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SHORT COMMUNICATION

Transcutaneous oxygen tension measurements following peripheral transluminal angioplasty procedure has more specificity and sensitivity than ankle brachial index

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Objective: To evaluate the superiority of transcutaneous oxygen pressure (TcPO₂) before, during and after peripheral transluminal angioplasty (PTA) in comparison with ankle brachial index (ABI) in patients with diabetes.

Methods: 40 consecutive patients with diabetes treated by PTA were included. This study shows results before, during and after PTA and their progression for 8 weeks.

Results: The TcPO₂ increased from 28.11 ± 8.1 to 48.03 ± 8.4 mmHg, 8 weeks after PTA ($p < 0.001$). The ABI increased from 0.48 ± 0.38 to 0.77 ± 0.39 after PTA ($p < 0.001$). After PTA, the stenosis of the vessel decreased from $58.33 \pm 20.07\%$ to $21.87 \pm 13.57\%$ ($p < 0.001$). TcPO₂ was determined in all the patients, but ABI could not be determined in all patients. Furthermore, we

determined patients with “false negatives” with an improvement in ABI and “false positives” in 12.5% of patients. Additionally, in this study, we monitored TcPO₂ while performing PTA, revealing variations in each phase of the radiological procedure.

Conclusion: The increase in TcPO₂ measurements following PTA procedure has more specificity and sensitivity than does ABI. The use of TcPO₂ may represent a more accurate alternative than traditional methods (ABI) used in assessing PTA results. The TcPO₂ also allows the radiologist to assess changes in tissue oxygenation during PTA, allowing changes to the procedure and subsequent treatment.

Advances in knowledge: This is the first time that a graph is shown with TcPO₂ results during PTA performance in many patients.

Critical limb ischaemia (CLI) is defined as a state of arterial insufficiency that reduces distal perfusion pressure to such an extent that microcirculation and nutrient blood flow to tissues are severely disturbed.¹ Peripheral transluminal angioplasty (PTA) has become an accepted endovascular treatment modality for patients with CLI. The effectiveness of PTA is assessed by determining peripheral pulses, the calculation of ankle brachial index (ABI) or the calculation of the toe brachial index.²

However, patients with diabetes with CLI have features that hinder the use of these parameters in assessing the success of PTA.³ Calcification of the arterial wall, complete obstruction of the artery and the presence of collateral circulation cause problems in ABI determinations that exclude up to 30% of patients treated with PTA^{4,5} from evaluation. It has even been found that

27% of patients with diabetes successfully treated by PTA, finally had to undergo amputation owing to vascular complications.⁶

Currently, the increasing prevalence of diabetic vascular disease induces a bigger number of PTA in patients with diabetes with CLI. Radiologists perform successful PTA that significantly reduces arterial stenosis but does not always lead to an improvement in distal reperfusion. Microcirculation is the most relevant indicator of skin health and therefore wound healing and an improvement of the oxygen pressure. The transcutaneous oxygen pressure (TcPO₂) is an indicator of oxygen and nutrients reaching the tissues through microcirculation.^{2,4} The aim of this study was to evaluate TcPO₂ before, during and after PTA in comparison with ABI in patients with diabetes.

METHODS AND MATERIALS

From 1 December 2011 to 1 January 2014, patients with consecutive limb ischaemia who were referred to the vascular radiology service for clinical evaluation and diagnostic tests (arteriography and/or CT angiography and ABI) were examined for their suitability for PTA. All the patients were evaluated for signs of posterior tibial and dorsalis pedis signals; ABI was measured with the Doppler continuous-wave technique; and TcPO₂ was measured on the dorsum of the foot with transcutaneous oximeter. Written informed consent was obtained from every patient after extensive explanation of the study and before enrolment in the study.

Duplex scanning was performed in cases with either reduced or absent foot signal; ABI <0.90 (in the absence of arterial calcification) or TcPO₂ <50 mmHg (in the absence of oedema). If at least two of these three examinations were abnormal, arteriography or CT angiography was carried out. Patients were selected for PTA or surgery according to the Inter-Society Consensus for the Management of Peripheral Arterial Disease [Trans-Atlantic Inter-Society Consensus (TASC) II] clinical criteria: "Recommendation 37: endovascular therapy for lesion Types A and B and surgery for lesions D and C"² (Figure 1). Finally, 40 patients before, during and up to 8 weeks after PTA were recruited with a new experimental protocol of the study.

All research met the ethical guidelines, including adherence to the legal requirements of the study.

Interventional procedures

PTA is a procedure for dilating blood vessels in the treatment of peripheral artery disease (Figure 2). Under fluoroscopic guidance, a balloon-tipped catheter is inserted into a stenotic artery,

Figure 1. Lesions included in the study according to the Trans-Atlantic Inter-Society Consensus II classification.²

Figure 2. Arteriography of the right lower limb shows multiple stenosis.

and the balloon is inflated. The inflated balloon may dilate the artery by stretching its elastic fibres or by flattening accumulation of plaque. The administration of contrast medium can be used to assess the stenosis reduction obtained by PTA. PTA was considered suitable when an angiographic study or CT angiography pointed to obstructions of >50% of the vessel lumen. PTA was performed under local anaesthesia through an antegrade puncture of the ipsilateral common femoral artery, following the usual technique. If obstructions were documented by duplex scanning in the iliac trunk or the common femoral artery, the puncture was performed by means of a contralateral approach. Vessel recanalization was considered successful if direct flow was obtained in the treated vessel without residual stenosis of >30% of the vessel diameter along the entire artery.

Transcutaneous oxygen pressure

The TcPO₂ was carried out in all patients 24 h before, 24 h after and 8 weeks after PTA to evaluate patency of the vessel. In addition, TcPO₂ was continuously monitored in the patients

during PTA, recording the times of the administration of radiological contrast medium and the application of PTA balloon. A record of the results during PTA was obtained by averaging the readings recorded in the last 5 min before and 10 min after the administration of the contrast agent or the application of PTA balloon.

TcPO₂ measurements were conducted 24 h before, 24 h after and then at 8 weeks after PTA on the dorsum of the foot with the patient resting in the supine position in an air-conditioned room maintained at 22 °C and with the electrode at 44 °C. The instrument used was a transcutaneous carbon dioxide monitor (Radiometer®, Copenhagen, Denmark) equipped with a Clark electrode. The measuring site was carefully cleaned using saline solution. The transducer was fixed to the skin with double-sided adhesive rings and contact liquid supplied by the manufacturer. The calibration period was 10–12 min, and the TcPO₂ signal was recorded continuously. Measurements of TcPO₂ were performed with the patients reformed of the procedures, and none was altered during the course of the study. TcPO₂ limit did not exceed 120 min during the monitoring of all patients.

Ankle brachial index

The ABI was measured using a 12-cm sphygmomanometer cuff placed just above the ankle, and a Doppler instrument with an 8-MHz frequency (Multi-Dopplex II®; Huntleigh Healthcare Limited, Cardiff, UK) was used to measure the systolic pressure of the posterior tibial and dorsal pedal arteries of each leg. These pressures were then normalized with the higher brachial pressure of either arm to determine the ABI.

Statistical analysis

Statistical analysis consisted of comparing the pre- and post-treatment results by the equality of means for paired data using paired Student's *t*-test. The relationships between variables were established by regression/correlation analysis, by calculating Pearson's linear correlation coefficient. The results were considered significant at a *p*-value of <0.01. Analysis was performed with a personal computer by using SPSS® for Windows software v. 15.0 (SPSS Inc., Chicago, IL).

RESULTS

The characteristics of the 40 patients recruited for this study are shown in Table 1. Figure 3 shows the TcPO₂ results as PTA was being carried out: before PTA (A), 27 ± 8.1 mmHg; after contrast (B), 17 ± 10.6 mmHg; after PTA balloon (C), 11 ± 10.1 mmHg; and following PTA (D), 39 ± 9.7 mmHg. Although we determined differences by gender, the effect of kidney function or duration of diabetes was not statistically significant.

Figure 4 shows the results of TcPO₂ and ABI in the 40 patients 8 weeks after PTA. The TcPO₂ increased from 28.11 ± 8.1 to 48.03 ± 8.4 mmHg 8 weeks after PTA (*p* < 0.001). The ABI increased from 0.48 ± 0.38 to 0.77 ± 0.39 after PTA (*p* < 0.001). After PTA, the stenosis of the vessel decreased from 58.33 ± 20.07% to 21.87 ± 13.57% (*p* < 0.001).

In only three cases (7.5%) was the TcPO₂ value less than it was before PTA. In five cases (12.5%), the ABI was low but with

Table 1. Demographic and clinical characteristics of the study population (*n* = 40)

Characteristics	Value
Age (years)	72.1 ± 9.2
Females/males (<i>n</i>)	11 (27.5)/29 (72.5)
Insulin/oral therapy	34 (85.0)/6 (15.0)
Diabetes duration (years)	18.65 ± 4.11
Glycated haemoglobin	9.63 ± 0.4
Coronary artery disease (history) (<i>n</i>)	27 (67.5)
Stroke (history) (<i>n</i>)	18 (45.0)
Antihypertensive therapy	33 (82.5)
Lipid lowering therapy	34 (85.0)
Creatinine >133 µmol l ⁻¹ (<i>n</i>)	29 (72.5)
No/ex/current smokers (<i>n</i>)	13 (32.5)/25 (62.5)/2 (5.0)
Ankle brachial index	0.48 ± 0.38
Transcutaneous oxygen pressure (mmHg)	28.11 ± 8.10
Trans-Atlantic Inter-Society Consensus (2007) A/B/C/D (<i>n</i>)	18 (45.0)/21 (52.5)/1 (2.5)/0 (0.0)
Rutherford 4	3 (7.5)
Rutherford 5	23 (57.5)
Rutherford 6	15 (37.5)

Data presented are means ± standard deviations or number (%) of patients.

a higher TcPO₂ (>30 mmHg) than before PTA. After PTA, the ABI was not measurable in six patients (15.0%) because of the absence of an arterial signal in one patient (2.5%) or as a result of the presence of arterial calcifications in five patients (12.5%). The ABI could be determined in 34 cases (85.0%). Of all the

Figure 3. Modifications of transcutaneous oxygen pressure (TcPO₂) during peripheral transluminal angioplasty (PTA): before PTA, A; after administration of radiological contrast medium, B; after PTA balloon, C; and following PTA, D.

Figure 4. Changes in transcutaneous oxygen tension (TcPO₂) and ankle brachial index (ABI) before, during and after peripheral transluminal angioplasty (PTA).

patients seen, seven cases (17.5%) displayed a normal ABI with low TcPO₂.

Statistical analysis of the results revealed minimal correlation between the techniques used (TcPO₂ and ABI), which means that both indices show a relationship that is conditioned by the patient's improvement rather than by any true correspondence between both the parameters ($r = 0.19$; $p < 0.215$).

DISCUSSION

In recent years, the use of PTA as a technique of revascularization in patients with CLI has increased, being the first choice of treatment for type A and B lesions according to the TASC II classification.² The ABI is the most widely used test to assess the success of PTA; however, recent studies have reported a series in which 27.3% of patients who were successfully treated with PTA

and assessed by ABI finally ended with their limbs being amputated below their knees.⁶

In our hospital, non-invasive tests (pain in the lower limb, Doppler, ABI and TcPO₂) are performed by the nursing department in the Vascular Radiology Service, and our results are consistent with the progression of our professional activity.^{4,7} We have observed that ABI cannot be determined in some cases (2.5%) or is unreliable when there is a calcified arterial medial layer (12.5% of cases), showing limitations in outcomes of success in PTA-treated patients (15% of total).^{4,6,7}

In this study, we monitored TcPO₂ while performing PTA revealing variations in each phase of the radiological procedure. We have not found previous references for this observation except that by Wagner *et al*⁶ that described similar changes in

only one patient. Therefore, this is the first time that a graph is shown with TcPO₂ results during PTA in many patients. Our results show that administration of contrast medium slowly decreases the distal TcPO₂ recovery as arterial blood flow resumes and enhances diffusion of tissue oxygen. The angioplasty balloon inflation causes a rapid reduction in TcPO₂ recovery after deflation of the balloon. These results show the relationship between the increase in the volume of blood in the lower treated limb and increase in TcPO₂.⁶ It also suggests the usefulness of determining TcPO₂ after PTA as a valuation technique of revascularization achieved after the radiological procedure.^{7,8} The maximum TcPO₂ monitoring was 2 h to keep the process within safety limits, avoiding the appearance of skin rash or skin burn.

Usually, PTA is considered successful when there is blood flow with residual stenosis of <30% of the vessel lumen. Our results show that in 17.5% of patients, PTA significantly reduced arterial stenosis at 8 weeks, which is accompanied by an improvement in ABI but not by an improvement in distal reperfusion based on the TcPO₂ finding. Therefore, the study of TcPO₂ should be used as a complement in these patients.

Another limitation of the ABI is the existence of partial arterial stenosis with calcified walls showing “false negatives”. This portrays a normal ABI in patients with CLI. In our study, another 15% of patients had these characteristics and could only be detected by TcPO₂. Several authors have proposed a range of 30–50 mmHg O₂ for moderate ischaemia and <30 mmHg O₂ as critical levels.²

A clinically relevant situation is that PTA can induce the formation of a “dust” of atheromatous plaque and distal embolization after treatment of stenosis.^{9,10} This might explain the reduction of oxygen in some patients in whom an increase in the arterial diameter is not followed by a concomitant increase in TcPO₂ but, paradoxically, shows a decrease in the same. In our study, another 7.5% of the patients had a TcPO₂ lower than the initial PTA and were inconspicuous after Doppler imaging (ABI).

By contrast, sometimes ABI can be low while TcPO₂ values are normal. It has been suggested that in these cases, the presence of collateral circulation could explain the tissue perfusion distal to the stenosis that results in a low ABI.¹¹ In our study, 12.5% of patients presented with this clinical situation.

Overall, 67.5% of our patients showed significant differences when assessed with ABI and TcPO₂. These results confirm that ABI is not well correlated with microcirculation and tissue

oxygenation in treated limbs.¹² Statistical analysis of our results revealed a scant correlation between the techniques used (TcPO₂ and ABI), which means that both indices show a relationship that is conditioned by the patients’ improvement rather than any true correspondence between both parameters.

Some authors report that after PTA, revascularization may be progressive and slow, and therefore suggest that the assessment of post-PTA TcPO₂ should be carried out days after the conclusion of revascularization procedure because it could continue to rise for days or even 1 month after PTA.^{6,13,14} In our study, TcPO₂ continued to increase up to 8 weeks after PTA, while the ABI remained constant throughout this period. It has been suggested that perhaps the revascularization in sparsely perfused areas causes an increase in the angiogenesis processes leading to an increase in capillary function.¹

A limitation of our study is that the parameters analysed (ABI, TcPO₂ or arteriography) do not report the clinical course of a patient, improved quality of life or establish a long-term prognosis. We intend to continue the study correlating these results with patients’ clinical progress after a year. Furthermore, in some studies where these controls are long term, these have limited usefulness since the progress of CLI and other associated diseases show a general tendency to decline and have high morbidity and mortality.²

Methods that provide functional information on tissue perfusion and skin viability, such as TcPO₂ measured on the dorsum of the forefoot, are still seldom used mainly because of their limited availability of a transcutaneous oximeter.¹⁵ When performed properly, forefoot TcPO₂ has a high prognostic value.¹⁶ This is a straightforward, quick and rapid technique that can be carried out in all patients (except those with significant oedema). Indeed, in our study, it was used with all patients, including the most severe cases that were excluded when employing the ABI by Doppler.⁴ According to Becker,¹ the use of TcPO₂ on a larger scale should be strongly encouraged in vascular clinics. Future studies might consider performing TcPO₂ measurements at control sites as a measure of resting perfusion index.

In conclusion, the increase in TcPO₂ measurements following PTA procedure has more specificity and sensitivity than does the ABI. The use of TcPO₂ may represent a more accurate alternative than traditional methods (ABI) used in assessing PTA results. The TcPO₂ also allows the radiologist to assess changes in tissue oxygenation during PTA allowing changes to the procedure and subsequent treatment.

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