Clinical Evaluation Guide of the Arteriograph Measured Arterial Function Parameters

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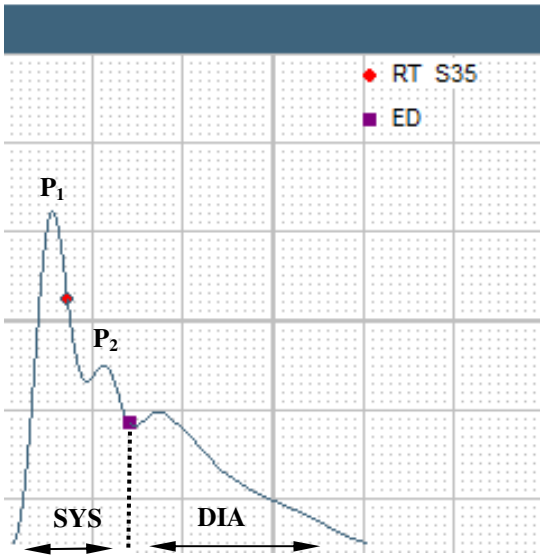


Suprasystolically recorded arterial (brachial) pressure curve during complete occlusion of the brachial artery (stop flow condition)

P_1 = forward (direct) systolic wave

P_2 = backward (reflected) systolic wave

Sys = systole
Dia = diastole
■ = dicrotic notch
(closing of the aortic valve)

Note that the systolic waves are clearly separated and recognizable!

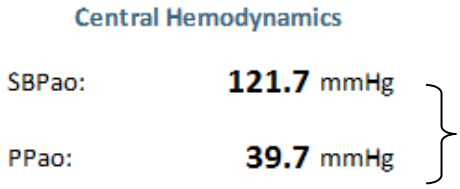
Suprasystolic record

Brachial Blood Pressure and Pulse Wave Analysis

Sys:	**133** mmHg
Dia:	**82** mmHg
PP:	**51** mmHg
MAP:	**99** mmHg
HR:	**75** /min
Aix brachial:	**-46.2** % →

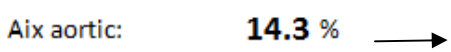
Peripheral (brachial) office blood pressure and heart rate
Evaluation = according to the relevant guidelines (NICE, ESH)

Brachial Augmentation Index strictly correlates (r = 0.94) with the aortic Aix, therefore it is as informative as the aortic Aix. However **we do not take it into account during the evaluation** due to conventional reasons, as the aortic Aix is used to being assessed in the scientific literature.



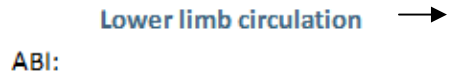
Central (aortic) systolic BP and pulse pressure

Evaluation:
The central (aortic) systolic BP (SBPao) is in **normal** range if it is **less then 140 mmHg**
The central (aortic) pulse pressure (PPao) is in **normal** range if it is **less than 50 mmHg**



Central (aortic) Augmentation Index

Evaluation:
The central (aortic) Augmentation Index (Aixao) is in **normal** range if it is **less than 33%**



Ankle - Brachial Index (ABI)

This is an optional measure of the device

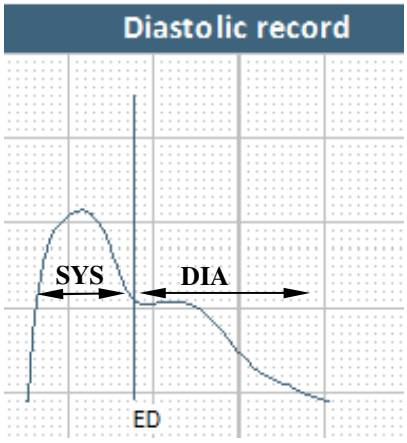
Evaluation:
According to the relevant guidelines

Ejection Duration (ED)

This is the time of mechanical systole, i.e. the time of the ejection of the blood into the aorta

Evaluation:
Nowadays this parameter has less clinical importance due to the generally used ultrasound assessment of ejection fraction.

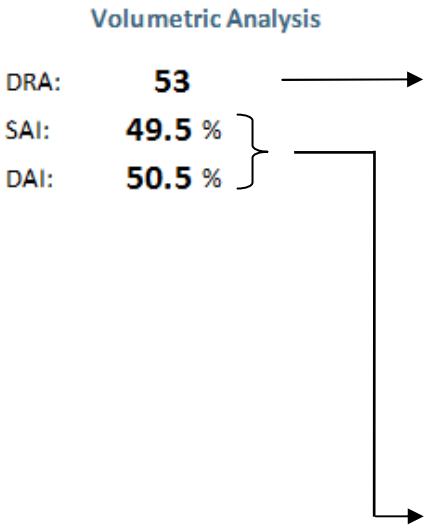
The normal values of ED are available in the paper by Weissler et al. (J Appl Physiol 18(5) 919-923; 1963.



Diastolic recording of pulse curve

This is a volumetric curve, recorded at diastolic pressure of the cuff, when **flow is maintained during the whole cardiac cycle**. In this situation marked diameter changes of the brachial artery can be seen – this is the reason why we call it volume curve, because the whole length (volume) of the brachial artery (covered by the cuff) contributes to the genesis of the signal.

Note that within systole no separated systolic waves (forward and backward) can be recognized!

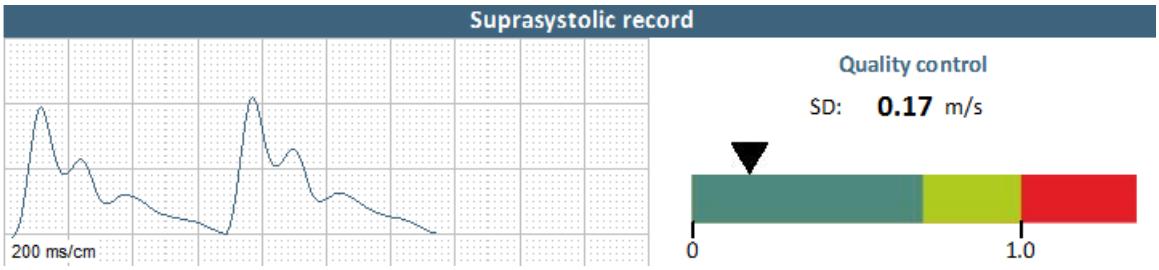


Diastolic reflection area (DRA)

Complex parameter, describes the diastolic wave reflection intensity and the duration of diastole. It is related to the diastolic filling conditions of the left coronary artery, which is mainly perfused during diastole.

Evaluation:
The diastolic reflection area is in **normal** range if it is **more than 40%**

From physiological point of view the longer the diastole the better the left coronary perfusion, consequently if the DAI is above 50%, it is beneficial.



Quality control

The quality indicator analyses the beat-to-beat measured aortic PWV values (collected within 8 seconds) and expresses their standard deviation (SD).

The standard deviation (SD) should preferably be kept in the green range (within 0.7 m/s) and could not exceed 1.0 m/s. If the SD is higher than 1.0 m/s the results of the analysis need to be rejected and the recording has to be repeated.

Pulse Wave Velocity measurement			
PWV:	**8.2** m/s	RT:	**129** ms

Aortic stiffness measured as aortic pulse wave velocity (PWVao) and return time (RT) of the direct (forward) systolic wave

They are closely related parameters, because the aortic PWV is calculated on the basis of the return time and the distance travelled by the pulse wave (PWVao = sternal notch – pubic bone distance divided by RT/2).

Evaluation:
The **aortic PWV** is within the **normal** range if it is **less than 9.0 m/s**.
The return time (RT) is within the **normal** range if it is **more than 124 msec**.

Interestingly the RT proved to be stronger marker to predict future cardiac event than PWV, referring to the fact that distance measurement could be biased by human error.

CLINICAL DECISION GUIDE BASED ON ARTERIOGRAPH PROVIDED ARTERIAL FUNCTION RESULTS

INCREASED PERIPHERAL (BRACHIAL) BLOOD PRESSURE

Follow the relevant guidelines (NICE, BHS, ESH, etc.). Ambulatory blood pressure monitoring is highly recommended in case of elevated office blood pressure, measured with Arteriograph.

INCREASED CENTRAL SYSTOLIC BP (SBPao) OR PULSE PRESSURE (PPao)

If the patient is under antihypertensive medication reconsider the given drugs. Beta blockers can increase the central SBP, even if the peripheral BP is within the normal range. In this case consider to quit beta blocker(s) or change to vasodilatative beta blocker(s).

High central SBP and PP is associated with high cardiovascular risk.

INCREASED AUGMENTATION INDEX (AIXao)

The Aix is primarily related to peripheral vascular (arteriolar) tone of the upper body, above the level of aortic bifurcation. Consequently it provides an actual status of the vasodilatation and vasoconstriction of the resistance arteries, meaning the small arteries and arterioles. In case of increasing peripheral vascular tone, e.g. increase of the peripheral resistance, the Aix will increase, while in case of decreasing peripheral vascular tone, the Aix also decreases. The mentioned physiological changes are determined by the endothelial NO synthesis, which deteriorates even in early atherosclerosis when only the endothelial dysfunction characterizes the pathological procedure. Consequently if the arterial function measurement is performed in standardized condition (practically the same conditions as standard office blood pressure measurement requires), the Aix provides meaningful information about the vasoconstrictive effect of the endothelial dysfunction. Increased Aix is associated with coronary artery disease and poor cardiovascular outcome.

In case of elevated Aix an active search is mandatory to reveal other, traditional cardiovascular risk factors, like smoking, obesity, dyslipidemia, hyperglycemia, hypertension, positive familiar anamnesis, sedimentary lifestyle, etc. If the above mentioned factors show abnormity it has to be managed according to relevant guidelines. Positive influence of the abnormal traditional risk factors may result an improvement in the Aix.

According to available scientific data we lack evidence concerning the positive effect of the lowering of Aix on hard cardiovascular endpoints. Consequently the direct modification of the Aix is still not a therapeutic target, however – due to physiological and pathophysiological reasons – the reduced vascular tone, e.g. the lower Aix, is equal to lowered cardiac afterload, which latter one is very beneficial in many pathologic conditions (hypertension, diabetes, endothelial dysfunction, congestive heart failure).

In case of elevated Aix in actively treated patient highlights the need to reconsider the given therapeutic regime. Non-vasodilatatory beta blockers could be responsible for the increased peripheral arterial tone and for the elevated Aix. Most of the antihypertensive drugs have positive effect on the reduction of Aix, apart from the mentioned beta blockers and the diuretics, which are told to be neutral.

INCREASED AORTIC PULSE WAVE VELOCITY (PWVao) AND SHORTENED RETURN TIME (RT)

The aortic PWV primarily informs us about the characteristics of the aortic wall. The more rigid, i.e. the stiffer the aortic wall, the faster the aortic PWV. Obviously, the stiffer the aortic wall, the shorter the time of pulse wave propagation is. In other words, the pulse wave travels faster in rigid (stiff) aorta, therefore the traveling time, the so called Return Time (RT) of the aortic pulse wave will decrease.

The aortic PWV cannot be considered to be a strictly constant value, because several factors can influence it (heart rate, stoke volume, blood pressure). Practically, all factors that increase the lateral tension of the aortic wall will increase the aortic stiffness, consequently the PWV. Despite of the above mentioned confounding factors the PWVao is strongly associated with adverse cardiac outcomes, and proved to be a very powerful and independent predictor of hard cardiac endpoints.

Taken into account the above mentioned facts, **elevated PWVao detects asymptomatic subjects to be in high risk**, and refers to a more developed status of the atherosclerotic procedure, when macrovascular (target organ) damage is occurred. Indeed a strong correlation was found between the Arteriograph measured aortic PWV and asymptomatic carotid atherosclerosis.

On the other hand we do not have evidence about the positive effect of the direct reduction of aortic PWV (i.e. destiffening of the aortic wall) on the improved cardiovascular outcome. Consequently not the PWVao has to be treated specifically as therapeutic goal, but instead, **the existing pathology has to be cured that leads to increased aortic stiffness** (hypertension, atherosclerosis).

Having observed elevated PWV, active search is mandatory to reveal macrovascular atherosclerosis. Indeed strong association was described between increased PWVao and coronary, carotid and peripheral atherosclerosis. In this respect the most effective tool is the carotid ultrasound, because both the intima-media thickness (IMT) and the plaques could easily be detected by this method. If asymptomatic atherosclerosis is verified, further steps in the management of the patient are clearly described in guidelines, regarding the care of asymptomatic subject with proven preclinical atherosclerosis. (ESH, ESC, NICE, BHS).

WHAT TO DO IF AN ARTERIAL FUNCTION PARAMETER IS ELEVATED, BUT WE WERE NOT ABLE TO FIND ANY CONCOMITANT PATHOLOGY?

Because of the A class evidence of the independent prognostic value of Aix and PWV, furthermore SBPao, these findings have to be taken seriously. It is well known that the classical risk factors are fluctuating during life, and it may easily happen, that at a certain moment normal values would be found. For this reason the patient with abnormal arterial function, but normal other results should be monitored and controlled regularly, because it is very probable, that during the next examinations, the hidden pathology will come to the surface.

It is also very plausible that aortic stiffness may indicate earlier atherosclerotic damage before it could be detected by carotid ultrasound or other visual methods. Consequently the algorithm should be the same as it was mentioned above, i.e. the first positive Arteriograph findings have to be followed by regular check-ups.

COST BENEFIT ANALYSIS

Although correct cost-benefit analysis can hardly be done, it is obvious, that a patient with abnormal arterial function parameters can easily be managed at the primary care level, which is more economic than to provide care to a patient with major cardiovascular event in a hospital. Furthermore it can be realistically estimated, that fewer events would happen due to the improved detection and active preventive management of high risk subjects.