Clinical Research

Feasibility of Photo-Optical Transcutaneous Oxygen Tension Measurement During Revascularization of the Lower Extremity

Bernard S. Leenstra,[1] *Christiaan Meerkerk,*[2] *Michael Conte,*[3] *Jan Willem Hinnen,*[2] *Gert J. de Borst,*[1] *and Bart Verhoeven*[2]

Abstract: Objectives: A novel approach in the evaluation of peripheral arterial disease is the photo-optical oxygen tension measurement (pTCpO2). This modality is suggested to be more practical in use in comparison to standard electro-chemical oxygen tension measurement. Hence, pTCpO2 might be of added value to evaluate revascularization of the lower extremities peri-procedural. We conducted a preliminary feasibility study to analyze the potential of pTCpO2 during revascularization.

Methods: Ten patients scheduled for revascularization of the lower extremities were enrolled. pTCpO2 values of the affected lower extremity were measured pre-operatively, during revascularization and after revascularization. Results were compared to the pre- and postoperative ankle-brachial index (ABI) and to perioperative angiography. Primary endpoint was the feasibility of perioperative pTCpO2 measurement. Secondary endpoints were concordance between pTCpO2, ABI, angiography and clinical outcome.

Results: Two out of twelve measurements were unsuccessful. Eight out of ten patients experienced significant clinical improvement and pTCpO2 increase. Two patients that did not experience clinical improvement corresponded with no changes in intraoperative angiography and without increase in ABI or pTCpO2. A significant and strong correlation was found between prior and after revascularization ABI and pTCpO2 measurements ($r = 0.82$ $P = 0.04$).

Conclusions: Photo-optical transcutaneous oxygen tension measurement may serve as an intraoperative tool to evaluate the success of revascularization. pTCpO2 could be an alternative for the ABI to determine the success of lower extremity revascularization.

INTRODUCTION

Recently, a novel photo-optical approach of TCpO2 measurement (pTCpO2), has been introduced.[1] This photo-optical technique defines the partial oxygen pressure based on a light-emitting-diode and photodiode. The underlying mechanism of this technique is explained elsewhere.[2] pTCpO2 has been proposed as more precise and more practical in use as the electro-chemical TCpO2 measurement.[3–5] Current pTCpO2 measurement might be an interesting alternative tool to assess the success of revascularization perioperative. To date, pTCpO2 measurement can be conducted with small handheld devices. Therefore, this technique is practical in use and probes are easily applied on the lower extremities during revascularization

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[1]*Department of Vascular Surgery, UMC Utrecht, Utrecht, Netherlands*

[2]*Department of Vascular and Endovascular Surgery, Jeroen Bosch Ziekenhuis, Netherlands*

[3]*Heart and Vascular Center, University of California, San Francisco, CA*

Correspondence to: Department of Vascular and Endovascular Surgery, Jeroen Bosch Ziekenhuis, Henri Dunantstraat 1, 5223 GZ 's-Hertogenbosch, Netherlands.; E-mail: ba.verhoeven@jbz.nl

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Table I. Patients' characteristics.

Characteristics	Number
Age (years, sd)	58.1 (10.5)
Females/males (*n*, %)	4 (40.0)/6 (60.0)
Diabetes (*n*, %)	7 (70.0)
Ex/current smokers (*n*, %))	6 (60.0)/4 (40.0)
Rutherford 2 (*n*, %)	5 (50.0)
Rutherford 3 (*n*, %)	4 (40.0)
Rutherford 5 (*n*, %)	1 (10.0)

providing real-time oxygen tension measurement. Hence, this technique may offer the option of noninvasive perioperative evaluation of revascularization. Finally, if peri-procedural measurement does not show improvement, the vascular surgeon might be able to adjust the procedure intraoperatively. This preliminary experimental study aimed to investigate the feasibility of perioperative pTCpO2 measurements in patients with lower extremity atherosclerotic disease undergoing endovascular revascularization (PTA).

MATERIAL AND METHODS

In total, twelve consecutive patients with peripheral arterial disease were approached to participate in this feasibility study. An overview of patients' characteristics is demonstrated in Table I. Written informed consent was obtained from every patient after explanation of the study and before enrolment in the study. The local Ethics and Research Committee approved this study and patients signed informed consent. Inclusion criteria were: patients diagnosed with PAD and scheduled for endovascular revascularization of the lower extremity. We excluded patients with contraindications for ABI measurement (deep vein thrombosis, severe pain of the lower extremity, patients not being able to remain in a supine position during examination) or not able to undergo the revascularization procedure. ABI measurements were carried out by an experienced vascular-laboratory assistant. ABI measurement was conducted according to standard operating protocol with visual Doppler measurement. ABI was conducted prior (T0) and within 24 hours after revascularization (T1). pTCpO2 measurement was conducted with MediCap Precise 8001. The probe of the MediCap was placed at the ventral-medial site of the calf. Hence, the anterior or posterior tibial artery angiosome was the preferred measurement location (Fig. 1). Measurements were

Fig. 1. Demonstration of probe application on lower extremity.

conducted at operation room temperature, default probes temperature was set at 44° degree Celsius. The measuring site was carefully cleaned using a decontamination solution. The probe was attached firmly to the skin with a patch and a contact liquid supplied by the manufacturer. Extra dressings were applied to prevent probe disconnection with underlying skin. pTCpO2 was recorded continuously and mm Hg values were noted at: prior to revascularization (T0), during vascular occlusion achieved by using PTA balloon (T1) and at the end of revascularisation prior to inguinal artery puncture pressure (T2). To determine the clinical outcome of revascularization patients visited outward clinic between five to six weeks after revascularization. Clinical success was defined as patients indicating significant improvement six weeks postoperative. To provide a general overview of ABI and pTCpO2 pre- and postoperative results, box and whiskers for each time point were plotted. Clinical success was compared with delta ABI (T1-T0), delta pTCpO2 (T2-T0) and perioperative angiographic success, defined as an increase of flow distal of the lesion, reviewed by two vascular surgeons blinded to ABI and pTCpO2 results. A delta TCpO2 (T2-T1) was determined to investigate if peri-procedural changes in the blood supply of the lower extremities could be detected.

Statistical Analysis

Descriptive statistics were used to present baseline characteristics. The relationships between the pTCpO2 and the ABI were rated by regression/correlation analysis, by calculating the Pearson correlation coefficient. The results were considered significant at a p-value of 0,05. Data analysis was conducted using Statistical Package for the Social Sciences (SPSS; version 25 IBM, Armonk, NY)

Table II. Mean of ABI and pTCpO2 measurement.

Baseline	
ABI T0 (average, sd)	0.74 (0.15)
ABI T24 (average, sd)	0.96 (0.21)
pTCpO2 T0 (mm Hg, sd)	50.1 (23.23)
pTCpO2 T1 (mm Hg, sd)	36.9 (20.41)
pTCpO2 T2 (mm Hg, sd)	64.7 (17.79)

RESULTS

In total, ten consecutive patients underwent successful ABI and pTCpO2 measurement during and after revascularization. The first two measurements were unsuccessful due to perioperative disconnection of the pTCpO2 probe. Therefore, the measurements from these two patients were excluded. Baseline ABI and TCpO2 measurements are demonstrated in Table II. ABI, pTCpO2, clinical and angiographic results are demonstrated in Table III. One patient experienced minimal clinical improvement with delta ABI +0.01, delta pTCpO2 +3.8 mm Hg and no angiographic improvement. One patient experienced no clinical improvement with delta ABI -0.11, delta pTCpO2 -31.0 mm Hg and no angiographic improvement. Eight patients experienced clinical improvement and were classified angiographic successful with average delta ABI +0.24 ($\sigma = 0.24$) and delta pTCpO2 + 21.7 ($\sigma = 19.8$). Significant strong correlation was found between delta ABI and delta pTCpO2 ($r = 0{,}82$ $P = 0.04$). Average delta pTCpO2 (T2–T1) was 27.7 mm Hg. Box and whiskers plots for ABI (T0–T1) and TCpO2 (T0–T2) are demonstrated in Figure 2.

DISCUSSION

We conducted the first feasibility study evaluating pTCpO2 measurement during revascularization of the lower extremities. In general, it is feasible to apply pTCpO2 probes and perform pTCpO2 measurements during PTA. However, attention is required concerning the adequate application of the probes. The co-provided adhesive rings were not strong enough resulting in two disconnections early during revascularization. This was successfully addressed with application of an extra bandage. In patients with improved clinical outcome after PTA, ABI and pTCpO2 improved. In addition, patients without clinical improvement after PTA, no improvement was found in ABI or pTCpO2. Specifically, the absence of clinical improvement after revascularization in two patients corresponding with no significant improvement in ABI and pTCpO2 indicates the potential reliability of pTCpO2. A study with electro-chemical TCpO2 measurement during revascularization found comparable results.[6] However, electro-chemical TCpO2 measurement has its limitations. The need for calibration prior to each measurement is time-consuming and heating of the probe can cause gas bubble formation between sensor foil of the probe degrading the characteristics of the sensor.[7] Also, it is suggested that electro-chemical TCpO2 measurement in comparison to photo-optical TCpO2 measurement provides a less accurate status of the actual vascularization of the extremity.[5] Therefore, if the added value of TCpO2 measurement during revascularization could be demonstrated photo-optical measurement would be recommended. A strong point of this study was the significant decrease at pTCpO2 T2 (Fig. 2) due to intra-arterial balloon presence, indicating direct detection of impaired blood supply. The small sample size in this study is a strong limitation. Therefore, conclusions on the added value of pTCpO2 during revascularization cannot be drawn, however, the primary outcome of this study is to demonstrate if this technique is feasible to measure perioperative pTCpO2. Another limitation was the use of a single probe device. Thus, no other region of the lower extremity could be measured simultaneously during revascularization. Ideally, a more extensive overview of the vascular status of the lower extremity would be beneficial to determine revascularization success. In extension, a perioperative pTCpO2 reference probe applied to a different region other than the lower extremity would be desirable. Also, several inconveniences with pTCpO2 measurement should be noted. First, as mentioned, the adequate application of probes was a minor difficulty. Second, to prevent thermal injury of the skin it is recommended continuous measurement should last no longer than two hours. Although we did not exceed this time limit, it is understandable that pauses between TCpO2 measurements are preferable. Nonetheless, the potential benefit of pTCpO2 during revascularization is substantial. If the ABI 24-hours after revascularization would be no longer needed this would have a logistic advantage and would lower workload at the vascular laboratory. Moreover, real-time notification of the vascular status could alter treatment strategy, if during revascularization no increase in mm Hg is found additional actions to generate sufficient blood supply to the affected area could be executed. Thus, avoiding another new revascularization

Table III. Overview of measurements.

N	Rutherford	Treated vessel	TASC-II prior	ABI T0	pTCpO2 T0	ABI T24	pTCpO2 T1	pTCpO2 T2	Delta ABI(T24-T0)	Delta pTCpO2(T2-T0)	Angiographic outcome	Clinical outcome
1	2	CIA/ EIA right	A/0	0.95	30.5	1.06	19.1	42.0	0.11	11.5	Successful	Improved
2	3	CIA / EIA left	B/B	0.70	66.2	0.68	50.6	70.8	-0.02	4.6	Successful	Improved
3	2	SFA right	A	0.68	35.6	0.97	16.3	90.3	0.29	54.7	Successful	Improved
4	2	In stent restenosis CIA right	A	0.79	74.8	1.16	72.8	88.9	0.37	14.1	Successful	Improved
5	3	CIA	A	0.73	86.2	0.62	59.5	55.2	-0.11	-31.0	Unsuccessful	No improvement
6	2	CIA right	A	0.95	73.2	1.11	53.1	79.8	0.16	6.6	Successful	Improved
7	5	AFS / ATA right	AFS (A) ATA (D)	0.50	18.3	1.13	16.2	67.6	0.63	49.3	Successful	Improved
8	2	CIA right	B	0.64	32.8	0.94	29.2	58.1	0.30	25.3	Successful	Improved
9	3	CIA / EIA left	B/B	0.43	48.5	0.44	31.6	52.3	0.01	3.8	Unsuccessful	Minimal improvement
10	3	CIA / EIA both sides	D/D	0.49	34.5	0.54	21.3	41.6	0.05	7.1	Successful	Improved

Overview of treated vessel, ABI, pTCpO2 measurements, reviewed angiography and clinical outcome (CIA, common iliac artery; EIA, external iliac artery; SFA, superficial femoral artery; ATA, anterior tibial artery) with T0 prior to revascularization, ABI T1 within 24-hours after revascularization, pTCpO2 during revascularization with (T1) prior to removing balloon and (T2) prior to entry wound pressure.

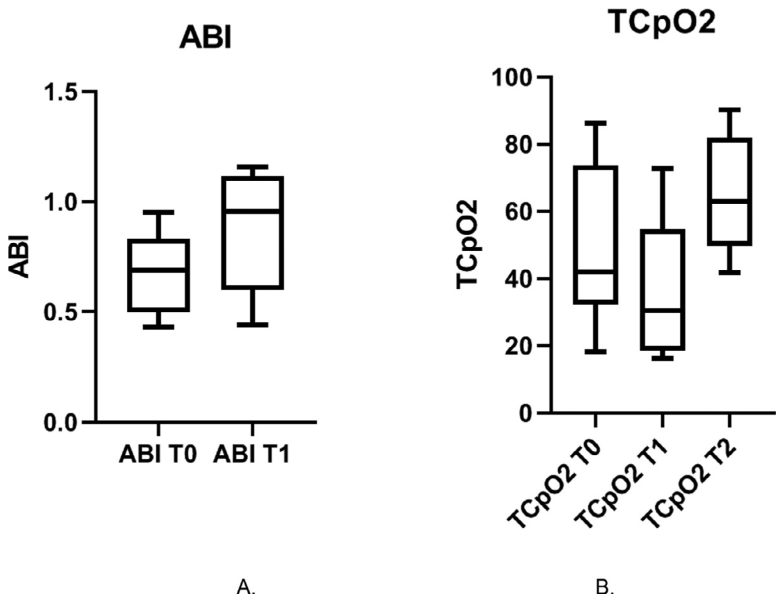

Fig. 2. Box and whiskers plot for ABI and pTCpO2
Box and whiskers for ABI and TCpO2. (A) ABI T0 prior to revascularization, ABI T1 within 24-hours after revascularization, (B) pTCpO2 during revascularization with (T1) prior to removing balloon and (T2) prior to entry wound pressure.

procedure. Although the initial clinical success rate of endovascular revascularization procedures is high, short-term failures do occur.[8] Despite the fact a more improved method of probe application is desirable, this feasibility study provides the basis for a larger observational study to be conducted to demonstrate if pTCpO2 is of added value during revascularization of the lower extremities.

CONCLUSION

Photo-optical transcutaneous oxygen tension (pTCpO2) potentially serves as an alternative noninvasive tool to assess vascularization of the lower extremities. Our findings indicate that pTCpO2 is feasible to detect intraprocedural differences in the perfusion status during endovascular revascularization

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