Hemodynamic consequences of internal iliac artery occlusion following endovascular abdominal aortic aneurysm repair assessed by near-infrared spectroscopy.

Category: Clinical investigation

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Short title: NIRS for gluteal ischemia

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ABSTRACT

The purpose was to evaluate endovascular aortic repair (EVAR) patients with known gluteal claudication using near infrared spectroscopy (NIRS), and secondly to assess the hemodynamic consequences of occluding one internal iliac artery (IIA) during EVAR.

EVAR interventions with occlusion of one IIA were examined. Gluteal claudicants were recruited from the outpatient clinic at their annual EVAR control (Group A; n=7) and a second cohort was collected consecutively and prospectively before and after the intervention (Group B; n=10). A treadmill test (12% incline, 2.4 km/h) with NIRS (INVOS-5100) sensors applied bilaterally on the gluteal regions was performed. NIRS was used to assess muscle oxygenation. NIRS data was divided into baseline, exercise and recovery values. Recovery times and absolute NIRS values (oxygenation) from the two gluteal sides were compared.

Mean recovery times (group A) of the occluded and patent sides were 512 sec [73-1207] and 137 sec [0-643] (p=0.046) respectively. Using 240 seconds (suggested by literature) as cut-off the sensitivity and specificity were both 71% for finding the occluded IIA. Group B revealed similar oxygenation level of the two gluteal regions pre EVAR. Post EVAR an overall absolute reduction of the oxygenation were noted and a significant difference in the recovery values of the two gluteal sides (p<0.05).

In this explorative study NIRS does show relevant changes of the oxygenation on the gluteal region following occlusion of an IIA in groups of patients. But given the lack of statistical power the efficacy of diagnostic use in individual patients has yet to be proven.

Keywords: aortoiliac aneurysm; endovascular; gluteal claudication; near infrared spectroscopy; gluteal muscle oxygenation
INTRODUCTION:

Abdominal aortic aneurysms (AAA), are accompanied by common iliac artery aneurysms or ectasia in approximately half of the cases[1,2], while isolated iliac aneurysms account for 2% of aortoiliac aneurysms[3,4]. Endovascular aortic repair (EVAR) is a well-established procedure for AAA repair. When the common iliac artery lacks an adequate distal landing zone the endovascular aortic repair (EVAR) has to be extended into the external iliac artery. This necessitates coverage of the internal iliac artery (IIA) unless a branched iliac stent graft can be applied. IIA exclusion may elicit ischemia of the pelvis organs, including impotence and fatality[5,6]. Moreover gluteal claudication has been reported in up to 50% following IIA occlusion[5,7]. This emphasises the potential devastating hemodynamic consequences of IIA coverage during EVAR. Also, the majority of AAA cases present with asymptomatic disease and thus the effect of iatrogenic pelvic ischemic disorders as described above are particularly upsetting for the patient.

It is desirable to assess the gluteal haemodynamics in EVAR but available literature is limited and ambiguous. The pelvic circulation has been examined by transcutaneous oxygen pressure (tcpO₂) and near infrared spectroscopy (NIRS) [8–12]. The latter technique has proven useful for assessment of changes of regional cerebral oxygen saturation[13], in vascular surgical patients[14] and in evaluation of patients with peripheral arterial disease[15]. Sugano et al[10] applied NIRS to evaluate the gluteal oxygen supply following an open operation for AAA with ligation of the IIA. NIRS sensors were applied over the gluteal regions. An extended recovery time, following a treadmill exercise test, correlated with the occurrence of gluteal claudication.
The primary aim of this exploratory study was to assess gluteal muscle oxygenation using NIRS in patients who developed gluteal claudication after EVAR including an IIA occlusion. The secondary aim was to assess gluteal muscle oxygenation before and after EVAR when IIA occlusion was added to the procedure.

The hypothesis was that NIRS would show a decreased signal on the relevant gluteal side.

**METHODS**

**Patients**

During a period of six months, we examined two groups of patients subjected to EVAR including concurrent occlusion of one IIA. First we examined patients who had developed gluteal claudication after EVAR, selected in the outpatient clinic, at their annual control visit (group A, n=7). Second we consecutively enrolled patients immediately before and after EVAR (group B, n=10). Four (40%) of these ten patients developed gluteal claudication after EVAR.

Demographic data of the seventeen men are listed in Table 1. All patients with gluteal claudication had symptoms corresponding to the side of the occluded IIA. None of the patients had symptoms of lower limb ischemia and all had an ankle-brachial-index above 0.9. Re-evaluation of the preoperative computed tomography angiography (CTA) by an experienced interventional radiologist (LL) revealed one patient with an asymptomatic 75% stenosis of the IIA in group A.

The elective endovascular procedures were performed under general anaesthesia. A Zenith stent graft (Cook Inc, Bloomington, Ind US) was deployed under fluoroscopy and
macro coils or an Amplatzer vascular plug (AGA Medical Corp, Plymouth, Minn US) was used to occlude the IIA. No patient had a branched iliac stent graft.

The study was approved by the local ethics committee (ethical protocol number: H-3-2011-104) and oral and written informed consent was obtained.

Table 1

<table>
<thead>
<tr>
<th>Descriptive data on patients</th>
<th>Group A</th>
<th>Group B</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(n=7)</td>
<td>(n=4)</td>
</tr>
<tr>
<td>Gender</td>
<td>Male</td>
<td>7 (100%)</td>
</tr>
<tr>
<td>Age (years)</td>
<td>Median [range] 68 [62-75]</td>
<td>75 [64-76]</td>
</tr>
<tr>
<td>Smoker*</td>
<td>Yes</td>
<td>6 (86%)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>Yes</td>
<td>1 (14%)</td>
</tr>
<tr>
<td>TCI, Stroke</td>
<td>Yes</td>
<td>0</td>
</tr>
<tr>
<td>Hypertension</td>
<td>Yes</td>
<td>3 (43%)</td>
</tr>
<tr>
<td>Cardiac morbidity*</td>
<td>Yes</td>
<td>5 (71%)</td>
</tr>
<tr>
<td>Pulmonary morbidity*</td>
<td>Yes</td>
<td>0</td>
</tr>
<tr>
<td>ASA*</td>
<td>1+2</td>
<td>2 (29%)</td>
</tr>
<tr>
<td></td>
<td>3+4</td>
<td>5 (71%)</td>
</tr>
</tbody>
</table>

Data are given as count (percentage) and median [range]. Group A: Seven patients tested during follow up post EVAR. Group B: Ten patients tested both before and after EVAR. *Current or history of smoking. **Cardiac and pulmonary morbidity defines all treatment required conditions. ASA = American society of anaesthesiologist score compressed to a dichotomous score for better reliability[16]

Near infrared spectroscopy (NIRS)

We used a continuous dual-wavelengths NIRS (INVOS-5100, Somanetics, Troy, MI, USA) to assess the muscle oxygenation. The system consists of a monitor/computer and disposable transducer sensors. Up to four sensors can be connected at the same time.

The sensors consist of one light-emitting diode and two detectors. The light-emitting diode sends out light in two wavelengths (730 and 810 nm) and the two detectors obtains the
return signal[17]. The two detectors are placed at different length from the light source (30 and 40mm) resulting in a shallow and a deep measurement. The INVOS-5100 subtracts the shallow from the deep signal and therefore gives a saturation value predominately of the deeper layer (4-5cm). The system provides the saturation as a ratio between oxygenated and deoxygenated haemoglobin.

NIRS sensors were applied over each gluteal region, five cm posterior to the landmark of the greater trochanter of the femur, in a vertical orientation (figure 1a). Corresponding to the NIRS sensors position at the gluteal region the thickness of cutaneous and subcutaneous tissue were determined three cm proximal and five cm posterior of the greater tubercle of femur based on the CTA images. The median distance of sensors to the gluteal muscles was 18mm [range, 10-36mm], and did not differ significantly in neither the groups nor the gluteal side.

**Exercise setup**

Standing and resting on a treadmill (h/p/cosmos sport and medical, mercury, Nussdorf-Traunstein, DE) baseline values were collected for two minutes. Thereafter the exercise was initiated at 2.4 km/h with a 12% inclination and continued until the onset of gluteal symptoms or fatigue. After exercise patients rested until NIRS recordings returned to baseline values and/or for a minimum of ten minutes (figure 1b).
Figure 1

Figure 1a: The sensors were applied 5 cm behind the bony prominence of the greater trochanter of the femoral bone in a vertical orientation.

Figure 1b: The laboratory treadmill setup. The treadmill was set with an incline of 12% and a speed of 2.4 km/h. The INVOS-5100 was placed on a table next and continuously monitoring both gluteal sides.

Data processing and statistics

NIRS recordings were separated into three phases: baseline -, exercise - and recovery values and mean values were calculated (figure 2). The mean of baseline values was used to achieve recovery time. Recovery time was defined as the time period between end of exercise until NIRS values return to baseline level. If NIRS values at the end of exercise were above baseline values, recovery time was set to null (figure 2).
A cut-off value of 240 seconds, as suggested by Sugano et al, was used to determine sensitivity and specificity[10] and a ROC-curve analysis was performed to find an optimal cut-off value.

Mean ± standard deviation (SD) was used to summarize continuous variables with symmetric distribution, and median [range] was used for non-symmetric distributions. Mann-Whitney U and Wilcoxon signed ranks tests were used to compare recovery times and the NIRS response, both over time and in between groups. The level of statistical significance was set to p value < 0.05.

All statistical calculations were performed using IBM SPSS Statistics 20 software (SPSS Inc, Chicago, Illinois). Graphs were printed in GraphPad Prism 5.0 software (GraphPad Software, San Diego California USA).

RESULTS

Recovery times are presented in figure 3. In group A recovery time of the IIA occlusion side and the patent IIA side were 512 sec [range: 73-1207] and 137 sec [range: 0-643] (p=0.046), respectively.

![Figure 3](https://via.placeholder.com/150)

Recovery times from each patient of the two groups. Each circle represents one gluteal side. Two circles and a connecting line represent one patient. The dotted vertical line indicates the 240 seconds cut-off value. ROC-curve analysis did not suggest a better cut-off value.
Using a cut-off value of 240 seconds, as suggested by Sugano et al[10], the “occluded” sides was separated from the “patent” sides, with a sensitivity and specificity both of 71%. Recovery times in group B (post EVAR test) disclosed a lower accuracy in identifying which side that was occluded. Moreover patients who complained of gluteal claudication (Symp) had shorter recovery time as compared to those who had no symptoms (Asymp) (p=NS).

We also evaluated the absolute oxygenation value given by the INVOS-5100. The ten patients in group B were examined before as well as after EVAR and their mean values of NIRS in the three phases, baseline, exercise and recovery, are presented in figure 4. No significant difference was found in gluteal muscle oxygenation before EVAR when comparing the two sides (Pre EVAR). However, after EVAR including an IIA occlusion a general reduction of gluteal muscle oxygenation and a more pronounced reduction on the side of IIA occlusion was shown. The Post EVAR test revealed a significant difference (p=0.045) of gluteal muscle oxygenation between the occluded and the open side in recovery values.

Figure 4
Gluteal muscle oxygenation at baseline, during exercise and in the recovery after exercise in patients treated with an EVAR that resulted in occlusion of one internal iliac artery. Patients were tested one day prior to and within days after the EVAR procedure (second or third day). Variables are presented in means and the included error bars are SEM for better graphical clarity.
†Indicates a significant difference (p<0.05) in recovery values between patent and occluded side after EVAR.
*Recovery values are for the first 300 seconds after end of exercise for comparison. 300 seconds was available on all patients.
DISCUSSION

This study demonstrated that NIRS may distinguish between a patent and an occluded IIA in groups of patients. But in order to obtain an individual clinical diagnosis this type of a test was less convincing. We were unable to reproduce the findings reported by Sugano et al.[10], demonstrating a sensitivity and specificity of 100%, respectively, in eight claudicants and ten asymptomatic gluteal sides. The even lower accuracy found in group B using recovery time stresses the limitations of NIRS usage as a diagnostics test for IIA occlusion/gluteal claudication. When investigating before and after EVAR, including the occlusion of an IIA, we found a general decrease of the global gluteal oxygenation and a more accentuated decrease on the relevant occluded side according to NIRS.

In the investigation for ischemic disease e.g. heart and peripheral arterial disease (PAD), exercise testing is widely used as a standard clinical examination[18,19]. It is reasonable to assume that patients with insufficient gluteal perfusion could be assessed in the same manner. Patients (in group A) complained of gluteal claudication while walking, especially uphill, hence the treadmill setup was chosen for the test. The main difference to our setup is the examining apparatus. NIRS describes the tissue oxygenation and therefore ought to be relevant in the investigation of reduced gluteal perfusion.

Blood supply changes following the occlusion of the IIA, with the involvement of additional collateral supply to sustain the demand. Iliopoulos et al.[20] suggest, based on pressure measurements, that the ipsilateral external iliac artery/profound femoral artery provides a major collateral pathway and the contralateral IIA only a minor pathway. In native patients the collaterals originates from the ipsilateral iliac artery, ipsilateral profound femoral artery, contralateral IIA, the inferior mesenteric artery and lumbar arteries, [21,22]. EVAR covering
the AAA will impede major collateral pathway, bringing more demand on those native vessels that remain open. Part of the change in circulation appears to happen immediately[21]. Studies state that in up to 50 % the symptoms are transient over time indicating development of collateral branches[7,23].

The gluteal ischemic patients in Group A disclosed a significant difference in recovery time, “occluded” versus “patent” side. The cut-off value for the diagnostic test did only prove the test to be fair and a different cut-off did not alter this fact (figure 3). The gluteal oxygenation following EVAR indicates that the oxygenation on the patent side is also reduced. This might be explained by the termination of collaterals excluded by the endostent per se. However, it might also be caused by a steal phenomenon, thus vessels recruited from the patent IIA. It is therefore relevant to consider to keep both hypogastic arteries open since the use of a branch iliac device significantly reduces the risk of gluteal claudication after EVAR of aortoiliac aneurysm[24].

The current EVAR follow-up methods i.e. CTA and duplex ultrasound cannot detect insufficient perfusion in the gluteal region following IIA occlusion. Technical developments in EVAR with more complicated devices to address anatomic barriers emphasize the importance to understand the arterial blood supply in the gluteal region in order to prevent ischemic complications. Gluteal claudication is a subjective statement defined as fatigue, discomfort, or pain that occurs in the muscle during effort due to exercise-induced ischemia as compared to limb claudication. Given PAD (defined as ankle-brachial-index <0.9) less than 10% complaints of claudication[18]. This circumstance is plausible also in patients with gluteal claudication.

**Limitation of the study**
This is an exploratory study with a small sample of patients i.e. a low statistical power. The algorithms by which the INVOS-5100 computes the saturation are not disclosed and therefore limit its use. The influence of tissue thickness on the NIRS signal is unknown. Though it is assumed that the arterial trunk that vascularises both the skin, subcutis and the muscle are in common[11]. Therefore the saturation measured by NIRS is only an indirect measure of the gluteal perfusion.

**Conclusion**

NIRS can distinct between an occluded and patent IIA in groups of patients, but as a diagnostic tool for describing gluteal claudication for individuals we could not confirm the findings of Sugano et al[10]. The hemodynamic changes detected by NIRS indicate a significant reduction of oxygen saturation on the occluded gluteal side compared with the patent side.
Acknowledgement:

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Conflicts of interest:

The authors declare no conflict of interest.
REFERENCE LIST:


