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## ‘Pole Test’ Measurements in Critical Leg Ischaemia

N. Paraskevas,<sup>1\*</sup> R. Ayari,<sup>1</sup> S. Malikov,<sup>1</sup> M. Mollo,<sup>1</sup> P. Branchereau,<sup>1</sup>  
F. Hut<sup>2</sup> and A. Branchereau<sup>1</sup>

Departments of <sup>1</sup>Vascular Surgery, La Timone Hospital, Marseille, France, and <sup>2</sup>General Surgery, Erasmus Hospital, Brussels, Belgium

**Background.** For the quantification of critical limb ischaemia (CLI) most vascular surgery units use sphygmo-manometric and transcutaneous oxygen pressure (TcPO<sub>2</sub>) measurements. However, measurements obtained by cuff-manometry can be overestimated especially in diabetic patients because of medial calcification that makes leg arteries less compressible. TcPO<sub>2</sub> measurements present a considerable overlap in the values obtained for patients with different degrees of ischaemia and its reproducibility has been questioned. Arterial wall stiffness has less influence on the pole test, based on hydrostatic pressure derived by leg elevation, and this test seems to provide a reliable index of CLI.

**Objective.** The objective of this study was to evaluate the pole pressure test for detection of critical lower limb ischaemia, correlating results with cuff-manometry and transcutaneous oxygen pressure.

**Design.** University hospital-prospective study.

**Materials and methods.** Seventy-four patients (83 legs) with rest pain or gangrene were evaluated by four methods: pole test, cuff-manometry, TcPO<sub>2</sub> and arteriography. CLI was present if the following criteria were met: (a) important arteriographic lesions + rest pain with an ankle systolic pressure (ASP) ≤40 mmHg and/or a TcPO<sub>2</sub> ≤30 mmHg, or (b) important arteriographic lesions + tissue loss with an ASP ≤60 mmHg and/or a TcPO<sub>2</sub> ≤40 mmHg. Fifty-seven lower limbs met the criteria for CLI.

**Results.** Measurements obtained by cuff-manometry were significantly higher to those obtained by pole test (mean pressure difference: 40 mmHg,  $p < 0.001$ ). The difference between the two methods remained statistically significant for both diabetics (50.73,  $p < 0.001$ ) and non-diabetics (31.46,  $p < 0.001$ ). Mean TcPO<sub>2</sub> value was 15.51 mmHg and there was no important difference between patients with and without diabetes. Overall, there was a correlation between sphygmomanometry and pole test ( $r = 0.481$ ). The correlation persisted for patients without diabetes ( $r = 0.581$ ), but was not evident in patients with diabetes. Correlation between pole test and TcPO<sub>2</sub> was observed only for patients with diabetes ( $r = 0.444$ ). There was no correlation between cuff-manometry and TcPO<sub>2</sub>. The pole test offered an accuracy of 88% for the detection of CLI. The sensitivity of this test was 95% and the specificity 73%.

**Keywords:** Pole test; Critical leg ischaemia.

### Introduction

Accurate assessment of the severity of lower limb ischaemia is necessary for the selection of patients requiring a surgical treatment. This is particularly important in case of critical ischaemia where adequate revascularisation can prevent a major amputation and where unnecessary aggressive treatment can lead to poor prognosis.

The quantification of critical leg ischaemia (CLI) has been discussed widely. The second European consensus document<sup>1</sup> proposed an objective assessment

of ankle systolic pressure (ASP) ≤50 mmHg, or a toe pressure (TP) ≤30 mmHg.

Rutherford<sup>2</sup> proposed different cut-off values and in addition recommends the use of the transcutaneous measurement of oxygen tension (TcPO<sub>2</sub>).<sup>3</sup>

It is recognized that sphygmomanometry measurements can overestimate pressures, especially in diabetics<sup>4,5</sup> because of the medial calcification that makes leg's arteries less compressible. It has been suggested that the systolic pressure at the toe level is more accurate, as smaller vessels are easier to compress<sup>6</sup> but this technique gives poor results at low temperatures<sup>7</sup> and is difficult to use when ulcers and gangrene are present. The measurement of TcPO<sub>2</sub> appears reproducible and correlates well with the existence of skin ischaemia and the Fontaine

\*Corresponding author. Dr Nikolaos Paraskevas, MD, Department of Vascular Surgery, La Timone Hospital, 264 rue Saint-Pierre, 13385 Marseille Cedex 05, France.  
E-mail address: nparaskevas@yahoo.com

classification clinical severity of leg ischaemia.<sup>8-10</sup> It also is useful in predicting the need for amputation in severe ischaemia.<sup>11</sup> However, there is a considerable overlap in the values obtained for patients with different degrees of ischaemia,<sup>12</sup> and the reproducibility of TcPO<sub>2</sub> has been questioned.<sup>13,14</sup> Moreover, technical problems with measurements are common.

The introduction of an alternative approach, the pole test,<sup>15</sup> using hydrostatic pressure derived by leg elevation, seems to provide a reliable index of severe leg ischaemia as it is less influenced by the degree of artery compressibility; nevertheless this test is not yet included in any definition of CLI and it is not used routinely in most vascular surgery units, despite of its simplicity.

The aim of this prospective study was to evaluate the pole pressure test by correlating it with cuff-manometry and TcPO<sub>2</sub> measurements and to investigate the ability of this test to detect critical lower limb ischaemia.

## Materials and Methods

From January 1999 to September 2000, 74 consecutive patients (83 legs) with clinical signs of critical ischaemia were referred to our vascular surgery unit, for evaluation of lower limb arterial disease. All patients were evaluated by four methods: pole test (P), cuff-manometry (S), TcPO<sub>2</sub> (T) and arteriography (A).

Critical limb ischaemia (CLI) was diagnosed when the following criteria were met:

Arteriographic evidence of at least two level lesions (stenosis >70% or occlusion) and/or important lesions of the three calf arteries without important collateral development, together with either (i) persistently recurring ischaemic rest pain requiring regular adequate analgesia for more than 2 weeks, with an ankle systolic pressure  $\leq 40$  mmHg and/or TcPO<sub>2</sub>  $\leq 30$  mmHg or (ii) ulceration or gangrene of the foot or toes, with an ankle systolic pressure  $\leq 60$  mmHg and/or TcPO<sub>2</sub>  $\leq 40$  mmHg.

Fifty-seven legs met the inclusion criteria for CLI.

### *Measurement by TcPO<sub>2</sub>*

This test was performed first, in the supine position. The electrode was placed on the dorsum of the foot (or nearest to an ulcer, if there was one). TcPO<sub>2</sub> was measured with a polarographic electrode (Micro Gas 7640, Kontron instruments) heated at 45°. Calibration

for atmospheric pressure was made before each measurement. A direct reading in mmHg was taken after a perfect stabilisation of the TcPO<sub>2</sub> (mean duration of the procedure was 30 min).

### *Measurement by pole test*

Measurement of pressures after 30 min in the supine position by insonating (8 MHz probe) the three ankle arteries (dorsalis pedis, posterior tibial and peroneal artery) and the hallux collateral artery, with a calibrated pole (zero pressure level being situated at the level of the left ventricle and corresponding to the anterior axillary line in a supine position). The foot was slowly elevated until the disappearance of systolic pressure signal. The height at which the signal disappeared corresponded to the systolic pressure in cmH<sub>2</sub>O and was transformed to mmHg (13 cmH<sub>2</sub>O = 10 mmHg). This procedure was repeated three times for each artery. The mean value of each artery was noted and the highest mean value was used. Intra-observer variability was good, for highest measurements mean standard deviation was 0.7 mmHg (range 0-5). Inter-observer variability was not assessed.

### *Measurement by cuff-manometry*

After 30 min in the supine position, measurement of arterial systolic pressures of the same four arteries, using a 15 cm wide cuff placed just above the malleoli and a 8 MHz Doppler probe. This procedure also was repeated three times for each artery and the highest mean value was used.

### *Arteriography*

All patients had an arteriographic examination.

Measurements of blood pressures derived from cuff-manometry and pole test were not feasible in some patients' limbs because of incompressibility of arterial walls and limited maximal leg elevation. If ASP was > 200 mmHg and or a persistent Doppler signal at maximal leg elevation occurred in the pole test were, limbs were excluded from statistical analysis (for comparisons and correlations). We also decided to include diabetic and long term renal dialysis patients in a single group, since both have arterial wall stiffness.

### *Analysis*

Comparisons between the three different non-invasive methods were made with rank sum two-sample test

**Table 1. Patient characteristic**

	All patients	Patients with diabetes	Patients without diabetes
Number of patients	74	Type I: 26 Type II: 13	35
Number of limbs	83	Type I: 27 Type II: 15	41
Sex ratio m/f	58/16	28/11	30/5
Mean age (years)	72.57 (31–92)	75.62	68.93
Smoking	46/74	20/74	26/74
Hypertension	44/74	22/74	22/74
Dyslipidemia	8 patients	4	4
On dialysis	13 patients (16 legs)	7 patients (8 legs)	6 patients (8 legs)
Rest pain	17 legs	4 legs	13 legs
Foot ulcers/ gangrene	66 legs	38 legs	28 legs

(Mann–Whitney). Correlations were obtained by linear regression. The  $r$  coefficient of linear correlation which is the measurement of the intensity of a linear relation between two diagnostic tests was calculated;  $p$  values  $<0.05$  were regarded as significant. Sensitivity, specificity, predictive values and accuracy were carried out for the evaluation of the pole test. ROC curves were used for the optimum cut-off value of the pole test for the detection of CLI. Finally, intra-observer variability of the pole test measurements was assessed.

## Results

The demographic details of the patients are shown in Table 1. For the 57 legs considered to have CLI, 51 had cuff-manometry measurements and 54 pole test measurements. TcPO<sub>2</sub> was obtained for all limbs. Forty-eight limbs were evaluated by both cuff-manometry and pole test, 51 by cuff-manometry and TcPO<sub>2</sub> and 54 by pole test and TcPO<sub>2</sub>. Forty-eight limbs were evaluated by all three methods.

Comparisons between measurements obtained by sphygmomanometry and pole test are shown in Table 2.

Mean TcPO<sub>2</sub> value was 15.51 (SD  $\pm$  14.18,  $n=57$ ) and there was no difference between patients with

diabetes ( $12.68 \pm 12.43$ ,  $n=28$ ) and those without diabetes ( $18.24 \pm 15.40$ ,  $n=29$ ),  $p=0.210$ .

Correlations between the three tests are shown in Table 3. There was a significant correlation between sphygmomanometry and pole test measurements ( $r=0.481$ ).

No correlation was found between cuff-manometry and pole test for patient with diabetes. However, there was a correlation between these two tests for patients without diabetes ( $r=0.581$ ). No correlation was observed between sphygmomanometry measurements and TcPO<sub>2</sub>. A correlation was found between pole test and TcPO<sub>2</sub> measurements only for patients with diabetes ( $r=0.444$ ).

According to our definition of CLI, from the 83 lower limbs assessed in our study, only 57 were classified as having CLI. We used the same definition as a gold standard for the evaluation of the pole test. From ROC curves, the optimum cut-off value of the pole test for the detection of CLI was of 50 mmHg (Fig. 1). The pole test when used alone to detect CLI showed a sensitivity of 94.7%, a specificity of 73.1%, a positive predictive value (PPV) of 88.5% and a negative predictive value (NPV) of 86.4%. The accuracy of the test was of 88.0%. These values are given in Table 4.

## Discussion

All pressures measured by sphygmomanometry were higher than those obtained by leg elevation in the pole test. This finding is in keeping with other authors.<sup>15,16</sup>

Pressures measured by both cuff-manometry and pole test were higher in patients with diabetes than in those without diabetes and these differences were statistically significant. The difference between the two methods was significantly greater for those with diabetes than for those without. Although, Smith<sup>15</sup> showed a similar trend, his data did not achieve statistical significance.

In the study by Smith<sup>15</sup> all patients investigated were assessed by pole test at the ankle level and no patient had a persistent Doppler signal at maximal leg elevation. On the contrary, Pahlsson *et al.*<sup>6</sup> found, that

**Table 2. Comparison between patients with and without diabetes for cuff-manometry and pole test measurements (legs in CLI)**

	All patients (mean $\pm$ SD, number)	With diabetes (mean $\pm$ SD, number)	Without diabetes (mean $\pm$ SD, number)	Pressure difference	$p$
Cuff-pressure (mmHg)	66.76 $\pm$ 35.51, $n=51$	80 $\pm$ 38.49, $n=23$	55.89 $\pm$ 29.25, $n=28$	24.11	$<0.001$
Pole pressure (mmHg)	26.76 $\pm$ 12.88, $n=54$	29.27 $\pm$ 12.61, $n=26$	24.43 $\pm$ 12.91, $n=28$	4.84	$<0.05$
Pressure difference (mmHg)	40	50.73	31.46		
$p$	$<0.001$	$<0.001$	$<0.001$		

Table 3. Correlations between the three tests (legs in CLI)

	<i>r</i>	<i>p</i>	<i>n</i>	Excluded
Cuff-pressure and pole test				
All patients	0.481	<0.001	48	9
With diabetes	0.344	0.131	21	7
Without diabetes	0.583	<0.005	27	2
Cuff-pressure and TcPO <sub>2</sub>				
All patients	0.000	0.999	51	6
With diabetes	0.022	0.921	23	5
Without diabetes	0.118	0.552	28	1
Pole test and TcPO <sub>2</sub>				
All patients	0.208	0.132	54	3
With diabetes	0.444	<0.05	26	2
Without diabetes	0.09	0.630	28	1

Table 4. Evaluation of the pole test in the detection of CLI

CLI/non-CLI	Pole test ≤50 mmHg
Sensitivity	94.7
Specificity	73.1
False-negatives	5.3
False-positives	26.9
PPV	88.5
NPV	86.4
Accuracy	88.0

at ankle level, the pole test provided a pressure measurement in less than half (42%) of legs: the remaining 58% had a persistent Doppler signal: this was attributed to the varying inclusion criteria. In our study, pole test measurements were possible in 62/83 legs (when we include all stage III and IV limbs). When we considered only limbs with CLI, the pole test measurements were attained from 54/57 legs.

The value of the pole test in the diagnosis of severe ischaemia is limited by lower leg length. The leg length of most patients does not permit pressures greater than 45 mmHg<sup>6</sup>–60 mmHg<sup>15,17</sup> to be measured at the ankle level. At the toe level higher pressures (55–70 mmHg<sup>6,17</sup>) can be measured because the distance from the hip to the toe is longer. In our study, we managed to measure pole test pressures as high as 70 mmHg but in many patients, because of the limited leg length or mobility in the elderly, values greater than 50 mmHg could not be measured.

There was a good correlation between sphygmomanometry and pole test measurements for patients without diabetes but there was no correlation for patients with diabetes. This is similar to the findings of

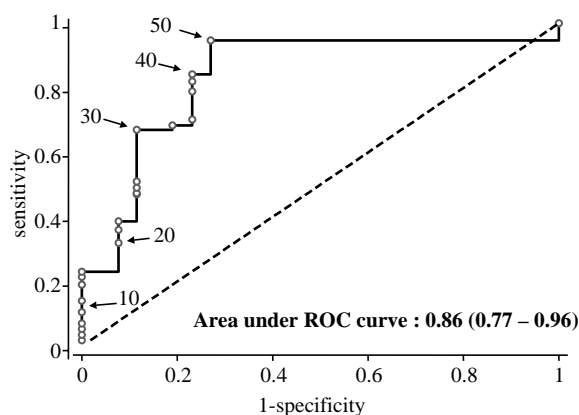


Fig. 1. ROC analysis of different cut-off values of pole test measurements (in mmHg) for the detection of critical limb ischaemia.

Jachertz<sup>16</sup> who found a better correlation between the two tests for patients without diabetes.

There is controversy about the influence of medial calcification on TcPO<sub>2</sub> measurements.<sup>18,19</sup> Like Wyss *et al.*<sup>19</sup> we did not find any statistical difference between TcPO<sub>2</sub> measurements in patients with and without diabetes. Wyss *et al.*<sup>20</sup> suggested that TcPO<sub>2</sub> and Ankle-brachial pressure measurements yield similar results for haemodynamic outcomes in patients without diabetes and in diabetics without important calcification, but our data, like those of Jachertz,<sup>16</sup> did not show a correlation between TcPO<sub>2</sub> and cuff-manometry for either group of patients. Nevertheless we found a correlation between pole test measurements and TcPO<sub>2</sub> in patients with diabetes. Perhaps this results from the fact that TcPO<sub>2</sub> depends on the microcirculation, which is influenced by diabetic microangiopathy.<sup>21,22</sup> However, Jachertz<sup>16</sup> found a good correlation between the two tests for patients without diabetes.

The pole test was evaluated in this study as a diagnostic test for CLI. Our study showed that the pole test was very accurate, with high sensitivity and high NPV for the detection of CLI. It also had good specificity and a high PPV. However, further work remains to assess the inter-observer variability of pole test measurements and the reproducibility of this test in different settings.

It is well-known sphygmomanometry is very specific for the detection of CLI but has a low sensitivity and a large number of false-negatives.<sup>23</sup> This is because critical ischaemia can exist with high ankle pressures especially in patients with stiff arteries (those with diabetes or on renal dialysis).

Transcutaneous oximetry is used regularly for the detection of CLI but its reproducibility<sup>13,14</sup> and accuracy<sup>23</sup> have been questioned. Furthermore, there is a big variation in the cut-off values proposed by different authors.<sup>2,3,23,24</sup>

The assessment of critical ischaemia by means of non-invasive measurements can probably be improved by the combination of several techniques. The pole test could play an important role in

the detection of CLI especially in patients presenting calcified incompressible leg arteries.

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