



disease (CAD) was 44% in PAD patients and 16% ( $p < 0.01$ ) in controls. The corresponding figures for cerebrovascular disease (CVD) were 31% and 10% ( $p < 0.01$ ). In a multivariate analysis including PAD, classic risk factors and CRP  $> 3$  mg/l, only PAD was significantly associated with history of CAD (OR 11.9, 95% CI 2.8-50.9), or CVD (OR 6.6, 95% CI 1.4-31.8). Although symptomatic, 45% of PAD patients were unaware of their condition.

**Conclusion.** PAD prevalence in a Mediterranean population is quite similar to that reported in other studies carried out in Anglo-Saxon countries. This, in addition to the unfavorable cardiovascular risk profile of PAD and the high prevalence of unknown cases, illustrates the need of ABPI measurements in older subjects with leg complaints and one of the risk factor significantly associated with PAD.

### Quality of life in patients with peripheral arterial disease in a North-American population: the PAD awareness, risk and treatment new resources for survival (PARTNERS) program.

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**Aim.** Health-related quality-of-life (HRQOL) assessments of peripheral arterial disease (PAD) patients with claudication, whether by treadmill walking or questionnaire measures, have shown significant impairment. However, these measures have not been thoroughly assessed in PAD patients (with or without claudication) in the community setting. The PARTNERS program was the first national study to comprehensively assess HRQOL in a large cohort of patients with PAD recruited from community practices across the United States (US).

**Methods.** The PARTNERS program conducted community-based PAD detection in 27 regional coordinating centers in 25 US cities. Each regional center identified primary care clinics in urban, suburban, and rural communities to serve as screening sites for PAD ( $> 350$ ). A total of 6 979 patients aged 70 or older or aged 50 through 69 years with history of cigarette smoking or diabetes were evaluated by history, by ankle-brachial index (ABI) measurement and by assessment of atherosclerosis risk factors. Patients were identified as having PAD only (defined by  $ABI < 0.90$ , a previous diagnosis of PAD, or a prior limb revascularization procedure), PAD and cardiovascular disease (CVD) (defined by a history of angina, MI, CABG, PTCA, AAA, TIA, or stroke), CVD only, or having neither PAD nor CVD. In addition to HRQOL assessments, main outcome measures included PAD frequency detection, physician and patient awareness of PAD diagnosis and treatment intensity in PAD compared to patients with other forms of CVD and healthy age-matched patients. In terms of HRQOL assessment, all patients completed the Walking Impairment Questionnaire (WIQ) and the Medical Outcomes Study (MOS) Short-Form 36 (SF-36).

**Results.** PAD was detected in 1 865 patients (29%); overall 13% had PAD only, 16% had PAD and CVD, 24% had CVD only and 47% had neither PAD nor CVD. There were 457 patients (55%) without CVD who were newly diagnosed with PAD only and 366 (35%) with CVD who were newly diagnosed with PAD during the course of the study. Patients with PAD had similar risk factor atherosclerotic risk factor profiles as patients with CVD but were overall less intensively treated than CVD patients. All HRQOL scores were reduced in the 2 groups who had PAD compared to the other groups. Examples of data from all groups is shown in Table I.

TABLE I.

Instrument	PAD-/CVD-	PAD-/CVD+	PAD+/CVD-	PAD+/CVD+
N	3 025	1 527	825	1 040
WIQ-distance	70±1	63±1	49±1*	42±1*
MOS-SF36-PFS	64.8±0.6	58.7±0.8	52.5±0.9*	47.1±1.0*

\* $P < 0.05$  difference from PAD-/CAD- group. Thus, HRQOL scores were worse in PAD than persons with CVD or healthy subjects. PFS= Physical functioning score.

**Conclusion.** PAD is very prevalent in primary care practices and can be easily diagnosed by ABI measurement. Patients with PAD are under-treated with regard to atherosclerosis risk factors. PAD, even in the absence of claudication, is associated with profound impairments of HRQOL, and PAD subjects are more limited than those with CVD alone. Intensification of the effort to assess and treat the functional impairment of PAD is clearly indicated.

### Quality of life assessment in patients with intermittent and disabling claudication

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**Aim.** The treatment of the peripheral arterial disease (PAD) is aimed both at limiting the long-term progression of disease, at reducing the cardiovascular events and mortality, and at improving the Quality of Life (QoL) of the patients. The European Medicinal Products Evaluation Agency (EMEA) fixed several hard evaluation points about efficacy and effectiveness of the PAD treatment including the assessment of QoL, and underlining that at present no fully validated scales are available for this purpose.

For these reasons we designed this Italian Study on Quality of Life measurement in patients with peripheral arterial disease. The main target of the study has been the influence of the PAD on the QoL, and the second one was the assessment of the relationship between the QoL and several clinical features commonly used in the clinical practice.

**Methods.** Eight-hundred and forty patients, 75.8% males (mean age 66.7±9.3 years) and 24.2% females (mean age 65.9±11.1), and 130 healthy control people (balanced for age and sex), have been recruited. Of this sample, 15% did not have any symptoms (silent arteriopathy, stage Fontaine 1), 38.1% had a moderate intermittent claudication (stable claudication, stage Fontaine 2a), 42.8% had a severe claudication (stage Fontaine 2b), 3.1% had a CLI, 1.7% with only rest pain (stage Fontaine 3) and 1.4% with rest pain and skin wound (stage Fontaine 4). After the anamnesis, carried out according to the Greenfield score index to evaluate the comorbidity, and an appropriate information concerning the tests and their aims, and after the delivery of the informed consensus, all people underwent the clinical examination, and the mini mental state examination MMSE, excluding the people with MMSE < 24. The eco-color Doppler of the lower limbs, with ABI measurement, and the 6 minutes walking corridor test (6-WCT) have been performed, assessing the initial and absolute claudication distance. In the healthy people the 6-WCT has been stopped after the 6th minute walking without pain. The treadmill test (slope 12% speed 12,5 km/h) has been realised if not contraindicated. At least all people received the following QoL questionnaires: - the SF-36 (generic questionnaire); - the Sigmata 22 (ST-22) (specific questionnaire for PAD); - the Walking Impairment Questionnaire (a specific questionnaire for PAD); - 2 utility measurement instruments, the Euro-QoL 5D and the visual analogic scale. T-test, ANOVA, Tukey and Pearson test, and the analysis of the variance have been utilised, considering the results significant if p was less than 0.05.

**Results.** All the used questionnaires yield equally reliable results. The QoL was impaired in the physical items since the initial stages of PAD, whilst the psycho-mental items was impaired from the third stage. Therefore this impairment has been more homogeneous and gradual if the patients are matched following the measured ambulatory performance than clinical data. ST-22, even if specific PAD instrument has been able to assess also the psycho-mental dimensions. WIQ showed good accuracy to assess the ambulatory performance, and it can be used an alternative to treadmill and WCT. The QoL index was always lower in women than in men, regardless of the instrument used. The age has been a damaging factor on the walking ability and on the self-evaluation of physical performance, but not on the social and psychological attitude. From the epidemiological point of view it appears that PAD affects more those who perform manual activity and that this patient's group also has a higher risk of a more severe comorbidity. On the other hand, the disease appears to affect less those who perform a mainly intellectual activity, even though in this groups the disease seems to appear earlier on.

**Conclusion.** This interesting observation seems to go along with the pathophysiological hypothesis of the existence of 2 different typologies of PAD (at least when considering the claudication symptom), with a higher or lesser evolutionary aggressiveness and suggest the need for further investigations.

## LECTURE

### The cerebrovascular risk

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In the 1999 WHO report, stroke accounts for the 2<sup>nd</sup> highest cause of death giving an overall figure of 9.5% of all death causes, as well as being the 7<sup>th</sup> cause of invalidism. In Italy strokes are the 3<sup>rd</sup> cause of death and resulting invalidism, with 130 000 stroke new cases every year. Hypertension has long been recognised as a major risk factor for stroke, in fact exists an approximately linear relationship between the usual level of blood pressure and the primary incidence of stroke in both the hypertensive and normotensive populations as showed by MacMahon meta-analysis, while Framingham study demonstrated an higher prevalence of stroke in hypertensive subjects than normotensive ones. Well demonstrated also appears the benefit in terms of stroke incidence reduction related to antihypertensive treatment as showed by several studies (*SHEP, STOP-Hypertension, Syst-aur, Stone*) with, respectively, a 33%, 31% and 60% risk reduction, but not clear appears the real bound of blood pressure lowering treatment in comparison with the possible "vessel oriented" action of drugs as like ACE-inhibitors and AT1 antagonist as demonstrated by HOPE study and LIFE study demonstrating an overlapping cerebrovascular risk reduction independent by blood pressure values in comparison with the result of UKPDS and the more recent PROGRESS study showing a risk reduction strictly dependent by antihypertensive action. Although the relation between serum total cholesterol and coronary heart disease has been well established, the association between serum cholesterol and stroke is unresolved. Epidemiological studies for Japanese and Japanese-Americans have shown that serum total cholesterol concentration was inversely associated with the incidence of cerebral haemorrhage, and, more recently, the MRFIT Trial showed that serum total cholesterol was inversely associated with death from cerebral haemorrhage and positively associated with death from cerebral infarction. Probably this association differs by the type of stroke as clearly demonstrated by the Akita Study, the only pathological study that has examined the association of serum cholesterol with stroke type, showing an association between serum cholesterol levels and atherosclerotic types of stroke, while Engstrom *et al.* reported how hypercholesterolemia is associated with high levels of inflammation sensitive plasma proteins (ISP), that these proteins increase the incidence of cardiovascular diseases and that, in absence of elevated ISP, no statistically confirmed association was found between hypercholesterolemia and ischemic stroke. Diabetes is a major risk factor for stroke, in fact in the Framingham Study the risk of stroke was 2.6 fold higher in men with type 2 Diabetes than in nondiabetic subjects and, more recently the Honolulu Heart Program and the Copenhagen Stroke Study have also showed the higher stroke prevalence of ischemic stroke in diabetic patients. Not well designed appears the clinical profile of stroke in the diabetics and regarding this topic our group has recently conducted a prospective case-control study by comparing 102 diabetics *versus* 204 non diabetic matched subjects all admitted to the Department of Internal Medicine and Cardioangiology of the University of Palermo and affected