Evaluation of a Noninvasive System for Determining Left Ventricular Filling Pressure

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Background: Measurement of left ventricular filling pressure (LVFP) provides an accurate assessment of left ventricular failure. Clinical and radiographic methods of estimating LVFP are unreliable. The noninvasive method of analyzing the decline in the arterial pressure during the strain phase of the Valsalva maneuver may be used to directly measure LVFP.

Objective: To examine the relationship and the level of accuracy of a noninvasive system (VeriCor) in directly determining left ventricular end diastolic pressure (LVEDP) using simultaneously recorded VeriCor and LVEDP measurements obtained during left heart catheterization.

Methods: During elective right and left heart catheterization, LVFP was assessed by measuring pulmonary capillary wedge pressure (PCWP) and LVEDP in 57 patients followed immediately by a Valsalva maneuver using the VeriCor assembly to estimate these pressures noninvasively.

Results: VeriCor measurements had a significant correlation with the catheter-measured LVEDP ($r=0.86$), comparable to the correlation of the catheter-measured PCWP with LVEDP ($r=0.81$). The predictive accuracy of VeriCor for LVEDP, however, appeared to be superior to that of catheter-measured PCWP for LVEDP: 84% of VeriCor measurements compared with only 41% of PCWP measurements were within 4 mm Hg of catheter-measured LVEDP, and 93% of VeriCor measurements compared with only 67% of PCWP measurements were within 6 mm Hg of catheter-measured LVEDP.

Conclusion: VeriCor is a reliable noninvasive tool for measuring LVFP.

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Measurement of left ventricular filling pressure (LVFP) allows detection of congestive heart failure (CHF) and helps assessment of the efficacy of therapy for CHF. Left ventricular filling pressure can be measured directly by placing a catheter in the left ventricle to obtain the end diastolic pressure (LVEDP) or indirectly by placing a catheter in the pulmonary artery to measure the pulmonary capillary wedge pressure (PCWP). Both of these invasive techniques involve cardiac catheterization with its attendant risks and expense. Clinical and radiographic methods of detecting CHF, however, are insensitive to alterations in LVFP and, hence, unreliable. A reliable noninvasive method of estimating LVFP would, therefore, be a useful tool in the detection and management of patients with CHF, since early detection and treatment of CHF have been shown to reduce the rate of hospitalization and mortality.

The noninvasive method of assessing PCWP by using the strain phase of the Valsalva maneuver has been found to be practical and promising. Preliminary studies using technology (VeriCor; CVP Diagnostics Inc, Boston, Mass) that calibrated the response to the Valsalva maneuver showed that PCWP could be predicted with a clinically useful degree of accuracy. Analysis of the mechanism by which PCWP was estimated by the calibrated Valsalva response suggested that the arterial pressure during the strain phase of the Valsalva maneuver may directly reflect the LVEDP. This is a report of a prospective study designed to examine the relationship and the level of accuracy of VeriCor in directly determining LVEDP using simultaneously recorded VeriCor and LVEDP measurements obtained during left heart catheterization. Right heart catheterization for PCWP was also performed to provide comparisons with this measurement.

Materials and Methods

Studies performed in 57 patients scheduled for elective cardiac catheterization in 2 hospitals (Veterans Affairs Medical Center, West Rox...
bury, Mass, and Maine Medical Center, Portland) form the basis of this report. Fifty-five patients were men and 2 were women, ranging in age from 40 to 82 years (mean, 62.6 years) Fifty-six patients had coronary artery disease and 1 patient had hypertension. Patients with significant aortic stenosis, mitral stenosis, uncontrolled hypertension, or arrhythmias were excluded from the study. The research protocol was approved by the institutional review board at both hospitals. After informed consent was obtained, all patients received training in the performance of the Valsalva maneuver and underwent right and left heart catheterization in the supine position. The PCWP was measured with a 7F, double-lumen, balloon-tipped catheter (Swan-Arrow or Swan-Abbott) after the wedge position was noted on fluoroscopy and confirmed by the waveform. When there was doubt, a blood sample was drawn from the wedge position to confirm arterial saturation. Pressures from the left ventricle were obtained with a 6F (Cordis-angled pigtail) catheter. Simultaneous records of the PCWP and the LVEDP were made on a 0- to 40 scale during at least 3 respiratory cycles. All pressures were measured with the transducer set at the midchest level. Hemodynamic measurements were followed immediately by the Valsalva maneuver to obtain the noninvasive measurement with the VeriCor system.

NONINVASIVE METHOD

Arterial pressure response to the Valsalva maneuver generally shows 4 distinct phases. In phase 1, the arterial pressure rises as a result of the transmission of increased intrathoracic pressure; in phase 2, systolic, diastolic, and pulse pressures are reduced as a result of decreased venous return with continuing strain; in phase 3, a sudden drop in arterial pressure occurs with release of strain; and in phase 4, the arterial pressure overshoots to levels above baseline, with a widened pulse pressure. The arterial pressure changes during the Valsalva maneuver are recorded by the VeriCor system (Figure 1).

Details of validation of the VeriCor method have been previously described. In brief, the VeriCor system uses a noninvasive blood pressure tonometer applied over the radial artery and a digital pulmonary manometer for the continuous acquisition of arterial and expiratory pressure signals during strain. The digital signals are collected and stored on a medical grade computer. The device acquires and analyzes radial arterial tonometric data during and after a period of continuously monitored expiratory strain (Valsalva maneuver).

From the arterial pressure signals during the strain phase, a range of predictive algorithms was developed by calibration of the various changes in the arterial pressure response to the Valsalva maneuver. These changes include the rate of decline of pulse pressure, the rate of change of the slope of the systolic pressure, rate of change of the dP/dt of the upstroke of the arterial pressure, and the ratio of the terminal to the initial amplitude of the strain-phase beats expressed as the pulse-amplitude ratio (Figure 1). A comprehensive analysis of the algorithms was performed by proprietary software (a customized version of LabVIEW systems; National Instruments Corp, Austin, Tex). Those algorithms that were most accurately predictive of PCWP and LVEDP were then applied and validated in new data sets as additional data sets were developed. The VeriCor device is mounted on a mobile cart powered by either a self-contained battery pack or an external power source, allowing testing to be done at the bedside or in any clinical setting.

The Valsalva maneuver was performed immediately after the recording of the invasive PCWP and LVEDP. After a normal inspiration, the patient was asked to exhale with enough force to raise a marker on the computer monitor to at least 20 mm Hg (range, 20-35 mm Hg). The strain was maintained for 8 to 12 seconds. A printout displaying the expiratory pressure, the arterial pressure, and the pulse-amplitude ratio during the early strain phase and the computed PCWP and LVEDP was obtained at the end of the maneuver.

Hemodynamic measurements of PCWP and LVEDP were repeated in 8 patients along with the VeriCor measurements to verify the reproducibility of the results. As mentioned before, hemodynamic measurements always preceded the VeriCor measurements to obviate the effect of the Valsalva maneuver on the hemodynamic measurement.

ANALYSIS OF THE DATA

Invasive measurements of the PCWP and LVEDP were made by an experienced cardiologist (G.V.R.K.S.) who was blinded to the results of the VeriCor measurement. For PCWP, the mean end expiratory value during at least 3 respiratory cycles was measured. For LVEDP, the post “a” value was measured. Computer estimates of the pulse-amplitude ratios of the strain phase during the Valsalva maneuver were checked by a physician experienced in reading the tracings and who was blinded to the invasive measurements (K.M.M.).

Standard least-squares linear regression analysis was used to examine the correlation between the VeriCor measurements of PCWP and LVEDP and the invasive PCWP and LVEDP measurements. For computation of correlations in the paired data, the nonparametric correlation coefficient p statistic was used because of the small sample size.

PREDICTIVE ACCURACY OF VERICOR

With the invasive LVEDP measurement as the “gold standard,” predictive accuracy of VeriCor was expressed as the num-
ber of VeriCor measurements that corresponded with invasive measurements of LVEDP within a 4.0- to 7.0-mm Hg range. A similar approach was used for determining the predictive accuracy of VeriCor for the PCWP (ie, the number of VeriCor measurements that corresponded with the invasive PCWP measurements within a 4.0- to 7.0-mm Hg range).

RESULTS

Of the 57 patients who underwent cardiac catheterization and VeriCor testing, the results had to be discarded in 8 patients because of ectopy during the Valsalva maneuver that rendered the analysis of the pulse-amplitude ratio difficult. Of the remaining 49 patients, 46 had simultaneous measurements of LVEDP and PCWP with VeriCor and 3 patients had only LVEDP with VeriCor (without PCWP). Eight patients with LVEDP and PCWP had duplicate studies, bringing the total number of LVEDP measurements to 57 and the PCWP measurements to 54.

The average time taken for setting up the VeriCor equipment and performance of the test was about 15 minutes. The time that elapsed between the recording of the hemodynamic measurements and the VeriCor measurement was 2 to 4 minutes. There were no complications during the study.

COMPARISON OF VERICOR MEASUREMENTS AND CATHETER-MEASURED LVEDP

VeriCor measurements correlate well \( r = 0.86 \) with the LVEDP (Figure 2). The following are the VeriCor measurements that correspond with the catheter-measured LVEDP values in the 4.0- to 7.0-mm Hg range (n=57).

<table>
<thead>
<tr>
<th>VeriCor-LVEDP Difference, mm Hg</th>
<th>Corresponding VeriCor Measurements, No. (%)</th>
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<tbody>
<tr>
<td>&lt;4.0</td>
<td>48 (84)</td>
</tr>
<tr>
<td>&lt;5.0</td>
<td>50 (88)</td>
</tr>
<tr>
<td>&lt;6.0</td>
<td>53 (93)</td>
</tr>
<tr>
<td>&lt;7.0</td>
<td>56 (98)</td>
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COMPARISON OF CATHETER-MEASURED PCWP AND CATHETER-MEASURED LVEDP

Correlation of the PCWP measurements with the LVEDP is shown in Figure 3. There was a good correlation of PCWP with LVEDP \( r = 0.81 \). Figure 4 shows a simultaneous display of the correlation of catheter LVEDP with VeriCor and the pulmonary artery catheter. VeriCor-determined LVEDP appears to have a better correlation \( r = 0.86 \) than that of the pulmonary artery catheter \( r = 0.74 \).

The following are the catheter-measured PCWP measurements that correspond to the catheter-measured LVEDP values (n=54). The predictive accuracy of the PCWP for estimating the LVEDP appears to be significantly less (4.0 mm Hg: 41%; 7.0 mm Hg: 83%) than that of VeriCor for estimating the LVEDP (4.0 mm Hg: 84%; 7.0 mm Hg: 98%).

COMPARISON OF VERICOR MEASUREMENTS AND CATHETER-MEASURED PCWP MEASUREMENTS

There was a good correlation between the VeriCor measurements and the PCWP measurements (Figure 5.
The following are the VeriCor measurements that corresponded to the catheter-measured PCWP measurements in the 4.0- to 7.0-mm Hg range (n=54).

<table>
<thead>
<tr>
<th>VeriCor-PCWP Difference, mm Hg</th>
<th>Corresponding VeriCor Measurements, No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;4.0</td>
<td>41 (76)</td>
</tr>
<tr>
<td>&lt;5.0</td>
<td>47 (87)</td>
</tr>
<tr>
<td>&lt;6.0</td>
<td>52 (96)</td>
</tr>
<tr>
<td>&lt;7.0</td>
<td>54 (100)</td>
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</table>

Correlations between the noninvasive and invasive measurements in 8 patients (n=16) yielded correlation coefficients of 0.89 for VeriCor vs catheter LVEDP and 0.73 for VeriCor vs catheter PCWP, indicating good reproducibility.

**COMMENT**

Although the "gold standard" for the LVFP is the LVEDP, because of the invasiveness and risks of left ventricular catheterization, the pulmonary artery catheter and the PCWP measurement have been in widespread use to estimate the LVFP. However, as pointed out by Rapaport and Dexter, PCWP is an approximation of the true pulmonary capillary pressure and only an indirect estimate of the LVEDP.

Previous attempts at quantification and correlation of the change in the arterial pressure during the strain phase of the Valsalva maneuver used PCWP as an index of left ventricular function. We believe that the slope of the arterial pressure during the strain phase is largely determined by the rate at which the left ventricle depletes the "fixed" blood volume sequestered in the lungs, the beat-to-beat change in the stroke volume and pulse pressure being a function primarily of a progressive decrease in left ventricular filling. A decline in slope with a tendency toward a square wave pattern of the arterial pressure during the strain phase, therefore, is associated with a progressive increase in LVEDP.

For this reason, we hypothesized that the relationship previously observed between the PCWP and the Valsalva response was primarily determined by LVEDP and secondarily determined by factors that influenced the column of blood between the left ventricle and the PCWP catheter. Thus, the arterial pressure slope of the early strain phase of the Valsalva maneuver would likely correlate well with the catheter estimate of both the LVEDP and the PCWP. However, between the VeriCor determinations of the LVEDP and the PCWP, the LVEDP should be considered as a critical contributor to left ventricular filling because it is the final determinant of the left ventricular end diastolic volume and the resultant stroke volume during the strain phase of the Valsalva maneuver.

The method and validation of the VeriCor System in the recording of the peripheral arterial pressure during the Valsalva maneuver have been previously described in detail by our group. Although peripheral arterial pressure waveforms have been known to differ significantly from central aortic pressures because of reflected waves and vascular impedance, using tonometry, O’Rourke et al have shown that noninvasively recorded peripheral arterial pressure waveforms are similar to those in the ascending aorta. The radial tonometry used by us used the same technology and transfer function used by Chen et al to reconstruct the central aortic waveforms from tonometric radial waveforms with clinically acceptable accuracy for systolic and pulse pressure.

The results of our study (Figures 2 and 5) show that VeriCor accurately measures the 2 important components of the left ventricular filling pressure, the LVEDP and the PCWP (r=0.86) and the PCWP (r=0.81), within a clinically acceptable range of variability. Between these 2 indices, VeriCor appears to have superior predictive accuracy for the LVEDP (Figure 4), supporting our hypothesis that VeriCor may sense the LVEDP directly and that the arterial pressure response during the strain phase of the Valsalva maneuver may be primarily determined by the LVEDP. VeriCor thus appears to be a valuable noninvasive tool in the determination of the LVEDP.

Considering the multiple physical, vasomotor, and neurohumoral mechanisms that govern the Valsalva maneuver, the VeriCor method, which is based on the arterial pressure response during the early strain phase, appears to be a fairly robust and reproducible index of the LVEDP, as also substantiated by the analysis of paired data in our study. Its apparent ability to directly sense the LVEDP perhaps renders it relatively immune to the influence of intrathoracic and intra-alveolar pressures that can interrupt the continuity of the column of blood between the pulmonary artery catheter and the left ventricle and falsify PCWP as an approximation of LVEDP.

In contrast to the reported insertion time and complications of the pulmonary artery catheter, the VeriCor method is quick and safe even in critically ill patients. Advantages to obtaining VeriCor LVEDP measurements in preference to catheter-measured PCWP also stem from the fact that major errors can be committed in the technique of obtaining and reading PCWP measurements by the pulmonary artery catheter. VeriCor technology thus facilitates immediate reading and display of the 2 components of LVFP (ie, PCWP and LVEDP) on the monitor screen soon after the comple-
tion of the test, eliminating errors in calculation and interpretation. Although the VeriCor test is noninvasive and safe and can be repeated as needed, there are important limitations. In patients with atrial fibrillation or frequent atrial or ventricular ectopy, there may be significant beat-to-beat variation in the arterial pressure pulse, which renders analysis of the slope difficult and erroneous. Patients with arrhythmias were, therefore, excluded from our study. Patients also need to maintain uniform strain at the desired level (20-35 mm Hg) during the Valsalva maneuver, if reliable results are to be obtained. Erratic initial strain (“spikes”) can transiently increase arterial pressure and alter the computation of the pulse amplitude ratio. Training of the patients helps in this regard.

Despite these limitations, VeriCor measurement of LVFP may prove to be a useful adjunct in the diagnosis and management of CHF, particularly in those clinical situations where repeated invasive measurements are impractical because of the time, safety, and cost considerations. Its advantages over the pulmonary artery catheter make it an attractive device for the screening and follow-up of patients in the office setting.

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REFERENCES