AMERICAN COLLEGE OF RADIOLOGY IMAGING NETWORK

ACRIN PA 4008

Arterial Stiffness and Wave Reflections as Determinants of Regression of Left Ventricular Hypertrophy and Fibrosis Assessed with Cardiac MRI After Aortic Valve Replacement for Severe Aortic Stenosis

Standard Operating Procedure for Arterial Tonometry

Introduction and Explanation

Pulse wave analysis (PWA) is a technique in which the arterial pressure wave form is analyzed to measure a number of physiologic parameters that are relevant for our study population.

This measurement takes a tracing of the radial pulse in the wrist and converts it into what that pulse would look like in the aorta, shortly after leaving the heart. In a second measurement, we obtain a tracing from the carotid artery, which may be a more direct estimation of the pressures in the aorta. From the shape of this aortic tracing combined with the aortic flow measured with phase-contrast MRI, we can measure left ventricular afterload accurately.

Because the arterial tonometry data need to be combined with MRI data flow, it is essential that phase-contrast (flow) data be acquired as the last step of the MRI protocol and that arterial tonometry be performed immediately after the cardiac MRI in the supine position but outside the magnet. Because the tonometry equipment is not MRI-compatible, this procedure cannot be done inside the scanner itself. An MRI-compatible stretcher should be used to transport the patient from the MRI scanner to a suitable location for tonometry measurements, in order to minimize orthostatic hemodynamic responses between the acquisition of flow data and the acquisition of tonometry data.
Procedure for Performing PWA Measurements

**Software setup:** the Sphygmocor software should be installed in the computer. It is preferable to use windows XP, but the software also works well with Windows Vista Professional. If you are using windows Vista, additional steps should be taken to modify the settings in order for the software to run and backup the data properly (see attached document). These modifications only have to be done only once, immediately after installing the Sphygmocor software. Note that in addition to the Sphygmocor software, the driver for the USB adaptor should be installed in the computer. This driver should be included in the Sphygmocor software CD.

**Patient positioning:** Have the patient lying supine without any pillows.

**Hardware setup:** Connect the Sphygmocor device to the computer via the USB adaptor. Connect the power cord to the computer laptop. Connect the power cord to the Sphygmocor device. Boot up the laptop completely. Turn the Sphygmocor device console on by flipping the power switch on the back of the console. Only once the Sphygmocor is turned on and connected to the computer, open the Sphygmocor software. Select the “patient” button on the upper row of buttons.
Select the “create new” button from the row of buttons in upper right of the screen. Confirm a new patient input by clicking “Yes”.

Enter the patient ID information as follows:
- Patient ID: Enter the patient’s study unique ID number.
- Last Name: Enter the initial for the patient’s last name
- First Name: Enter the initial for the patient’s first name
- Code: Enter the appropriate site code for your study site.
- Date of Birth: Click on the patient’s year of birth and enter the patient’s year of birth, leaving date as January 1 for all patients (date of birth is an identifier and we need the tonometry data to be de-identified).
- Sex: Select patient’s sex.
- Leave other fields blank (you do not have to enter weight or height).

Select the “Update” button in upper right corner of screen. When Prompted:

“Would you like to accept the changes made to the Patient Data?”
Select “Yes”.
Radial Tonometry

Select the “Patient” button in the upper row of buttons on the screen. Confirm that “PWA” (pulse wave analysis) is selected on the top left column of buttons: If “PWV” rather than “PWA” is selected, click the “PWA” button as shown above to make sure it is selected.
Select the “Study” button in upper left corner of screen.

You will see a different screen, like the one shown below. Obtain systolic and diastolic blood pressure measurements using a well-validated oscillometric device (i.e., Omron HEM-907 device). Use those numbers to compute the mean arterial pressure as follows: MAP = DBP + 0.4 (SBP-DBP). Fill in the values in the sphygmocor software for diastolic blood pressure and mean pressure. Leave the “Systolic pressure” box empty. However, make sure to annotate the systolic pressure in the Notes box as shown below (example: “SBP: 126”). Only diastolic blood pressure and mean arterial pressure will be used to calibrate the pressure waveform.
Please also annotate which radial artery you are performing the procedure on (left versus right), because follow-up tonometry procedures will have to be done on the same side.

Leave the height, weight, and medication boxes blank.

Also enter your initials under “Operator”.

Make sure that the “Enable Output” box is not checked.
Select the checkbox for “radial” artery.

Select the “capture data” button on the upper right corner of the screen.
As a first choice, palpate the right radial pulse and place the tonometer directly above the patient’s radial pulse, perpendicular to the patient’s skin using light pressure. Be sure to remove the plastic cover from the tonometer tip.

Assess whether the software is capturing the patient’s radial pulse tracing by watching the computer monitor. When approximately 10 seconds (2 screens) of “clean” data (a clear, reproducible signal) have been recorded on the computer screen that represents a plausible radial pulse tracing, press the space bar on the computer to capture the data. Please note that the software actually discards the last 2 seconds worth of data, which effectively gives you 2 seconds to stop holding the tonometer and press the spacebar. Once you press the spacebar, the software will switch to a results display screen and the composite tracings, data values, and actual tracings will be visible on the screen.

Repeat the data collection steps, if necessary, until one or less of the four numbers in the “quality control” column to the right of the tracing is red. All green and white numbers is optimal. Below is an example is which too many numbers (2) are red. In addition, watch the value of the operator index. A value of 100 is optimal, and we should make all attempts to get values above 90 for radial tonometry.
If a study is clearly non-physiologic or does not meet our quality requirements, please delete the study by clicking on the “delete” button on the upper right of the screen after highlighting the offending study in the left column.
Carotid Tonometry

Repeat the procedure exactly as for radial tonometry, but acquire the carotid signal instead:
Select the “Patient” button in the upper row of buttons on the screen:

Confirm that “PWA” (pulse wave analysis) is selected on the top left column of buttons. If “PWV” is selected, click on it and select “PWA”.
Select the “Study” button in upper left corner of screen.

You will probably see that the radial checkbox is checked. Since you are now about to perform carotid tonometry, you will need to change this setting by double clicking on the heart, as indicated by the long arrow below.
At this point you will be prompted with the following message: “Do you really want to enable the aortic (no processing) capability to process this study with?”. Click “Yes”. At this point the “Aortic” checkbox will be enabled and checked.
Enter the values for diastolic blood pressure and mean arterial pressure in the appropriate fields to calibrate the waveform. Leave the systolic blood pressure blank, but type the systolic blood pressure in the “notes” field (e.g: “SBP 123”). Similarly, annotate the side in which you will perform the carotid tonometry. Only diastolic blood pressure and mean arterial pressure will be used to calibrate the pressure waveform. Leave the height, weight, and medication boxes blank.

Select the “capture data” button on the upper right corner of the screen. Make sure that the “Enable Output” box is not checked.

Palpate the right carotid pulse as a first choice and place the tonometer directly above the patient’s carotid pulse, perpendicular to the patient’s skin, using light pressure. It may help to have the patient turn their head to the left slightly to make the carotid pulse more accessible. It may also help to place a rolled towel under the neck to extend the neck as much as possible. This maneuver helps bring the carotid arteries anteriorly, towards the front of the neck.

Assess whether the software is capturing the patient’s carotid pulse tracing. When approximately 10 seconds of data have been recorded on the computer screen that represents a plausible carotid pulse tracing timed with the ECG, press the spacebar key on the computer to capture the data.
Carotid-Femoral Pulse Wave Velocity

On the patient screen, click on PWV (left menu) and then click on “Study” (top menu). The screen shown below will appear. Enter values for mean pressure, diastolic pressure, distal and proximal distances. Palpate the right carotid pulse. Using a measuring tape, measure the distance to the nearest millimeter from right carotid pulse to the midline point of the suprasternal notch. Record this value as the “proximal” distance. Palpate the right femoral pulse. Using a measuring tape, measure the distance to the nearest millimeter from the femoral pulse directly to the umbilicus and continue to the midline point of the suprasternal notch. Record this value as the “distal” distance. Leave “Height” and “Weight” blank.
Select the “capture data” button on the upper right corner of the screen. An ECG tracing should be scrolling across the computer monitor with a net positive QRS complex. Palpate the patient’s right carotid pulse and place the tonometer directly above the patient’s carotid pulse, perpendicular to the patient’s skin, using light pressure. It may help to have the patient turn their head to the left slightly to make the carotid pulse more accessible.

Assess whether the software is capturing the patient’s carotid pulse tracing. When approximately 10 seconds of data have been recorded on the computer screen that represents a plausible carotid pulse tracing timed with the ECG, step on the foot pedal or press the spacebar key on the computer to capture the data.

While collecting data, the yellow tracing represents the patient’s real time ECG and the white line represents the pressure values from the tonometer. If the pressure tracing is off the top of the screen when the scale on the left of the screen shows 4000, less pressure should be applied to the tonometer. Similarly, if the pressure tracing is a flat line at the bottom of the computer display below 50, more pressure should be applied to the tonometer.

A message box from the software will pop-up that alerts the technician that the software has correctly captured a tracing from the carotid pulse which the software will call “site A”. Press enter to begin capturing femoral pulse information.

Palpate the patient’s right femoral pulse and place the tonometer directly above the patient’s femoral pulse, perpendicular to the patient’s skin, using light pressure.

Assess whether the software is capturing the patient’s carotid pulse tracing. When approximately 10 seconds of data have been recorded on the computer screen that represents a plausible carotid pulse tracing timed with the ECG, press the space bar on the computer to capture the data.

The PWV will be calculated and displayed in the lower right corner of the computer monitor on the results page. The standard deviation of the measurement should represent less than 15% of the magnitude of the measurement. If the standard deviation is larger than that, re-measure the patient’s proximal and distal distances and re-record the carotid and femoral tracings. The two values for the standard deviation of the time measurements for both carotid and femoral tracings should be less than 10% of the magnitude of the mean time measurements. If not, re-measure and attempt to ascertain more reproducible values.
Post Measurement

At any time after measurement, you can correct any mistakes you may have made when entering the data by clicking on the “Modify” button in the report screen (the study that you plan to correct should be highlighted on the left column)

When you click on “Modify” you will see a screen that allows you to change the artery selected, the notes and the BP values. For instance, if you initially planned to do the tonometry on the right side but you ended up choosing the left side because this side resulted in a better quality tracing, simply modify the “Notes” box. After you have corrected the data, click on “Modify” as shown below and accept the changes.
Exporting individual studies: export both measurements (carotid and radial) to a text file for further analyses that will be performed using separate software. In order to do this, click on “Report” from the group of buttons on the top left of the main SphygmoCor screen. Then select the study to export (if there are more than one study from the same visit, choose the one with the best quality). This is represented by the green arrows in the figure below. Then, click the little down-arrow that is located to the right of the “Export” button on the top right of the screen (red arrow in figure below). It is important that you click the arrow rather than the “Export” button itself.

When you click the arrow, you will see a pop-up menu with 2 options: “As text” or “As Graphic”. Select “As Text”. You will then see a new window menu that allows you to select the name and folder location of the exported file. Click on the “Select” button:
You will be prompted to select the folder and filename where the study will be saved. Save all files under a folder called “ACRIN AS data” which should be created in a location of your choice (such as C:\). After clicking on the Select button as above, direct the folder browser to the “ACRIN AS data” folder and type a name for the file. **Name the files according to the subject ID, the artery studied and time of measurement** (example: 008_Radial_V1.txt for subject ID 8, radial tracing from visit one). Other examples are 007_PWV_V1.txt for subject ID 7, pulse wave velocity for visit 1 or 009_Carotid_V1.txt for subject ID 9, carotid tracing from visit 1.

After trying the file name click on the “Export” button. **If you have exported the tracing successfully, you should be able to see a new txt file in the “ACRIN AS” folder** (green arrow in figure below). If you double click on the file, you will see that it is a textfile that contains many numerical values (red arrow):

![Image](image.png)

Whereas you are welcome to open this file, please **DO NOT MODIFY THE TEXTFILE**.

Perform this export process for the carotid, radial and PWV tracing for each visit.

**IMPORTANT: THE CONTENTS OF THE “ACRIN AS DATA” FOLDER SHOULD BE BACKED UP REGULARLY TO PROTECT US AGAINST DATA LOSS.**

**DO NOT UPGRADE THE SPHYGMOCOR SOFTWARE ONCE THE STUDY HAS STARTED, SINCE THE FORMAT OF THE EXPORTED TEXT FILE CHANGES WITH EACH VERSION OF THE SOFTWARE, AND THIS MAY CREATE ERROR IN SUBSEQUENT PROCESSING OF THE TEXT FILES.**
**Turning Off the Device**

Turn off the Sphygmocor device by flipping the power switch on the back of the device.

Quit the Sphygmocor software package on the computer. **Be sure to exit the Sphygmocor program before disconnecting the USB cable from the laptop.** If you disconnect the Sphygmocor device from the laptop prior to exiting the software, the computer may crash.

Once the software has closed, disconnect the device from the laptop.

In addition to backing up individual text files as above, the entire Sphygmocor database should be backed up on a separate computer from the study laptop by copying the entire “data” subdirectory located in “C:Program Files\AtCor\SphygmoCor CvMS\”. This directory contains a file names SCOR.mdb or SCOR.xyz (depending on your version of the software), which contains all previously acquired tonometry data.
Sample Description of Tonometry Studies for Participants

“The next test will attempt to measure the stiffness of your blood vessels. This test measures the pressures in the arteries close to your heart with a technique called “pulse wave analysis (PWA)”. We will do this non-invasively by attempting to take pictures of your pulse in 2 different locations using a pencil-like wand with a pressure-sensing tip on its end. This wand is placed over your skin above locations where a pulse can be felt (wrist, neck, groin).

Important Note: Emphasize to each patient that understanding the significance of these data is the ultimate goal of this research. These measurements will not aid in their clinical care. We will be in a much better position to know what any individual subjects’ values mean (and importantly, in the future, how they may be treated) after several years of research.
Quality Control / Quality Assurance Plan

**Initial Training/Certification:**

Initial training and certification would include:
1. Protocol review by the site
2. Performance of 3 independent measurements on standard subject(s) during a training session (not a study subject) with operator quality indices >85 for radial tonometry and >70 for carotid tonometry.

**Adequacy of Individual Studies:**

Each site will be primarily responsible for the local data quality. A good indicator of acceptable quality is that in the pulse wave analysis mode, tonometry values such that at least 3 of 4 quality control indices must be green (rather than red) for a study to be considered adequate. We will also look at the operator indices.

The core lab will also monitor study adequacy regularly. We will assess the adequacy of studies by evaluating quality control indices built into the Sphygmocor software and visual assessments of the waveforms. The SCOR.xyz files (or SCOR.mdb file, depending on your software version) and the individual exported txt files should be uploaded at regular intervals to an ACRIN secure server for review and quality control by the study team.

Operators with deficient studies on regular reviews must be re-certified on standard subjects before continuing enrollment.