The accuracy of the Innovo Deluxe Fingertip Pulse Oximeter perfusion index in predicting hypotension during balanced general anesthesia induction – a prospective observational study*

Brian Rainier T. Herradura, MD; Beverly Anne P. Portugal, MD and Olivia C. Flores, MD, MEM

Abstract

Introduction Balanced general anesthesia technique is a popular choice for induction because it can minimize potential side effects from individual drugs when otherwise used alone. However, hypotension is still a common occurrence during induction. Perfusion Index (PI) has been used as a measure of systemic vascular resistance and has shown to predict hypotension after regional anesthesia and propofol induction. This study aimed to determine whether baseline PI can predict hypotension following balanced general anesthesia induction and determine a cut-off value where hypotension is expected to occur.

Methods Thirty-five ASA I/II adults for elective surgery under general anesthesia were enrolled. Heart rate, blood pressure and PI were measured every minute from baseline to 5 minutes following induction and 10 minutes after endotracheal intubation. Hypotension was defined as fall in systolic BP (SBP) by >30% of baseline and/or mean arterial pressure (MAP) to <60 mmHg. Severe hypotension (MAP of <55 mm Hg) was treated.

Results No hypotension was observed in the first 5 minutes. Within 10 minutes, hypotension occurred in 8.6% by SBP criterion and 2.6% by MAP criterion. Within 15 minutes, hypotension was seen in 5.7% by SBP and MAP criterion, respectively. PI showed very low ($r < 0.2$) to low ($r = 0.2$ to 0.39), negative to positive and insignificant correlation ($p > 0.05$) with hypotension whether using SBP or MAP criterion and whether observed at 10 or 15 minutes of anesthesia induction. The Area under the ROC curve is 0.397, 95% CI [0 .126, 0.667], $p = 0.431$.

Conclusion This study lends inconclusive evidence on the usefulness of Innovo Deluxe Fingertip Pulse Oximeter with Plethysmograph and Perfusion Index to predict intraoperative hypotension following balanced general anesthesia induction for this sample of patients. However, there was a positive, moderate ($r=0.538$, 0.501 and 0.469) and significant ($p<0.05$) correlation between perfusion index and SBP, Diastolic BP and MAP, respectively.

Key words: Perfusion index, blood pressure, arterial blood pressure, general anesthesia, hypotension, pulse oximetry

Correspondence:
Beverly Anne P. Portugal, MD, Department of Anesthesiology and Pain Medicine, University of the East Ramon Magsaysay Memorial Medical Center, Inc., 64 Aurora Boulevard, Barangay Doña Imelda, Quezon City, PH 1113; e-mail: bevpantanilla@yahoo.com

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Department of Anesthesiology and Pain Medicine, University of the East Ramon Magsaysay Memorial Medical Center, Inc.

Many surgical patients cannot tolerate perioperative hypotension because of co-morbid conditions. Hypotension during balanced anesthesia induction is frequently encountered. A tool that can predict the occurrence of hypotension during induction of general anesthesia will be beneficial in identifying this subset of patients. Measures can then be instituted to avoid hypotension during induction of anesthesia.

The pulse oximeter perfusion index (PI) has been used as an indicator of systemic vascular resistance (SVR). It is measured as a ratio of the pulsatile blood flow to the non-pulsatile or static blood in peripheral tissue. Studies using PI in measuring SVR and predicting hypotension in both regional and general anesthesia are few. In general, perfusion index decreases because of local vasoconstriction and increases with vasodilation in the monitoring site.[1] Therefore, PI can be used as a continuous, indirect, non-invasive measure of peripheral perfusion. Studies have shown that PI is useful in monitoring effectiveness of regional anesthesia, depth of general anesthesia, successful epidural placement and hemodynamic status of critically-ill patients.[2-9]

A study by Mehandale and Rajasekhar concluded that PI could predict hypotension following propofol induction.[10] All previous studies used expensive pulse oximeters to measure PI. However, newer portable and affordable pulse oximeters already have this feature built in. No study correlating the measurements of the newer affordable pulse oximeters with hypotension in the perioperative setting have been encountered. This study is geared toward supplementing studies done is the past to strengthen the use of perfusion index as a useful intraoperative and perioperative monitoring equipment especially in addressing hypotension during anesthesia induction using an inexpensive pulse oximeter with built-in ability to measure PI. The authors hypothesize that baseline pulse oximeter PI taken from portable pulse oximeters can predict hypotension following balanced general anesthesia induction and a cut-off value can be determined beyond which the incidence of hypotension is more frequent.

Methods

A prospective observational study was performed in a tertiary care hospital after approval from the institutional ethics committee (RIHS ERC Code: 0632/E/H/18/143). Adults aged between 18 and 65 years belonging to the American Society of Anesthesiologists' Physical Status 1 and 2 for elective surgery under general anesthesia who agreed and gave their written informed consent were included. Patients who were pregnant, hypertensive, taking vasoactive medications, assessed to have a difficult airway, or had body mass index (BMI) > 35 kg/m^2 were excluded from the study. No premedications were given to the patients. Upon reception in the operating room, electrocardiograph, non-invasive blood pressure (BP), pulse oximeter (Innovo Deluxe Fingertip Pulse Oximeter with Plethysmograph and Perfusion Index, Innovo Medical, Stafford, TX) were connected, and baseline values of heart rate (HR), PI, systolic blood pressure (SBP), diastolic blood pressure (DBP) and mean arterial pressure (MAP) were recorded. Pre-oxygenation with 100% FiO_2 was done. Intravenous midazolam 1-2 mg and fentanyl 1 ug/kg were administered followed by titrated doses of propofol until loss of response to verbal communication was achieved. Sevoflurane was then started at 1 MAC and a neuromuscular blocker of choice (atracurium 0.5 mg/kg or cisatracurium 0.15 mg/kg or rocuronium 0.6 mg/kg) was administered. The parameters were recorded every minute for 15 minutes. The trachea was intubated by a resident or consultant anesthesiologist 5 minutes after giving the neuromuscular blocker. Maintenance of anesthesia was maintained with sevoflurane. Hypotension was defined as a drop in SBP to < 30% of baseline or absolute MAP < 60 mm Hg. MAP < 55 mm Hg (severe hypotension) was treated immediately by rapid intravenous fluid administration (10 mL/kg) and ephedrine 5 mg IV boluses. Bradycardia was defined as HR < 50 bpm or decrease by more than 30% below the baseline value, whichever was lower, and was treated with atropine 0.5 mg IV boluses. The incidence of hypotension was computed at 5-minute intervals as to differentiate between the effects of anesthesia induction, endotracheal intubation and maintenance of anesthesia. A cut-off value of baseline PI below which hypotension post-induction could be predicted was the primary outcome, while positive and negative predictive values of the relationship between PI and other parameters (HR, SBP, DBP, MAP) were secondary outcomes.

The sample size was calculated to observe effect size of at least 0.503 based on a study by Mehandale for correlation of PI and change in the SBP after propofol induction.[10] For an alpha error of 5% and 80% power, the sample size required was found to be

29. Factoring in an attrition rate of 20%, the sample size was 35 participants. Sample size was computed using UCSF Clinical and Translational Science Institute online sample size calculator. Data were collected and computed using Microsoft Excel Home and Student 2016 (Microsoft Corporation, Redmond, Washington, 2016) and analyzed using SPSS version 21. Continuous variables were expressed as mean ± standard deviation (SD). Point biserial correlation was used to determine the correlation between baseline PI and incidence of hypotension using SBP and MAP criteria. Spearman rank order correlation was utilized to determine the correlation between PI and the other hemodynamic variables (HR, SBP, DBP, MAP). Correlation was classified as very weak ($r < 0.20$), weak ($r = 0.20$ to 0.39), moderate ($r = 0.40$ to 0.59), strong ($r = 0.60$ to 0.79), or very strong ($r > 0.80$). A p-value < 0.05 was used as cut-off value for significance. A receiver operating characteristic (ROC) curve was constructed to determine the utility of baseline perfusion index to predict hypotension during general anesthesia induction.

Results

Thirty-five patients with a mean age of 36 years, mean BMI in the ideal body weight range were included in the study; there were more women and more patients were classified as ASA 1, as shown in Table 1. As seen in Table 2, there was a decrease in the average measurements of the HR, SBP, DBP and MAP on the 5th and 10th minutes. The HR was noted to return to baseline levels while the blood pressure parameters increased slightly on the 15th minute. The PI was noted to increase from baseline to the 15th minute.

There was a negative weak correlation of PI with heart rate at all time points. There was a positive moderate to strong correlation of PI with SBP, DBP and MAP at all time points and all were significant, as shown in Table 3. The correlation coefficient was observed to be highest (r = 0.68, 0.62 and 0.62)

Table 1. Baseline characteristics of 35 participants.

Parameter	
Age (yr) (mean ± SD)	36.2 ± 12.80
BMI (kg/m^2) (mean ± SD)	24.0 ± 3.46
Sex – n (%)	
Male	15 (43)
Female	20 (57)
ASA classification – n (%)	
ASA 1	30 (86)
ASA 2	5 (16)

ASA – American Society of Anesthesiologists; SD – Standard deviation

Table 2. Hemodynamic measurements at baseline, 5, 10, and 15-minute intervals.

Parameter (Mean ± SD)	Baseline	5 min	10 min	15 min
Heart rate	80.5 ± 15.8	76.4 ±14.0	74.8 ± 14.5	81.7 ± 14.3
Systolic blood pressure	131.6 ± 18.9	120.4 ± 18.0	110.1 ± 18.1	122.3 ± 21.0
Diastolic blood pressure	80.9 ± 12.8	72.4 ± 12.0	55.4 ± 11.2	74.4 ± 15.9
Mean arterial pressure	98.3 ± 13.7	88.3 ± 13.9	81.9 ± 16.0	93.1 ± 17.8
Perfusion index	4.9 ± 3.7	5.4 ± 4.5	5.4 ± 5.2	7.8 ± 4.5

Table 3. Correlation between perfusion index and hemodynamic variables at 5, 10, 15 minutes and overall.

Time	HR*	SBP*	DBP*	MAP*
5 min	-0.14 (0.405)	0.48 (0.004)	0.47 (0.005)	0.41 (0.014)
10 min	-0.01 (0.963)	0.68 (0.000)	0.62 (0.000)	0.62 (0.000)
15 min	-0.02 (0.922)	0.56 (0.000)	0.48 (0.004)	0.54 (0.001)
Overall	-0.18 (0.309)	0.54 (0.001)	0.50 (0.002)	0.47 (0.005)

*Spearman rank order correlation: r (p-value)
HR – heart rate; SBP – systolic blood pressure; DBP – diastolic blood pressure; MAP – mean arterial pressure

between PI and SBP, DBP and MAP, respectively, at 10 minutes post-induction. Overall, there was a positive, moderate (r = 0.54, 0.50 and 0.47) and significant (p = 0.001, 0.002, 0.005) correlation between PI and SBP, DBP and MAP, respectively (Table 3).

Hypotension was not observed within the first 5 minutes post-induction. By the 10th minute, hypotension occurred in four patients (three by SBP criterion and one by MAP criterion). By the 15th minute, hypotension was seen in two patients, by SBP and MAP criteria, respectively. Perfusion index showed very weak to weak, negative to positive and insignificant correlation (p = 0.124 to 0.453) with hypotension whether using SBP or MAP criterion and whether observed at 10 or 15 minutes of anesthesia induction as seen in Table 4.

The area under the ROC curve (AUC) was 0.397 (95% CI (0 .126, 0.667, p = 0.431). Having an area close to 0.5 and a curve that follows an almost diagonal path from the lower left-hand corner to the upper right-hand corner, indicates inconclusive evidence on the usefulness of perfusion index to predict intraoperative hypotension for this sample of patients (Figure 1).

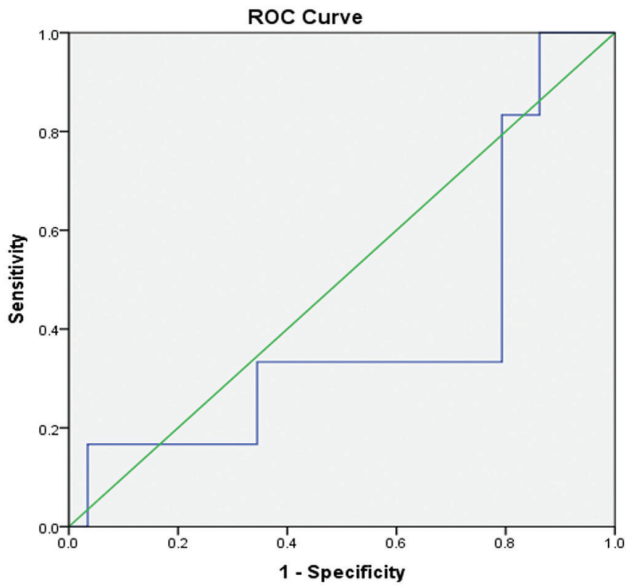

Figure 1. Receiver operating characteristic (ROC) curve of perfusion index predicting hypotension

Discussion

The study by Mehandale and Rajasekhar concluded that baseline PI could predict hypotension after propofol induction and that a baseline PI < 1.05 was associated with a higher incidence of hypotension.[10] This study was designed to try to replicate their results using a different and more affordable device to measure PI. The investigators did not intend to affirm nor invalidate their work. Cardiac monitors or dedicated high-end pulse oximeters with the ability to measure PI are expensive to acquire. Given that the types of surgical procedures done in large, state of the art hospitals are similar to those done in smaller yet sufficiently equipped medical facilities, the applicability of Mehandale and Rajasekhar's study could have been expanded further if the results held true using an affordable finger clipped pulse oximeter with the ability to measure PI.

The decision to conduct the study on ASA 1 and 2 patients as subjects was reached in order to eliminate confounding physiologic states that could possibly be present in the critically-ill, pregnant, pediatric, use of vasoactive medications and extreme elderly. The applicability of the study to these subsets of patients can be attained if this method of measuring hemodynamics is already well-understood. The decision to induce with titrated doses of propofol until loss of response to verbal stimulus was reached in order to make a uniform objective end point and remove possible confounders when giving fixed doses.

Table 4. Correlation between baseline perfusion index and hypotension.

Perfusion Index	Hypotension			
	Using SBP criteria		Using MAP criteria	
	10 minutes	15 minutes	10 minutes	15 minutes
Correlation coefficient (r)	0.265	-0.197	-0.131	0.229
p-value*	0.124	0.256	0.453	0.186

*Point bi-serial correlation

This study lends inconclusive evidence on the usefulness of the Innovo Deluxe Fingertip Pulse Oximeter with Plethysmograph and Perfusion Index to predict intraoperative hypotension following balanced general anesthesia induction for this sample of patients. Since PI is a measure of perfusion and the strength of pulsatile activity in the measured area, it could generally be concluded that vasodilation will increase PI and vasoconstriction will do the opposite. Due to the vasodilatory effects of general anesthesia, there was the expected downward trend of hemodynamic variables in the first 5-7 minutes. This was accompanied by slowly increasing PI which could be attributed to the vasodilation brought about by general anesthetics. The return to baseline or near baseline of hemodynamic values at the 15th minute and accompanied by the gradual increasing trend of PI can be explained by the down titration of inhalational anesthetic and decreasing effect of propofol while maintaining their vasodilatory effects. The predicted sympathetic surge during endotracheal intubation which could result in increase in systemic vascular resistance and a subsequent decrease in PI was not observed in this study. Tachycardia and transient elevation of blood pressure were seen during endotracheal intubation but the acute changes in PI were not seen. This may be explained by the possible inability of the Innovo Pulse Oximeter to detect abrupt changes in PI. The decrease in PI with increasing SVR was already observed in a study where a decrease in PI by 10% from baseline was used as a criterion for a positive intravascular epidural test dose (lidocaine + epinephrine) injection.[1] Surgical cutting time did not occur within 15 minutes from start of induction in this population. Therefore, it can be safely mentioned that the return to baseline hemodynamic values on the 15th minute was not because of surgical stimulus.

No hypotension was observed in the first 5 minutes. Within 10 minutes, hypotension occurred in 8.6% by SBP criterion and 2.6% by MAP criterion. Within 15 minutes, hypotension was seen in 5.7% by SBP and MAP criterion, respectively. There was no severe hypotensive episode that necessitated giving of ephedrine. In the current results, there seems to be very weak to weak negative to positive and insignificant correlation ($p > 0.05$) between PI and incidence of hypotension whether using SBP or MAP criteria. Therefore, the authors cannot recommend using PI to predict hypotension.

Since circulatory volume affects a patient's hemodynamics, it will likewise affect the PI readings. Authors have suggested a PI median value of 1.4 as normal for healthy individuals.[11] Patients who are relatively hypovolemic with reflex vasoconstriction and low PI could experience hypotension with general anesthesia induction. These patients could benefit from volume loading prior to induction.

Overall, there was a positive, moderate and significant association between PI and SBP, DBP and MAP. The current results were different from Mehandale and Rajasekhar's findings which showed a weak negative correlation of PI with SBP, DBP, MAP and HR.[10] In their study, SBP was the only independent predictive variable with correlation coefficient of $r = -0.503$ ($p < 0.001$). Their scatter plot of baseline PI showed a bell-shaped curve with very high and very low SBP values being associated with low PI. They explained that a low PI with a low SBP is attributable to loss of pulsatility and is seen with hypovolemia and use of vasopressors.[12] However, high SBP with low PI may be due to concomitant increases in the non-pulsatile component (circulatory volume or SVR). The current study showed a positive correlation of PI not only with SBP but also with DBP and MAP. Starting with induction, there was a slight decrease of hemodynamic parameters and a concomitant gradual increase in PI. There was a steady rise in PI even when hemodynamic values had returned to baseline or near baseline. All patients were started with intravenous fluids running at maintenance rates at least 8 hours prior to induction of general anesthesia. The authors assume that these patients were well hydrated and had adequate circulatory volume right before the start of induction. The gradual progressive increase in PI could be explained by consistent vasodilatory effect of inhalational anesthetics but without the reflex vasoconstriction that is seen in volume-depleted patients. HR showed a poor, negative and not significant correlation with PI.

The usefulness of PI to predict post induction hypotension has been inconclusive in this study. The area under the ROC curve (AUC) (0.397, 95% CI [0 .126, 0.667], $p = 0.431$) failed to establish a cut-off value beyond which hypotension occurs more often.

This study is limited by the lack of direct evidence for the explanations proposed which are only based on hypothesis. Current results are inconsistent with similar studies. This could not be attributed to the study design and data collection as the researchers

implemented these in such a way that the authors could closely resemble their methods. The difference of this study from previous ones was the use of a low-cost finger clipped pulse oximeter versus their use of more sophisticated, standard, operating room monitors manufactured by Masimo or Philips. As of this writing, there is no available literature comparing PI readings of these pulse oximeters.

The data show that PI can be used as a measure of hemodynamic status. The data from a simple pulse oximeter can be very useful in critical ways if clinicians are trained to interpret it. An inexpensive clip-on pulse oximeter that can measure PI that is easy to use and is more readily available can give a clinician another tool for measuring the hemodynamic status of patients. This study lends inconclusive evidence on the usefulness of Innovo Deluxe Fingertip Pulse Oximeter with Plethysmograph and Perfusion Index to predict intraoperative hypotension following balanced general anesthesia induction for this sample of patients. However, there was a positive, moderate ($r = 0.54$, 0.50 and 0.47) and significant ($p < 0.05$) correlation between perfusion index and SBP, DBP and MAP, respectively.

References

1. Mowafi HA, Ismail SA, Shafi MA, Al-Ghamdi AA. The efficacy of perfusion index as an indicator for intravascular injection of epinephrine-containing epidural test dose in propofol-anesthetized adults. Anesth Analg 2009 Feb; 108(2): 549-53.
2. Hager H, Reddy D, Kurz A. Perfusion index - a valuable tool to assess changes in peripheral perfusion caused by sevoflurane. Anesthesiology 2003; 99: A593.
3. Kowalczyk M, Fijalkowska A, Nestorowicz A. New-generation pulse oximetry for the assessment of peripheral perfusion during general anaesthesia - a comparison between propofol and desflurane. Anaesthesiol Intensive Ther 2013; 45(3): 138–44.
4. Krishnamohan A, Siriwardana V, Skowno JJ. Using a pulse oximeter to determine clinical depth of anesthesia - investigation of the utility of the perfusion index. Paediatr Anaesth 2016 Nov; 26(11): 1106-11.
5. Mizuno J, Morita Y, Kakinuma A, Sawamura S. General anaesthesia induction using general anaesthetic agents and opioid analgesics increases perfusion index (PI) and decreases pleth variability index (PVI): Observational clinical study. Sri Lankan J Anaesth 2012; 20(1): 7-12.
6. Kakazu CZ, Chen BJ, Kwan WF. Masimo set technology using perfusion index is a sensitive indicator for epidural onset. Anesthesiology 2005; 103: A576.
7. Uemura A, Yagihara M, Miyabe M. Pulse oxymeter perfusion index as a predictor for the effect of pediatric epidural block. Anesthesiology 2006; 105: A1354.
8. Atef HM, Fattah SA, Abd Gaffer ME, Al Rahman AA. Perfusion index versus non-invasive hemodynamic parameters during insertion of I-gel, classic laryngeal mask airway and endotracheal tube. Indian J Anaesth 2013; 57: 156-62.
9. Klijn E, Groeneveld AB, van Genderen ME, Betjes M, Bakker J, van Bommel J. Peripheral perfusion index predicts hypotension during fluid withdrawal by continuous venovenous hemofiltration in critically ill patients. Blood Purif 2015; 40: 92-8.
10. Mehandale SG, Rajasekhar P. Perfusion index as a predictor of hypotension following propofol induction - a prospective observational study. Indian J Anaesth 2017; 61: 990-5.
11. van Genderen ME, Bartels SA, Lima A, Bezemer R, Ince C, Bakker J, van Bommel J. Peripheral perfusion index as an early predictor for central hypovolemia in awake healthy volunteers. Anesth Analg 2013 Feb; 116(2): 351-6.
12. Lu W, Dong J, Xu Z, Shen H, Zheng J. The pleth variability index as an indicator of the central extracellular fluid volume in mechanically-ventilated patients after anesthesia induction: Comparison with initial distribution volume of glucose. Med Sci Monit 2014; 20: 386-92.