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Informed consent in balloon Eustachian tuboplasty: a systematic review of possible complications and preventive measures

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Review Article

Syed Zohaib Maroof Hussain takes responsibility for the integrity of the content of the paper

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Abstract

Objective. To systematically identify the complications associated with balloon Eustachian tuboplasty and their frequency of occurrence. This study will also highlight the measures that can be employed to avoid these complications and perform this procedure more safely.
Methods. Systematically reviewed relevant papers published until January 2023. Each reference was checked and evaluated for any potential manuscripts. There was no registered protocol; the Preferred Reporting Items for Systematic Reviews and Meta-Analyses was used.
Results. Sixty-nine publications were found, from which 14 publications met our inclusion criteria: 2 randomised clinical trials, 5 retrospective studies, 2 systematic reviews, 2 case series and 3 case reports. Studies with balloon Eustachian tuboplasty procedure only were included, regardless of ethnicity, gender and age. All studies were excluded in which more than one procedure was performed.
Conclusion. Balloon Eustachian tuboplasty is a relatively safe procedure with an overall complication risk of 1.66 per cent. Major complication rate was 0.43 per cent. Surgical emphysema was the most common, around 0.40 per cent.

Introduction

Eustachian tube dysfunction is a physiological disorder. Eustachian tube dysfunction is further classified into three subtypes: dilatory (or obstructive), baro-challenge-induced and patulous Eustachian tube dysfunction.[1] Eustachian tube dysfunction traditionally has been treated with pharmacological agents, mechanical devices and nasal surgery. However, the results have not been satisfactory.[2,3] Balloon Eustachian tuboplasty was first introduced to patients in 2010 for chronic obstructive Eustachian tube dysfunction.[4,5] The goal of balloon Eustachian tuboplasty is to prevent, reverse or stop the progression of these diseases by widening the cartilaginous part of the Eustachian tube, and thereby improving its function.[4]

Balloon Eustachian tuboplasty is a promising treatment for both adults and children that has encouraging results.[4,5] Although balloon Eustachian tuboplasty is generally considered a low-risk procedure and several studies on the effect of balloon Eustachian tuboplasty have been published,[6]it is a comparatively new intervention with limited evidence so far in terms of efficiency and risks.[4]

Some studies have discussed complications associated with balloon Eustachian tuboplasty.[7–9] However, data are scarce and true figures are lacking to describe common and uncommon adverse events and their incidence. This is primarily important for clinicians to know these so that common and uncommon adverse events and their incidence can be discussed in the consenting process. It is also noteworthy that indications and outcomes of balloon Eustachian tuboplasty are neither fully proven nor widely accepted so far. Hence, balloon Eustachian tuboplasty still is an emerging procedure. This makes it even more vital for clinicians to inform patients about possible risks so they can weigh the benefits and the complications.

Therefore, we aim to conduct a systematic review of the literature, especially randomised, controlled trials (RCTs) and other sources of primary evidence to identify the possible complications and their approximate incidence based on published data. Simultaneously we also aim to investigate what pre-, peri- and post-operative measures should be taken to avoid possible complications.

Methods and Materials

We searched the Medline, Cochrane Library, PubMed and Embase databases for relevant papers published up to January 2023. The following keywords were used to search for articles: 'eustachian tube,' 'auditory tube,' 'dilation,' 'dilatation' and 'balloon.' The search was limited to articles published in English only and was supplemented by using the 'related article' function. The search was repeated on Google Scholar to locate additional abstracts. A manual search of references of eligible manuscripts was also performed. Each

reference was checked and evaluated for any potential manuscripts. We only included studies published on balloon Eustachian tuboplasty with a clinical diagnosis of obstructive Eustachian tube dysfunction. Duplicate articles were removed. We excluded all studies in which more than one procedure was performed. Two reviewers reviewed all the articles together. In case of disagreement, the opinion of the more senior author was taken. We included studies regardless of ethnicity, gender or age (Table 1). There was no registered protocol, the Preferred Reporting Items for Systematic Reviews and Meta-Analyses ('PRISMA') was used.

Results

Initial search was made using our keywords. However, studies that had balloon Eustachian tuboplasty only were considered for final analysis. A total of 69 studies met our initial search using Google Scholar, Medline, Cochrane library, PubMed, and Embase databases. Of these 69 studies, 14 met our inclusion criteria and were selected for data extraction and analysis. These 14 studies included two randomised, controlled trials (RCTs),[7,8] two systematic reviews,[6,9] five retrospective studies,[10–14] two case series[5,16] and three case reports.[17–19] The study-selection process is illustrated in the flow chart in Figure 1.

Review of literature by the level of evidence

Level IB

Two randomised, controlled trials (RCTs) were analysed. The two trials included a total of 309 patients. No life-threatening or major complications were reported. Following that, balloon Eustachian tuboplasty was considered as a safe and effective procedure for Eustachian tube dysfunction.[5,7,8]

Level II

Two systematic reviews were analysed. Of 726 patients that were reviewed, two patients developed surgical emphysema. Both patients were managed conservatively.[6,9] Despite two complications, authors reported balloon Eustachian tuboplasty as a safe procedure.[6,9]

Level III

Five studies were analysed retrospectively. Of 2430 patients that were analysed, 10 patients developed post-operative emphysema, including three patients with extension into mediastinum and developed pneumomediastinum.[10–14] Howard *et al.* concluded that balloon Eustachian tuboplasty was a relatively safe intervention with an overall complication rate of 4.7 per cent in a paediatric population.[15] Similarly, Skevas *et al.* reported balloon Eustachian tuboplasty as a safe and effective procedure with major complication rates less than 1 per cent.[13]

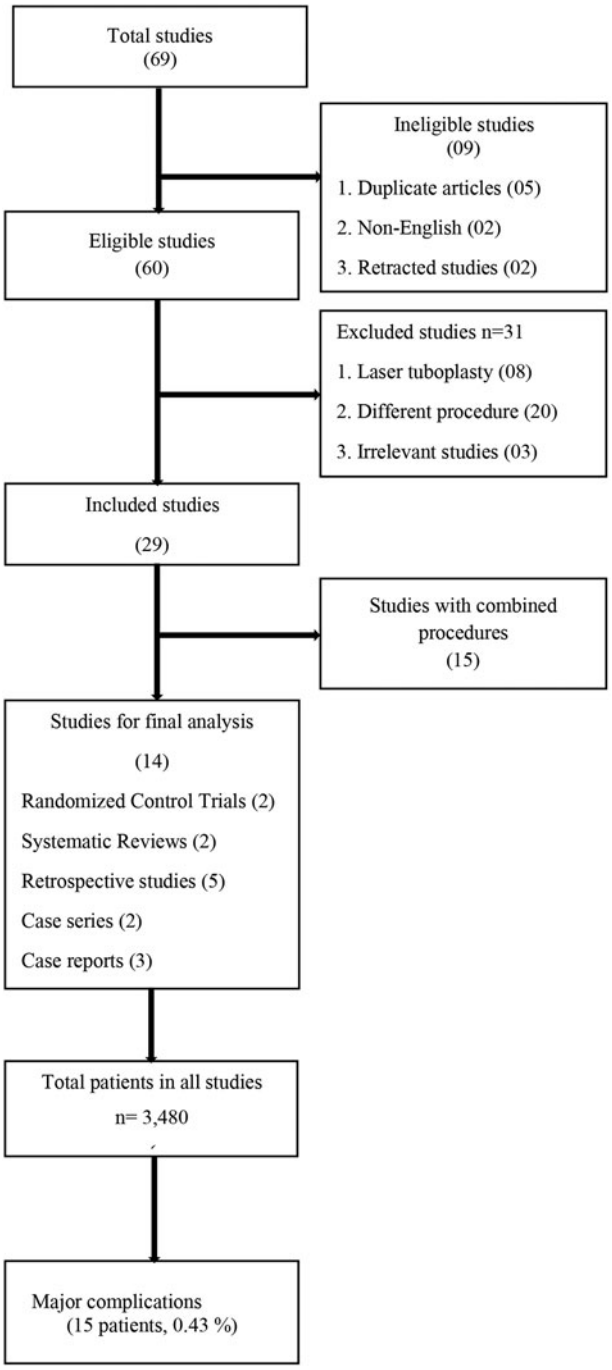

Figure 1. Flow chart presentation of all studies.

Table 1. Inclusion and exclusion criteria

Participants	Studies published on balloon Eustachian tuboplasty with a clinical diagnosis of obstructive Eustachian tube dysfunction only Exclusion: presence of secondary pathology like adenoid hypertrophy, cleft palate, neoplasms etc. Studies did not mention complications of the procedure
Intervention	Balloon dilation Eustachian tuboplasty Exclusion: all other procedures or any additional procedure
Study design	Any Exclusion: abstracts, publications without peer review
Language	English Exclusion: All other languages
Demographics	All ages, gender, and ethnicity Exclusion: None

Level IV

Two case series were published. Twelve patients were included. No major or life-threatening complications were reported in any of the cases. Jurkiewicz *et al.* reported an overall improvement in symptoms post-balloon Eustachian tuboplasty.[16]

Level V

Three cases were published online. One case was transient asystole, and two cases were subcutaneous emphysema

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extending to the mediastinum and developed pneumomediastinum. All patients were managed conservatively.[17–19] All studies reporting complications are shown in Table 2.

Review of literature by type of complication

We divided the complications according to severity. We described major complications as being those requiring further therapy with an increase in the level of care or requiring hospitalization. Events not requiring any additional treatment or hospital admission were regarded as minor. Complications reported as a single case report are described under the heading of rare complications because it is difficult to ascribe procedure effects with single reports.

Major complications

The most commonly reported major complication was surgical emphysema. Of 3480 patients, 14 patients had surgical emphysema. In five patients, surgical emphysema was extending into the mediastinum leading to pneumomediastinum (0.14 per cent).[13,18,19] The overall percentage for surgical emphysema was 0.40 per cent.

Miscellaneous complications

Some studies reported minor complications, including patients with slight tenderness, epistaxis, hemotympanum, temporary increase of tinnitus, serous otitis media, rhinitis, transient dysesthesia of the tongue secondary to chorda tympani compression, temporary patulous Eustachian tube and transient ischaemic attack (TIA) unrelated to balloon Eustachian tuboplasty at the fifth post-operative day.[6,9–13] Their incidences, as per our review, are given in Table 3.

Rare complications

There was one case of transient asystole during balloon Eustachian tuboplasty. This happened as soon as the balloon

Table 2. Studies reporting complications of balloon Eustachian tuboplasty

Authors	Year	Country	Study design	Sample size	Major complications	Minor complications	Any surgical intervention*
Kjaer *et al.* [7]	2022	Denmark	RCT	13	None	None	NA
Poe *et al.*[8]	2018	USA	RCT	296	None	None	NA
Saniasiaya *et al.*[9]	2022	Malaysia	SR	283	None	13 cases of serous otitis media 5 cases of epistaxis 2 cases of hemotympanum vertigo in 1 patient, unrelated to BET	No
Randrup & Ovesen[6]	2015	Denmark	SR	443	2 cases of emphysema	11 cases of minor epistaxis 2 cases of temporarily increased tinnitus	
Cheng *et al.*[10]	2021	Australia	RS	62	None	TIA unrelated to BET at 5th post-operative day	No
Schmitt *et al.*[11]	2018	France	RS	38	None	1 case of rhinitis 1 transient dysesthesia of the tongue secondary to chorda tympani compression	No
Si *et al.*[12]	2018	China	RS	50	None	1 case temporary patulous ET	No
Skevas *et al.*[13]	2018	Germany	RS	2272	10 post-operative emphysema, including 3 patients with extension into mediastinum and developed pneumomediastinum.	1 patulous ET 3 cases of temporary tinnitus 1 case acute otitis media epistaxis (number not reported)	No
Dai *et al.*[14]	2016	China	RS	08	None	None	No
Ockermann *et al.*[5]	2010	Germany	CS	08	None	None	NA
Jurkiewicz *et al.*[16]	2013	Poland	CS	04	None	None	No
Chung *et al.*[17]	2022	Korea	CR	01	Transient asystole	None	NA
Long *et al.*[18]	2021	USA	CR	01	Pneumomediastinum	None	No
Shah *et al.*[19]	2018	USA	CR	01	Subcutaneous emphysema and pneumomediastinum	None	No

*NA = Not applicable; ET = Eustachian tube; BET = balloon Eustachian tuboplasty; RCT = randomised, controlled trial; SR = systematic review; RS = retrospective study; CS = case series; CR = case report; TIA = transient ischaemic attack

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in the Eustachian tube was inflated, and it lasted for 13 seconds. The patient recovered sinus rhythm spontaneously. The balloon Eustachian tuboplasty was successfully performed after prophylaxis with vagolytic drugs. It is thought to be a neurally mediated vagal reflex, and both anaesthesiologists and otologic physicians should pay proper attention to monitoring during the procedure.[17]

Another case of TIA was reported in a retrospective case series of 62 patients, from our Australian colleagues.[10] However, TIA developed on the fifth post-operative day. The case was investigated further to find the cause; despite thorough investigations, Cheng *et al.* could not find a relationship to the procedure. All complications are summarised in Table 3.

Discussion

The present study systematically reviewed 14 articles for possible complications associated with balloon Eustachian tuboplasty. Out of 3480 post-balloon Eustachian tuboplasty patients (14 studies), 15 patients (0.43 per cent) had post-balloon Eustachian tuboplasty major complications. Other minor complications also were recorded. In all studies, patients were managed conservatively. Our findings are consistent with other studies published on balloon Eustachian tuboplasty complications. Balloon Eustachian tuboplasty seems to be a relatively safe procedure with a risk of major complications of less than 1 per cent.[13,20]

Table 3. Percentages of all reported complications post-Balloon Eustachian tuboplasty

Complications	Total number of patients; *n* = 3480	Percentages (%)
Major complications		
– Surgical emphysema	9	0.25
– Pneumomediastinum	5	0.14
– Carotid artery related	0	0
Minor complications		
– Epistaxis	16	0.45
– Serous otitis media	13	0.37
– Tinnitus	5	0.14
– Hemotympanum	2	0.05
– Patulous ET	2	0.05
(This study was retracted)		
– Vertigo	1	0.02
– Rhinitis	1	0.02
– Transient dysesthesia of the tongue secondary to chorda tympani compression	1	0.02
– Acute otitis media	01	0.02
Rare complications		
– Transient asystole[1]	1	
– TIA at 5th post-operative day[2]	1	
Total number of complications	58	1.66

[1]Because these were just single case reports, estimating incidence wouldn't be possible
[2]Not related to BET as per authors; *NR = not reported; ET = Eustachian tube; BET = Balloon Eustachian tuboplasty; TIA = transient ischaemic attack

Different surgical procedures were developed to treat chronic Eustachian tube dysfunction until the introduction of balloon Eustachian tuboplasty.[5] Although balloon Eustachian tuboplasty seems to be a relatively a safe procedure, possible adverse events have been documented. McCoul *et al.* reported a complication rate of 2 per cent for balloon Eustachian tuboplasty.[21] Most complications were minor and self-limiting. Most complications found in our review also were minor. The overall complication rate in our study was 1.66 per cent (58/3480), all of which were managed conservatively.

Tucci *et al.* [22] reached a consensus regarding the risks associated with balloon Eustachian tuboplasty and pre-operative discussions with patients. They included bleeding, scarring, infection, development of PETD, and/or need for an additional procedure for consenting to balloon Eustachian tuboplasty.[22] However, we think that there are other important complications as well, which we divided into major and minor complications (Table 3). We recommend including these complications in the consenting process with a patient.

Surgical emphysema is a well-documented complication associated with balloon Eustachian tuboplasty.[13] Skevas *et al.* reported that post-operative emphysema was 0.27 per cent in their study.[13] Similarly, in our analysis, overall post-balloon Eustachian tuboplasty surgical emphysema was 0.40 per cent.

We also reviewed the literature to identify measures that can be taken to prevent post-balloon Eustachian tuboplasty complications. Based on our review we have divided them into three categories: (1) pre-operative assessment and patient selection, (2) peri- and intra-operative care and (3) post-operative care.

Pre-operative assessment and patient selection

It is crucial to select the correct patients for balloon Eustachian tuboplasty to prevent procedure-related complications. Cheng *et al.* reported pre-operative patient selection criteria in their study to carefully consider a patient for balloon Eustachian tuboplasty surgery.[1,10,23] Possible measures to prevent post-balloon Eustachian tuboplasty complications are noted in Table 4.

Balloon Eustachian tuboplasty's success largely depends on proper patient selection. It is essential to select a candidate with true primary dilatory Eustachian tube dysfunction before offering balloon Eustachian tuboplasty. Because patulous Eustachian tube dysfunction and dilatory Eustachian tube dysfunction symptoms commonly crossmatch, lack of in-depth assessment may lead to poor outcomes and even harm in some cases.[22] In addition, Tucci *et al.* emphasized identifying the secondary causes of Eustachian tube dysfunction, such as allergic rhinitis, rhinosinusitis, and laryngopharyngeal reflux.[22] Targeted therapy will help in the symptomatic treatment of extrinsic causes.[22] The role of preoperative computed tomography scans also has been investigated to rule out carotid artery dehiscence by Abdel Aziz *et al.*, however they did not find sufficient evidence to support its use to predict adverse events.[24]

Peri- and intra-operative care

Mucosal injury of the Eustachian tube orifice during catheter adjustment for the correct position of the insertion instrument is thought to be one of the most plausible causes of post-interventional emphysemas. Another possibility is mucosal

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Table 4. Measures to prevent post-balloon Eustachian tuboplasty complications

Preoperative	Peri- and intra-operative	Post-operative
Correct patient selection	Avoid mucosal injury	Avoid
Exclude	Avoid entering false tract	– Valsalva for 2–3
– **Patulous ET**	Use recommended pressures (10–12 bars)	weeks post-BET
– **Extrinsic causes of obstruction**	Inflation no more than 2 minutes	– Straining
– **Prior radiation therapy**	Use of antibiotics in advent of obvious mucosal injury	– Constipation
– **Systemic diseases affecting nasal mucosa**		– Heavy lifting (7 kg/15 lbs)
– **Chronic rhinosinusitis**		– Sneezing for 2 weeks

damage inside the Eustachian tube through a 'kinking' of the balloon catheter or even due to the relatively hard catheter itself, even though its form is regarded to be atraumatic. Thus, air can escape to the peri-tubal tissues, involve the soft tissues of the face and neck, and extend up to the mediastinum. Results from studies showing rupture of the mucosal barrier during balloon Eustachian tuboplasty reinforce the above assumptions.[13]

Furthermore, it is thought that catheter material plays an important role as well. Rigid catheters can be difficult to insert and cause injury to the mucosa, which can lead to major complications. For example, Pau *et al.* raised concerns regarding possible mucosal ruptures inside the Eustachian tube secondary to a relatively inelastic catheter.[25]

Careful catheter insertion and less manipulation are key in preventing any adverse incident. In addition, extra care is needed in case of increased vulnerability of the mucous membranes of the upper airways. For instance, earlier radiation therapy, systemic diseases, or chronic infections with mucosal involvement may notably increase the risk of emphysematous complications. For example, Skevas *et al.*'s report of one patient with an eosinophilic disease supports this assumption, since the patient developed emphysemas after both balloon Eustachian tuboplasty procedures.[13]

Two different balloon catheter systems for dilating the cartilaginous portion of the Eustachian tube have been described in the literature: (1) Acclarent sinus balloon catheter (Acclarent, Menlo Park, CA, USA), which is 5 mm wide and 16 mm long, and (2) Bielefeld balloon catheter (Spiggle & Theis Medizintechnik, Overath, Germany), which is 20 mm long with a diameter of 3.28 mm. The balloon sizes of the Acclarent system are wider compared to the Bielefeld catheter with diameters of 5–7 mm.[26] While the Acclarent system inflates the balloon at 12 atmospheres for between 30 seconds and 2 minutes, the Bielefeld system inflates the balloon at 10 atmospheres for 2 minutes. Despite this difference in dimensions and recommended pressure, emphysematous complications with the Acclarent system do not exceed the ones reported with the Bielefeld balloon.[27,28]

Prophylactic antibiotic also has been recommended in cases of mucosal injury to prevent soft-tissue infections. Schröder *et al.* reported that catheter tips are potential sources of infection.[29] They noted that catheter tips have a wide range of bacterial species including the normal flora of pharyngeal mucosa such as *Corynebacterium*, *Staphylococcus hominis*, *Proteus mirabilis*, *Escherichia coli*, *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Streptococcus pyogenes* and *Klebsiella oxytoca*. Mucosal injury can provide a medium for organisms to spread into soft tissues and lead to infection, even sepsis in certain cases.[29] Hence, the use of broad-spectrum antibiotics covering both gram-positive and gram-negative seems essential in the event of complications. Similarly, Skevas *et al.* recommended use of prophylactic antibiotics in case of mucosal injury.[13]

Post-operative care

Post-balloon Eustachian tuboplasty, patients were told in the majority of the studies to perform the Valsalva manoeuvre immediately after the procedure.[13] However, it was found that the Valsalva manoeuvre, along with other factors, was actively responsible for post-balloon Eustachian tuboplasty emphysema.[13] Hussain *et al.*[30] reported that a patient advised to perform the Valsalva manoeuvre post-balloon Eustachian tuboplasty, developed extensive subcutaneous emphysema immediately after the Valsalva manoeuvre. They recommended delaying the Valsalva manoeuvre for 2 weeks post-operatively.[30] Similarly, Skevas *et al.* recommended delaying the Valsalva manoeuvre 3 weeks post-operatively.[13] Additionally, patients should be instructed to sneeze with an open mouth and consider the use of stool softeners in case of constipation in the immediate post-operative period. Patients also should be advised against heavy weightlifting, and straining.[30] Likewise, Shah *et al.* reported that their patient was sneezing vigorously and lifting heavy weights (30–40 lb at work), which subsequently led to bilateral extensive subcutaneous emphysema in the head, neck and chest, with significant pneumomediastinum.[19] Hence, they recommended strict avoidance of exertion post-operatively for at least 48–72 hours.

We recommend avoidance of the Valsalva manoeuvre, vigorous sneezing, coughing, constipation and lifting weights. We could not find any specifications in the literature that related lifting weights to balloon Eustachian tuboplasty. However, international consensus guidelines on spontaneous cerebrospinal fluid leak does mention less than 15 lb (7 kg), which seems reasonable for balloon Eustachian tuboplasty as well.[31]

- Balloon Eustachian tuboplasty is a new and safe treatment modality addressing chronic obstructive dysfunction of the Eustachian tube
- Balloon Eustachian tuboplasty is still not very widely practised in the UK
- We found an overall complication risk of 1.68 per cent, with major complications of less than 0.42 per cent
- The most common major complication was surgical emphysema, which was 0.39 per cent
- Surgeons need to discuss possible complications with patients before balloon Eustachian tuboplasty, and take all possible measures to prevent these complications
- Preventive measures are divided into pre-operative assessment, peri- and intra-operative care, and post-operative care

In our study, it was difficult to thoroughly analyse all the balloon Eustachian tuboplasty success rates because different authors have adopted different parameters to determine a satisfactory result. However, the success rate is about 60–90 per cent.[32] We think this is an area of future research to exactly determine balloon Eustachian tuboplasty success in terms of resolution of symptoms for obstructive Eustachian tube dysfunction. This is crucial in the consenting process so that the patient can weight risks and benefits.

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Conclusion

Balloon Eustachian tuboplasty is a relatively a safe procedure with an overall complication risk of 1.66 per cent. Excluding unsatisfactory results, the incidence of major complications is less than 0.43 per cent. The most common major risk is surgical emphysema with an incidence of around 0.25 per cent, although minor adverse events (e.g. nose bleeds, pain, patulous Eustachian tube, soft tissue emphysema, and transient dysesthesia of the tongue) have been reported more frequently. Less frequent but serious complications such as pneumomediastinum (0.14 per cent) and transient asystole (only one case reported) also have been described in the literature.

Based on our literature review we recommend implementing the measures detailed in Table 4. Moreover, it is crucial to discuss not only the possible complications and their incidence but also strictly advise patients about the preventive measures described in Table 4.

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Conflict of interests. None

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