# RESEARCH



# Feasibility study of using perfusion index to predict the timing of laryngeal mask insertion: an observational study



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## Abstract

**Background** Currently, no objective indicators are available to predict the optimal timing for laryngeal mask insertion. Anesthesia depth monitoring devices such as the Bispectral Index (BIS) are not widely applicable for daysurgery patients due to their high cost. Previous literature has reported a correlation between the perfusion index (PI) and the anesthesia depth. Thus, the aim of this study is to verify whether the PI can serve as an indicator for predicting the timing of laryngeal mask insertion.

**Methods** This trial was conducted at a specialized pediatric hospital, with a final enrollment of 164 pediatric patients. After the children entered the room, baseline vital signs and Pl<sub>1</sub> were recorded. Three minutes after routine anesthesia induction, Pl<sub>2</sub> was recorded, and then a laryngeal mask was inserted. Then children were divided into the body movement group and the non-body movement group. The diagnostic efficacy of Pl and the Pl ratio for predicting the timing of laryngeal mask insertion were calculated using ROC curves.

**Results** The area under the ROC curve (AUC) for using PI to predict the timing of laryngeal mask insertion was 0.641 (95% confidence interval, 0.542–0.740), P = 0.009, and the cutoff value was 4.37. When PI > 4.37 was used to predict the timing of laryngeal mask insertion, the sensitivity was 53.2%, and the specificity was 73.7%. The AUC for using the PI ratio to predict the timing of laryngeal mask insertion was 0.751 (95% confidence interval, 0.657–0.844), P < 0.001, and the cutoff value was 2.955. When the PI ratio > 2.955 was used to predict the timing of laryngeal mask insertion, the sensitivity was 85.7%, and the specificity was 63.2%.

**Conclusion** The PI ratio is more suitable than PI alone for predicting the timing of laryngeal mask insertion. When PI increases to three times the baseline PI after induction, laryngeal mask insertion can be considered.

**Clinical trial registration** : This trial was registered at the Chinese Clinical Trial Registry (https://www.chictr.org.cn. Registration number ChiCTR2400083111, Weiwei Cai, 16 April 2024.)

Keywords Perfusion index, Laryngeal mask, Prediction, Timing of insertion

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## Introduction

The laryngeal mask is a supraglottic airway device that is easy to insert, does not damage the airway, and causes minimal stimulation, making it widely used in pre-hospital emergency care, anesthesia, and intensive care units [1]. Since the emergence of laryngeal mask, the usage of the laryngeal mask (first generation) has reached 500 million, the safety of laryngeal mask use deserves the attention of anesthesiologists. Currently, the timing for laryngeal mask insertion remains unclear. In cases of shallow anesthesia, inserting the laryngeal mask may lead to body movement and hemodynamic fluctuations, increasing the risks of throat injury, tooth loss, oral bleeding, and laryngospasm. In clinical practice, doctors often assess the timing for laryngeal mask insertion by lifting the patients' jaw to observe for any response, but this method is generally not reliable. If A-line Autoregression Index (AAI) or bispectral index (BIS) is used to monitor the depth of anesthesia to determine the timing of inserting a laryngeal mask [2], it will increase healthcare costs and is not easy to implement widely in clinical practice. Therefore, finding a simple, cost-effective, reliable, and objective new indicator has important clinical significance.

The perfusion index (PI) is calculated by pulse oximeters based on the pulse wave at the end of the limb. It represents the ratio of pulsatile blood flow to non-pulsatile blood flow at the monitoring site, reflecting the perfusion of peripheral tissues. Currently, it is widely used for predicting the effects of nerve block, monitoring hemodynamic changes, and guiding fluid therapy [3-8]. In recent years, some studies have found a correlation between changes in PI values and anesthesia depth. Krishnamohan A et al. [9] discovered that PI can predict the depth of anesthesia in pediatric patients. Pei-Pei Liu et al. [10] found a strong correlation between PI and BIS. Additionally, Abdel-Ghaffar et al. [11] noted that PI also demonstrates a good correlation with AAI(A-line Autoregression Index) in monitoring anesthesia depth. Therefore, we hypothesize that PI may reflect the depth of anesthesia in children. Currently, there are no studies focused on the use of PI for predicting the timing of laryngeal mask insertion. Therefore, this research has a certain level of innovation. The aim of this trial is to explore whether PI can be used to predict the timing of laryngeal mask insertion, and provide a theoretical basis for clinical practice.

## **Materials and methods**

This study was performed at the Children's Hospital of Nanjing Medical University from May to June 2024 and was approved by the Ethics Committee of the Children's Hospital of Nanjing Medical University (approval number:202402006-1). Inclusion criteria: (1) Patients aged 6–10 years undergoing elective general anesthesia for inguinal hernia repair. (2) Patients can cooperate with the medical staff. Exclusion criteria: (1) Patients with preexisting cardiopulmonary diseases and cannot tolerate non-intubated general anesthesia, (2) Emergency patients with a full stomach, (3) Patients undergoing head, neck or oral surgeries, (4) Patients with neurological disorders, and receive treatment with antiepileptic or antidepressant medications, (5) Preoperative use of vasoactive drugs, (6) Preoperative use of sedatives, (7) Patients' guardians do not agree to participate in this trial.

## Anesthesia

An intravenous route was established before the patient was brought to the operating room. Upon entering, a pulse oximeter (model: Mecun, MC-FA-1) was used to monitor PI and SpO<sub>2</sub>, along with monitoring temperature, blood pressure, ECG, and respiratory rate. Once PI stabilized within a certain range, the preoperative vital signs (T1) were recorded. Induction drugs included 10% propofol 3 mg/kg, sufentanil 0.3ug/kg (the concentration of sufentanil was 1ug/ml), and anesthesia was maintained using sevoflurane 2-3%, all drugs were administered slowly (each drug was administered over 30 s to 1 min) to maintain spontaneous breathing. Three minutes after induction, a laryngeal mask (selected according to the patient's weight, NINGCHUANG MEDICAL, China) was placed. Vital signs were recorded at the time of laryngeal mask insertion (T2) and 5 min after the start of surgery (T3), and whether the patients exhibited body movement was also recorded. If the child exhibited body movement during the insertion of the laryngeal mask, the insertion was stopped, then 1 mg/kg propofol and 0.1 ug/kg sufentanil were administered intravenously, and three minutes later the laryngeal mask was re-inserted, if this attempt failed, the patient would be excluded from this trial.

#### PI monitoring

PI is calculated by the pulse oximeter based on the pulse waveform at the end of the limb, representing the ratio of pulsatile blood flow to non-pulsatile blood flow at the monitoring site. After entering the room, the sensor (model: Mecun, MC-FA-1) was placed at the distal end of the index finger on the infusion side, and the monitoring area was shielded from light. Once the PI value stabilized (PI values fluctuated within  $\pm$  0.2), the median value was recorded. The PI recorded at time T1 was noted as PI<sub>1</sub> (baseline PI), The PI was recorded at time T2 was noted as PI<sub>2</sub>, and the PI recorded at time T3 was noted as PI<sub>3</sub>.

## **Definition of movement**

Movers were defined as patients who showed any visible spontaneous muscle movement, such as withdrawal or flexor movement of the arms and legs, frowning of the forehead muscles or coughing, within 1 min of LMA insertion [2].

## **Outcome variables**

The primary outcomes are the patients' PI values (PI<sub>1</sub>, PI<sub>2</sub>, PI<sub>3</sub>). The secondary outcomes include the PI ratio (PI<sub>2</sub>/PI<sub>1</sub>), the patients' baseline data (gender, age, height, weight, etc.), as well as vital signs at T1, T2, and T3. Additionally, whether the patients exhibited body movement during laryngeal mask insertion and whether any complications occurred during the procedure (such as oral bleeding, patient falling from the bed, dental injuries, laryngospasm, bronchospasm, etc.) were also recorded.

## Statistical analysis

This study utilized GPower 3.1 software for sample size estimation. In preliminary pilot trials, we observed that the mean  $PI_2$  in the movement group was approximately 3.9, while that in the non-movement group was approximately 4.7. The proportion between the movement and non-movement groups was approximately 35%. With a significance level ( $\alpha$ ) of 0.05, statistical power (1- $\beta$ ) of 0.95, and a 20% loss to follow-up was also considered, the trial required a minimum of 108 patients. Therefore, this study meets the necessary sample size requirements.

According to whether the children exhibited body movement after laryngeal mask insertion, they were divided into the Body Movement Group (BM Group) and the Non-Body Movement Group (NBM Group), and the two groups were compared. SPSS 23.0 software was used for analysis, and normally distributed quantitative data were expressed as mean± standard deviation. Independent sample t-test was used for group comparisons, and the Chi-square test or Fisher's exact probability method was used for count data comparisons. ROC curve analysis was performed to assess the diagnostic efficacy and Cutoff value of  $PI_2$  and PI ratio for predicting the timing of laryngeal mask insertion.

## Results

A total of 170 patients were included in this trial, of which 6 were excluded due to failed secondary laryngeal mask insertion. Finally, 164 patients were included, including 126 patients in the NBM group and 38 patients in the BM group (Fig. 1). The baseline data of the children are detailed in Table 1. The area under the ROC curve for using PI<sub>2</sub> to predict the timing of laryngeal mask insertion was 0.641(95% confidence interval, 0.542–0.740), P = 0.009, and the cutoff value was 4.37. When PI > 4.37 was used to predict the timing of laryngeal mask insertion, the sensitivity was 53.2%, and the specificity was 73.7%. The area under the ROC curve for using the PI ratio to predict the timing of laryngeal mask insertion was 0.751 (95% confidence interval, 0.657–0.844), P < 0.001, and the cutoff value was 2.955. When the PI ratio > 2.955 was used to predict the timing of laryngeal mask insertion, the sensitivity was 85.7%, and the specificity was 63.2% (Fig. 2; Table 2). There were statistical differences in PI<sub>1</sub>, PI<sub>2</sub>, and PI<sub>2</sub>/PI<sub>1</sub> between the two groups, while no significant statistical difference was observed in PI<sub>3</sub> (see Figs. 3 and 4).

In this trial, the BM Group had 5 patients with oral bleeding, 3 children with laryngospasm, and 1 patient with tooth loosening. In the NBM Group, 1 patient experienced tooth loosening. Besides, no other complications were observed(Table 3).

## Discussion

As a supraglottic ventilation device, the laryngeal mask airway is widely used in clinical practice due to its simple insertion and minimal damage to the airway. However, when the laryngeal mask is inserted during shallow anesthesia, it can cause children to exhibit resistance to the mask, which may result in serious complications such as oral bleeding, tooth loosening, and laryngospasm, endangering the safety of the patient during the perioperative period. Therefore, choosing the appropriate timing for the placement of the laryngeal mask is crucial. At present, the timing of laryngeal mask insertion mainly relies on clinicians manually supporting the patient's lower jaw and subjectively judging by observing whether the patient responds. Currently, there is still a lack of objective indicators. This study found that both PI and PI ratio can be used to determine the timing of laryngeal mask insertion, but the PI ratio has higher accuracy, sensitivity, and specificity compared to PI. Therefore, the PI ratio can be used to predict the timing of laryngeal mask insertion.

Perfusion index (PI) is calculated by a special pulse oximeter based on the pulse waves at the extremities. It represents the ratio of pulsatile blood flow to nonpulsatile blood flow at the monitored side, reflecting the perfusion level of local tissues. Now, this indicator is commonly used in clinical practice to predict the effect of nerve block, guide the use of vasoactive drugs, predict hypotension after induction, and assess the severity of pain, etc. Additionally, some researchers have found a correlation between PI and anesthesia depth, and studies have also shown a correlation between neurophysiological arousal function and sympathetic nervous system tension [12]. After general anesthesia, peripheral vascular tension decreases, terminal blood flow perfusion increases, and PI rises. After surgery, the patient gradually awakens, the tension of the sympathetic nervous system gradually increases, peripheral vascular resistance increases, terminal blood flow perfusion decreases, PI gradually decreases, and returns to baseline levels. Anirudh Krishnamohan et al. [9] found a correlation



Fig. 1 Patients inclusion and trial data collection flowchart

between PI and the minimum effective concentration (MAC) of alveolar gas, and the perfusion index changed significantly during different stages of anesthesia. An observational study [11] found a correlation between PI and AAI. When AAI < 25 was used as the intubation indicator, ROC curve analysis showed that the optimal PI for intubation was 1.48. In addition, Peipei Liu et al. [10] found a correlation between BIS values and PI in patients under different sedation states during anesthesia resuscitation. These studies suggest that PI can be used to predict anesthesia depth, providing a theoretical basis for PI to predict the timing of laryngeal mask insertion. Hosam M Atef et al. [13] found that PI can be used to monitor sympathetic response during laryngeal mask insertion in adult patients, which is similar to this study.

PI is an indicator of central and peripheral perfusion status, primarily determined by cardiac output and the balance between sympathetic and parasympathetic states. When the sympathetic nervous system is activated, peripheral vasoconstriction occurs, leading to a decrease in local tissue perfusion, while the impact on vital organ perfusion is relatively minor. Therefore, the variability of PI at the finger site is relatively high. In this study, it was found that there was a statistical difference in baseline PI between the two groups of patients, indicating that there was a significant difference in baseline PI between individuals. This suggests that using finger PI as an indicator to predict the timing of laryngeal mask insertion has certain limitations. In this study, the area under the ROC curve for PI in predicting the timing of laryngeal mask insertion was 0.641.

The sensitivity of PI>4.37 for predicting the timing of laryngeal mask insertion was only 53.2%, and the specificity was 73.7%. Due to the significant impact of base-line variability on diagnostic efficacy, the reliability of this indicator is poor. The PI ratio refers to the ratio of PI

	BM Group NBM group(n=126)		Р	
	( <i>n</i> = 38)		value	
Age (y)	7.31±1.24	7.00±1.22	0.175	
Gender				
Male	26	87	0.942	
Female	12	39		
Height (cm)	128.71±12.20	125.63±12.66	0.187	
Weight (kg)	$28.20 \pm 7.62$	$27.05 \pm 8.71$	0.464	
HR				
T1 (次/分)	118.37±24.73	116.06±26.75	0.635	
T2 (次/分)	$107.11 \pm 14.19$	104.75±17.60	0.451	
T3 (次/分)	$112.03 \pm 16.91$	108.02±19.31	0.251	
MAP				
T1 (mmHg)	$81.03 \pm 14.10$	$85.98 \pm 14.70$	0.068	
T2 (mmHg)	69.61±10.29	69.40±11.00	0.917	
T3 (mmHg)	$70.47 \pm 14.49$	70.46±14.68	0.966	
LMA				
2	14	41	0.797	
2.5	14	45		
3	10	40		

 Table 1
 Baseline information of the children

BM Group: Body Movement Group, NBM Group: Non-Body Movement Group, HR: Heart rate, MAP: Mean arterial pressure, LMA: laryngeal mask airway



Fig. 2 Receiver operator curve (ROC) to assess the ability of PI and PI ratio to predict the timing of laryngeal mask insertion





Fig. 3 Perfusion index (PI) at T1, T2, and T3

before laryngeal mask insertion to baseline PI. Previous studies [14] have used this indicator to predict the effectiveness of nerve block and found that the PI ratio can mitigate the impact of high baseline PI variability. Compared to PI alone, the PI ratio is better suited for predicting the effects of nerve block. Therefore, this study used the PI ratio to predict the timing of laryngeal mask insertion, with an area under the ROC curve of 0.751, indicating a higher diagnostic efficacy compared to using PI alone. The sensitivity and specificity of PI ratio>2.955 for predicting the timing of laryngeal mask insertion are 85.7% and 63.2%, respectively. It means that the PI ratio is more suitable for predicting the timing of laryngeal mask insertion; thus, when PI increases to three times the baseline level after induction, laryngeal mask insertion may be considered.

As an upper airway management tool, laryngeal mask has become increasingly widespread in perioperative care in recent years. However, the process of inserting the laryngeal mask can lead to damage to the throat, potentially causing complications that jeopardize the safety of pediatric patients during the perioperative period. Therefore, it is very important to ensure the safety of patients under general anesthesia with a laryngeal mask. In this study, 5 children in the BM Group experienced oral bleeding and 3 children experienced laryngeal spasms, primarily due to patient movement during the insertion

Table 2 The area under the ROC curve for PI and PI ratio in predicting the timing of LMA insertion

	AUC	Standard error	P value	Cut-off value	95% confidence interval	
					Lower limit	Upper limit
PI	0.641	0.051	0.009	4.370	0.542	0.740
Pl ratio	0.751	0.048	< 0.001	2.955	0.657	0.844

AUC: Area under the ROC curve, LMA: Laryngeal mask airway





Fig. 4 Perfusion index ratio (PI ratio) between the two groups

 Table 3
 Complications between the two groups

	BM Group( <i>n</i> = 126)	NBM Group	Р
		( <i>n</i> = 38)	Value
Oral bleeding n(%)	0(0%)	5(7.89%)	0.001*
Laryngospasm n(%)	0(0%)	3(5.26%)	0.012*
Tooth loosening n(%)	1 (0.78%)	1(2.63%)	0.411

process. This resulted in friction between the laryngeal mask and the oral mucosa, which lead to bleeding. Subsequently, the blood reflux stimulated the glottis, causing laryngospasm. After positive treatment, the children completed the surgery. The non-movement group demonstrated a significantly lower incidence of the aforementioned complications compared to the movement group, indicating that laryngeal mask insertion under adequate anesthesia depth reduces adverse events. By monitoring Perfusion Index (PI) changes and delaying insertion until PI reaches the critical threshold, clinicians may further minimize laryngeal mask-related complications. In addition, conventional monitoring of anesthesia depth such as BIS can be costly, comparatively and is not suitable for large-scale use in patients undergoing day surgery. However, PI values are free, non-invasive, easy to obtain, and can be monitored for their dynamic changes in real time. Thus, it is more suitable than anesthesia monitoring devices such as BIS for determining the timing of laryngeal mask insertion in patients undergoing day surgery.

There are several limitations in this study: (1) This trial is a single-center, small-sample study. Further research is needed to determine the specific values of PI and PI ratio for predicting the timing of larvngeal mask insertion. (2) The observational metric in this trial was the PI measured at the fingertip, which has a high degree of variability, and some literature reports that the PI at the earlobe is more stable. When the sympathetic nervous system is activated, to ensure the perfusion of important organs, the blood vessels at the end of the fingers contract, and the PI decreases significantly. Therefore, the variability of PI at the finger is relatively large, while the earlobe is close to the brain, and its perfusion can be relatively guaranteed, resulting in a more stable measured PI [15]. Therefore, further studies can consider using earlobe PI as an observation indicator. (3) The age range of the observed children in this experiment was mainly 6–10 years old. Further research is required to determine the specific PI values for children under 6 years old and over 10 years old. 4) The type of surgery in this study was inguinal hernia repair, and further exploration is needed for other types of surgeries. 5) The potency of propofol and sufentanil produced by different manufacturers may vary, which can lead to variations in the results.

This study shows that both PI and PI ratio can be used to predict the timing of laryngeal mask insertion. However, due to the high variability of baseline PI, the PI ratio can eliminate the impact of baseline variability, making it more suitable for predicting the timing of laryngeal mask insertion. When the PI measured at the fingertip increases to three times the baseline PI after induction, laryngeal mask insertion can be considered.

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#### Author contributions

Weiwei Cai is the first author. He designed this trial, collected data, performed statistical analysis, and wrote the manuscript. Yuting Song and Fei Sun were responsible for data collection. Huiying Shao and Huanhuan Ni are corresponding authors.

#### Funding

Not applicable.

#### Data availability

The trial data can be obtained directly by contacting the corresponding author.

#### Declarations

#### Ethics approval and consent to participate

The experimental protocol was established according to the ethical guidelines of the Helsinki Declaration and was approved by the Ethics Committee of the Children's Hospital of Nanjing Medical University (approval number:

202402006-1). Written informed consents were obtained from the guardians of the participants.

#### **Consent for publication**

Not applicable.

## **Competing interests**

The authors declare no competing interests.

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