Continuous cardiac output monitoring with an uncalibrated pulse contour method in patients supported with mechanical pulsatile assist device

Sabino Scolletta, Fabio Miraldi, Salvatore Mario Romano, Luigi Muzzi

Abstract

We evaluated the accuracy of an uncalibrated pulse contour method called Pressure Recording Analytical Method (PRAM) compared with continuous thermomilution for cardiac output (CO) monitoring in patients implanted with a pulsatile left ventricular assist device (LVAD). Twelve adult patients implanted with the HeartMate i-XVE device were studied. CO was simultaneously evaluated by PRAM and by continuous thermomilution. Blood flow values displayed by the LVAD’s console were also used for the comparison. Bland–Altman and linear regression analyses were applied. A total of 72 CO measurements (range 3.8–6.7 l/min) were obtained. Mean CO was 5.23±0.70 l/min for the ‘hot’ pulmonary thermodilution technique (ThD-CCO) method, 5.28±0.63 l/min for PRAM and 4.83±0.67 l/min for LVAD-CO. A high correlation (r=0.90), a good agreement (mean bias 0.04 l/min, precision ±0.38 l/min) and a low percentage of error (7.3%) were observed between PRAM-CO and ThD-CCO. A good correlation was found between LVAD-CO and either ThD-CCO (r=0.88) or PRAM-CO (r=0.86), but an overestimation of 10% was observed for both PRAM-CO (mean bias 0.44 l/min) and ThD-CCO (mean bias 0.39 l/min). Our results demonstrated good agreements between PRAM-CO, ThD-CCO and LVAD-CO. PRAM derives CO from a peripheral artery without calibration and may be a complementary tool in the hemodynamic assessment of patients supported with a VAD.

Keywords: Heart failure; Ventricular assist device; Cardiac output; Pulse contour analysis; Thermomilution technique

1. Introduction

Mechanical circulatory support has become an essential part of the treatment strategy for patients suffering acute, reversible ventricular dysfunction or end-stage heart failure. Nowadays, different types of device able to provide either pulsatile or continuous blood flow are available for clinical use, and their own specific indication mainly depends on the degree of support required, the estimated duration of assistance, the invasiveness of the implantation procedure and the patient’s need for postoperative mobility.

Irrespective of the type of ventricular assist device (VAD), cardiac output (CO) monitoring is a critical issue in patients implanted with a mechanical circulatory support since low-output syndrome with reduced organ perfusion still remains the main cause of death in such patients [1–3]. However, the hemodynamic changes subsequent to VAD implantation somehow limit the application of current methods for CO determination [4]. The thermomilution (ThD) technique employing a pulmonary artery catheter (PAC) is generally used to monitor CO and is considered to be the gold standard system in clinical practice [5].

Methods based on ‘cold’ pulmonary ThD (ThD-CO) as well as systems for continuous ‘hot’ ThD (ThD-CCO) are theoretically suitable in patients assisted with a left VAD (LVAD) but are unreliable techniques for patients on right VAD (RVAD) due to ‘cold or hot’ indicator loss bypassed by the pump from the right heart sections [6]. Similar limitations exist for systems based on transpulmonary ThD, which cannot be applied to any patient on mechanical circulatory support [RVAD, LVAD or biventricular assist devices (BiVAD)] since indicator loss would happen in both the right and left heart sections [7].

Various methods capable of deriving CO from the analysis of arterial pulse wave [pulse contour method (PCM)] are now available for clinical use [8]. These are low-invasive techniques and allow beat-by-beat CO determinations. Among those systems, an uncalibrated PCM named Pressure Recording Analytical Method (PRAM) has been recently developed and validated in humans, animals and patients assisted with axial flow pumps [9–12]. This new method does not require any ThD calibration and could be a reliable...
CO-monitoring technique applicable to either left, right or biventricular mechanical support.

The aim of this study is to assess the accuracy and reliability of the PRAM, compared with the continuous ThD-CCO technique, in monitoring the blood flow of patients supported with a pulsatile LVAD.

2. Materials and methods

2.1. Study design

Twelve patients assisted with the pulsatile mechanical circulatory support HeartMate-I XVE (HM-I; Thoratec Corporation, Pleasanton, CA, USA) were enrolled in the study. All patients gave written informed consent, and the Ethics Committee approved the study.

Diagnosis of heart failure was based on the patient’s medical history, current clinical signs (e.g. dyspnea, orthopnea, elevated jugular venous pressure), ultrasound and heart-invasive assessment findings. The demographic data and characteristics of the patients are described in Table 1.

2.2. Hemodynamic measurements

The patients were routinely monitored with a peripheral arterial catheter (radial artery) used for continuous invasive arterial blood pressure monitoring. In all patients, a PAC (Vigilance; Edwards, Irvine, CA, USA) was placed for the continuous ThD-CO evaluation. A transesophageal echocardiography probe was intraoperatively used to exclude the presence of a patent foramen ovale or aortic or tricuspid regurgitation, and to assess aortic valve movements after the beginning of pump assistance. The PRAM was connected to the analogic output of the main monitoring system, and blood pressure signals, derived from the radial artery (without any adjunctive vascular access), were used for non-invasive continuous recording of the arterial pressure waves and the subsequent CO computation. An in-depth explanation of the theory underlying the PRAM device can be found in previously published papers [9–13].

For each patient, three simultaneous CO determinations – HM-CO (values obtained from the HM-I console), ThD-CCO...

Table 1. Patients’ demographic data and characteristics

<table>
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<th>Height (cm)</th>
<th>BSA (cm²)</th>
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<td>64</td>
<td>165</td>
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<td>DCM</td>
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BSA, body surface area (Dubois formula); DCM, dilative cardiomyopathy; AMI, acute myocardial infarction; MYO, myocarditis.

Fig. 1. Schematic representation of Pressure Recording Analytical Method (PRAM). PRAM is connected to the analogic output of the standard monitoring system for the continuous non-invasive recording of the radial arterial pressure waves. The signals are acquired at 1000 Hz by means of an analogic–digital multifunction card (PCMCIA) and filtered at 25 Hz to avoid resonance effects caused by the catheter–transducer system without degrading the pressure wave amplitude. On a personal computer are displayed beat-by-beat PRAM-CO values (left-hand side) and radial pressure waves (right-hand side). The dotted lines under the pressure curve represent the exact identification of the dicrotic notches. CO, cardiac output.
and PRAM-CO – were twice recorded during the intensive care unit stay. The first CO evaluation was performed on the second postoperative day, and the second CO determination was recorded on the fourth postoperative day (before radial artery catheter or the PAC was removed). At the time of CO recording, the pump was operating in a fixed rate mode, and the heart was paced at 86 beats/min. In all cases, the patients remained hemodynamically stable with no or low-dose inotropic/vasoactive drugs. Simultaneous echocardiographic (transesophageal echocardiography or transthoracic echocardiography) evaluation was obtained in order to assess the opening of the aortic valve.

2.3. Statistical analysis

CO data from all patients were used to compute the mean and standard deviation (S.D.). Pearson’s correlation and the Bland–Altman method were used [14]. The bias (mean difference between the measurements) and the 95% limits of agreement (LoA; within which 95% of the differences will lie) of HM-CO compared with ThD-CCO and PRAM-CO were computed. The bias and 95% LoA of ThD-CCO compared with PRAM-CO were also computed. The percentage error was calculated as reported by Critchley and colleagues, as the LoA of the bias (2 S.D.) divided by the mean CO from the compared methods [15].

3. Results

A total of 72 paired data points (36 for each interval) were collected over a range of HM-CO values from 3.8 to 6.0 l/min. ThD-CCO ranged from 4.0 to 6.7 l/min, and PRAM-CO ranged from 4.3 to 6.6 l/min.

Both ThD-CCO and PRAM-CO values showed a relative overreading with respect to HM-CO. The mean bias between HM-CO and ThD-CCO was −0.40 l/min (precision ±0.64 l/min), with a 95% LoA result of −1.04 to +0.24. The mean bias between HM-CO and PRAM-CO was −0.44 l/min (precision ±0.76 l/min), and 95% LoA was −1.20 to +0.32. Mean bias between ThD-CCO and PRAM-CO was −0.04 l/min (precision ±0.38 l/min), with 95% LoA of −0.42 to +0.34. Mean CO values, biases and 95% LoAs, coefficient of correlation values and percentage of error values are presented in Table 2. Linear correlations and Bland–Altman analyses are shown in Figs. 2–4.

4. Discussion

Our findings showed that ThD-CCO and PRAM-CO estimations were well matched, whereas both techniques overestimated HM-CO values of approximately 400 ml/min. In fact, compared with LVAD-CO values, different biases of ThD-CCO overestimation of up to 500 ml/min have already been reported by other studies [5, 6]. In order to address these findings, some considerations about the hemodynamic changes occurring during LVAD assistance need to be taken into account.

Incomplete left ventricle (LV) unloading during mechanical circulatory support can occur as the result of an inadvertent and transient increase in preload (e.g. heart-lung interactions in patients who are mechanically ventilated) [2]. As a consequence, the native heart can unpredictably open the aortic valve and eject a variable
amount of blood into the ascending aorta. Furthermore, when the LVAD is set to operate in fixed-rate mode, independently of patient’s heart rate, such a discrepancy can itself determine the occurrence of residual effective LV contractions and stroke outputs that can contribute to ‘total’ CO (blood flow generated by the LVAD plus stroke volumes produced by the native heart).

Depending on the patient’s heart rate and the device’s stroke rate, arterial blood pressure waves related to ventricular ejection may coincide with LVAD arterial pulse waves (being unapparent) or may be variably interposed between the LVAD arterial pulse waves (Fig. 5).

A posteriori analysis by PRAM of those residual ventricular-related arterial pressure waves demonstrated that the native heart actually contributed an adjunctive stroke volume (SV) of approximately 10–20 ml at each systole (Fig. 6). Although they are associated with a relatively small amount of ejected blood, in one minute the number of these stroke volumes actually contributed an additional 400–600 ml of volume to the ‘total’ blood flow (i.e. approx. 10% of the ‘total’ PRAM- and ThD-estimated CO; Fig. 6). This occurrence may represent the main determinant of the presumed ThD-CCO and PRAM-CO overreading in respect to LVAD-CO.

The ThD technique measures the right heart CO (which is conditioned by the systemic venous return and by ‘total’ left CO), whereas PRAM derives it from an analysis of radial artery pulse waves. Thus, both ThD-CCO and PRAM-CO estimations could actually represent the true systemic blood flow resulting from the sum of two possible contributions (blood directly ejected into the aorta by the mechanical pump plus the unpredictable blood ejected through the aortic valve by the native LV).

Continuous ThD-CO can be a suitable technique for patients on LVAD but, due to the ‘indicator loss’ bypassed by the pump from the right heart sections, it is unreliable with RVAD. Likewise, PCMs based on transpulmonary ThD calibration bolus techniques (unless a modified set-up for calibration bolus is used for application during isolated RVAD) [7] cannot be applied in any patient on mechanical circulatory support. Conversely, as PRAM does not need any ThD bolus for external calibration [9], and does not experience the problems inherent in ThD, this new tool may provide reliable estimations of ‘total’ left CO during any kind of mechanical assistance (right, left or biventricular).

Owing to basic physiological principles, a limit of this device (as for all PCMs) resides in the fact that an arterial pulsatile pressure wave (i.e. pulse pressure) must be present for CO estimation. Thus, some issues about its reliability exist for non-pulsatile VADs [4], where incomplete LV unloading must occur to generate a pulse pressure sufficient to allow PRAM
to compute CO. With pulsatile VADs, an arterial pulsatility can be anyhow detected, independently of ventricular loading or unloading conditions, and consequently in the present study PRAM was able to analyse the arterial pressure wave morphology (either mechanical or physiological) and to compute CO values at different times.

5. Conclusions

The development of mechanical circulatory support technology is now moving from displacement pumps (pulsatile flow) to axial and centrifugal pumps (continuous flow). Although such devices still retain their usefulness and indications, our study aimed to assess one of the manifold applications of PRAM inherent to its physiological principle and characteristics because pulsatile assist devices perfectly fit the hemodynamic conditions necessary for pulse wave analysis.

Under the conditions studied, we demonstrated that this new uncalibrated PCM showed a good performance for CO assessment and good agreement with the reference monitoring technique. This method overcomes the limitations of either ThD techniques or transpulmonary ThD based-PCMs to estimate the ‘total’ systemic blood flow in patients assisted with a VAD. PRAM may represent an additional monitoring tool that can complement the hemodynamic evaluation of patients supported with mechanical circulatory support.

References

eComment: Hemodynamic monitoring with LiDCOplus system in the patients supported by isolated right ventricular assist device

Authors: Hynek Riha, Institute for Clinical and Experimental Medicine, Videnska 1988, 140 21 Prague, Czech Republic; Tomas Kotulak, Petr Syrovatka, Ivan Netuka
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We read with interest the paper by Scolletta et al. [1] dealing with continuous cardiac output (CO) monitoring during left ventricular assist device (LVAD) support. We would like to comment on the related problem of CO monitoring during isolated right ventricular assist device (RVAD) support.

As mentioned by Scolletta et al. [1], in the case of an implanted RVAD there is an inherent problem of blood bypassed by the RVAD from the right heart causing indicator loss. Since 2007 we have been successfully using a modified set-up of lithium bolus dilution for the calibration of a LiDCOplus hemodynamic monitor (LiDCO Ltd, Cambridge, UK) in patients supported by a Levitronix CentriMag (Levitronix GmbH, Zurich, Switzerland) ventricular assist system (magnetically levitated centrifugal pump) in the RVAD configuration (i.e. between the right atrium and pulmonary artery). The LiDCOplus monitor continuously (beat-by-beat) calculates CO by analysis of the arterial blood pressure waveform (arterial pulse power analysis) following calibration with lithium bolus dilution [2].

Briefly, just before lithium bolus administration to the central venous catheter, we increase the RVAD’s revolutions per minute (RPM) as much as possible to ensure that all the blood flows through the RVAD and, simultaneously, to avoid RVAD suction events. This is carried out under the control of transesophageal echocardiographic examination which confirms blood flow to the RVAD and excludes any intracardiac shunt. The increase in RPM before calibration causes streamlined blood flow from the right atrium to the RVAD, excluding blood leakage through the native right ventricle. As a result, the dilution curve of lithium concentration over time is of standard shape (CO value for subsequent calibration is calculated from the amount of administered lithium and the area of the primary dilution curve, representing CO before lithium recirculation).

In our experience, this approach to the calibration of the LiDCOplus monitor provides accurate measurement of the left heart CO. The calibration procedure is very important to ensure accurate CO readings because it has been documented that uncalibrated measurements with pulse power analysis in cardiac surgical patients are not reliable [3]. Continuous CO monitoring is extremely useful, especially during RVAD weaning. In this case, the left heart CO is conditioned by two variables: RVAD output (measured directly and displayed on the CentriMag’s console) and the output of the native right ventricle. Decreasing the RVAD’s RPM during weaning causes the increase in the amount of blood pumped to the pulmonary circulation by the right ventricle. The titration of pharmacological support (i.e. inotropes, selective pulmonary vasodilators, etc.) for the native right ventricle is thus much easier with beat-by-beat values of the left heart CO determined by the LiDCOplus monitor.

In conclusion, we described a modified sequence of LiDCOplus hemodynamic monitor calibration by lithium bolus dilution in patients with an implanted Levitronix CentriMag RVAD. The procedure can be attached to other modified set-ups for calibration bolus which were documented in the patients supported by isolated RVAD [4].

References