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Original Article

Use of the Hypotension Prediction Index During Cardiac Surgery

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Objective: The hypotension prediction index (HPI) is a novel parameter developed by Edwards Lifesciences (Irvine, CA) that is obtained through an algorithm based on arterial pressure waveform characteristics. Past studies have demonstrated its accuracy in predicting hypotensive events in noncardiac surgeries. The authors aimed to evaluate the use of the HPI in cardiac surgeries requiring cardiopulmonary bypass (CPB).
Design: Prospective cohort feasibility study.
Setting: Single university medical center.
Participants: Sequential adult patients undergoing elective cardiac surgeries requiring CPB between October 1, 2018, and December 31, 2018.
Interventions: HPI monitor was connected to the patient's arterial pressure transducer. Anesthesiologists and surgeons were blinded to the monitor output.
Measurements and Main Results: HPI values and hypotensive events were recorded before and after CPB. The primary outcomes were the area under the curve (AUC) of the receiver operating characteristic curve, sensitivity, and specificity of HPI predicting hypotension. The AUC, sensitivity, and specificity for HPI lead time to hypotension five minutes before the event were 0.90 (95% confidence interval [CI]: 0.853-0.949), 84% (95% CI: 77.7-90.5), and 84% (95% CI: 70.9-96.8), respectively. Ten minutes before the event AUC, sensitivity, and specificity for HPI lead time to hypotension were 0.83 (95% CI: 0.750-0.905), 79% (95% CI: 69.8-88.1), and 74% (95% CI: 58.8-89.6), respectively. Fifteen minutes before the hypotensive event AUC, sensitivity, and specificity for HPI lead time to hypotension were 0.83 (95% CI: 0.746-0.911), 79% (95% CI: 68.4-89.0), and 74% (95% CI: 58.8-89.6), respectively.
Conclusion: HPI predicted hypotensive episodes during cardiac surgeries with a high degree of sensitivity and specificity.

Key Words: intraoperative hypotension; hypotension prediction index; cardiac surgery; cardiopulmonary bypass; arterial pressure waveform analysis

INTRAOPERATIVE HYPOTENSION is common despite the monitors and pharmacologic interventions currently available.[1] Intraoperative hypotension is associated with adverse outcomes. Studies have established a correlation between the degree of intraoperative hypotension and the incidences of postoperative myocardial ischemia, acute kidney injury (AKI), and overall mortality following noncardiac surgeries.[2-4] Similar correlations also are observed following cardiac surgeries with respect to stroke, renal injury, and prolonged hospital stay.[5-7]

Clinicians have several tools available to monitor intraoperative hemodynamics that vary in their accuracy and invasiveness. The hypotension prediction index (HPI) monitor (Edwards Lifesciences, Irvine, CA) is a novel device that uses machine learning to develop an algorithm that integrates select parameters from the arterial pressure waveform to predict the likelihood of a hypotensive event.[8] Previous studies using HPI have validated this parameter for noncardiac surgeries.[8,9] HPI

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values predicted the occurrence of hypotension five-to-15 minutes before the event, with sensitivity and specificity both greater than 80%.[8,9] Furthermore, Wijnberge et al. showed significant reduction of total hypotensive time when the HPI monitor was used.[10] No literature currently exists for the use of HPI in cardiac surgeries. These procedures include a high incidence of sudden manual surgical interventions and significantly abnormal physiologic conditions, such as an open thorax and post-cardiopulmonary bypass (CPB) vasodilatation that might compromise the HPI performance. The goal of this study was to evaluate the use of the HPI during cardiac surgery requiring CPB.

Methods

Patient Selection and Enrollment

This cohort feasibility study was a retrospective analysis of data collected as part of a quality improvement comparison of noninvasive cardiac output monitors performed at a single medical center. The need for written informed consent was waived after institutional review board review of the protocol. All patients older than 18 years and scheduled for elective cardiac surgery requiring CPB between October 1, 2018, and December 31, 2018, were sequentially studied.

Data Collection

Before induction of anesthesia, radial arterial access was obtained in all patients, after which the Acumen IQ transducer (Edwards LifeSciences, Irvine, CA) was connected to an EV-1000 (Edwards LifeSciences, Irvine, CA) monitor with the HPI software. No specific tests were performed to assess damping coefficients. There were no standardizations or guidelines for anesthetic care or hemodynamic management associated with this study. The anesthesia care team was blinded to all of the output of this monitor. The left ventricular stroke volume variation, contractility (dP/dt), and vascular tone (Eadyn) parameters were updated every 20 seconds, and the HPI value was presented on a scale of 1 to 100. Data collection began at the start of each case until CPB was initiated, paused during CPB, then re-initiated once the patient was separated from the bypass circuit. Continuous waveform data were transferred from the EV-1000 monitor for analysis at the end of the surgical procedure.

Data Analysis

The collected data were analyzed offline and summarized using Microsoft Excel. They were then divided into five cohorts: all data, pre-CPB, post-CPB, chest open, and chest closed. To facilitate comparisons with previous HPI validation studies, the authors designated the HPI value of 85 as the predictive threshold for the purpose of their study. Similarly, a hypotensive event was defined as a mean arterial pressure (MAP) of <65 mmHg for >1 minute, and a severe hypotensive event was defined as MAP of <50 mmHg for >1 minute. A receiver operating characteristic (ROC) curve model, with the y-axis being sensitivity, and the x-axis as 1-specificity, was constructed to summarize the data for each cohort. The area under the curve (AUC) was calculated in each cohort to determine HPI discrimination ability and overall performance at each time interval (five, ten, and 15 minutes).

In addition, the positive and negative predictive values (NPVs) were calculated for an HPI value of 85 and the occurrence of a hypotensive event within 15 minutes. A true positive (TP) event was defined as an HPI value >85 and MAP <65 for one minute within a 15-minute window. A false positive (FP) event was an HPI value >85 and no MAP <65 for one minute within a 15-minute window. A true negative (TN) event was an HPI value <85 and no MAP <65 for one minute within a 15-minute window. A false negative (FN) event was an HPI value <85 and MAP <65 for one minute within a 15-minute window. The positive predictive value (PPV) was the number of TP events divided by the sum of the total TP and FP events: PPV = #TP/(#TP+#FP). The NPV was defined as the number of TN events divided by the sum of the total TN and FN events: NPV = #TN/(#TN+#FN).

All statistical comparisons and ROC curve analysis used GraphPad Prism version 8.4.3 for Windows (GraphPad Software, San Diego, CA, www.graphpad.com).

Results

A total of 37 patients were studied. The surgical procedures included coronary artery bypass grafting, aortic/mitral/tricuspid valve repair or replacement, combined coronary artery bypass grafting and valve surgeries, Bentall procedure, thoracoabdominal aneurysm repair, septal defect repair, atrial mass excision, and vascular ring division. Demographic data are shown in Table 1. Five patients were not able to have data collected after CPB, due to data collector availability and one

Table 1
Patient Demographics

	All Data (n = 37)	Before CPB (n = 36)	After CPB (n = 31)	Chest Open (n = 33)	Chest Closed (n = 32)
Sex	9F, 28M	9F, 27M	7F, 24M	6F, 27M	6F, 26M
Age, y	63 ± 12	63 ± 12	63 ± 12	63 ± 11	63 ± 11
Weight, kg	86 ± 21	86 ± 21	86 ± 20	88 ± 20	89 ± 19
Height, cm	171 ± 9	171 ± 9	172 ± 9	172 ± 9	172 ± 9

NOTE. Values are shown as mean ± standard deviation.
Abbreviations: CPB, cardiopulmonary bypass; F, female; M, male.

procedure did not require CPB. All available data from all 37 patients were included in the analysis.

The incidence and characteristics of the observed hypotensive events are summarized in Table 2. Of the patients in the study, 97% experienced hypotension with MAPs <65 mmHg; 94% of the subjects experienced hypotension before CPB and 84% after CPB. Hypotension was more frequent when the chest was open (91%) compared with when the chest was closed (67%). The absolute number of hypotensive events for each patient ranged from zero to 15, with an average of seven ± five per patient and a total of 253 events for the entire data set. The average total duration of hypotension for each individual patient was 27 ± 29 minutes and was similar before (14 ± 18 minutes) and after (14 ± 20 minutes) CPB. The average total duration for each individual patient was subjectively greater (19 ± 18 minutes) when the chest was open as compared with when the chest was closed (nine ± 15 minutes), but this difference was not statistically significant. Similarly, the average total AUC for hypotensive events for each individual patient was 182 ± 228 mmHg/min and was similar before (90 ± 142 mmHg/min) and after (82 ± 165 mmHg/min) CPB. The average total duration was also subjectively greater (129 ± 127 mmHg/min) when the chest was open as compared with when the chest was closed (63 ± 136 mmHg/min), but this difference was not statistically significant. The average duration of hypotension for all individual events was four ± five minutes and was similar for all data sets (Table 2). Severe hypotensive episodes with MAP <50 mmHg for >one minute were seen in 70% of patients. Severe hypotension occurred in 50% of patients before CPB and in 36% of patients after CPB.

The ROC curve for all patients, with combined data from before and after CPB, was constructed for five-, ten-, and 15-minute windows from the time of the hypotensive event warning (HPI >85) to the actual event. These results are presented in Figure 1; for clarity, only the curves for the five- and ten-minute windows are included. The values for AUC of the ROC curve and the corresponding sensitivity and specificity for HPI lead time to hypotension are presented in Table 3. Five minutes before the event, AUC of the ROC curve, sensitivity and specificity were 0.90 (95% confidence interval [CI]: 0.853-0.949), 84% (95% CI: 77.7-90.5), and 84% (95% CI: 70.9-96.8), respectively. Ten minutes before the event, AUC, sensitivity, and specificity for HPI lead time to hypotension were 0.8 (95% CI: 0.750-0.905), 79% (95% CI: 69.8-88.1), and 74% (95% CI: 58.8-89.6), respectively. Fifteen minutes before the hypotensive event, AUC, sensitivity, and specificity for HPI lead time to hypotension were 0.83 (95% CI: 0.746-0.911), 79% (95% CI: 68.4-89.0), and 74% (95% CI: 58.8-89.6), respectively. Subgroup analysis also was performed using ROC curve analysis for HPI before and after CPB, and with the chest closed or open. The AUC, sensitivity, and specificity for these curves also are summarized in Table 3 and graphed in Figure 2.

The positive and NPVs were calculated for an HPI value of 85 and the occurrence of a hypotensive event within 15 minutes. These results are summarized in Table 4. For all data points, HPI had a PPV of 0.90 (95% CI 0.890-0.905) and an

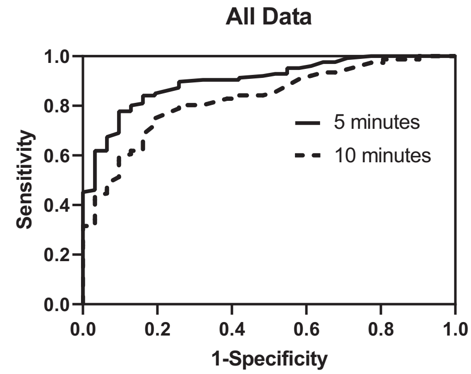

Fig 1. Receiver operator characteristic (ROC) curves for HPI ≥85 predicting significant hypotension (mean arterial pressure <65 mmHG for >one minute) within five or ten minutes before its occurrence.

Table 2
Incidence and Characteristics of Hypotension

	All Data (n = 37)	Before CPB (n = 36)	After CPB (n = 31)	Chest Closed (n = 33)	Chest Open (n = 32)
Monitoring time per patient, min	234 ± 79 (123, 236, 318)	139 ± 51 (75, 148, 200)	96 ± 29 (59, 93, 132)	98 ± 30 (61, 100, 134)	146 ± 56 (72, 164, 200)
Patients with MAP <65 mmHg	36 (97%)	34 (94%)	26 (83%)	22 (67%)	29 (91%)
Number of hypotensive events, total	253	126	94	67	161
Total duration of hypotension, min per patient	27 ± 29 (4, 17, 73)	14 ± 18 (1, 8, 29)	13 ± 20 (0, 5, 41)	9 ± 15 (0, 4, 27)	19 ± 18 (1, 11, 45)
Total area <65 mmHg (mmHg/min)	182 ± 228 (36, 107, 300)	90 ± 142 (5, 59, 145)	82 ± 165 (0, 38, 187)	63 ± 136 (0, 25, 122)	129 ± 127 (13, 87, 278)
Average number of hypotensive events	7 ± 5 (1, 5, 15)	4 ± 3 (1, 3, 7)	3 ± 3 (0, 2, 8)	2 ± 2 (0, 2, 5)	5 ± 4 (1, 5, 12)
Average duration of each hypotensive event, min	4 ± 5 (1, 2, 8)	4 ± 5 (1, 2, 9)	4 ± 6 (1, 3, 9)	5 ± 7 (1, 3, 8)	4 ± 5 (1, 2, 8)
Patients with MAP <50 mmHg	26 (70%)	18 (50%)	11 (36%)	3 (9%)	22 (69%)

NOTE. Incidence and duration characteristics of hypotensive events for each data cohort including both total numbers and average values for each patient. Total area <65 mmHg calculated as mmHg/min. Values are shown as mean ± standard deviation (10th, 50th, and 90th percentiles).
Abbreviations: CPB, cardiopulmonary bypass; MAP, mean arterial pressure.

Table 3
ROC Curve Analysis

All Data	5 Min	10 Min	15 Min
AUC	0.90 (0.853.0.949)	0.83 (0.750, 0.905)	0.83 (0.746, 0.911)
Sensitivity	84% (0.777, 0.905)	79% (0.698, 0,881)	79% (0.684, 0.890)
Specificity	84% (0.709, 0.968	74% (0.588, 0.896)	74% (0.588, 0.896)
Before CPB			
AUC	0.92 (0.863, 0.976)	0.86 (0.772, 0.953)	0.84 (0.740, 0.944)
Sensitivity	84% (0.747, 0.925)	76% (0.646, 0.904)	77% (0.632, 0.911
Specificity	85% (0.694, 1.00)	80% (0.625, 0.975)	80% (0.625, 0.975)
After CPB			
AUC	0.88 (0.785, 0.980)	0.80 (0.653, 0.952)	0.86 (0.727, 0.994)
Sensitivity	79% (0.677, 0.907)	77% (0.627, 0.921)	81% (0.657, 0.979)
Specificity	88% (0.646, 1.0)	75% (0.450, 1.0)	75% (0.450, 1.0)
Chest closed			
AUC	0.86 (0.735, 0.984)	0.79 (0.602, 0.979)	0.82 (0.621, 1.015)
Sensitivity	73% (0.575, 0.879)	69% (0.460, 0.915)	73% (0.464, 0.990)
Specificity	71% (0.380, 1.0)	71% (0.380, 1.0)	71% (0.380, 1.0)
Chest open			
AUC	0.95 (0.900, 0.991)	0.88 (0.789, 0.963)	0.90 (0.823, 0.985)
Sensitivity	89% (0.816, 0.956)	79% (0.677, 0.899)	82% (0.700, 0.941)
Specificity	85% (0.650, 1.0)	77% (0.540, 0.998)	85% (0.650, 1.0)

NOTE. Area under the curve, sensitivity, and specificity for hypotension prediction index predicting a hypotensive event five, ten, and 15 minutes before occurrence. All values presented with 95% confidence intervals.
Abbreviations: AUC, area under curve; CPB, cardiopulmonary bypass.

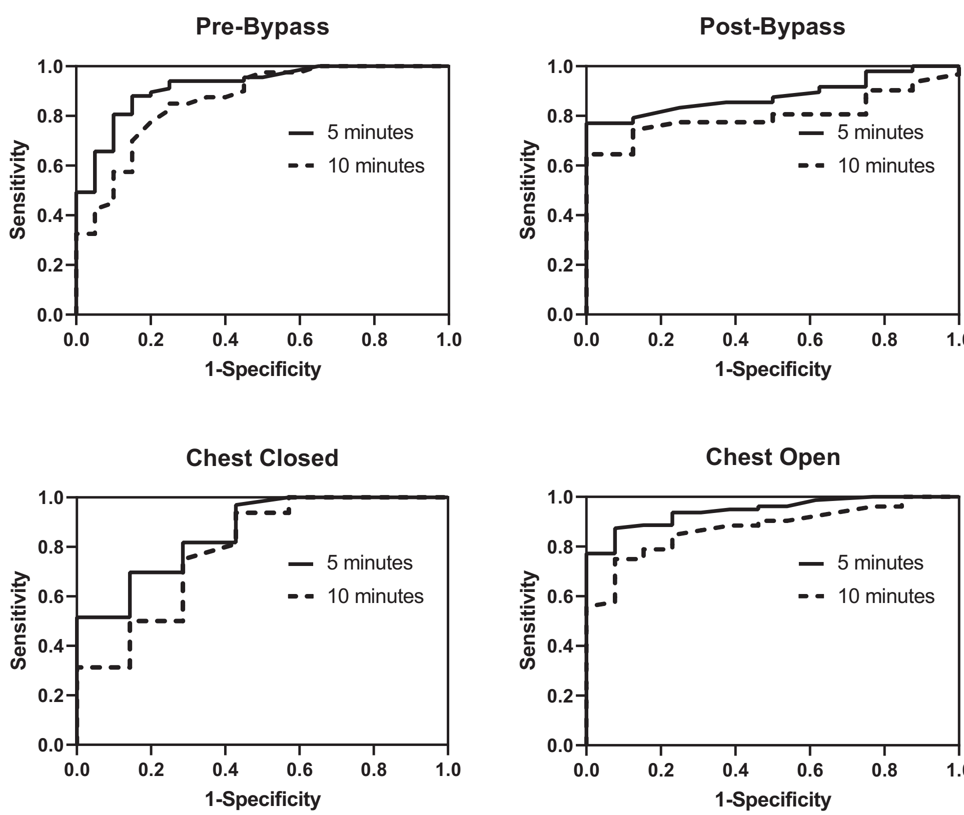

Fig 2. Receiver operator characteristic (ROC) curves for HPI ≥85 predicting significant hypotension (mean arterial pressure <65 mmHG for >one minute) within five or ten minutes before its occurrence during specific intraoperative periods. Before bypass, before initiation of cardiopulmonary bypass; after bypass, after separation from cardiopulmonary bypass; chest closed, after induction of anesthesia, before sternotomy, and after sternal closure, until procedure complete; chest open, after sternotomy, before initiation of cardiopulmonary bypass and after separation from cardiopulmonary bypass, before sternal closure.

Table 4
Positive and Negative Predictive Values

	PPV (95% CI)	NPV (95% CI)
All data	0.90 (0.890-0.905)	0.37 (0.358-0.372)
Before CPB	0.89 (0.883-0.903)	0.38 (0.366-0.384)
After CPB	0.88 (0.866-0.892)	0.33 (0.321-0.347)
Chest closed	0.95 (0.940-0.959)	0.35 (0.335-0.358)
Chest open	0.88 (0.874-0.894)	0.34 (0.326-0.346)

NOTE. Values are calculated for a hypotension prediction index ≥85 and the occurrence of a critical hypotensive event (mean arterial pressure <65 mmHg for at least one minute) within 15 minutes.
Abbreviations: CPB, cardiopulmonary bypass; NPV, negative predictive value; PPV, positive predictive value.

NPV of 0.37 (95% CI 0.358-0.372). The PPV and NPV were comparable among all data sets (Table 4).

Discussion

Intraoperative hypotension is associated with adverse postoperative outcomes.[2-7] The HPI monitor (Edwards Lifesciences, Irvine, CA) integrates select parameters from the arterial pressure waveform to predict the likelihood of a hypotensive event.[8] HPI has been validated in noncardiac surgical patients.[8-10] The authors' findings support a similar use in cardiac surgical patients.

Several definitions of intraoperative hypotension have been proposed, based on different assessments of clinical significance. In noncardiac surgical patients, a decrease in systolic blood pressure >20% of baseline is a threshold used in many studies.[1] Salmasi et al. demonstrated differences in measured outcomes when MAP <65 mmHg was used as the threshold during noncardiac surgical procedures.[3] Because of the variable associated with consistently establishing a baseline blood pressure in the perioperative setting, the authors used this definition for their analysis. The duration of hypotension is also an important consideration. Wesselink et al. suggested that MAP <80 mmHg for >ten minutes may lead to organ injury.[4] In cardiac surgical patients, studies have shown various critical thresholds. Sun et al. showed that increased duration of before CPB MAP <55 mmHg and after CPB MAP <65 mmHg were associated with a higher incidence of postoperative stroke, although adjusted odds ratios failed to show a significant correlation.[7] AKI is also a significant postoperative complication, although not all studies show a clear correlation between absolute values of intraoperative MAP and the incidence of AKI.[11,12] Ono et al. used cerebral oximetry to derive the lower limit of each patient's cerebral autoregulation MAP as a surrogate for renal autoregulation. MAP significantly below the individuals' autoregulation threshold was associated with postoperative AKI.[13]

To consistently and objectively evaluate the performance of the HPI algorithm in this cardiac surgical patient population, the authors chose the definition of MAP <65 mmHg for critical hypotension and arbitrarily selected 50 mmHg as a critical data point for supplemental clinical data characterization. Currently, HPI is fixed to predict MAP <65 mmHg as the critical threshold. However, previous studies demonstrated the variability of critical hypotensive thresholds and the need for clinical judgment in determining the optimal blood pressure goal in patients with advanced diseases.

A separate challenge from establishing each patient's hypotensive threshold is maintaining the goal BP. Currently, HPI uses MAP <65 mmHg for greater than one minute as the critical hypotensive threshold.[3] Hypotensive episodes in this study population occurred at high frequency (98% of patients), with 70% experiencing severe hypotension. These findings underscored the opportunities for improvement with current methods of blood pressure monitoring and management. A potential solution presented by this study is to use an enhanced monitoring technique to detect early signs of impending hypotension. However, this study was not large enough to evaluate specifically associated adverse outcomes.

The Hypotension Prediction Index is an algorithm developed through machine learning and high-fidelity analysis of arterial pressure waveforms.[8] Individual arterial pressure cycles from a large deidentified database were characterized by more than 3,000 individual features and more than two million combined features. These features were introduced into a machine learning training model to identify 23 of the most predictive features that then were used to construct a final predictive model that was externally validated in a separate deidentified database. The initial presentation of this development by Hatib et al. demonstrated that the HPI algorithm effectively could predict hypotension in noncardiac surgeries.[8] Using the same definitions (HPI >85, MAP <65 mmHg, >one minute duration) in their external validation cohort, the area under the receiver-operator characteristic curves (mean 95% CI) for HPI to predict hypotension was similar to the results of this study at five (0.95 [0.93-0.96]), ten (0.92 [0.90-0.94]), and 15 (0.91 [0.89-0.94]) minutes, respectively. Sensitivities and specificities were also similar: five minutes (86.8% [86.3-89.9], 88.5% [84.9-92.0]), ten minutes (84.2% [80.2-88.4], 84.3% [80.2-88.4]), and 15 minutes (83.6% [78.2-89.0], 83.3% [78.9-87.8]). Davies et al. subsequently confirmed the use of HPI in a larger general surgical population.[9] In 255 patients undergoing major surgical procedures, the area under the receiver-operator characteristic curves (mean [95% CI]) for HPI to predict hypotension at five minutes was 0.926 (0.925-0.926), at ten minutes 0.895 (0.894-0.895), and at 15 minutes was 0.897 (0.879-0.880). Sensitivities and specificities also were similar: five minutes (85.8% [85.8-85.9], 85.8% [85.8-85.9]), ten minutes (81.7% [81.6-81.8], 81.7% [81.6-81.8]), and 15 minutes (80.6% [80.5-80.7], 80.6% [80.5-80.7]). The authors have demonstrated similar findings in cardiac procedures requiring CPB.

Several potentially confounding factors specific to cardiac surgery were considered. First, the surgical manipulation of the major vessels and the heart during these operations may interfere with the hemodynamic parameters required to obtain accurate HPI values. No specific cardiovascular manipulations were configured into this study. Manipulations, such as arterial and venous cannulation, were not recorded and the HPI and hemodynamic data at these times were included in the analysis. Another major consideration is the effect of CPB on the use of HPI. CPB triggers a host of hemodynamic disruptions, including systemic inflammatory response, often resulting in vasoplegic shock and coagulopathy.[14] Immediately following CPB and in the setting of septic shock with decreased systemic vascular resistance requiring vasopressor support, radial arterial blood pressure has been shown to underestimate the central blood pressure.[15] Therefore, the authors sought to compare the use of HPI before and after CPB. Furthermore, sternotomy and the open chest alter the changes in intrathoracic pressure associated with mechanical ventilation and blunt the magnitude of the associated dynamic monitors of cardiac function, such as the stroke volume variation.

The authors' results demonstrated that the HPI monitor predicted hypotensive episodes during cardiac surgeries with a high degree of sensitivity and specificity. The ROC analysis for all data shows a statistically significant AUC for all three lead times of five, ten, and 15 minutes. Given that hypotensive episodes occur often during cardiac procedures, a question arises whether the elevated HPI accurately predicts the occurrence of hypotension or if elevated HPI randomly coincides with the frequent hypotensive episodes. However, the average frequency of hypotensive episodes in the authors' study was approximately one per 33 minutes—more than twice the length of their lead time, which argues against random associations between HPI values and hypotension. This also was demonstrated by the high PPV of the critical HPI value of 85. Furthermore, the data showed increasing predictability with shorter lead times, with the five-minute lead time showing the highest AUC, sensitivity, and specificity of 0.90, 84%, and 84%, respectively. This suggests a higher degree of predictability of HPI with more imminent hypotension.

In comparing the use of HPI before and after CPB, ROC analyses showed statistically significant AUC for all lead times. This suggested that the parameters used by the HPI monitor remain valid despite the vasoplegic state occurring after CPB; however, central versus peripheral arterial pressure gradients were not specifically recorded or assessed in this initial validation. In addition, having an open or closed chest also did not show a significant difference and furthermore suggested that surgical manipulation of major vessels and heart with the open chest did not affect performance of the HPI monitor.

One of the limitations of this study was the small sample size, with heterogeneous characteristics. The diverse pathologies of the subjects were demonstrated by the wide spectrum of cardiovascular procedures performed in this cohort. Though the results of this study demonstrated that HPI was useful for cardiac surgery patients, the authors did not investigate whether certain cardiac conditions can affect the use of HPI. Similarly, there were no restrictions or guidelines for the anesthetic management of these patients. A larger study, with subcohorts of specific cardiac pathologies or structured anesthetic management plans, would be required to specifically answer these questions.

Extrapolating from the findings of this study, other endpoints should be considered regarding the application of the HPI monitor in cardiac surgery. There is no fixed magnitude or duration of hypotension definitively associated with end-organ injury in an individual patient. Furthermore, HPI has been demonstrated to predict hypotension, not clinical outcomes. These limitations provide guidelines for further investigations. As Wijnberge et al. measured, in a noncardiac surgical population, a similar study observing the total magnitude and duration of hypotension with and without using the HPI monitor in cardiac surgery could further assess the use of HPI monitor.[13] Ultimately, analyzing the complications of varying severity and duration of hypotension and associated adverse clinical endpoints (AKI, myocardial ischemia, and stroke) to assess the clinical effects of incorporating HPI into cardiac anesthesiology practice would provide valuable information.

The total incidence of hypotension numbers suggests that a majority of the hypotensive events were not therapeutic or the consequences of surgical manipulations. There are, consequently, many opportunities for improved intraoperative hemodynamic management. The HPI algorithm provides predictive information both before and after sternotomy. Inotropes and vasoconstrictors commonly were used following CPB, and the overall incidence numbers confirmed these did not compromise performance of the HPI algorithm. Although the assessment of HPI is still in early stages, this study demonstrated the potential benefit of this intraoperative monitor to improve outcomes in cardiac procedures.

Conflict of Interest

Neal Fleming has supported contracted research and received honoraria from Edwards LifeSciences for invited presentations.

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