediately on hand. All nurses and physicians involved in the study were certified in advanced cardiac life support, with refresher courses annually, and a minimum of 12-month experience using propofol in accordance with local regulatory laws.

Propofol was administered as the sole sedative agent under the supervision of two senior gastroenterologists (JMI and AJL), with expertise on nonanesthesiologist propofol administration (33, 34). An initial bolus of 20–40 mg of propofol (Generic product 10 mg/ml, Fresenius Kabi, Bad Homburg, Germany) was administered intravenously in all patients. An observation period from 2 to 5 min was set to promptly detect immediate allergic reactions. Afterward, additional boluses of 20–40 mg at the discretion of the endoscopist were administered intended to a deep sedation target along the procedure.

Allergy study

Standardized food allergy work-up, including food-specific IgE and skin prick tests, was performed in all patients from both centers. Atopy patch test (APT) is not standardized and was not performed in one center, so therefore it was not evaluated. A patient was considered to be sensitized to a food with at least a positive result in one test. Food-specific serum IgE was determined from peripheral blood by using the ImmunoCAP test (Pharmacia Diagnostics AB, Uppsala, Sweden). All values above 0.35 KU/l were considered as a positive food serum-specific IgE test (35).

Skin prick test (ALK-Abelló laboratories, Madrid, Spain) was carried out against egg (white and yolk), chicken (cross-reactivity with egg), soy, and the remaining legumes potentially cross-reactant with soy (peanut, lentils, chickpea, and beans) (36). Skin prick test was performed on the forearm with disposable lancets (ALK-Abelló laboratories, Madrid, Spain) by pricking through a drop of the extract, which was then absorbed. Every individual drop was separated at least 2 cm of the next. Reactions were recorded by measuring the largest diameter of the wheal in millimeters at 15 min. Histamine (10 mg/ml) was used as positive control and saline solution as negative one. The test result was considered positive if the largest diameter of the wheal was at least 3 mm.

Review of literature on allergic reactions to propofol

A literature search was conducted through PubMed (from January 1983 to January 2013) examining all published

articles linking the MeSH search terms 'propofol', 'anaphylaxis', 'allergy', 'egg', 'soy', and 'peanut' from English language journals. All articles were identified through manual review. Furthermore, the reference lists of these articles were reviewed to include further appropriate articles. As our intention was not to perform a systematic review with a meta-analysis component, we did not include abstracts from international meetings in the search strategy.

Statistical analysis

Continuous data were described as means and standard deviations or median and range if not normally distributed. Proportions were reported for categorical data. Analyses and summaries were produced using the PASW statistical program, version 18.0 (SPSS Inc., Chicago, IL, USA).

Results

Baseline characteristics of patients

A total of 113 patients with a diagnosis of EoE were evaluated during the study period. Fifty-three patients with an EoE diagnosis were also excluded because they had all upper endoscopies unsedated. The flow chart of the study is summarized in Fig. 1. Finally, 60 patients who were administered propofol in at least an upper endoscopy were included. The mean age in the cohort was 28 years (range: 14–56) with a clear male predominance (90%). Of note, atopy was present in 53 patients (88%), with a high prevalence of rhinoconjunctivitis, asthma, and airborne or food allergens sensitization. A total of 57 patients (91%) underwent elimination diet and subsequent individual food reintroduction (47 patients SFED and 10 patients elimination diet guided by skin prick test), whereas the remaining three patients were re-evaluated after topical steroid therapy. The baseline demographic, clinical, and endoscopic characteristics of these patients, according to EFERS classification (37), are shown in detail in Table 1.

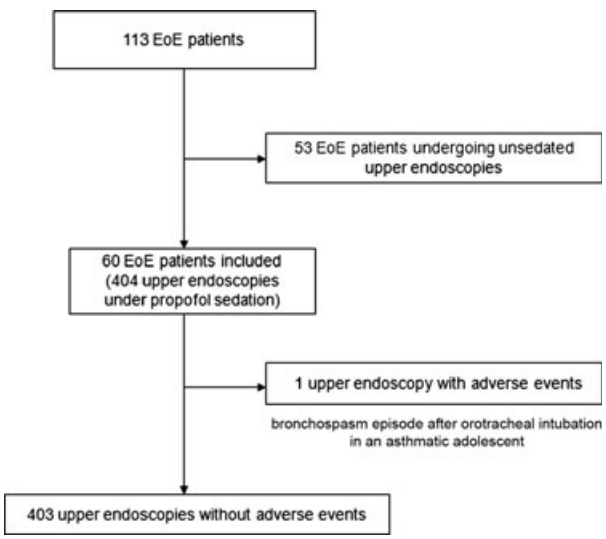

Figure 1 Flow chart of the study.

Food sensitization profile

As for food sensitization evaluation, 52 patients (86%) were sensitized to either egg, soy, or peanut. The rates of sensitization for each food were egg (41%), soy (53%), peanut (66%), lentils (50%), chicken (16%), chickpea (6%), and bean (5%). Overall food sensitization rates, overall and broken down by IgE or skin prick test, are listed in Table 2.

Food allergy profile

Eighteen patients (28%) showed a history of allergic reactions to egg, legumes, and nuts and therefore strictly avoided these foods in their daily diet. One patient had both legume and nuts allergy. A more detailed information on food allergies and clinical manifestations of these patients is displayed in Table 3.

Allergic events during propofol sedation procedures

A total of 404 upper endoscopies were performed under propofol sedation (401 under endoscopist supervision and

Table 1 Baseline demographic, clinical, and endoscopic characteristics of the cohort of adult EoE patients evaluated in the study

No. of patients	60
Demographics	
Male/female	54/6 (90/10%)
Age, yrs	28 (14–56)
Smoking habit	13 (21%)
Atopy	53 (88%)
Rhinoconjunctivitis	46 (76%)
Asthma	40 (67%)
Aeroallergen sensitization	45 (78%)
Atopic dermatitis	7 (11%)
Urticaria	5 (8%)
Angioedema	5 (8%)
Anaphylaxia	2 (3%)
History of allergy to egg, soy, or peanut	18 (28%)
Egg	2
Legumes	4
Nuts	13
Indication for endoscopy, *n* (%)	
Dysphagia	43 (71%)
Food impaction	45 (75%)
Heartburn	10 (16%)
Chest pain	5 (8%)
Endoscopic findings, *n* (%)	
Linear furrows	51 (85%)
Rings	30 (50%)
Whitish exudates	26 (43%)
Narrow caliber esophagus	12 (20%)
Stricture	8 (13%)

Table 2 Food sensitization rates in adult EoE patients receiving propofol sedation for upper endoscopy

	Total $n = 60$	IgE	Skin prick test
Egg or soy or peanut, *n* (%)	52 (86)	43 (71)	17 (28)
Egg, *n* (%)	25 (41)	15 (25)	18 (30)
Soy, *n* (%)	32 (53)	23 (38)	19 (31)
Peanut, *n* (%)	40 (66)	30 (50)	31 (51)
Egg and soy, *n* (%)	13 (21)	7 (11)	5 (8.3)
Egg and peanut, *n* (%)	17 (28)	12 (20)	7 (11)
Soy and peanut, *n* (%)	27 (45)	19 (31)	10 (16)
Egg, soy, and peanut, *n* (%)	11 (18)	6 (10)	5 (8.3)
Chicken, *n* (%)	10 (16)	3 (5)	10 (16)
Lentil, *n* (%)	30 (50)	13 (21)	24 (40)
Chickpea, *n* (%)	4 (6)	2 (3)	2 (3)
Bean, *n* (%)	3 (5)	1 (1.6)	3 (5)

Table 3 Clinical manifestations in patients allergic to egg, legumes, or nuts in the cohort ($n = 18$) undergoing upper endoscopy under propofol sedation

Food antigen	Clinical manifestation
Egg ($n = 2$)	Anaphylaxis ($n = 1$)
	Gastrointestinal manifestations ($n = 1$)
Legumes ($n = 4$)	Anaphylaxis ($n = 1$)
	Glottic edema ($n = 2$)
	Oral allergy syndrome ($n = 1$)
Nuts ($n = 13$)	Anaphylaxis ($n = 4$)
	Glottic edema ($n = 1$)
	Angioedema ($n = 2$)
	Urticaria ($n = 2$)
	Oral allergy syndrome ($n = 6$)

three under general anesthesia). Mean number of upper endoscopies was 6.9 per patient (1–19), and median propofol dose used in each procedure was 174 mg (range: 62–284). No anaphylactic or allergic adverse events were reported, except a bronchospasm episode after orotracheal intubation in an asthmatic 14-year-old boy. This patient underwent general anesthesia for esophageal food bolus removal and received ketamine, midazolam, atropine, and propofol for anesthesia. His medical history included atopic dermatitis, clinical food allergy to fruit and nuts, polysensitization to airborne allergens with seasonal moderate-to-severe asthma, and rhinoconjunctivitis and skin sensitization without clinical manifestations to cow's milk, egg, wheat, and fish. Allergic work-up, including leukocyte histamine release test and skin prick test, could not prove serum or skin sensitization to any of these drugs. Specifically, skin prick test with propofol, Intralipid and midazolam, performed at concentrations of 1 : 10, 1 : 100, and 1 : 1000, respectively, were negative.

Literature review

Regarding the review of available literature on propofol-associated allergic reactions over the last 30 years, we identified 45 patients with reported allergic or anaphylactic reactions, presumably associated with propofol administration (Table 4). To begin with, no skin prick test was performed in 22 of 45 patients (48%) receiving multiple anesthetic drugs. Among patients with positive skin sensitization to propofol ($n = 16$), SPT to the lipid emulsion was positive in 1, negative in eight, and not performed in seven cases. Furthermore, in patients with no skin sensitization to propofol ($n = 7$), SPT to lipid emulsion was negative in one and not evaluated in the remaining six patients. No patient with a presumptive propofol allergic reaction showed negative SPT to propofol, but positive SPT to the lipid emulsion.

Discussion

The present study represents the first series in adult patients and the largest to date addressing the safety of propofol administration in patients with documented polysensitization to egg, soy, and peanut and, most importantly, with clinical allergy to these foods in almost one-third of cases. In spite of first exposure or multiple re-exposure to propofol, none of these patients suffered from allergic reactions or additional side-effects. In the particular patient with a bronchospasm episode after orotracheal intubation, propofol could not be demonstrated to be the cause and we are inclined to think that it could have been related to his bronchial hyperreactivity background. Our findings, similarly to the recent first pediatric series on egg-allergic patients (26), suggest that the use of propofol is likely to be safe regardless of baseline food allergies. Even though EoE is not mediated through immediate type I hypersensitivity, we believe that high rates of IgE sensitization, documented by either IgE or SPT, and egg, legume, and peanut type I allergic reactions in the study population represent a valid method to evaluate cross-reactivity between propofol and egg, soy, or peanut allergy.

Intralipid® (Fresenius Kabi, Hamburg, Germany), a fat emulsion used for patients requiring parenteral nutrition, contains egg yolk lecithin and soybean oil, just the same as propofol. The likelihood of egg and soy contained in these formulas of inducing allergic reactions is theoretically quite low. The main triggers for egg anaphylaxis are ovalbumin, ovomucoid, and conalbumin, present in egg white and not in egg yolk. Similarly, soybean oil is highly refined and is unlikely to contain significant quantities of allergenic particles. As a matter of fact, the US Food and Drug Administration does not contraindicate the administration of Intralipid® in egg- or soy-allergic patients (38). Therefore, it makes no sense to contraindicate propofol in these patients considering that propofol and Intralipid® share the same egg and soy content (39). In a 1998 series from Spain (40), 25 egg-allergic patients showed no skin sensitization to egg lecithin, soy lecithin, propofol, and Intralipid. The authors then speculated that propofol itself would be the most probable responsible agent for hypersensitivity reactions rather than its lipid-based vehicle, albeit this speculation required further confirmation after propofol administration in clinical practice. Our current research just corroborates the aforementioned hypothesis for adult patients.

Table 4 Literature on allergic adverse reactions after propofol administration, presumably related to baseline egg, soy, or peanut sensitization

First author and year of publication	Publication type	*n*	Atopy	Skin prick test				
				Propofol	Intralipid	Egg	Soy	Peanut
Laxenaire MC, 1998	Case report	2	No	+++ 1/2	Neg			
Naquib M, 1989	Series	13	No					
Laxenaire MC, 1992	Series	14	4/14 (28%)	+++ 8/13	Neg 4/4			
De Leon-Casasola, 1992	Case report	1	No	+++	Neg			
McHale SP, 1992	Case report	1	No	++				
Couldwell WT, 1993	Case report	2	No					
Ducart AR, 2000	Case report	1	No	+++				
Tsai MH, 2001	Case report	1	No					
Nishiyama T, 2001	Case report	2	Allergic rhinitis Atopic dermatitis					
Tai Y, 2003	Case report	1	No					
Hofer KN, 2003	Case report	1	Reactive airway Eczema					
Hattori JI, 2003	Case report	1	Sick house syndrome	+++	Neg			
Inal MT, 2008	Case report	1	No	+++	Neg			
Tashkandi J, 2010	Case report	1	Eczema Food allergies			+++	+++	
Koul A, 2011	Case report	1	No	+++				
Fontaine M, 2011	Case report	1	No	Negative		Neg	Neg	+++
You BC, 2012	Case report	1	No	+++	+++			

+, positive; Neg, negative; blank boxes stand for the absence of skin prick test.

Propofol contains two potential allergenic molecules: the diisopropyl side chain and phenol. Allergic reactions on first exposure are usually because of the isopropyl groups, present in many cosmetic and dermatological products, whereas reactions on re-exposure are believed to be triggered by the phenol molecule (4, 6, 7). In our critical review of available literature on propofol-associated allergic reactions over the last 30 years, we identified several methodological drawbacks in case reports and case series, preventing us from considering cross-reactivity to food molecules the cause of allergic reactions. In line with the result of the current research, we propose that it is most likely that propofol itself, instead of its lipid emulsion containing egg and soy, might have been the main trigger for allergic reactions previously reported in the literature. Indeed, an anaphylactoid reaction associated with a novel microemulsion of propofol, devoid of lipid solvent, has been recently reported (41). Overall, our findings do not support the avoidance of propofol in patients with documented egg, soy, or peanut sensitization or allergy, and therefore, labeling warnings regarding the use of propofol in these patients should be at least reconsidered. These results might be applicable to all EoE patients, regardless of the therapeutic intervention. Empirical food elimination with subsequent reintroduction of foods may have the potential of triggering IgE-mediated reactions (e.g., anaphylaxis), specially upon food reintroduction or propofol exposure in patients with IgE sensitization to egg, soy, or peanut, but this was not the case in the present study.

The relevance of our findings is strengthened by the homogeneity of a multicenter sample of patients, all of them suffering from the same allergic disorder and mostly exhibiting positive IgE-mediated sensitization to foods. Additionally, they are also reinforced by a common methodology of allergy testing and procedural sedation, who were undertaken with propofol as the only sedative agent in the bulk of endoscopic procedures. However, our study has several limitations. The main drawbacks are derived from the retrospective nature of the design, as well as the lack of a control group. We only included adult population, in whom egg allergy is less common than in children, as shown in our results (35).

In conclusion, propofol can be safely administered for procedural sedation in adult EoE patients, regardless of documented sensitization to egg, soy, or peanut. The present study adds objective evidence to the train of thought that propofol can be safely administered in these patients (42), opening up the debate to reconsider labeling warnings regarding the use of propofol in this context.

Author contributions

Javier Molina-Infante and Alfredo J. Lucendo involved in study concept and design, patient enrollment and performance of endoscopic procedures, statistical analysis and interpretation of data, drafting of the article, critical revision of the article for important intellectual content, and final approval of the article. Angel Arias involved in acquisition of data, statistical analysis and interpretation of data, drafting of the article, critical revision of the article for important intellectual content, and final approval of the article. Daniel Vara-Brenes and Raul Prados-Manzano involved in acquisition of data, performance of endoscopic procedures, critical revision of the article for important intellectual content, and final approval of the article. Jesús González-Cervera and Manuela Alvarado-Arenas involved in allergy testing,

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Conflicts of interest

The authors declare no conflicts of interest.

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