The Heart Surgery Forum #2018-2177
21 (6), 2018 [Epub November 2018]
doi: 10.1532/hsf.2177

Online address: http://journal.hsforum.com

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.

Received August 22, 2018; received in revised form September 29, 2018; accepted October 1, 2018.

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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. Conventionally, 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

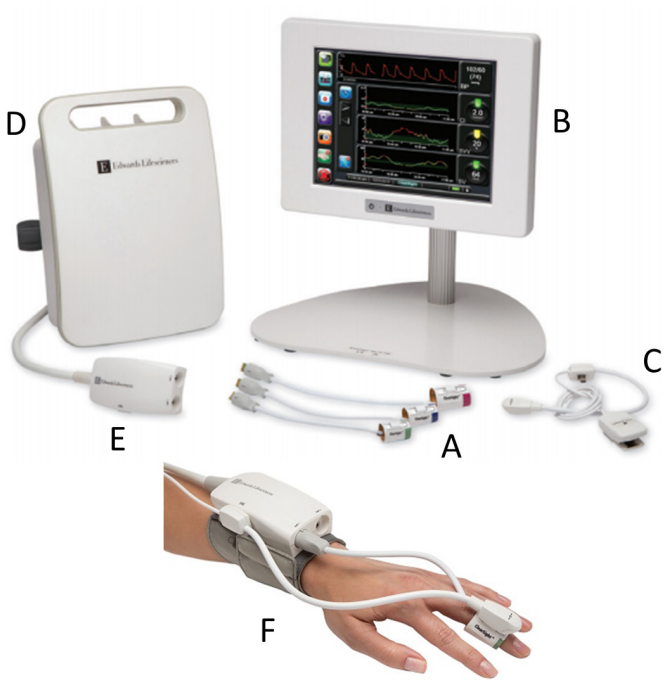

Figure 1. ClearSight system components (Edwards Lifesciences, with permission). (A) Finger cuff (3 sizes available); (B) EV1000 NI clinical platform for clear data presentation; (C) the hydrostatic pressure changes due to difference in height between the finger and heart are compensated by the HRS; (D)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

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.

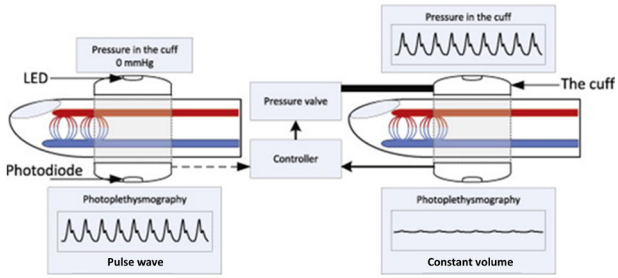

Figure 2. Schematic representation of the Nexfin volume-clamp principle. Figure source: [Peter 2014]. The finger cuff inflates and deflates over the course of a cardiac cycle to counter the pressure exerted by the pulse wave in the finger artery, such that the volume in the finger artery remains constant. 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].

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 according to signals from an integrated photoplethysmography sensor. This sensor detects fluctuations in infrared light absorption by the red blood cells (RBCs) that reflect volume changes in the finger artery during pulsation; absorption (and therefore finger blood volume) increases during systole and falls during diastole. The resulting absorption curve is therefore an indication of arterial blood volume. The aim of dynamic cuff inflation/deflation is to apply the exact pressure required to counteract the pressure changes in the finger artery throughout the cardiac cycle, preventing changes in the diameter of the vessel and maintaining a constant finger volume (volume-clamp technique) [Raggi 2017]. A flat absorption curve indicates that this state has been reached, at which point the counterpressure exerted by the cuff over the cardiac cycle may be considered equivalent to that exerted by the pulse wave in the finger artery. An algorithm reconstructs this pressure curve at the brachial level [Kalmar 2013]; no arm cuff calibration is required. Subsequently, pulse contour analysis and a 3-element Windkessel model for cardiac afterload can be used to quantify related

Evidence for the Accuracy and Precision of Nexfin Technology Compared to Invasive Monitoring Techniques*†

Study‡	Nos. of Patients and Condition and/or Setting	Comparator	BP bias (SD), mmHg	CO bias (SD [% error]), L·min^{-1}
Stover et al, 2009	10 critically ill patients	Radial A-line and PTD	MAP: −2 (8)	0.23 (1.05 [29])
Martina et al, 2010	18 patients during CPB	Radial A-line	MAP: −1.3 (6.5)	
Bogert et al, 2010	25 awake patients after CABG	PTD		Supine: 0.44 (0.81 [<30]) Sitting: 0.34 (0.83 [<30])
Van de Vijver et al, 2011	45 critically ill patients in ICU	TPTD		0.4 (1.16 [36.1])
Fischer et al, 2012	44 patients admitted to ICU after conventional cardiac surgery	Radial A-line and TPTD	SAP: 5.7 (14.4) DAP: −8.9 (7.0) MAP: 4.6 (6.5)	
Martina et al, 2012	50 cardiothoracic surgery patients in whom invasive measurement is not warranted	Radial A-line	SAP: −0.5 (6.7) DAP: 2.8 (6.4) MAP: 2.2 (6.4)	
Monnet et al, 2012	45 patients undergoing volume expansion	Femoral A-line and TPTD	MAP: −2.0 (10.4)	Cardiac index: 0.2 (1.0 [57])§
Broch et al, 2012	40 patients before/after elective CABG	TPTD		Before: −0.1 (0.3 [23]) After: −0.1 (0.4 [26])
Kalmar et al, 2012	110 patients under general anesthesia	Radial A-line	MAP: 3.0 (9.0)	
Broch et al, 2013	50 patients scheduled for elective coronary surgery	Femoral/radial A-line	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)	
Bubenek-Turconi et al, 2013	28 patients who underwent on-pump cardiac surgery	PTD		Baseline: −0.1 (1.0 [39]) After PM: 0.0 (1.1 [38]) Both: 0.0 (1.0 [38])
Hohn et al, 2013	25 critically ill surgical patients	Femoral A-line	SAP: −9.0 (25.0) MAP: 6.0 (12.0)	
Ameloot et al, 2013	45 critically ill patients admitted to ICU	TPTD/PiCCO		0.4 (1.2 [36])/0.2 (1.2 [37])
Ameloot et al, 2014	45 critically ill medical, surgical, and burns patients	Femoral A-line	SAP: −8.3 (13.8) DAP: 9.4 (6.9) MAP: 1.8 (5.1)	
Hofhuizen et al, 2014	20 sedated patients after cardiac surgery	TPTD	SAP: −2.7 (22.2) DAP: −4.9 (13.6) MAP: −4.2 (13.7)	0.26 (2.2 [39])
Maass et al, 2014	53 patients scheduled for elective, non-emergent CPB	PTD		Before incision: 0.18 (1.1 [52]) Before bypass: −0.01 (1.2 [56]) After bypass: 0.78 (1.4 [47]) Arrival in ICU: −0.14 (1.4 [55]) 1 day PO: 0.01 (1.4 [51])
Vos et al, 2014	120 patients undergoing elective general surgery	Radial A-line	MAP: 2 (9)	
Weiss et al, 2014	31 patients during anesthesia induction for elective surgery	Radial A-line	SAP: −3.8 (16.2) DAP: −8.8 (10.7)	
Balzer et al, 2016	20 patients undergoing moderate-risk orthopedic surgery	Radial A-line	SAP: 5 (16) DAP: −5 (12) MAP: −1 (13)	
de Wilde et al, 2016	19 patients following upper abdominal surgery	Radial A-line	SAP: −3.8 (7.8) DAP: 2.4 (4.2) MAP: 0.8 (5.0)	

Evidence for the Accuracy and Precision of Nexfin Technology Compared to Invasive Monitoring Techniques*† [Continued]

Study‡	Nos. of Patients and Condition and/or Setting <<Q4>>	Comparator	BP bias (SD), mmHg	CO bias (SD [% error]), L·min^{-1}
Schraverus et al, 2016	30 morbidly obese patients undergoing laparoscopic surgery	Brachial A-line		0.60 (1.62 [46])
Heusdens et al, 2016	25 patients receiving general anesthesia for carotid endarterectomy	Radial A-line	SAP: –3.3 (10.8) DAP: 6.1 (5.7) MAP: 3.5 (2.2)	
Berkelmans et al, 2018	31 patients with atrial fibrillation admitted to an ICU or medium care unit	Radial A-line	SAP: –4 (12) DAP: 1 (7) MAP: 0 (8)	
Sperna Weiland et al, 2018	51 patients undergoing cardiac surgery	TPTD		0.1 (0.8 [37])

*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 thermodilution monitoring strategies in multiple small-scale studies across various clinical settings (Table) [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]. In general, studies appear to report acceptable mean arterial pressure (MAP) biases when compared to the gold standard arterial catheter method [Stover 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 [Stover 2009;

Bogert 2010] and during coronary artery surgery [Broch 2012] (data presented in Table).

Two years ago, we carried out our own assessment of the accuracy and reliability of the ClearSight system during valve interventions. Over the course of several months, approximately 100 patients undergoing valve replacement at our site were subjected to simultaneous invasive (femoral A-line by implanter team, transpulmonary thermodilution, FloTrac [Edwards Lifesciences], and TEE) and noninvasive (ClearSight system) periprocedural hemodynamic monitoring. This revealed a striking similarity between the data produced by the 2 approaches, such that we have now switched to using the ClearSight system only during such procedures. Over the last 2 years, we have performed over 400 procedures with the ClearSight system and have found the reliability of data and patient outcomes to be extremely satisfactory. In particular, the ready availability of SV, SVI, SVV, CO, and SVR data (none of which are obtainable from just an A-line) provides additional useful information on which to base decision-making, with beat-by-beat monitoring allowing early detection of hemodynamic changes and shorter response times.

EFFICIENCY

As noted by several groups before us, a clear advantage of Nexfin technology is that setup time is extremely short when compared to the multistep procedure required for arterial line placement [Stover 2009; Broch 2012; Bubenek-Turconi 2013; Berg 2014]. As such, a patient's hemodynamic profile can be obtained rather quickly upon entry into the procedure room. At our site, we have found that we can connect a patient to the ClearSight apparatus and begin data transmission within 1-2 minutes, allowing the procedure start time to be under 15 minutes after entering the operating room, compared with up to 45 minutes with the placement and calibration of arterial catheters and central venous catheters. This fast turnaround corresponds to a relative time saving of approximately 30 minutes per patient, creating a window for up to 2-3 additional procedures per day. This shortens waiting lists and allows greater site efficiency. Furthermore, a single team and a single operating room can be used to perform all procedures, rather than constantly switching and wasting time and resources. At our site, when fewer interventions are scheduled in one day, this frees up the hybrid OR for use by other surgical teams, further increasing the center's productivity. Importantly, the learning curve associated with the ClearSight system is also minimal, requiring only a simple setup procedure that requires little operator skill [ClearSight System Setup Guide 2013; Kuster 2015]. This is in contrast to the extensive training required for arterial cannulation, with one study reporting residents requiring an average of 20 attempts to reach a success rate of just 80% and failing to reach 100% success even after 70 procedures [Konrad 1998].

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 [Scheer 2002; Lorente 2006; Safdar 2013; Berg 2014; Nuttall 2016]. 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 [Nuttall 2016]. 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% [Scheer 2002]. Similarly, in 514 patients across intensive care units (ICU) in 6 countries monitored by a pulse contour cardiac output (PiCCO; Pulsion Medical Systems SE, Munich, Germany) device, the incidences of site inflammation and catheter-related infection were 2% and 0.78%, respectively [Belda 2011]. All of the above indicate the huge potential for reducing such periprocedural complications through use of a noninvasive continuous monitoring system such as ClearSight. Given that valve interventions are generally performed in an elderly, high-risk population for whom complications would be particularly serious [Osnabrugge 2013], any procedural modifications which further reduce their likelihood is especially welcome.

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 [Stelfox 2006; Moist 2012]. 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 avoid 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 [Falcao-Pires 2011]. This patient subset is particularly susceptible to infection, and the risk associated with cannulation may be higher. Noninvasive monitoring techniques may therefore be beneficial in this sense; however, a recent study showed the accuracy and precision of Nexfin technology to be negatively affected by the presence of diabetes or other vasculopathy-related conditions, such as Raynaud disease [Heusdens 2016; Alfano 2017]. Consequently, care should be taken when using the system in such patients.

POTENTIAL FOR COST SAVINGS

The initial economic outlay for the ClearSight system is not insubstantial, and a new finger cuff is required for every patient. However, when one cuff is used alone, it may serve for up to 72 hours, which is considerably longer than the periprocedural period typically surrounding valve interventions [Mayr 2015]; where longer-term monitoring is desired, use of 2 cuffs simultaneously allows switching between fingers. It

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 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

Peter Bramlage prepared the first draft of the article; Edwards Lifesciences funded the first-draft preparation.

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