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Monitoring of Foot Oxygenation with Near-infrared Spectroscopy in Patients with Critical Limb Ischemia Undergoing Percutaneous Transluminal Angioplasty: A Pilot Study

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WHAT THIS PAPER ADDS

This pilot study describes non-invasive measurements of foot oxygenation with near-infrared spectroscopy in CLI patients before, during, and after percutaneous transluminal angioplasty. Near-infrared spectroscopy measurements appear to be safe and feasible, even in patients with ulcers. This paper also shows that near-infrared spectroscopy is able to monitor hemodynamic changes in feet after endovascular treatment. Therefore, near-infrared spectroscopy is a promising technique to provide information concerning the state of oxygenation of ischemic feet after endovascular revascularization. Large cohorts are warranted to explore the clinical value of near-infrared spectroscopy measurements of ischemic feet in predicting the success of endovascular revascularization.

Objective: Near-infrared spectroscopy (NIRS) non-invasively determines tissue oxygen saturation (Sto_2) in muscle tissue. Its application to monitor real time hemodynamic changes during percutaneous transluminal angioplasty (PTA) and Sto_2 changes in feet 4 weeks after PTA was evaluated.

Methods: This study included 14 patients with critical limb ischemia (CLI, six patients Rutherford classification Stage IV, two patients Stage V, and six patients Stage VI). In patients with arterial ulcers, NIRS optodes were placed near the ulcer of the diseased foot (Optode 1), and at the same spot at the contralateral foot (Optode 2). In patients without arterial ulcers, Optode 1 was placed on the dorsum of the diseased foot, and Optode 2 was placed on the dorsum of the contralateral foot. Single Sto_2 values, ankle brachial indices, and toe brachial indices were obtained at rest before the start of endovascular revascularization and 4 weeks after treatment. During the endovascular procedure, continuous Sto_2 measurements were recorded throughout the intervention. Completion angiograms were used to evaluate the success of intervention.

Results: Patients underwent treatment of the superficial femoral artery (79%), popliteal artery (21%), and below the knee arteries (43%). In 13 of the 14 patients, completion angiograms showed successful treatment of target lesions. Ankle brachial indices and toe brachial indices significantly increased 4 weeks after treatment (both $p < .01$). Single Sto_2 values of Optode 1 also significantly increased four weeks after treatment ($p < .01$). In contrast, single Sto_2 values of Optode 2 did not ($p = .73$). During the endovascular procedure, continuous Sto_2 measurements of Optode 1 and 2 did not increase ($p = .80$, and $p = .61$, respectively).

Conclusions: NIRS monitoring of foot oxygenation in patients undergoing endovascular revascularization is safe and feasible. NIRS is a promising non-invasive technique to monitor hemodynamic changes in the feet of CLI patients after endovascular treatment using single Sto_2 values.

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INTRODUCTION

Patients with critical limb ischemia (CLI) are treated by percutaneous transluminal angioplasty (PTA) of the femoropopliteal and below the knee arteries for re-establishment of adequate perfusion.[1] Digital subtraction angiography (DSA) is used to assess the effect of endovascular treatment, but only shows re-establishment of blood flow in the main arteries and large side branches of the lower extremities and feet. On DSA, critical blood flow to

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the microcirculation of the actual ischemic target tissue is not visible.[2] In CLI patients undergoing endovascular revascularization, monitoring of oxygen saturation of the ischemic target tissue might allow for better surveillance of the effect of revascularization than DSA. However, no gold standard is available for the assessment of the effects of revascularization on oxygen saturation in lower extremity muscles.[3]

Near-infrared spectroscopy (NIRS) is a non-invasive technique that determines single tissue oxygen saturation (Sto_2) values of muscle tissue in most areas of the lower extremity.[4] Kagaya and co-workers[5] showed that single Sto_2 values in ischemic feet are more accurate in predicting locations of ulcerated regions in CLI patients than the angiosome model using angiograms. Consequently, NIRS might be a promising tool to assess the effect of endovascular treatment on oxygen saturation in feet after the intervention. Also, NIRS has the ability to measure Sto_2 values continuously. This feature could enable the surveillance of the hemodynamic effects of balloon inflation and balloon deflation in feet during the intervention, and could determine the extent of the endovascular procedure.

NIRS might be especially useful in CLI patients with arterial ulcers of the foot. In these patients, placement of NIRS optodes on the skin near the arterial ulcer provides direct information regarding the target tissue of endovascular treatment.

This pilot study had three goals: first, to examine the ability of NIRS to monitor hemodynamic changes in the foot after endovascular revascularization using single Sto_2 values; second, to investigate the correlation between single Sto_2 values and ankle brachial indices (ABIs) and toe brachial indices (TBIs); and, third, to explore the safety and feasibility of NIRS to monitor real time effects of revascularization on oxygen saturation in the foot during endovascular treatment using continuous Sto_2 measurements.

MATERIAL AND METHODS

The Ethics Review Board of the St. Antonius Hospital, Nieuwegein, approved this pilot study. NIRS measurements were performed in 14 consecutive CLI patients (9 men, mean age 73.7 $\pm$ 10.7 years, all Caucasian), undergoing PTA of the femoropopliteal and/or below knee arteries. Patients experienced chronic ischemic rest pain or arterial ulcers (Rutherford classification Stage IV, V, or VI). Patients had a mean resting ABI of 0.35 $\pm$ 0.20 and a mean resting TBI of 0.23 $\pm$ 0.08. All patients underwent pre-procedural imaging to confirm the diagnosis of chronic arterial occlusive disease (magnetic resonance arteriography [MRA], computed tomography arteriography [CTA], or DSA). After individual assessment of the peripheral vascular status in each patient by a team of vascular surgeons and interventional radiologists, endovascular revascularization of the lower extremity was chosen as the optimal treatment. Hereafter, patients were asked to participate in the current study. Written informed consent was obtained from all included patients. Patients with a body mass index over 30 kg/m^2 were excluded. All patients had an overlying tissue thickness at the measurement spots of less than 10 mm. None of the patients suffered from pulmonary disease.

Near-infrared spectroscopy

The NIRS technique was first described by Frans Jöbsis in 1977.[6] NIRS uses wavelengths of the red and near-infrared region to non-invasively measure the Sto_2 of cerebral and muscle tissues. Most NIRS optodes consist of a light source and two receiving photodetectors, mounted in line on a flexible frame. The light source emits red light and near-infrared light through the sampled tissue to its photodetectors. In the near-infrared region, light absorption in biological tissue is dominated by hemoglobin.[7] Because the absorption spectra of red and near-infrared light vary between oxygenated and deoxygenated hemoglobin, NIRS is able to determine the proportion of oxygenated hemoglobin in small vessels from the amount of light detected at the photodetectors.[8] Thus, the provided Sto_2 value reflects the ratio in percentages between concentrations of oxygenated hemoglobin and deoxygenated hemoglobin in the measured tissue, and is defined as [oxygenated hemoglobin]/([oxygenated hemoglobin] + [deoxygenated hemoglobin]), where [] denotes concentration.

NIRS has a maximum penetration depth of approximately 15 mm.[9] In this study, a Hamamatsu NIRO-200 system (Hamamatsu Photonics K.K, Hamamatsu, Japan) was used to perform NIRS measurements.

In patients with arterial ulcers, NIRS Optode 1 was attached to the skin of the diseased foot, 2 cm distal to the arterial ulcer. NIRS Optode 2 was placed at the same spot at the contralateral foot, as reference measurement. In patients with arterial ulcers located on the toes, optodes were placed 2 cm proximal to the arterial ulcer at the distal metatarsal level. In patients without arterial ulcers, NIRS Optode 1 was applied to the dorsum of the foot of the diseased lower limb, and NIRS Optode 2 was attached to the dorsum of the foot of the untreated contralateral lower extremity.

Measurement of single Sto_2 values

A single Sto_2 measurement was performed at the measurement spot in both feet before the endovascular procedure started. These Sto_2 values were used as a baseline value and set at 100%. Locations of optode placement were marked and photographed to ensure similar probe placement during follow up measurements. Four weeks after endovascular revascularization, follow up measurements were performed in the outpatient clinic. Patients were asked to lie in the supine position for 20 minutes. After this resting period, a single Sto_2 value was obtained at the marked measurement spot in both feet.

Measurement of ABIs and TBIs

Patients also underwent measurement of ABI and TBI of both legs before the start of the endovascular procedure and during the follow up measurements 4 weeks after

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