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Evaluation of peripheral arterial occlusive disease with arterial oscillograph prototype

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Abstract – Arterial oscillography (AO) is a non-invasive pneumatic technique for measurement of blood volume changes inside an organ or body part. In presented study, a peripheral arterial disease (PAD) of 19 individuals (35 legs) was measured using AO prototype instruments. The results of AO evaluation were compared to results of computed tomography angiography (CTA), which is the gold standard for diagnosis of PAD. The sensitivity and specificity of AO prototype instrument in amount of 79% and 81%, respectively was calculated.

Keywords **– leg pain, plethysmography, diagnostics**

I. INTRODUCTION

Peripheral arterial disease (PAD) can be defined as a range of noncoronary arterial syndromes that are caused by the altered structure and function of the arteries that supply the brain, visceral organs, and the limbs [1,2]. Based on objective testing, reported in several epidemiologic studies [2-5], an overall prevalence of PAD in value of 3% to 10% has been found. These values are even higher (15% to 20%) in persons older then 70 years. The majority of patients with PAD are asymptomatic. The ratio of patients with symptomatic and asymptomatic [2,3,5,6] PAD is in the region of 1:2 to 1:4. Patients with symptomatic PAD have a significantly higher risk of death from cardiovascular disease [1,2,7].

In this study, an evaluation of PAD using arterial oscillograph prototype was performed. Arterial oscillography (AO) is based on measurement of change in volume of the extremity caused by the cyclic nature of arterial inflow. Early instruments used a mercury strain gauge placed around the extremity. Change in volume causes a change in circumference, and therefore, in the electrical resistance of the strain gauge. The resistance is easily measured and plotted on a strip chart, which results in a waveform that has the same basic contour as the pressure wave [8]. Impedance plethysmography works on similar principles; it monitors electrical impedance, which is inversely proportional to volume of the limb.

These devices have been largely replaced by arterial oscillography (arterial air plethysmography), which monitors pressure in a cuff placed around the extremity and inflated to 65 mmHg. Raines [9] and Raines et al, [10] who developed these instruments, called them pulse volume recorders; the term still used today. These devices are more rugged and easier to use than the strain gauges that they have replaced.

Like segmental pressure measurements, waveforms obtained with pulse volume recording (PVR) at various levels of the lower extremity can be used to infer the presence and location of arterial occlusive disease. The normal pulse contour has a rapid upslope, a sharp systolic peak, a dicrotic notch, and a downslope that bows toward the baseline (Fig. 1).

Downstream from stenotic segments, the waveform becomes dampened. Thus, a decrease in pulsatility (either the amplitude or upstroke) from one segment to the next indicates the presence of stenosis upstream. The extent of the changes in the waveform is related to the severity and extent of the proximal disease.

The upstroke becomes less steep, the dicrotic notch is lost, and the overall amplitude is decreased. The test is confounded by similar waveform changes that may be caused by downstream disease.

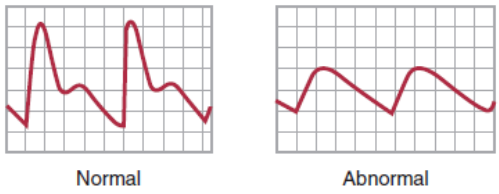

Figure 1. Normal and abnormal pulse volume contours recorded at the ankle level. The normal form shows a prominent dicrotic wave on the downslope. Cuff pressure, 65 mm Hg; cuff volume, 75 mL.

II. METHOD

Thirty-five legs in 19 patients with evidence of PAD were studied prospectively by physical examination, AO and CTA in Vascular laboratory of General Hospital Novo mesto during a 12-month period from October 2016 to September 2017. After a single examination by one senior vascular surgeon, measuring data were recorded. The patients were currently seeking care by a vascular surgeon for worsening of PAD symptoms.

A prototype instrument for PAD was designed, fabricated and characterized together with readout electronics. Prototype instrument presented in Figure 2 consists of Riester's 24-32 cm standard reusable manual inflation blood pressure cuff (www.riester.de), silicon piezoresistive pressure sensor and readout electronics. Silicon piezoresistive pressure sensor FER-PS111 (Fig.2) was designed and fabricated in Laboratory of Microsensors Structures and electronics (LMSE). The details of fabrication process and temperature compensation were described elsewhere [11,12]. Measurements in this clinical test were performed with National Instruments 16-Bit USB multifunction I/O device USB-6212 connected to personal computer, which acts as readout electronics and serves as pressure sensors voltage source (5V).

Changes in leg volume were measured by wrapping a cuff around the lover extremity as shown in Fig.3. The cuff was placed 5 cm above the medial malleolus (ankle) and inflated to 65 mm Hg. During the measurement, patient was in supine position (lying horizontally with the face and torso facing up) with elevated measured leg.

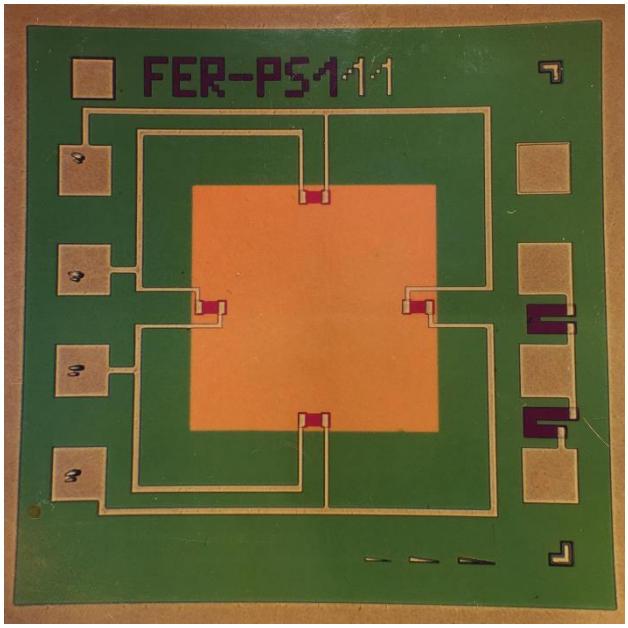

Figure 2. Micrograph of Silicon piezoresistive pressure sensor FER-PS111 used in prototype. Diffused resistors are placed on edge of 25µm thin silicon diaphragm and connected to Wheatstone bridge.

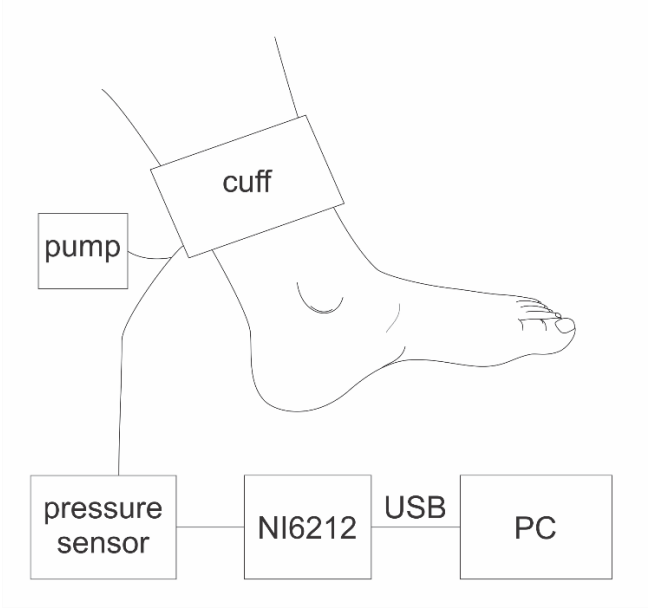

Figure 2. Measurement setup during clinical test

Measuring results obtained from prototype instrument were used to calculate AO rise times, which were further compared with the results obtained with computed tomography angiography (CTA). Based on comparison of measuring results a sensitivity, specificity and efficiency of AO method was calculated from Equations (1). The rise time longer than 220 ms was considered pathologic [13], shorter than 200 ms normal, 200-220 ms uncertain (Fig.4).

III. RESULTS

The patient group consisted of 12 men and 7 women with age range from 59 to 83 years (a mean of 73.4 years). Clinical examination was performed at initial presentation with the standard criteria.

sensitivity or true positive rate (TPR)

$$TPR = TP / (TP+FN)$$

specificity (SPC) or true negative rate

$$SPC = TN / (TN+FP)$$

efficiency (EFF) or diagnostic accuracy

$$EFF = (TP+TN) / (TP+FN+FP+FN)$$

TP - true positive, TN - true negative
FP - false positive, FN - false negative

(1)

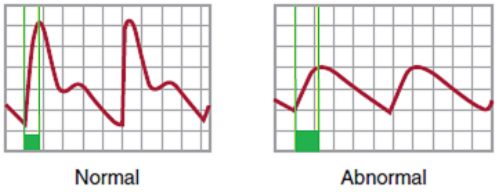

Figure 4. Normal raise time is less than 200 ms

The analysed results of AO show the PAD in 15 limbs and missed the disease in 4 limbs. In addition, AO results show 13 normal limbs, but missed 3 limbs (Table I).

From measuring results, presented in Table I, and Equations (1) sensitivity, specificity and efficiency of the AO method was determined in amount of 79 %, 81 %, and 80%, respectively.

IV. Discussion

As early detection and early intervention of PAD is becoming more important in community health care, the need for a sensitive test is becoming more important.

TABLE I. Comparison of AO rise times and CTA results (P).

P	[ms] right AO	pathologic right CTA	[ms] left AO	pathologic left CTA
1	205	NO	193	NO
2	223	YES	229	YES
3	182	NO	208	YES
4	185	NO	188	NO
5	178	NO	175	NO
6	239	YES	237	YES
7	192	NO	202	NO
8	215	YES	222	YES
9	amputated limb		215	YES
10	198	NO	187	NO
11	185	NO	185	YES
12	234	YES	221	YES
13	227	YES	109	NO
14	192	YES	amputated limb	
15	172	NO	185	NO
16	243	YES	212	YES
17	ulcus cruris		192	NO
18	206	YES	225	YES
19	193	YES	183	YES

This study demonstrated that the sensitivity and specificity of AO for detecting PAD was comparable with other studies [14]. AO is less affected than segmental pressure measurements (ankle-brachial index) by arterial calcification. So the AO is more accurate in diabetic patients, which have usually calcified vessels. The combination of segmental pressure measurements and AO is more accurate than either method alone for detecting PAD. AO has the same limitations as most other indirect tests, including segmental pressure measurements. Like the other indirect tests, AO is used less often in most laboratories that have access to duplex scanning, which provides more accurate and detailed information.

Traditionally, clinical symptoms are considered to be important in diagnosing PAD. However, the presence of intermittent claudication largely depends on the activity level of patients. In chronic debilitating condition such as diabetes mellitus and chronic renal failure, PAD may manifest as a critical limb ischemia even in patients without claudication. As PAD is closely associated with ischemic cardiovascular disease, early detection and early intervention (such as risk reduction medication and exercise programs) for PAD have become more important. And with rapid progression in the technology of interventional endovascular procedures, timely intervention in selected patients could decrease amputation, procedural morbidity, and mortality.

V. Conclusion

Although AO can provide an assessment of the overall physiologic function of the arterial system, it is most useful as a relatively simple and non-invasive measurement to detect the presence of PAD. CTA is usually used in patients with symptomatic PAD to check the anatomic location of disease before any interventional procedure. It is considered as accurate as digital subtraction angiography, a gold standard diagnostic method in PAD. However, as CTA needs a bolus injection (usually >100 mL) of iodine-contained contrast agent, and potential serious complication such as nephrotoxicity and anaphylaxis limits its usage as a primary diagnostic method, especially in patients with decreased renal function.

AO is an optimal measuring method of the presence or absence of PAD when no further information concerning the arterial hemodynamic situation is desired. If information on the severity of PAD or evaluation of improvement after arterial surgery is required, a quantitative test will be more useful.

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