Clinical Investigation

Perfusion index versus non-invasive hemodynamic parameters during insertion of i-gel, classic laryngeal mask airway and endotracheal tube

Address for correspondence:
Dr. Hosam M Atef,
Department of Anesthesiology,
Faculty of Medicine,
Suez Canal University,
Ismailia, Egypt.
E-mail: hosamatef375@yahoo.com

Hosam M Atef, Salah Abd Fattah, Mohammed Emad Abd Gaffer, Ahamed Abd Al Rahman

Department of Anesthesia, Faculty of Medicine, Suez Canal University, Ismailia, Egypt

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ABSTRACT

Background: Perfusion index (PI) is a non-invasive numerical value of peripheral perfusion obtained from a pulse oximeter. In this study, we evaluated the efficacy of PI for detecting haemodynamic stress responses to insertion of i-gel, laryngeal mask airway (LMA) and endotracheal tube and compare, its reliability with the conventional haemodynamic criteria in adults during general anaesthesia. **Methods:** Sixty patients scheduled for elective general surgery under general anaesthesia were randomised to three groups. (i-gel, LMA and ET groups (n=20/group). Heart rate (HR) (positive if ≥10 bpm), systolic blood pressure (SBP), diastolic blood pressure (DBP) (positive if ≥15 mm Hg) and PI (positive if ≤10%) were monitored for 5 min after insertion. Main outcome measures: SBP, DBP, HR and PI were measured before induction of anaesthesia and before and after insertion of the airway device. **Results:** Insertion of airway devices produced significant increases in HR, SBP and DBP in LMA and ET groups. Moreover, PI was decreased significantly by 40%, 100% and 100% in the three groups. Using the PI criterion, the sensitivity was 100% (CI 82.4-100.0%). Regarding the SBP and DBP criterions, the sensitivity was 44.4% (CI 24.6-66.3%), 55.6% (CI 33.7-75.4%) respectively. Also, significant change in the mean PI over time (from pre-insertion value to the 1st min, 3rd min, until the 4th min after insertion without regard the device type), (P<0.001). **Conclusion:** PI is a reliable and easier alternative to conventional haemodynamic criteria for detection of stress response to insertion of i-gel, LMA and ET during propofol fentanyl isoflurane anaesthesia in adult patients.

Key words: Airway management, classic laryngeal mask airway, endotracheal tube, equipment design, i-gel, intubation, laryngeal masks, perfusion index, stress response

INTRODUCTION

Perfusion index (PI) is an assessment of the pulsatile strength at a specific site such as the fingers or toes.[1] It is calculated by expressing the pulsatile signal (during arterial inflow) as a percentage of the non-pulsatile signal, both of which are derived from the amount of infrared (940 nm) light absorbed.[2] It is a valuable objective during anaesthetic practice to find out non-invasive methods for predicting the haemodynamic responses to anaesthetic drugs, techniques and to intraoperative stimuli. A practically applicable method of evaluating sympathetic tone or responsiveness would be of clinical utility.[3] Direct laryngoscopy and endotracheal intubation induces clinically relevant changes in haemodynamic variables.[4-6] In addition, studies showing the effect of i-gel, laryngeal mask airway (LMA) and endotracheal tube (ET) insertion on PI versus conventional haemodynamic stress responses are lacking. Also, based on internet research; one study correlate between PI and conventional haemodynamic parameters (heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP)) during insertion of different

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airway devices.[7] The aim of this study was to investigate whether changes in PI correlate with non-invasive haemodynamic criteria (HR, SBP, DBP) following i-gel, LMA and ET insertion and to compare its reliability.

METHODS

After local research committee approval and informed patient consent, 60 patients scheduled for elective body surface surgery under general anaesthesia in supine position in our University Hospitals were included in the study. This study is a prospective, randomised, controlled comparative trial. Patients included were ASA Class I or II, Age 21-60 years, BMI less than 30 kg/m^2. Patients with pre-existing cardiovascular, pulmonary or metabolic diseases or anticipated difficult intubation were excluded. Power analysis was based on the detectable difference between the means of HR amongst the LMA and ET=13 beat/min.[8] With Standard deviation 10; considering alpha (zα) error (*P*=0.05; therefore, 95% confidence desired (two-tailed test); zα =1.96) and beta (z) error (20% beta error, therefore, 80% power desired (one-tailed test); zβ =0.84).[9] Therefore, the calculated sample was 18 patients/group. By adding 10% of that number to compensate for the dropouts, the final number/groups was about 20 patients/group. Therefore, the total sample size number was 60 patients; randomly allocated to the study groups: ET, LMA and i-gel group (20 patients in each group) using an online research randomiser (http://www.randomizer.org) into three groups (20 patients each). The patient's age, gender, ASA status, duration and type of surgery were recorded.

Midazolam 2 mg, Metoclopramide 10 mg was given by intravenous route, 3 min before induction of anaesthesia, The whole technique and anaesthetic procedures were performed by the same researcher anaesthesiologist (Atef HM).

Electrocardiographic HR and non-invasive oscillometric arterial blood pressure (NIBP) were measured using an S/5 anaesthesia monitor (Datex-Ohmeda, Finland). The PI was monitored using a Masimo Radical SET (Masimo Corporation, Irvine, CA). For Masimo Radical SET, the PI upper and lower limits reported by the manufacturer were 0.02-20.00%. The oximeter probe used to monitor the PI was attached to the middle fingertip of the hand contralateral to the site of BP monitoring and was wrapped in a towel to minimise heat loss and contamination by ambient light. Baseline readings of the oxygen saturation (SpO_2), arterial blood pressure (ABP), HR were recorded. Pre-oxygenation with 100% oxygen for at least 3 min was carried out. Anaesthesia was induced with intravenous fentanyl 1 μg/kg and propofol 2.5 mg/kg. Rocuronium 0.6 mg/kg was administered for mechanical ventilation via the i-gel, LMA and ET. Tracheal intubation or insertion of an airway device was attempted after complete suppression of the TOF as guided by the neuromuscular monitor. In the ET group, intubation of the trachea was attempted with a cuffed tracheal tube (internal diameter 7.5 mm for women and 8.5 mm for men) using direct laryngoscopy. The LMA (Henley-on-Thames, UK) or i-gel (Intersurgical Ltd, Wokingham, Berkshire, UK) was inserted according the manufacturers' instructions.[10,11] In the LMA group, the size of LMA was determined by the attending anaesthetist based on the patient's body weight and the manufacturer's recommendation. In the case of i-gel, Gastric tube was inserted through the gastric channel (Size 12 gastric tube for i-gel size #5, gastric tube size 10 for i-gel size #4 and gastric tube size 8 for i-gel #3). If it is not possible to ventilate the lungs, the following airway manoeuver was performed: Chin lift, jaw thrust, head extension, or flexion on the neck. The position was also allowed to be adjusted by gently pushing or pulling the device. After any manoeuver, the adequacy of ventilation was re-assessed. In such cases, the patients were excluded. Patients' lungs were mechanically ventilated and minute volume was set to maintain end-tidal CO2 at 30-35 mm Hg. Fluid administration was standardised to 10 mL/kg/h of Ringer's lactate solution, and the ambient temperature was maintained at 25°C-26°C. Throughout the procedure, Isoflurane maintained adequate level of anaesthesia at 1-1.5 of the minimal alveolar concentration, air/oxygen mixture in 50%:50% volume ratios or 100% oxygen. HR, NIBP and PI were measured before induction of anaesthesia and before and after insertion of the airway device every minute for 5 min before starting the surgery. Positive HR, SBP, DBP and PI responses to device insertion were prospectively defined from previous reports as a HR increase of ≥10 bpm, a SBP and DBP increase of ≥15 mm Hg, and a PI decrease ≥10% after the insertion of the devices.[12] Sensitivity, specificity, positive predictive values and negative predictive value were determined for SBP, DBP and PI variables based on HR as the gold standard.

Primary objective

To evaluate the PI as a non-invasive monitor of haemodynamic responses in comparison to HR and blood pressure following insertion of ET, LMA and i-gel.

Secondary objective

To compare the haemodynamic responses to i-gel and LMA insertion with endotracheal intubation using PI.

Statistical analysis

Analysis was performed using the program SPSS version 15 (SPSS Inc, Chicago, IL) for windows. The 95% confidence interval (CI) for sensitivity, specificity and predictive values were calculated with the Wilson score method as described by Newcombe.[13] Numerical data were presented as mean±SD, and categorical data as proportions (%). Statistical significance will be determined at 95% level of confidence (i.e., differences will be considered statistically significant if $P<0.05$). One-way ANOVA was used for comparison of mean differences in demographic data, and baseline values of haemodynamic parameters and PI between groups. For comparison of changes in the criteria over time in different groups, data were analysed by Mixed-design ANOVA. Bonferroni *Post-hoc* test for multiple comparisons was then calculated for significant differences in ANOVA. For analysis of categorical variables, the Chi-square test (χ^2) was used, while Exact test was used when any expected frequency was <1 or 20% of expected frequencies are ≤5).

RESULTS

There were no significant differences between groups with respect to age, weight, height and gender distribution [Table 1].

Table 1: Patient characteristics

Characteristic	Tube group (*n*=20)	LMA group (*n*=20)	i-gel group (*n*=20)
Age (years)			
Mean±SD	31.6±8.6	29.9±11.8	33.7±10.5
Range	23-51	24-51	22-55
Sex			
Male (%)	11 (55)	10 (50)	12 (60)
Female (%)	9 (45)	10 (50)	8 (40)
Height (cm)			
Mean±SD	175.7±13.9	179.7±16.8	172.4±12.6
Weight (kg)			
Mean±SD	71.6±8.8	73.1±10.5	72.4±9.6
BMI (kg/m^2)			
Mean±SD	23.13±2.15	22.91±4.03	24.65±3.14
Range	(21-25)	(20-25)	(22-27)

LMA – Laryngeal mask airway; BMI – Body mass index

Table 2: Comparison of pre-insertion haemodynamic parameters (*n*=20 per group)

Parameter	Mean±SD	*F* (df)	*P* value
Heart rate (bpm)			
i-gel	85.60±14.39	1.73 (2,57)	0.187
LMA	81.20±12.05		
Tube	88.40±10.29		
Systolic blood pressure (mmHg)			
i-gel	127.20±8.99	1.76 (2,57)	0.181
LMA	129.20±12.22		
Tube	133.30±9.98		
Diastolic blood pressure (mmHg)			
i-gel	75.40±10.06	2.58 (2,57)	0.084
LMA	78.40±9.04		
Tube	81.90±7.94		
Perfusion index			
i-gel	1.94±0.44	5.37 (2,57)	0.007*[a]
LMA	2.13±0.34		
Tube	2.41±0.56		

*Statistically significant at $P<0.05$ and 95% confidence level; [a]Bonferroni *post-hoc* test for multiple comparisons was applied; LMA – Laryngeal mask airway

Pre-insertion evaluation of haemodynamic parameters showed that there was no statistically significant difference between the three groups regarding the HR, SBP, DBP (P=0.187, 0.181, 0.084 respectively), however, there was a statistically significant difference between them regarding the PI; P=0.007 [Table 2]. Bonferroni *post-hoc* test for multiple comparisons showed that, the only significant difference in the mean PI was between the i-gel group and the tube group (P=0.006) with no significant differences between any other groups.

Based on the haemodynamic criteria (HR, SBP and DBP), the Tube device showed the greatest percentage of positive stress responses, followed by the LMA device; $P<0.05$. However, all patients with the Tube and LMA devices showed positive stress responses compared to 40.0% of those in i-gel device regarding the PI criterion; $P<0.001$ [Table 3].

Insertion of airway devices produced significant increases in HR, SBP and DBP in (LMA and ET) groups. HR criterion were 0%, 30% and 60% in i-gel, LMA and ET, respectively, after insertion of the airway devices. SBP criterion were 0%, 30% and 40% in the studied group respectively. In addition, DBP criterion were 0%, 10% and 40%.

Moreover, PI were decreased significantly by 40%,

100% and 100% in the three groups (i-gel, LMA and ET) respectively.

Using the PI criterion, the sensitivity and specificity were 100% (CI 82.4-100.0%) and 28.6% (CI 17.2-43.6%) [Table 4]. The positive and negative predictive values were 37.5% (CI 25.0-30.2%) and 100% (CI 83.6-100%). Regarding the SBP and DBP criterions, the sensitivity and specificity were 44.4% (CI 24.6-66.3%), 55.6% (CI 33.7- 75.4%) and 85.7% (CI 72.2-93.3%), 100% (CI 91.6-100%) respectively. The positive and negative predictive values were 57.1% (CI 44.4-69.6%), 100% (CI 95.3-100%) and 78.3% (CI 67.9-88.7%), 84% (CI 74.6-93.1%) respectively.

Table 3: Comparison of positive haemodynamic stress response heart rate, systolic blood pressure, diastolic blood pressure, perfusion index between three studied groups. (*n*=20 per group)

Criterion	i-gel (%)	LMA (%)	Tube (%)	*P* value
HR criterion (increase ≥10 bpm)	0 (0.0)	6 (30.0)	12 (60.0)	<0.001*[a]
SBP criterion (increase ≥15 mmHg)	0 (0.0)	6 (30.0)	8 (40.0)	0.005*[b]
DBP criterion (increase ≥15 mmHg)	0 (0.0)	2 (10.0)	8 (40.0)	0.002*[b]
PI criterion (decrease ≥10%)	8 (40.0)	20 (100.0)	20 (100.0)	<0.001*[b]

*Statistically significant at *P*<0.05 and 95% confidence level; [a]Chi-square test; [b]Exact test (when any expected frequency is <1 or 20% of expected frequencies are ≤5) HR – Heart rate; SBP – Systolic blood pressure; DBP – Diastolic blood pressure; PI – Perfusion index; LMA – Laryngeal mask airway

Table 4: Sensitivity, specificity, positive and negative predictive values based on haemodynamic criteria for stress response (*n*=60)

Criterion	Value (%)	95% confidence interval
SBP criterion (increase ≥15 mmHg)		
Sensitivity	44.4	24.6-66.3
Specificity	85.7	72.2-93.3
Positive predictive value	57.1	44.4-69.6
Negative predictive value	78.3	67.9-88.7
DBP criterion (increase ≥15 mmHg)		
Sensitivity	55.6	33.7-75.4
Specificity	100.0	91.6-100.0
Positive predictive value	100.0	95.3-100.0
Negative predictive value	84.0	74.6-93.1
PI criterion (decrease ≥10%)		
Sensitivity	100.0	82.4-100.0
Specificity	28.6	17.2-43.6
Positive predictive value	37.5	25.0-30.2
Negative predictive value	100.0	83.6-100.0

SBP – Systolic blood pressure; DBP – Diastolic blood pressure; PI – Perfusion index

A 2 × 3 mixed design ANOVA was calculated to examine the effects of device type (i-gel, LMA, and Tube) and time (pre-insertion, 1st min, 3rd min, and 5th min postinsertion) on the PI [Table 5 and Figure 1]. A significant (time ξ device type) interaction was present ($F(6,171)=15.60$, $P<0.001$). In addition, the main effect for time was significant ($F(3,171)=66.04$, $P<0.001$). The main effect for device type was not significant ($F(2,57)=0.29$, $P=0.77$). Bonferroni *post-hoc* test for multiple comparisons showed that there are significant changes in the mean PI over time (from pre-insertion value to the 1st min, 3rd min, till the 4th min postinsertion without regard the device type), ($P<0.001$).

DISCUSSION

PI is the numerical value of the amplitude of the plethysmo graphic pulse wave that is displayed on many pulse oximeters. The pulsating signal is indexed against the non-pulsating signal and expressed as ratio, it is commonly referred to as the "PI" = AC × 100/DC%. In general terms, PI reflects the peripheral vasomotor tone.[12] Low PI suggests peripheral vasoconstriction (or severe hypovolaemia) and high PI suggests vasodilation. PI is sensitive to several things such as temperature of the finger, exogenous vasoactive drugs, sympathetic nervous system tone (pain, anxiety, and so on) and stroke volume.[14]

Although there are several confounders influencing peripheral perfusion, determination of a decrease in PI ≤10% as a threshold for stress response seems to be reasonable.[14,15-18]

Several studies investigated the effects of low peripheral perfusion caused by hypothermia, vasoconstriction or sympathetic nerve activity.[19-23]

Table 5: Perfusion index time trend in the three studied groups

Time of measurement	Mean in each group (Mean±SD)			Overall mean (Mean±SD)	Mean difference* (95% CI)	*P* value[a]
	i-gel	LMA	Tube			
Pre-insertion	1.94±0.44	2.13±0.34	2.41±0.56	2.16±0.49		
1st minute	1.90±0.32	1.57±0.36	1.47±0.76	1.65±0.54	−0.51 (−0.35,−0.68)	<0.001
3rd minute	2.07±0.28	1.90±0.21	1.84±0.59	1.94±0.40	0.29 (0.38, 0.20)	<0.001
5th minute	2.18±0.35	2.14±0.26	2.04±0.56	2.12±0.41	0.18 (0.14, 0.23)	<0.001

Based on estimated marginal means: *The mean difference from its preceding measurement is significant at *P*<0.05; [a]Adjustment for multiple comparisons: Bonferroni test; LMA – Laryngeal mask airway; CI – Confidence interval

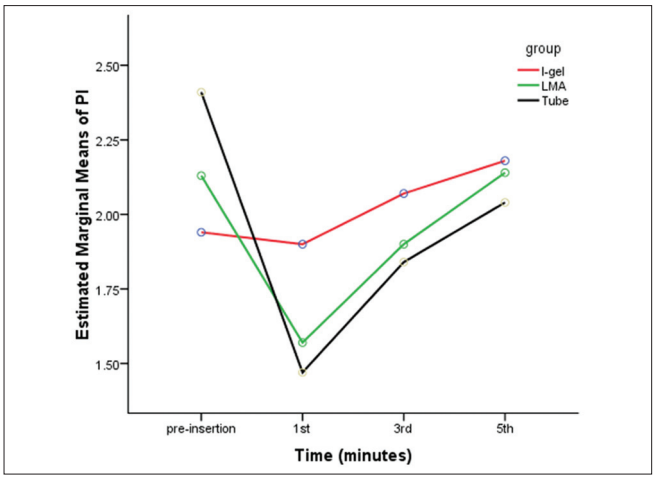

Figure 1: Changes in the mean perfusion index in the endotracheal tube, laryngeal mask airway and i-gel groups

Therefore, variation in PI is associated with potentially numerous causes, especially a small variation of 10% as observed in this study. In this context, Landsverk and colleagues investigated variations in plethysmographic waveform amplitude in deeply sedated and mechanically ventilated patients. They observed slow and large spontaneous oscillations in skin microcirculation per laser doppler flowmetry related to the sympathetic nervous system and presumed that this mechanism determined the large variability of pulse oximetry photoplethysmographic waveform signal.[24]

The main finding in the present study was that percent PI response criterion achieved 100% sensitivity in detecting the stress response to insertion of ET, LMA and i-gel during propofol fentanyl isoflurane anaesthesia in adult patients. On the other hand, SBP and DBP achieved sensitivity (44.4%, 55.6%) in detecting haemodynamic stress responses in this population.

PI, HR, SBP and DBP values in the i-gel group were significantly lower than that of ET and LMA recorded for 5 min after the airway instrumentation. Moreover, LMA evoked less PI reduction compared to endotracheal intubation.

In the i-gel group; HR, SBP, DBP showed no significant response while PI detected 40% change earlier time when compared to the conventional haemodynamic parameters. Although the PI did better in detecting stress response than did changes in HR and blood pressure, the study was not large enough to show a notable difference. The study was powered to examine the change in HR postinsertion of the airway device, not to demonstrate a statistical difference from PI monitoring. It would be important to know if the PI is truly better than HR and blood pressure for indicating haemodynamic stress response before it could be considered a standard of care. Although many investigators have documented a relationship between detrimental circulatory responses with direct laryngoscopy and intubation, there are no reports of changes in the PI during these procedures.[7,25-27]

Intraocular pressure and haemodynamic responses to insertion of the i-gel, LMA or ET were investigated.[7] The main finding was that insertion of the i-gel did not increase IOP, whereas insertion of the LMA or tracheal intubation did. Another finding was that the pressor responses to insertion of the i-gel were significantly less than LMA or tracheal intubation.

The efficacy of PI as an indicator for intravascular injection of epinephrine-containing epidural test dose in propofol-anaesthetised adults was investigated by Hany A. Mowafi *et al*. PI has been used to reflect an evident response with 100% sensitivity and specificity to epinephrine-containing epidural test dose. HR criterion was 95% reliable in detecting the intravascular injection of a simulated test dose containing epinephrine during TIVA. The sensitivity of SBP criterion was 90% in detection of IV epinephrine.[12]

The efficacy of haemodynamic and T-wave criteria for detecting intravascular injection of epinephrine test dose in propofol-anaesthetised adults was investigated by Takahashi S *et al*.[28] The minimal effective dose of epinephrine associated with 100% sensitivity and specificity was 10 μg based on the SBP criterion, and was 5 μg based on the HR and T-wave criteria.

The sensitivity of PI, SBP and DBP criterions in the present study were 100%, 44.4%, 55.6% respectively in the detection of stress postinsertion. This finding is in contrast to the previous studies that showed 100% sensitivity of PI.[15,28] HR sensitivity criteria were (85% up to 95%) in mowafi and Takahashi studies. However, these studies measured BP invasively via arterial catheters, a practice that was not justified in our patients. The use of intermittent and non-invasive measurement of BP may have decreased its reliability to detect haemodynamic changes, because the temporary SBP increases may be easily missed between cycles.[25] Failure to demonstrate high efficacy of the SBP and DBP criteria as markers for

confirming stress response during propofol fentanyl isoflurane anaesthesia represents a limitation of these conventional haemodynamic responses.[12,16]

Moreover, Galvin and colleagues found that PI increased with successful sympatholysis of peripheral and neuroaxial block.[29] Another main finding in our study was that the pressor responses (HR, SBP and DBP) to i-gel insertion were found to be significantly less than that with LMA and ETT airway instrumentation.

Based on the literature, we anticipated that the insertion of a LMA and i-gel would elicit a much smaller haemodynamic and catecholamine response than tracheal intubation.[30,31]

Lack of laryngoscopy during insertion of LMA or i-gel is a major reason.[32-34]

PI can provide information about the relative balance between nociception and antinociception. It is quite likely that, in the next decade, the pulse oximeter will evolve into a multiparameter monitor with several PI-derived indices being displayed.

There were some limitations in our study, as collection of data wasn't blinded for all devices, however, data were collected later on from the memory of the monitor. All of the studied patients were ASA I or II and the study didn't include any patients with difficult airway or hypertension, so results might not be applicable to patients with ASA grade more than II, difficult airway and hypertension. We didn't use invasive monitoring parameters as invasive blood pressure might prone the patient to risk without benefit.

CONCLUSION

PI is a reliable and easier alternative to conventional haemodynamic criteria for detection of stress response to insertion of i-gel, LMA and ET during propofol fentanyl isoflurane anaesthesia in adult patients.

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