Use of the ClearSight® System for Continuous Noninvasive Hemodynamic Monitoring during Heart Valve Interventions: Review of the Literature and Single-Site Experience

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ABSTRACT

During interventional and structural cardiology procedures, such as mitral valve (MitraClip, BMV), aortic valve (TAVR, BAV), tricuspid valve (MitraClip), left atrial appendage (Watchman, Lariat), atrial septum (ASD/PFO closure), and coronary artery intervention (high-risk PCI), among others, patients are at a high risk of hemodynamic instability and require continuous monitoring. This is conventionally achieved through arterial catheterization and transpulmonary thermodilution. However, such invasive techniques are time-consuming and have been associated with steep learning curves, vascular complications, and increased risk of infection. In line with the ongoing simplification and improvement of the catheter-based valve intervention, it is logical to investigate the effectiveness of continuous noninvasive hemodynamic monitoring in this setting. Over the last 2 years, our team has performed over 400 valve procedures with continuous hemodynamic monitoring via the noninvasive ClearSight system. This system is based on a finger-cuff and automated volume-clamp technology integrated into a simplified clinical platform (EV1000 NI). Although current evidence suggests that the technology results in slight differences in arterial pressure (AP) and cardiac output (CO) relative to the current, commercially available, invasive approaches, we have found the bias to be acceptable. Both the noninvasive and the invasive approaches have the same percentage of error when compared to the true CO and provide beat-by-beat detection of acute changes facilitating shorter response times. In addition to AP and CO, the system provides up-to-date information on stroke volume (SV), stroke volume variation (SVV), and systemic vascular resistance, which can be useful in aiding decision-making and provide better postoperative outcomes, such as shorter length of stay (LOS), decreased postoperative infection, decreased postoperative arrhythmia, decreased postoperative renal failure, decreased postoperative congestive heart failure (CHF), and decreased readmission.

Additionally, the simplicity of the system setup has translated into a time saving of up to 3 hours per day, allowing one team to perform an additional 2 to 3 valve interventions without moving rooms. Moving forward, a formal study comparing patient outcomes and cost-effectiveness between invasive and noninvasive hemodynamic monitoring techniques in valve replacement would be insightful.

INTRODUCTION

During interventional and structural cardiology procedures, such as mitral valve (MitraClip [Abbott, Abbott Park, IL, USA], BMV), aortic valve (TAVR, BAV), tricuspid valve (MitraClip), left atrial appendage (Watchman [Boston Scientific, Marlborough, MA, USA], Lariat [SentreHEART, Redwood City, CA, USA]), atrial septum (ASD/PFO closure), and coronary artery interventions (high-risk PCI), among others, patients are at a high risk of hemodynamic instability and require continuous monitoring. During aortic valve intervention, for example, this is due to the rapid pacing used to reduce cardiac output for balloon dilation and valve implantation [Fassl 2009]; the potential for complications such as aortic regurgitation, left ventricular or aortic rupture, cardiac tamponade, and new-onset arrhythmias [Giustino 2014; Dolmatova 2017]; and the high prevalence of carotid, aortic, valvular, coronary, and peripheral vascular diseases commonly found in patients with aortic stenosis [Cattaneo 2010]. Because insufficient or delayed hemodynamic management during the procedure has been associated with a higher likelihood of mortality [Tamburino 2011], close monitoring of cardiac parameters throughout the intervention is paramount. Conventional, hemodynamic monitoring is accomplished through the placement of invasive arterial/central venous catheters. However, catheterization is time-consuming, requires a high level of technical skill, and can result in complications such as vascular injury, thrombosis, and infection [Scheer 2002]. Furthermore, use of mean AP (MAP) alone to detect acute hemodynamic alterations is unreliable, because such changes are generally related to blood flow rather than alterations in vasotone and physiological adaptation may maintain MAP despite variations in cardiac output (CO) [Petzoldt 2015]. The invasive alternative, transpulmonary thermodilution, requires calibration with cold fluid boluses, creating an additional fluid load. Given that valve procedures are becoming ever more simplified, with movement towards...
greater use of conscious sedation [Landes 2017; Lee 2017], a logical next step is to reduce the reliance on such invasive monitoring techniques with the aim of improving patient experience and increasing center productivity.

A number of noninvasive approaches to continuous hemodynamic monitoring have been developed to address the limitations of invasive monitoring. These include thoracic bioimpedance/bioreactance, pulse wave transit time based on electrocardiogram/plethysmography, and pulse contour analysis based on finger-cuff pressure devices [Joosten 2017]. The ClearSight system from Edwards Lifesciences (Irvine, CA, US) is based on the latter principle and allows real-time beat-to-beat monitoring of multiple cardiac parameters [Kalmar 2013]. The Nexfin® technology underlying the ClearSight system has been evaluated in a number of clinical settings [Stover 2009; Bogert 2010; Martina 2010; Van de Vijver 2011; Broch 2012; Fischer 2012; Kalmar 2012; Martina 2012; Monnet 2012; Ameloot 2013; Broch 2013; Bubenek-Turconi 2013; Hohn 2013; Ameloot 2014; Hofhuizen 2014; Maass 2014; Vos 2014; Weiss 2014; Balzer 2016; de Wilde 2016; Heusdens 2016; Schraverus 2016; Berkelmans 2018; Sperna Weiland 2018]; however, its specific impact on valve procedures remains to be determined. Herein, we present insights from the Banner - University Medical Center Phoenix (Phoenix, AZ, USA), an experienced site performing valve interventions, and contextualize our observations within the existing literature.

THE CLEARSIGHT SYSTEM

The ClearSight system (Figure 1) employs Nexfin technology, which was originally developed and introduced onto the market by BMEYE (the Netherlands) in 2007. As such, it also relies on the Physiocal™ autocalibration unloading algorithm in combination with the volume-clamp technique, but has been integrated into a simplified clinical platform (EV1000 NI) for clearer, more versatile visual support. An in-depth description of Nexfin technology can be found in Kalmar et al, 2013 [Kalmar 2013], whereas a schematic representation is provided in Figure 2.

Briefly, ClearSight consists of a disposable pneumatic finger cuff that inflates and deflates over the course of a cardiac cycle to counter the pressure exerted by the pulse wave in the finger artery, such that the volume in the finger artery remains constant. The pressure in the cuff may then be considered equal to arterial pressure. This is periodically recalibrated on the basis of the shape of the plethysmogram by the Physiocal™ algorithm. The resulting pulse wave is then reproduced at a brachial level. Finally, an afterload model is used to determine other parameters such as stroke volume (SV), stroke volume variation (SVV), and cardiac output (CO) [Kalmar 2013].

Figure 1. ClearSight system components (Edwards Lifesciences, with permission). (A) Finger cuff (3 sizes available); (B) EV1000 NI clinical platform for clear data presentation; (C) the hydrostatic pressure changes due to difference in height between the finger and heart are compensated by the HRS; (D) pump unit; (E) pressure controller; (F) correct placement of a single finger cuff, heart reference sensor, and pressure controller on a patient.

Figure 2. Schematic representation of the Nexfin volume-clamp principle. Figure source: [Peter 2014]. The finger cuff inflates and deflates over the course of a cardiac cycle to counter the pressure exerted by the pulse wave in the finger artery. The resulting pulse wave is then reproduced at a brachial level. Finally, an afterload model is used to determine other parameters such as stroke volume (SV), stroke volume variation (SVV), and cardiac output (CO) [Kalmar 2013].
### Evidence for the Accuracy and Precision of Nexfin Technology Compared to Invasive Monitoring Techniques*†

<table>
<thead>
<tr>
<th>Study‡</th>
<th>Nos. of Patients and Condition and/or Setting</th>
<th>Comparator</th>
<th>BP bias (SD), mmHg</th>
<th>CO bias (SD [% error]), L·min⁻¹</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stover et al, 2009</td>
<td>10 critically ill patients</td>
<td>Radial A-line and PTD</td>
<td>MAP: –2 (8)</td>
<td>0.23 (1.05 [29])</td>
</tr>
<tr>
<td>Martina et al, 2010</td>
<td>18 patients during CPB</td>
<td>Radial A-line</td>
<td>MAP: –1.3 (6.5)</td>
<td>Supine: 0.44 (0.81 [&lt;30]) Sitting: 0.34 (0.83 [&lt;30])</td>
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<td>Bogert et al, 2010</td>
<td>25 awake patients after CABG</td>
<td>PTD</td>
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<td>0.4 (1.16 [36.1])</td>
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<td>Van de Vijver et al, 2011</td>
<td>45 critically ill patients in ICU</td>
<td>TPTD</td>
<td></td>
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<tr>
<td>Fischer et al, 2012</td>
<td>44 patients admitted to ICU after conventional cardiac surgery</td>
<td>Radial A-line and TPTD</td>
<td>SAP: 5.7 (14.4) DAP: –8.9 (7.0) MAP: 4.6 (6.3)</td>
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<tr>
<td>Martina et al, 2012</td>
<td>50 cardiothoracic surgery patients in whom invasive measurement is not warranted</td>
<td>Radial A-line</td>
<td>SAP: –0.5 (6.7) DAP: 2.8 (6.4) MAP: 2.2 (6.4)</td>
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<tr>
<td>Monnet et al, 2012</td>
<td>45 patients undergoing volume expansion</td>
<td>Femoral A-line and TPTD</td>
<td>MAP: –2.0 (10.4)</td>
<td>Cardiac index: 0.2 (1.0 [57])§</td>
</tr>
<tr>
<td>Broch et al, 2012</td>
<td>40 patients before/after elective CABG</td>
<td>TPTD</td>
<td>MAP: 3.0 (9.0)</td>
<td>Before: –0.1 (0.3 [23]) After: –0.1 (0.4 [26])</td>
</tr>
<tr>
<td>Kalmar et al, 2012</td>
<td>110 patients under general anesthesia</td>
<td>Radial A-line</td>
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<tr>
<td>Broch et al, 2013</td>
<td>50 patients scheduled for elective coronary surgery</td>
<td>Femoral/radial A-line</td>
<td>SAP: 6.5 (17.5)/11.4 (17.1) DAP: 9.3 (15.8)/13.0 (13.5) MAP: 6.2 (11.7)/10.9 (13.0)</td>
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<tr>
<td>Bubenek-Turconi et al, 2013</td>
<td>28 patients who underwent on-pump cardiac surgery</td>
<td>PTD</td>
<td></td>
<td>Baseline: –0.1 (1.0 [39]) After PM: 0.0 (1.1 [38]) Both: 0.0 (1.0 [38])</td>
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<tr>
<td>Hohn et al, 2013</td>
<td>25 critically ill surgical patients</td>
<td>Femoral A-line</td>
<td>SAP: –9.0 (25.0) MAP: 6.0 (12.0)</td>
<td>0.4 (1.2 [36])/0.2 (1.2 [37])</td>
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<tr>
<td>Ameloot et al, 2013</td>
<td>45 critically ill patients admitted to ICU</td>
<td>TPTD/PiCCO</td>
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<tr>
<td>Ameloot et al, 2014</td>
<td>45 critically ill medical, surgical, and burns patients</td>
<td>Femoral A-line</td>
<td>SAP: –8.3 (13.8) DAP: 9.4 (6.9) MAP: 1.8 (5.1)</td>
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<tr>
<td>Hofhuizen et al, 2014</td>
<td>20 sedated patients after cardiac surgery</td>
<td>TPTD</td>
<td>SAP: –2.7 (22.2) DAP: –4.9 (13.6) MAP: –4.2 (13.7)</td>
<td>0.26 (2.2 [39])</td>
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<td>Maass et al, 2014</td>
<td>53 patients scheduled for elective, non-emergent CPB</td>
<td>PTD</td>
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<tr>
<td>Vos et al, 2014</td>
<td>120 patients undergoing elective general surgery</td>
<td>Radial A-line</td>
<td>MAP: 2 (9)</td>
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<tr>
<td>Balzer et al, 2016</td>
<td>20 patients undergoing moderate-risk orthopedic surgery</td>
<td>Radial A-line</td>
<td>SAP: –3.8 (7.8) DAP: 2.4 (4.2) MAP: 0.8 (5.0)</td>
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<tr>
<td>de Wilde et al, 2016</td>
<td>19 patients following upper abdominal surgery</td>
<td>Radial A-line</td>
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</table>
Evidence for the Accuracy and Precision of Nexfin Technology Compared to Invasive Monitoring Techniques*† [Continued]

<table>
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<tr>
<th>Study‡</th>
<th>Nos. of Patients and Condition and/or Setting &lt;&lt;Q4&gt;&gt;</th>
<th>Comparator</th>
<th>BP bias (SD), mmHg</th>
<th>CO bias (SD [% error]), L·min⁻¹</th>
</tr>
</thead>
<tbody>
<tr>
<td>Schraverus et al, 2016</td>
<td>30 morbidly obese patients undergoing laparoscopic surgery</td>
<td>Brachial A-line</td>
<td>SAP: –3.3 (10.8)</td>
<td>0.60 (1.62 [46])</td>
</tr>
<tr>
<td>Heusdens et al, 2016</td>
<td>25 patients receiving general anesthesia for carotid endarterectomy</td>
<td>Radial A-line</td>
<td>DAP: 6.1 (5.7)</td>
<td>0.60 (1.62 [46])</td>
</tr>
<tr>
<td>Berkelmans et al, 2018</td>
<td>31 patients with atrial fibrillation admitted to an ICU or medium care unit</td>
<td>Radial A-line</td>
<td>SAP: –4 (12)</td>
<td>0.60 (1.62 [46])</td>
</tr>
<tr>
<td>Sperna Weiland et al, 2018</td>
<td>51 patients undergoing cardiac surgery</td>
<td>TPTD</td>
<td>DAP: 1 (7)</td>
<td>0.60 (1.62 [46])</td>
</tr>
</tbody>
</table>

*Biases are based on Bland-Altman analysis [Bland 1986]. For some studies, only limits of agreement were presented, in which case SD was calculated by dividing the mean of the 2 limits by 1.96.
†BP, blood pressure; SD, standard deviation; CO, cardiac output; A-line, arterial line; PTD, pulmonary thermodilution; MAP, mean arterial pressure; CPB, cardiopulmonary bypass; CABG, coronary artery bypass graft; ICU, intensive care unit; TPTD, transpulmonary thermodilution; SAP, systolic arterial pressure; DAP, diastolic arterial pressure; PM, preload-modifying maneuver; PICCO, pulse contour cardiac output; PO, postoperatively.
‡Each entry in the “Study” column refers to the corresponding reference in the “References.” Also, note that each date given in this table is the date of the reference and is not necessarily the date of the study.
§Unit: L·min⁻¹·(m²)⁻¹.

variables such as stroke volume (SV), stroke volume index (SVI), stroke volume variation (SVV), CO, and systemic vascular resistance (SVR) on a beat-by-beat basis. To compensate for ongoing changes in vascular physiology that may also contribute to arterial volume, the finger cuff is automatically recalibrated every 5–70 beats in response to information from the photoplethysmography sensor [Stenglova 2017]. This means that BP changes due to variations in cardiac parameters are immediately and easily discernible from confounding influencers.

**ACCURACY AND PRECISION COMPARED TO INVASIVE HEMODYNAMIC MONITORING SYSTEMS**

The accuracy and precision of hemodynamic data from Nexfin-based devices have been evaluated relative to invasive A-line and thermomodulation monitoring strategies in multiple small-scale studies across various clinical settings (Table) [Stower 2009; Bogert 2010; Martina 2010; Van de Vijver 2011; Broch 2012; Fischer 2012; Kalnar 2012; Martina 2012; Monnet 2012; Ameloot 2013; Broch 2013; Bubenek-Turconi 2013; Hohn 2013; Ameloot 2014; Hofhuizen 2014; Maass 2014; Vos 2014; Weiss 2014; Balzer 2016; de Wilde 2016; Heusdens 2016; Schraverus 2016; Berkelmans 2018; Sperna Weiland 2018]. In general, studies appear to report acceptable mean arterial pressure (MAP) biases when compared to the gold standard arterial catheter method [Stower 2009; Martina 2010; Fischer 2012; Martina 2012; Ameloot 2014; Hofhuizen 2014; de Wilde 2016; Heusdens 2016; Berkelmans 2018]. Therefore, the accuracy and precision values recorded for the Nexfin technology may be considered adequate for the purposes of perioperative monitoring in valve interventions, especially when taken in the context of its noninvasive advantage and the additional cardiac variables it provides. Indeed, almost all comparative studies report Nexfin arterial pressure biases that fall within <10 mmHg of the reference method [O’Brien 2010].

Whereas certain noninvasive devices have only been validated in sedated patients in normal sinus rhythm and arrhythmia may result in inaccuracies with many peripheral monitoring systems, it is of particular note that the Nexfin/ClearSight system is much less affected by this potential source of error. Maggi and colleagues evaluated the technology in 22 patients undergoing interventional electrophysiology procedures which are characterized by critical situations of hypotension triggered by tachyarrhythmia or by intermittent incremental ventricular temporary pacing [Maggi 2010]. They found that the output of the Nexfin was not affected. A linear correlation for a range of BP values from 41 to 190 mmHg was found between noninvasive and intra-arterial BP among a total of 1055 beats from 3 patients who underwent simultaneous recordings with both methods (coefficient of correlation of 0.81, P < .0001).

Although conventional monitoring generally makes use of invasive pulmonary artery or transpulmonary thermodilution for determination of CO, the ClearSight system allows both BP and CO readings to be performed simultaneously and noninvasively. Nexfin technology has been shown to meet the currently accepted percentage-of-error requirements on a number of occasions both in awake patients [Stower 2009;
of a foreign entity into the body, A-line placement has been reported to have a success rate of just 80% and failing to reach 100% success rates in residents requiring an average of 20 attempts to reach a successful arterial cannulation, with one study reporting a success rate of 78%.

This is in contrast to the extensive training required for the ClearSight system periprocedural hemodynamic monitoring. This system requires little operator skill, and the learning curve associated with the ClearSight system is relatively flat, allowing for quick setup and data transmission within minutes after entering the procedure room. At our site, we have found that we can connect a patient to the ClearSight apparatus and begin data transmission within approximately 10 minutes.

A patient's hemodynamic profile can be obtained rather quickly upon entry into the procedure room, and the ClearSight apparatus allows for beat-by-beat monitoring allowing early detection of hemodynamic changes and shorter response times.

**PATIENT SCOPE**

A-line hemodynamic monitoring is often complicated in elderly and obese patients owing to exhausted, unsuitable, or damaged vasculature and a lack of clear anatomic landmarks. This is particularly pertinent in valve interventions, given that many patients have a high BMI and are of an advanced age. The lack of necessity for artery location and self-calibration of the ClearSight system avoids such problems. Indeed, use in obese patients is facilitated by the availability of 3 different finger-cuff sizes that allow the technology to be adapted to body habitus. As in an elderly population, diabetes is also highly prevalent in these patients, and many patients are of an advanced age. The lack of necessity for artery location and self-calibration of the ClearSight system avoids such problems. Indeed, use in obese patients is facilitated by the availability of 3 different finger-cuff sizes that allow the technology to be adapted to body habitus.

**SAFETY**

Besides the general discomfort related to the introduction of a foreign entity into the body, A-line placement has been associated with a number of complications. These include hematomas, abscesses, puncture site bleeding, pseudoaneurysms, air embolization, median nerve paralysis, local infection, thrombosis, arterial occlusion, and sepsis. A recent study of 57,787 surgical patients found A-line–associated vascular complications or nerve injuries to occur at a rate of 3.6 per 10,000 patients, with this rate rising to 9.7 per 10,000 in patients undergoing cardiac procedures. A large-scale metaanalysis found temporary occlusion to occur at a rate of 19.7% in individuals cannulated for hemodynamic monitoring purposes, with a local infection incidence of 0.72%-0.78%.
is also worth noting that monitors for invasive hemodynamic monitoring systems are similarly expensive, that much of the apparatus is designed for single use, and that the iced solution required for thermodilution must also be purchased [Malbrain 2005]. Consequently, material costs may not be dissimilar between the 2 approaches. Furthermore, the potential for departmental cost avoidance due to time saved in preparing patients, reduced staffing requirements, and elimination of catherization-related complications is substantial with the ClearSight system. The economic implications of doing more procedures per day have not yet been formally determined.

**POTENTIAL LIMITATIONS OF THE CLEARSIGHT SYSTEM**

Firstly, A-line access does not merely provide BP information, but also permits blood sampling, analysis, and acid–base monitoring. The ClearSight system is unable to provide such information, though does offer a range of other parameters that are not currently available from an A-line alone.

Secondly, although our experience is that the quality of hemodynamic management during valve interventions is not adversely affected by switching to noninvasive monitoring and clinical outcomes are largely positive, this has not yet been formally evaluated. There is potential, though, for vertical repositioning of the limbs to affect pressure readings [Siddiqui 2007]. However, ClearSight is equipped with a heart reference system and automatically compensates for inaccuracies resulting from hand positioning. Furthermore, the psychological advantages of a noninvasive technique from a conscious patient’s perspective should not be overlooked. Personally, we have used the ClearSight system in a large number of patients undergoing valve interventions under conscious sedation at our site and found it to be equally as efficient in this patient population as in general anesthesia patients. A further personal impression was patient satisfaction due to the lack of line placement pre- or intraoperatively and due to comfort postoperatively due to the lack of pain caused by an A-line or central-line/PA catheter.

Finally, the accuracy, precision, adaptability, and safety profiles of other continuous noninvasive hemodynamic monitoring approaches have not been directly compared to that of Nexfin technology during valve interventions. Though our experience is with the ClearSight system, it is possible that similar benefits may be achieved with other noninvasive systems. Comparative studies between noninvasive methods that include gold standard hemodynamic monitoring techniques as a reference and provide an analysis of relative cost-effectiveness would now be informative.

**CONCLUSIONS**

Although the accuracy and precision of ClearSight BP and CO readings are limited when compared with the gold standard A-line, we have found the biases to be tolerable during heart valve interventions. Furthermore, other factors such as safety, adaptability, applicability, and costs must also be considered when determining a system’s effectiveness. Finally, better postoperative outcomes, such as shorter length of stay (LOS), decreased postoperative infection, decreased postoperative arrhythmia, decreased postoperative renal failure, decreased postoperative CHF, and decreased readmission have been observed. On balance, we consider the ClearSight system’s user-friendliness, speed, potential to reduce complications, and likely cost-effectiveness to outweigh its slight inaccuracies and have thus adopted it as standard at our center. Furthermore, because many procedures are becoming increasingly simplified, we bring into question the appropriacy of invasive monitoring measures when reasonable noninvasive alternatives exist. Formal studies are now required to corroborate our observations.

**ACKNOWLEDGMENTS**

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**REFERENCES**


