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ORIGINAL ARTICLE

The Effect of Intravenous Lidocaine Versus Midazolam on the Incidence and Severity of Post-extubation Laryngospam in Children Undergoing Adenotonsillectomy: A Randomized Control Clinical Trial

Ertiame MT[1]; Elsayed AS[2]; Farag NM[2]; Botros AR[2]

[1] Department of Anesthesia and Intensive Care, Faculty of Medicine, ALZawia University, Libya

[2] Department of Anesthesia, Intensive Care and pain management, Faculty of Medicine, Zagazig University, Egypt.

* **Corresponding author:** Mahmod Taher Ertiame
Email: alrtemi202013@gmail.com

ABSTRACT

Background: Post-extubation laryngospasm is a common and serious complication in children.

Objective: The effect of intravenous lidocaine versus midazolam on the incidence and severity of post-extubation laryngospasm.

Patients and methods: This randomized clinical trial included 120 young children who were undergoing elective adenotonsillectomy. These children were randomly divided into three equal groups. Two minutes before extubation, these groups had received intravenously either 5 ml of normal saline **(Control group),** 1.5 mg/kg of lidocaine **(L group)** or 0.03 mg/kg of midazolam **(M group).** The incidence and severity of post-extubation laryngospasm, the means of heart rate (HR), arterial pressure (MAP), oxygen saturation (SpO_2), recovery time and the associated complications were recorded.

Results: The incidence and severity of post-extubation laryngospasm in both L and M groups were statistically comparable and significantly lower than in C group. The mean HR and MAP values at 2,5,10 and 20 minutes post-extubation in L and M groups were statistically significantly lower than the corresponding values in C group and in the L group were significantly higher than in M group. The mean SpO_2 values are only at 2 min. post-extubation in C group was statistically lower than the corresponding mean values in both tested groups. Recovery times of the three groups were statistically comparable. Post-extubation, hypoxemia was the only associated complication and occurred in 10% of cases in C group.

Conclusion: Lidocaine (1.5 mg/kg) and Midazolam (0.03 mg/kg) have comparable safe effects in reducing the incidence and severity of pos-extubation laryngospasm when they have been given intravenously 2 minutes pre-extubation in children undergoing adenotonsillectomy**.**

Keywords: Adenotonsillectomy; Laryngospasm; Lidocaine; Midazolam.

INTRODUCTION

Tonsillectomy with or without adenoidectomy is considered one of the most common surgical procedure in young children **(1).** Post-extubation laryngospasm is more prevalent in such surgical procedures because they are accompanied by the presence of upper airway stimulatory factors as hemorrhage and salivary secretions **(2).** The incidence of post-extubation laryngospasm following general anesthesia (GA) is inversely related to the patients' age **(3-5).** Generally, the incidence of post-extubation laryngospasm in tonsillectomy varies between 12 and 25% **(6).**

Post-extubation laryngospasm is a life-threatening event that results in complete or partial blockage of the airway. Prolonged airway blockage lead to oxygen desaturation, bradycardia, obstructive negative pressure pulmonary edema, pulmonary aspiration, cardiac dysrhythmias, cardiac arrest, irreversible hypoxic brain injury and death; therefore, it is necessary to treat post-extubation laryngospasm immediately **(7-9).** Prevention the occurrence of post-extubation laryngospasm is better than its treatment**(4).**

There are several methods for the prevention of this complication as complete hemostasis during surgery, gentle suctioning of the oropharynx before extubation, awake tracheal extubation, and the use of drugs **(10).** Lidocaine and midazolam are the commonly used drugs for the prevention and treatment of post-extubation laryngospasm in children and adults **(11-13).**

Because the published literature did not reveal which one of them is more efficient in the prevention or at least in lowering the incidence and severity of post-extubation laryngospam, therefore, *the aim* of this study was to compare the effect of intravenous (iv) injection of lidocaine and midazolam on prevention of post-extubation laryngospasm following adenotonsillectomy in young children.

PATIENTS AND METHODS

Study design

This prospective, randomized, double-blind, clinical trial was conducted at Zagazig university hospital in Zagazig city, Sharkia governorate, Egypt, from May 2021 to April 2022. The study protocol of this work was reviewed and approved by the University Institutional Review Board (IRB). One hundred and twenty both-sex patients, aged 4 to 8 years, with physical status (ps) of class I or II according American Society of Anesthesiologists (ASA) classification who were candidates for elective adenotonsillectomy were subjected to this study. The exclusion criteria were refusal of the patient's parent or guardian the participation in this study, the presence of upper respiratory tract infection, history of cardiac, respiratory and renal diseases, history of allergy to the tested drugs and surgery duration longer than 1.5 hour.

This study was carried out in according to the Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.

Randomization and blinding

According to a computer-generated randomization chart, the patients were assigned to be one of the 3 equal groups (40 patients in each group) as the following: **Control group (C group)** which had received 5 ml of normal saline iv 2 minutes before extubation.

Lidocaine group (L group) which had received 1.5 mg/kg of lidocaine (diluted up to 5 ml with normal saline) iv 2 minutes before extubation.

Midazolam group (M group) which had received 0.03 mg/kg of midazolam (diluted up to 5 ml with normal saline) iv 2 minutes before extubation**.**

Operational design and data collection

All of children were visited at the night before the surgery for assessment, and preparation and taken informed consent on the type of anesthesia which intended to be given from their parents or guardians. Assessment of patients included identification of patient's age/years, body weight/kg, body height/m, body mass index (BMI) and vital signs, taking history about medical disorders, previous surgical procedures, the current medications, examination of various body systems and asking for routine investigation as complete blood count, sedimentation rate, bleeding time and chest-X ray.

During patients' preparation, instruction was given to allow solid food intake until midnight of the day of surgery and clear liquids until 2 hours before the start of surgery. Premedication was not prescribed to any study subject.

This study was double-blinded i.e. the patients and anesthesia assistant (the person evaluating the effect of the tested drug) were not informed the type of the tested drug. Only the anesthesiologist (the person prescribing the tested drug) was aware of the type of the tested drug in order to take the necessary measures in case of the occurrence of any adverse medical complications.

In the operating room, a peripheral intravenous cannula (22-24gauge) was established and secured and devices for monitoring of heart rate (HR), non invasive mean arterial pressure (MAP) and peripheral oxygen saturation (SpO_2) were applied to the patients and baseline values of HR, MAP, and SpO_2 were recorded. General anesthesia was induced by iv injection of 1mcg/kg of fentanyl sulfate and inhalation of 8% sevoflurane in air/oxygen (50%:50%). After loss of lash reflex and relaxation of the jaw muscles, direct vision laryngoscopy and oral endotracheal intubation with suitable size for age non cuffed tube had been performed. After fixation of oral endotracheal tube, a wet pharyngeal pack was applied around the tube to avoid pulmonary aspiration of blood or secretion. Immediately after endotracheal intubation, all the patients had received 10mg/kg acetaminophen suppository to avoid or at least minimize postoperative pain. anesthesia was maintained with 1.5–2% sevoflurane in air/oxygen (50%:50%) and mechanical ventilation was aided by iv administration of 0.4 mg/kg atracurium besilate. Intra-operatively, all patients received Ringer lactate solution IV. At the end of surgery, inhalational anesthesia was discontinued and on the start of attempts of spontaneous respiration, a mixture of 4 mcg/kg of neostigmine and 2 mcg/kg of atropine was given iv for reversal of muscle relaxant effect, then pharyngeal suctioning and removal of pharyngeal pack had been performed. Two minutes before extubation, either normal saline (placebo) or each of the tested drugs had been given to the corresponding group. The primary outcome was the incidence and severity of post-extubation laryngospasm during 30 minutes post-extubation Severity level of post-extubation laryngospasm were evaluated by a four-point scale **(14)** : 0= lack of laryngospasm; **1**

(mild) = Partial occlusion of cords, stridor during inspiration with decreased tidal volume and stable pulse oximeter oxygen saturation [SpO_2 >95%]; **2** (moderate) = Total occlusion of cords (i.e. respiratory silence with ventilatory obstruction, which can be characterized by inspiratory efforts of the accessory muscles and paradoxical thoracic movements, and SpO_2>85%) and **3** (severe) = Cyanosis associated with desaturation i.e. SpO_2 <85% and bradycardia of a severe type.

Treatment of post-extubation laryngospasm was standardized as the following: At first removal of the offending stimulus, jaw thrust, and manual ventilation with 100% oxygen by bag and mask is performed **(15).** When the first measure fail, application of a firm pressure at a laryngospasm point, which lies behind the ear lobe, between the mastoid process and the ramus of the mandible is performed **(16).** When the above mentioned two measures fail, 0.5mg/kg of succinylcholine is injected iv and manual ventilation with 100% oxygen by bag and mask with manual face mask ventilation is performed till return back of spontaneous breathing. When the above mentioned three measures fail, laryngospasm is considered sustained and treated like severe laryngospasm from the start by iv injection of 1.0–1.5mg/kg of succinylcholine, endotracheal intubation and manual ventilation with 100% oxygen till return back of spontaneous breathing **(17).** The secondary outcomes included the HR, MAP changes at 2, 5, 10, 20 and 30 min post-extubation, recovery time and the associated complications as bradycardia, tachycardia, hypertension, hypotension, hypoxemia and delayed recovery were also recorded and compared. Hypotension and hypertension were considered if the decrease or the increase in MAP respectively is more than 20% of age-related BP. Bradycardia and tachycardia were considered if the decrease or the increase in HR is more than 20% of age related HR **(16).** Hypoxemia was considered if the SpO2 is below 92%. Hypotension and bradycardia, they would be corrected by ephedrine (0.02 mg/kg/iv) and atropine (0.0 1mg/kg/iv) respectively **(18).** Hypertension and tachycardia, they would be corrected by treating the cause **(19, 20).** Hypoxemia would be corrected by assisted ventilation with 100% oxygen till return back SpO_2 to normal levels. Recovery time is defined as the time per minutes from the end of anesthesia till the achievement of score 6 (i.e. fully recovery) according to **Steward** post-anesthetic recovery scoring system **(21)**.

Statistical analysis

Assuming the efficacy of lidocaine versus placebo was 92% versus 70% at 80% power and 95% CI according to previous study by **Malik et al., (22),** the estimated sample size was 136 cases, 34 in each group. For compensation of the dropped cases, each group size increased to 40 patients. Open Epi Info Program was used for calculation of sample size. All data were analyzed with SPSS software version 16 (SPSS Inc., Chicago, IL, USA). Descriptive information of qualitative data were expressed in the form of ratios and percentages. Chi-square and Fisher's exact tests were used to compare the incidence of post-extubation laryngospasm. Student's t-test and Mann-Whitney nonparametric test were used to compare changes of HR, MAP, SpO_2 and recovery time. In all analyses, p-values less than 0.05 were considered significant and less than 0.001 were considered highly significant.

RESULTS

Statistically, the patients' demographic characteristics (age, body weight, height, BMI, sex ratio and ASA ps classes, and durations of surgery and anesthesia were comparable in the three studied groups **(Table 1).** The incidence and severity of post extubation laryngospasm in both L and M groups were statistically comparable and significantly lower than the corresponding incidence and severity of post extubation laryngospasm in C group **(Table 2).** Severe laryngospasm, occurred only in one patient in C group. This case was relived by iv injection of 0.5 mg/kg succinylcholine and manual ventilation with 100% oxygen via bag and mask till return back of spontaneous breathing. The mean heart rate and MAP values during 2,5,10 and 20 minutes after extubation in L and M groups were statistically significant lower than the corresponding values in C group and in L group were significantly higher than in M group **(Table 3 and 4**). The mean SpO_2 values at 2 min post-extubation in C group was statistically lower than the corresponding mean values in both tested groups. The mean SpO_2 values at the other times of measurements were statistically comparable **(Table 5)**. Although the mean recovery time in M group (19.13 ± 4.35 min) was numerically longer than the mean recovery times in C (17.95 ± 3.54 min) and L (17.87 ± 3.42 min) groups but, the recovery times of the three groups were statistically comparable (**Table 6)**. Following extubation, hypoxemia occurred in 10% (4 out of 40 patients) of cases in C group and did not occur in the other two tested groups. Statistically, the

incidence of hypoxemia in C group was significantly higher than it's incidence in the other two tested groups (**Table 6)**.

Table (1): Patients' demographic characteristics and durations of surgery and anesthesia.

	C group n=40)(	**L group n=40)(**	**M group n=40)(**	**P value**
Age (years):	**6.18±1.25**	**5.96±2.27**	**6.15±2.35**	**0.949 NS**
Body weight (Kg):	**21.85±4.16**	**22.05±3.19**	**21.95±4.06**	**0.985 NS**
Height (cm):	**117.76±3.13**	**117.39±3.33**	**118.15±3.19**	**0.739 NS**
BMI	**15.80±0.50**	**15.6±0.73**	**15.70 ±0.39**	**0.28 NS**
Sex ratio: *Male*s [N(%)]. *Femal*es [N(%).]	 **24 (60%)** **16 (40%)**	 **25 (62.5%)** **15 (37.5%)**	 **23 (57.5%)** **17 (42.5%)**	**0.913 NS**
ASA PS class: Class I [N(%)]. Class II [N(%)].	 **33(82.5%)** **7(17.5%)**	 **34(85%)** **6(15%)**	 **32(80%)** **8(20%)**	**0.47 NS**
Duration of surgery (min.).	**29.56±4.47**	**30.25±5.63**	**31.71±4.52**	**0.272 NS**
Duration of Anesthesia (min.).	**38.95±6.20**	**39.98±5.15**	**41.09±5.15**	**0.281 NS**

Data are expressed as Mean ± Standard Deviation (SD) and numbers (%).
n =Group number.
N(%)= Number and percent of the variable in the corresponding group.
NS = non-significant difference.

Table (2): The overall incidence and severity of post-extubation laryngospasm.

	C group n=40)(	**L group n=40)(**	**M group n=40)(**	**P value**
The overall incidence of post-extubation laryngospasm [N (%)].	**14 (35%)**	**3 (7.5%)**	**3 (7.5%)**	**P1<0.001**** **P2<0.001**** **P3 >0.919 NS**
Severity grades of post-extubation laryngospasm: 0=No laryngospasm 1=Mild [N(%)]. 2=Moderate [N(%)]. 3=Severe [N(%)].	 **26 (65%)** **10 (25%)** **3 (7.5%)** **1(2.5%)**	 **37 (92.5%)** **3 (7.5%)** **0 (0.0%)** **0(0.0%)**	 **37 (92.5%)** **3 (7.5%)** **0(0.0%)** **0(0.0%)**	 **P1< 0.001**** **P2< 0.001**** **P3 >0.999 NS**

Data are expressed by numbers and percent. n= number of patients in each group.
N(%)=Number and percent of the variable in the corresponding group.
NS = Non-significant difference. ****** = statistically highly significant difference.
P1=C group versus L group. P2=C group versus M group.
P3=L group versus M group.

Table (3): The heart rate values at different times of measurement.

HR/min.	**C group n=40)(**	**L group n=40)(**	**M group n=40)(**	***P* value**
Baseline	**96.0 ± 3.04**	**97.5 ± 2.18**	**96.5 ± 2.41**	**P>0.05 NS**
After extubation: **2min.**	**116.6 ±4.82**	**85.5 ± 2.91**	**104.1 ± 2.95**	**P1<0.001**** **P2<0.001**** **P3<0.001****
5 min.	**115. 5 ± 3.88**	**85.7 ± 3.68**	**105.1 ± 2.73**	**P1<0.001**** **P2<0.001****

HR/min.	C group n=40)(	L group n=40)(	M group n=40)(	*P* value
				P3<0.001**
HR/min.	C group	L group	M group	
10 min.	114.4 ± 4.25	87.1 ± 2.46	101.7 ± 1.98	P1<0.001** P2<0.001** P3<0.001**
20 min.	105.2 ± 6.4	89.8 ± 2.11	100.0 ± 2.22	P1<0.001** P2<0.001** P3<0.001**
30 min.	96.9 ± 2.22	96.53 ± 2.97	97.48 ± 2.3	P>0.05 NS

Data are expressed as Mean ± Standard Deviation (SD). n= number of patients in each group.
NS=non-significant difference. **= statistically highly significant difference.
P = C group versus L group. P2=C group versus M group.
P3=L group versus M group.

Table (4): Mean arterial pressure (MAP) at different times of measurements.

MAP /mmHg.	C group n=40)(	L group n=40)(	M group n=40)(	*P* value
Baseline	65.80 ±4.21	66.0 ± 5.32	66.08 ±4.42	P>0.05NS
After extubation: 2min.	72.3 ± 2.87	62.85 ± 4.99	51.6 ± 4.56	P1 <0.001** P2 <0.001** P3<0.001**
5 min.	67.5 ± 5.17	61.4 ± 3.48	54.1 ± 5.61	P1 <0.001** P2 <0.001** P3<0.001**
10 min.	67.3 ± 6.75	61.4 ± 4.97	54.4 ± 4.82	P1 <0.001** P2 <0.001** P3<0.001**
20 min.	66.4 ± 5.99	62.58± 4.88	55.0 ± 4.06	P1 <0.001** P2 <0.001** P4<0.001**
30 min.	65.2 ± 5.6	65.4 ± 4.18	64.6 ±4.52	P>0.05 NS

Data are expressed as Mean ± Standard Deviation (SD). n= number of patients in each group.
NS= non-significant difference (NS). **= statistically highly significant difference.
P= C group versus L group. P2= C group versus M group.
P3= L group versus M group.

Table (5): Mean SpO_2 (O_2%) values at various times of measurements.

SpO_2 (O_2%) at room air.	C group n=40)(	L group n=40)(	M group n=40)(	*P* value
Basel readings.	98.72±0.91	98.75 ± 1.06	98.71 ± 0.87	0.992 NS
After extubation: 2 min.	94.25 ±0.71	97.13 ± 0.78	97.39± 0.85	P1<0.05* P2< 0.05* P3 >0.05*
5 min	98.09±0.67	98.48 ± 1.0	98.41 ± 0.88	0.094 NS
10min.	98.23±0.69	98.61 ± 1.0	98.44 ± 0.48	0.063 NS
20 min.	98.35±0.65	98.7 ± 1.0	98.53 ± 0.69	0.15 NS
30 min.	98.52±0.62	98.79 ± 0.76	98.69 ± 0.78	0.417 NS

Data are expressed as Mean ± Standard Deviation (SD). n= number of patients in each group.
NS= non-significant difference. *= statistically significant difference.
P1= C group versus L group. P2= C group versus M group.
P3= L group versus M group.

Table (6): The recovery times and the incidences of the associated complications.

	C group (n=40)	L group (n=40)	M group (n=40)	P value
Recovery time (min.)	**17.95 ± 3.54**	**17.87 ± 3.42**	**19.13 ± 4.35**	**P> 0.05 NS**
Hypoxemia [N(%)].	**4(10%)**	**0(0.0%)**	**0(0.0%)**	**P1≤0.05* P2≤0.05* P3>0.05 NS**

Data are expressed by mean±SD and numbers and percent. n= number of patients in each group.
N(%)=Number and percent of the variable in the corresponding group.
NS= non-significant difference. *= statistically significant difference.

DISCUSSION

Laryngospasm is one of the common and serious complications seen during anesthesia especially during extubation. The exact cause of laryngospasm is unknown but multiple factors have been attributed to its occurrence. These factors involved light plane of anesthesia during tracheal extubation, hyperactive airway and pain beside airway irritants such as a laryngoscope blade, an irritating volatile agent, a suction catheter, surgical debris, mucus, blood, or another foreign body **(23).**

In the present study, it was found that, in comparison with control group, iv administration of each of 1.5 mg/kg lidocaine and 0.03 mg/kg medazolam 2min before extubation produced statistically significant decrease in the incidence and severity of post-extubation laryngospasm. Also the incidence and severity of post-extubation laryngospasm of the two tested groups were statistically comparable.

The detected efficient effect of lidocaine in prevention of post-extubation laryngospasm was in agreement with many workers. **Baraka (24)** reported that, iv administration of 2 mg/kg of lidocaine one minute prior to extubation, prevented post-postextubation laryngospasm in children. **Malik et al., (22)** reported that, iv administration of 1.5 mg/kg lidocaine 2 minutes before extubation decreased the incidence and severity of postextubation laryngospasm in children undergoing tonsillectomy. **Xiaojing et al., (25)** after they had performed a network meta-analysis on the efficacy of lidocaine in laryngospasm prevention in pediatric surgery, they reported that, both iv and topical lidocaine could prevent laryngospasm in pediatric surgery. **Aljonaieh, (26)** reported that, the incidence of post-extubation laryngospasm in placebo group was 19.5% and in lidocaine (1mg/kg) treated group was 0%; this difference was statistically significant.

The detected efficient effect of midazolam in prevention of post-extubation laryngospasm was in agreement with many workers. **Salah and Azzazi (13)** reported that, iv administration of 3 mcg/kg midazolam was effective in treatment of post-extubation laryngospasm after oropharyngeal surgeries. **Shaban (27)** reported that, iv administration of 5 mcg/kg of midazolam before tracheal extubation decreases the incidence and severity of post-extubation laryngospasm and coughing in adult patients undergoing oropharyngeal surgeries.

The mechanism of occurrence of post-extubation laryngospasm was attributed to activation of N-methyl-D-aspartate (NMDA) receptors in the brain stem by afferent signals from vocal cord and larynx which in turn leads to an efferent vagal response resulting in vocal cord adduction i.e. laryngospasm **(28).**

The mechanism of laryngospasm preventing effect of iv lidocaine is unknown. The possible mechanisms included either a central nervous system depressant property with subsequent increased depth of anesthesia **(29),** or central interruption of the reflex pathway or direct peripheral action on the sensory and motor nerve terminals **(30).** However, a reflex response to laryngeal irritation is mediated at subcortical levels and therefore a cortical effect may be inadequate to reduce the response to laryngeal irritation**(31).**

The mechanism of laryngospasm preventing effect of midazolam was attributed to its suppressive effect on the upper airway reflexes **(13).**

In the present study, it was found that, the mean heart rate and MAP values during 2, 5, 10 and 20 minutes after extubation in C group were statistically significant higher than the corresponding values in L and M groups. These findings were in agreement with the reported finding of **Sanikop and Bhat (23).** They reported that, there was a significant increase in the heart rate postoperatively during 10 minutes following extubation in control group compared to lidocaine group. In contrast, **Abou Madi et al., (32)** reported that, iv administration of 1mg/kg of lidocaine two minutes before endotracheal intubation, prevented coughing with

no changes in blood pressure and heart rate during and after extubation.

In the present study, following extubation, hypoxemia occurred in 4 patients (10%) in control group and did not occur in the other two tested groups. The causes of this hypoxemia were moderate and severe post-extubation laryngospasm that occurred in three patients and one patient respectively. This finding was in agreement with the reported findings of **Sanikop and Bhat (23).** They reported that, there was a significant fall in oxygen saturation as the result of severe post-extubation laryngospasm in control group but did not occur after extubation in lidocaine group**.**

In this study, recovery time was not statistically affected by iv administration of each of lidocaine and midazolam. This finding was in agreement with the reported findings of some workers. **Mraovic et al., (33)** reported that, iv administration of 1.5 mg/kg of lidocaine at discontinuation of sevoflurane had no effect on the recovery from anesthesia when compared with administration with pacebo (5ml of normal saline). **Cho et al., (34)** reported that, iv administration of 0.03 mg/kg of midazolam before the end of surgery did not delaying the emergence time.

In the present study, it was found that, the used iv doses of each of lidocaine (1.5 mg/kg) and midazolam (0.03 mg/kg) for prevention of post-extubation laryngospasm did not statistically affect the recovery time. This finding was in agreement with the reported findings of some workers. **Mraovic et al., (33)** reported that, iv administration of 1.5 mg/kg of lidocaine at discontinuation of sevoflurane had no effect on the recovery from anesthesia when compared with administration with pacebo (5ml of normal saline). **Cho et al., (34)** reported that, iv administration of 0.03 mg/kg of midazolam before the end of surgery did not delaying the emergence time.

The limitations of this study were the relatively small group size and the optimal dose of each of lidocaine and midazolam required for prevention of post-extubation laryngospasm in children after adeno-tonsillectomy had not been established. The tested drugs doses that had been used in the current study were based on the reported data that these are the optimal effective doses in prevention of post-extubation laryngospasm. Further studies are needed to establish the most appropriate doses of the tested drugs for prevention of post-extubation laryngospasm. **In conclusion:** Lidocaine (1.5 mg/kg) and Midazolam (0.03 mg/kg) have comparable safe effects in reducing the incidence of pos-extubation laryngospasm when they have given intravenously 2 minutes before extubation in children undergoing adenotonsillectomy.

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Conflicts of interest

The authors declare that, they have no conflicts of interest.

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