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Comparison Of Efficacy of Beclomethasone Inhaler and Topical Lidocaine in Reducing Postoperative Complications of Endotracheal Intubation in Patients Undergoing Major Selective Surgeries

Afzal Shamsi[1], Zainab Hashim Aziz Almusawi[2], Mojgan Rahimi[3], Hossein Majedi[4], Hussein Zayed Kareem[5]

[1] *Department of Anesthesia, School of Allied Medical Sciences, Tehran University of Medical Sciences, Tehran, Iran. Nursing and Midwifery Care Research Center, Tehran University of Medical Sciences, Tehran, Iran.*
Email: Afzal_sh63@yahoo.com
https://orcid.org/0000-0001-6231-0547
[2] *Iraqi bord of anasthesia M.B.Ch. B / FICMS A&IC bint-alhuda teaching hospital for obstetrics and pediatric surgery –head of department of aneasthesia and ICU.*
[3] *Departmen of Anesthesiology and Critical Care, Associated Professor, Tehran University of Medical Sciences, Tehran, Iran*
[4] *MD, AFSA Associated Professor, Pain research center, Neuroscience Institute, Imam Khomeini Hospital Complex, Anesthesiology and Pain Medicine, Tehran University of Medical Sciences. Tehran, Iran.*
[5] *Student of Anesthesia Technology, Department of Anesthesia, School of Allied Medical Sciences, Tehran University of Medical Sciences, Tehran, Iran.*
Email: husseinkareem123@gmail.com

***Correspondence author:** Hussein Zayed Kareem (husseinkareem123@gmail.com)

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Abstract

Background and Aim

Sore throat, cough and hoarseness of voice are common problems after endotracheal general anesthesia. They may be very distressing to the patient and they may have many unwanted sequelae. Various preparations of lidocaine and corticosteroids have been frequently used to prevent or attenuate these complications. The aim of this study to compare the effect of lidocaine lubricant gel (on endotracheal tube) and beclomethasone inhalation preoperatively on the incidence and severity of postoperative sore throat, cough, and hoarseness of voice.

Method

This study included 90 patients (20–35 years of age) male patients undergoing elective major surgeries with ASA physical status I were randomized into three groups of 30 patients as follows (group A: Topical lidocaine, group B: Beclomethasone inhaler, group C: Control). The endotracheal tubes in group (A)were lubricated with lidocaine gel 5%. Group (B) patients receive 2 puffs (100 ug) of beclomethasone inhaler. In the group C patients, no medication was administered or applied. Patients were interviewed by a blind investigator for sore throat, cough and hoarseness (as none, mild, moderate, or severe), at 2 h, 6 h, 12 h, and 24 h after full recovery.

Results

Beclomethasone inhaler significantly decreases the incidence and severity of sore throat in comparison with

lidocaine lubricant and control groups especially in the first 6 hours postoperatively (P-value < 0.05). There was no statistically significant difference in all three groups regarding cough and hoarseness of voice (P-value >0.05).

Conclusion

Beclomethasone inhalation preoperatively was an effective method in decreasing the incidence and the severity of post-intubation sore throat compared to lidocaine lubricant.

Keywords

Beclomethasone, Lidocaine, Sore Throat, Cough, Hoarseness, Tracheal Intubation.

Postoperative sore throat, cough, and hoarseness of voice:

Postoperative pulmonary complications account for a substantial proportion of morbidity and mortality related to surgery and anesthesia and can lead to a prolonged hospital stay [1]. Although there is no standard definition of postoperative pulmonary complications, most investigators include postoperative pneumonia, respiratory failure (usually defined as the need for ventilator support), atelectasis, and airway complications (ex: bronchospasm, laryngospasm, throat related complications....) [2]. Throat related complications may present with various signs and symptoms. For example, sore throat is an ordinary expression of pharyngitis, which by itself can have several causes. It may also include a variety of symptoms including burning pain, discomfort, scratching and numbness in throat, hoarseness, dysphagia, and odynophagia ([3,4]. These symptoms are common problems after general anesthesia [5]. The sore throat has been rated by patients as the eighth-most adverse outcome in the postoperative period [6].A number of predisposing factors have been identified and the most notable ones seems to be the size of the endotracheal tube used, cuff pressure, duration of anesthesia, use of dry and cool anesthetic gas, surgical positioning, use of succinylcholine, concurrent use of a nasogastric tube, aggressive oropharyngeal suctioning and the technique of airway management (i.e. endotracheal tube (ETT) , laryngeal mask airway (LMA) or face mask) [7-9].

1. Sore throat:

After tracheal intubation, the incidence of sore throat varies from 14.4% to 50% [10–14] and after laryngeal mask insertion from 5.8% to 34% [15-17]. The wide variation in these figures is presumably due to different skills and techniques among anesthetists, the differences between individual anesthetists and patients in the definition of sore throat and the fact that patients concentrate on symptoms that directly related to the operative site and do not immediately associate sore throat with anesthesia and surgery. [2]

2.Cough:

Coughing during emergence from general anesthesia, and later in the post anesthesia care unit (PACU), is a common problem that can be triggered by many factors. Tracheal intubation may initiate an alteration of the laryngeal mucosa which can lead to unwanted effects at emergence from anesthesia [18]. Contributing factors such as smoking status, pharyngeal secretions, and chemical irritation due to inhalational volatile anesthetics are known to have an influence on cough at emergence and extubation [19,20]. Moreover, endotracheal tube cuff inflating to prevent air leaks during controlled ventilation causing a mechanical irritation of the tracheal mucosa [21].

Although cough is a protective mechanism, there are circumstances where surgical patients are vulnerable and susceptible to coughing and bucking. For instance, the cough may trigger a sudden increase in the intraocular and intracranial pressures; may lead to arterial and venous hypertension, tachycardia, arrhythmia, and airway complications, like in patients with asthma. Moreover, coughing can affect surgery results, causing potentially dangerous patient movements, and increase wound bleeding [22,23].

3.Hoarseness of voice:

There is a large variation in the reported incidence of hoarseness immediately following short-term tracheal intubation. It occurs in between 4% and 42% of patients ([24,25]) and maybe a long-term problem in less than 1% [26]. However, typically the hoarseness disappears after a few days. In some cases, more concern is expressed when the hoarseness is severe, when aphonia occurs, or when the hoarseness is associated with severe pain on swallowing.

The following four major areas contribute to postoperative hoarseness [27,28].

(1) The act of intubation: Intubation can cause various degrees of laryngeal trauma, including thickening, edema, erythema, hematoma, and granuloma of the vocal folds [29]. Injuries of the laryngeal muscles and suspensory ligaments are possible.

(2) Concomitant bronchitis or bronchopneumonia: Whether these infections exist preoperatively or occur in the postoperative period, they seem to exacerbate the laryngeal reaction by constantly bathing the ulcerated mucosa with bacteria, thereby producing a spreading infection [30].

(3) Any operation in the neck or upper thorax: The recurrent laryngeal nerves course downward in the neck from behind the carotid artery laterally to the front of the carotid artery and then below the aortic arch on the left side or below the subclavian artery on the right side to enter the larynx just posterior to the cricothyroid joint. It used to be true that thyroid operations were among the most common ones causing recurrent laryngeal nerve paralysis. Now, with the decrease in thyroid operations and with the increase of many other neck procedures, the statistics are changing [31].

(4) An allergic reaction involving the larynx: Blood and blood products may provoke a systemic allergic reaction with the larynx participating in the generalized reaction. [32]

4. The sequelae:

Although typically they are considered a minor and not incapacitating and rarely lasting > 48 h postoperatively, these sequelae can be very uncomfortable and maybe especially annoying to patients. [33] as they can lead to:

- Dissatisfaction, discomfort, sleep disturbances, and unpleasant memories after surgery.
- Sequelae related to individual symptoms e.g: Coughing exacerbates pain and increases intracranial(ICP) or intraocular pressure(IOP) in patients with brain disease or glaucoma (as mentioned previously).
- Swallowing difficulties (dysphagia and odynophagia)
- They can delay a patient's return to normal routine activities [34].

The aim of this study to compare the effect of lidocaine lubricant gel (on endotracheal tube) and beclomethasone inhalation preoperatively on the incidence and severity of postoperative sore throat, cough, and hoarseness of voice.

Material and method

1. Study setting:

This study was conducted over a period of around 3 months (from 2022- 2020) in AL-Hussein teaching hospital – Nasiriyah city.

2. Sample:

After obtaining the Institutional Ethics Committee's approval, 90 consenting males patients scheduled for under general anesthesia elective major surgeries were involved in this prospective, randomized study.

Inclusion criteria included having Age between (20-35 years)**,** patients are males, Elective surgeries, ASA physical status I, II and Duration of surgery <60 minutes.

Exclusion criteria included having Patient with ASA > II**,** Patients with airway symptoms or airway disease (ex: asthma, allergic bronchitis, obstructive sleep apnea ...)**,** Smokers, Patients allergic to drugs in the study, Patients using inhaled or oral steroids, Anticipated airway difficulty, Morbidly obese patient.

Dropped cases included having Unanticipated difficult airway (Patients in whom laryngoscopy was attempted more than once or the duration of laryngoscopy was more than 15 seconds), Patients needed to be re-intubated for any cause, Extubation problems, Intubation time more than 60 min**.**

3.Preprocedure process:

In the pre-operative waiting area, at the morning time of surgery day, the participants' age, medical history, and vital signs were recorded. They were assigned to one of three groups of equal number (30 n): (A) Topical lidocaine lubricant, (B): Beclomethasone inhaler and (C): Control group (no medication will be applied). Intravenous access was secured with 18-gauge cannula, IV fluid (500 ml crystalloid), were administered.

4.The operative technique was as follow:

Group A:

1-A standard monitoring (electrocardiograph, blood pressure, pulse oximeter, and end-tidal carbon dioxide [ETCO2]) was applied.
2- Patients were preoxygenated with 100% O_2 (for 3 min.) before induction.
3- GA was induced with injection propofol 1.5-2.5 mg/kg, rocuronium 0.6- fentanyl 1-2 mcg\kg.
4- A lubricated standard PVC (cuffed) endotracheal tubes (size 8-8.5) with lidocaine gel 5% were used.
5-Immediately after intubation, tracheal tube cuffs were filled with the minimal volume of room air required to prevent an audible leak (6-8 ml).
6-Maintenance of anesthesia was with isoflurane (1-1.5%) and controlled ventilation(PCV) was introduced to the patients (Vt: 5-10 ml\Kg, RR:12, I: E ratio 1:2).
7-At the end of surgery, switch off the inhalational agent and neuromuscular blockade was reversed with intravenous neostigmine (0.03-0.07 mg/kg) + atropine (0.04 mg\kg)
8-After full recovery and awakening, extubation was done with gentle suctioning. Patients were then transferred to the post anesthesia care unit.

Group B:

1-After a standard monitoring was applied (electrocardiograph, blood pressure, pulse oximeter, and end-tidal carbon dioxide [ETCO2]), patients received 2 puffs of inhaled beclomethasone (100 µg) via a spacer device during 2 deep inspirations (in sitting position).
2-Then they were preoxygenated with 100% O_2 (for 3 min.) followed by the same technique of induction as in group A.
3- Patients were intubated with a PVC cuffed endotracheal tubes (size 7-7.5) with no medication was applied on to followed by the same maintenance and awakening technique as in group A

Group C:

1-A standard monitoring (electrocardiograph, blood pressure, pulse oximeter, and end-tidal carbon dioxide [ETCO2]) was applied.
2- Patients were preoxygenated with 100% O_2 (for 3 min.) followed by the same technique of induction as in group A.
3- Patients were intubated with a PVC cuffed endotracheal tubes (size 7-7.5) with no medication was applied on ETT followed by the same maintenance and awakening technique as in group A.

5.Postoperative assessment:

Assessment of patients was done. Patients were interviewed at 2 hr., 6 hr., 12 hr., and 24 hr. after full recovery for post-operative sore throat (and related symptoms), cough, and hoarseness using the questionnaire based on the scoring system. Patients complaining of moderate to severe sore throat after 24 hours were advised lukewarm saline gurgle, strepslis, and decongestant medications. IV dexamethasone (8mg) was given in severe cases, and oto-rhino-laryngology consultation was requested. The study design has been reviewed by the Ethics Committee of Tehran University of Medical Sciences and has been registered with the ethics code (IR.TUMS.MEDICINE.REC.1401.195). Researchers adhered to research ethics at all stages of the research including nurses' human values, informed consent, and confidentiality.

6. Statistical analysis:

SPSS (the Statistical Package for Social Sciences) version 24, was used to analyze the data.

Numerical data were expressed as mean, standard deviation, and standard error mean.

The categorical data were presented as frequencies and percentages.

One way ANNOVA was used to analyze the association between the numerical data, a (p-value) less than 0.05 considered statistically significant.

Chi-square test was used to study the association among categorical data, a (p-value) less than 0.05 considered statistically significant.

7.Results

The total number of the participated patients was 90; they were divided into three groups, with 30 patients in each group. They were matched with respect to the age, intubation time, and duration of surgery, mean arterial pressure, and heart rate.

Table (1): Age distribution of the three groups.

Variable	Group	N	Mean (SD)	Std. Error	p-value
Age (years)	Lidocaine lubricant(A)	30	25.93(5.25)	0.959	0.362
	Beclomethasone inhaler(B)	30	27.70(5.35)	0.977	
	Control(C)	30	27.53(5.21)	0.951	

No significant difference was found in comparing the three groups in age as the p-value was 0.362

Table (2): Comparison in vital signs, among the three groups.

Variables	Group	Mean (SD)	p-value
MAP (mmHg)	Lidocaine	88.8(7.57)	0.971
	Beclomethasone	89.2(7.31)	
	Control	89.2(7.31)	
HR (beat/min.)	Lidocaine	84.57(8.5)	0.769
	Beclomethasone	84.07(8.2)	
	Control	83.07(7.71)	

Table (2) shows non-significant difference when comparing the three groups in vital signs, including MAP (mmHg) and HR (beat/min.); (p-values>0.05).

Table (3): Comparison in operative details among the three groups.

Operative details	Group	Mean (SD)	p-value
Duration of laryngoscopy and intubation (sec.)	Lidocaine	11.97(1.7)	0.098
	Beclomethasone	11(2.34)	
	Control	10.8(2.15)	
Tube size(mm)	Lidocaine	8.27(0.25)	0.958
	Beclomethasone	8.25(0.25)	
	Control	8.25(0.25)	
Duration of surgery(min.)	Lidocaine	40.47(4.61)	0.966
	Beclomethasone	42.37(4.54)	
	Control	41.17(4.25)	
Intubation time(min.)	Lidocaine	49.43(6.41)	0.988
	Beclomethasone	48.3(6.89)	
	Control	48.57(6.72)	

Table (3) shows non-significant association when comparing the three groups in duration of laryngoscopy and intubation, tube size, intubation time and duration of surgery (p-values>0.05).

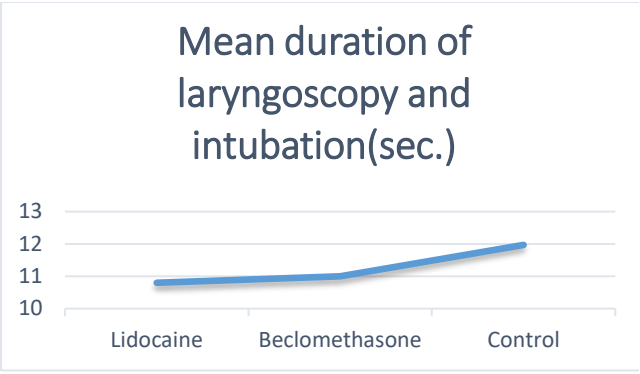

Figure (1): Comparison in the mean duration of laryngoscopy and intubation (in seconds) among the three groups.

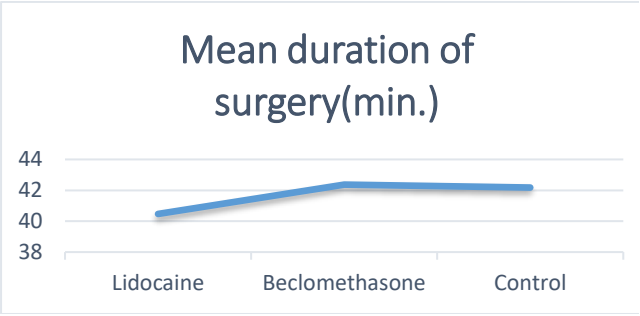

Figure (2): Comparison in the mean duration of surgery (in minutes) among the three groups.

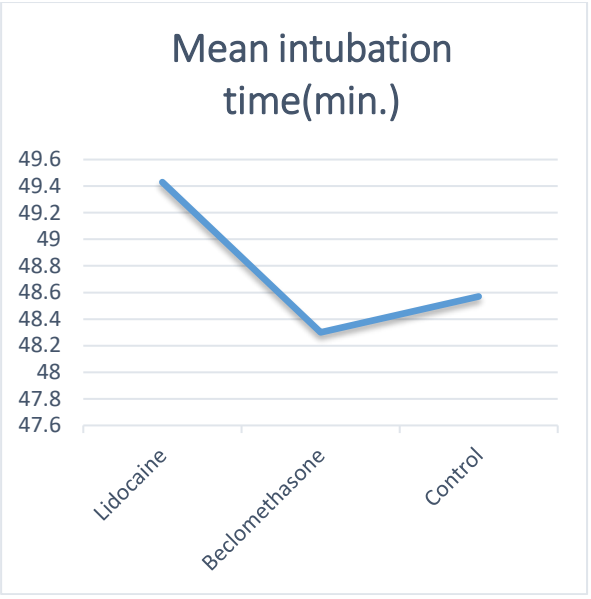

Figure (6-3): Comparison in mean intubation time (in minutes) among the three groups.

Table (4): Comparison in incidence, and severity of sore throat among the three groups.

Time	Variables		Group			p-value
			(A)Lidocaine No. (%)	(B)Beclomethasone No. (%)	(C)Control No. (%)	
2H sore throat	Total incidence		10(33.3%)	5(16.7%)	12(40.0%)	A+C=0.592 B+C=0.0497 A+B=0.01
	Severity	Mild	8(26.6%)	5(16.7%)	7(23.3%)	
		Moderate	2(6.6%)	0	3(10%)	
		Severe	0	0	2(6.6%)	
6H sore throat	Total incidence		9(30%)	3(10%)	13(43.3%)	A+C=0.02 B+C=0.0012 A+B=0.0023
	Severity	Mild	6(20%)	3(10%)	9(30%)	
		Moderate	3(10%)	0	2(6.6%)	
		Severe	0	0	2(6.6%)	
12H sore throat	Total incidence		7(23.3%)	3(10%)	10(33.3%)	A+C=0.078 B+C=0.034 A+B=0.01
	Severity	Mild	5(16.6%)	3(10%)	8(26.6%)	
		Moderate	2(6.6%)	0	1(3.3%)	
		Severe	0	0	1(3.3%)	
24H sore throat	Total incidence		3(10%)	2(6.6%)	4(13.3%)	A+C=0.78 B+C=0.698 A+B=0.209
	Severity	Mild	3(10%)	2(6.6%)	3(10%)	
		Moderate	0	0	1(3.3%)	
		Severe	0	0	0(0%)	

Table (5): Comparison in incidence, and severity of cough among the three groups.

Time	Variables		Group			P-value
			(A)Lidocaine NO.(%)	(B)Beclomethasone NO.(%)	(C)Control NO. (%)	
2H cough	Total incidence		4(13.3%)	6(20%)	9(30%)	A+C=0.264 B+C=0.786 A+B=0.098
		Mild	2(6.6%)	4(13.3%)	5(16.6%)	
		Moderate	2(6.6%)	2(6.6%)	3(10%)	
		Severe	0	0	1(3.3%)	
6H cough	Total incidence		4(13.3%)	5(16.6%)	10(33.3%)	A+C=0.389 B+C=0.128 A+B=0.498
	Severity	Mild	3(10%)	4(13.3%)	6(20%)	
		Moderate	1(3.3%)	1(3.3%)	2(6.6%)	
		Sever	0	0	2(6.6%)	
12H cough	Total incidence		3(10%)	2(6.6%)	6(20%)	A+C=0.096 B+C=0.823 A+B=0.13
	Severity	Mild	2(6.6%)	1(3.3%)	4(13.3%)	
		Moderate	1(3.3%)	1(3.3%)	2(6.6%)	
		Severe	0	0	0	
24H cough	Total incidence		1(3.3%)	2(6.6%)	4(13.3%)	A+C=0.067 B+C=0.36 A+B=0.143
	Severity	Mild	1(3.3%)	1(3.3%)	2(6.6%)	
		Moderate	0	1(3.3%)	2(6.6%)	
		Severe	0	0	0	
	Severity	Mild	1(3.3%)	0	2(6.6%)	
		Moderate	0	0	0	
		Severe	0	0	0	

Table (6): Comparison in incidence, and severity of hoarseness among the three groups.

Time	Variables		Group			P-value
			(A)Lidocaine NO. (%)	(B)Beclomethasone NO. (%)	(C)Control NO. (%)	
2H hoarseness	Total incidence		4(13.3%)	5(16.6%)	7(23.3%)	A+C=0.230 B+C=0.789 A+B=0.088
	Severity	Mild	3(10%)	5(16.6%)	5(16.6%)	
		Moderate	1(3.3%)	0	1(3.3%)	
		Sever	0	0	1(3.3%)	
6H hoarseness	Total incidence		5(16.6%)	4(13.3%)	6(13.3%)	A+C=0.39 B+C=0.088 A+B=0.09
	Severity	Mild	5(16.6%)	4(13.3%)	4(13.3%)	
		Moderate	0	0	2(6.6%)	
		Sever	0	0	0	
12H hoarseness	Total incidence		2(6.6%)	1(3.3%)	4(13.3%)	A+C=0.630 B+C=0.78 A+B=0.142
	Severity	Mild	2(6.6%)	1(3.3%)	4(13.3%)	
		Moderate	0	0	0	
		Sever	0	0	0	
24H hoarseness	Total incidence		1(3.3%)	0	2(6.6%)	A+C=0.897 B+C=0.078 A+B=0.230
	Severity	Mild	1(3.3%)	0	2(6.6%)	
		Moderate	0	0	0	
		Sever	0	0	0	

At the time intervals of 2 hours and 6 hours, beclomethasone inhaler significantly decreases the incidence of sore throat, which occurred significantly as mild cases only in the beclomethasone group, no severe cases of sore throat occurred in both topical lidocaine, and beclomethasone inhaler groups. At 12 hours interval, regarding sore throat, there was a significant decrease in incidence and severity in the beclomethasone group compared to lidocaine and control groups. No significant differences were found between lidocaine and control groups. No statistically

significant differences were found in comparing the three groups in incidence and severity of sore throat at 24 hours interval.

Regarding cough, the incidence was comparable between the beclomethasone group and the lidocaine group. Both having a lower value in comparison with the control group but failed to reach statistical significance. Also, there is no statistically significant differences were found in comparing the three groups in severity at all times intervals. Most of the documented cases of hoarseness were mild and moderate in severity, there was one documented severe case at 2 hour interval in control group. No statistically significant differences were found in comparing the three groups in the incidence and severity of hoarseness at all times intervals.

7.Discussion

Sore throat, cough, and hoarseness are frequent complaints after general anesthesia with endotracheal intubation which is considered a major leading cause of trauma and irritation of pharyngolaryngeal mucosa [35], The contributing factors are known to be age, sex, type of procedure, surgical manipulation of the airway, size and cuff pressure of the endotracheal tube, use of succinylcholine, use of a nasogastric tube, and excessive oral suctioning [36,37]. In order to avoid potential confounding factors that may affect the incidence and severity of symptoms, male's patients were selected so that the sex factor was eliminated, patients are of similar ages (mainly young adult aged men), the surgical site is distal to the airway structures. Comparable sizes of endotracheal tubes were used between the three groups.

In many previous studies, various steroids and lidocaine preparations have been used to attenuate throat symptoms. Steroid preparations are synthetic glucocorticoids that attenuate airway symptoms mainly through their anti-inflammatory and immunosuppression effects, also, they have an antiemetic, and analgesic effects. [38] Lidocaine has been commonly used to suppress airway reflexes, reduce bronchial hyper-reactivity, and attenuate hemodynamic responses from intubation due to its anesthetic\analgesic and anti-inflammatory properties. [39]

Conclusion

The present study demonstrated that the incidence and severity of postoperative sore throat was significantly reduced in the beclomethasone inhaler group compared with lidocaine lubricant and control groups. The frequency of cough insignificantly reduced in both lidocaine and beclomethasone groups interval but the incidence and severity of hoarseness was not significantly different between groups at all times intervals.

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Conflict of interest

There is no conflict of interest in the present study.

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