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In-vivo validation of VASCOVID device, a hybrid diffuse optical platform for the assessment of microvasculature health in the intensive care.

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Abstract: We present preliminary in-vivo validation of VASCOVID device, a hybrid diffuse optical platform designed for automatized microvasculature health assessment in the intensive care. The in-vivo validation was run on more than hundred subjects. © 2024 The Author(s)

1. Introduction

The combination of near-infrared spectroscopy (NIRS) and vascular occlusion tests (VOT), a localized ischemia provoked by inflating a n c uff, h as b een c onsidered a s a n on-invasive p otential p rognostic t ool f or t he global hemodynamic status in critically ill patients, such those with septic shock, acute respirator distress syndrome and COVID-19 [1]. Monitoring the tissue oxygen saturation (StO_2, %) during this challenge provides insights into local metabolism, through the calculation of deoxygenation rate during cuff occlusion (DeO_2, %/min) , and endothelial function, through the calculation of the reoxygenation rate (ReO_2, %·s) and hyperemic peak (AUC StO_2, %·min) upon cuff release . Despite their usefulness in intensive care units (ICU), existing StO_2 monitors have limitations in accurately measuring absolute StO_2 values and direct indices of blood perfusion and metabolism, serving primarily as compact trend monitors. In the Horizon2020 project VASCOVID, we developed a compact hybrid diffuse optical device combining state-of-the-art time domain NIRS (working at 685 and 828 nm, 1 Hz), diffuse correlation spectroscopy (working at 785 nm, 38 Hz), combined with an automatized tourniquet. The platform, equipped with a pulse oximeter for arterial oxygenation (SpO_2, %), allows for more direct information on the metabolic rate of oxygen consumption ($MRO_2 \approx (SpO_2\text{-}StO_2)\cdot BFI$, %·cm^2/s). VASCOVID has been also provided with all necessary sensors in order to ensure real-time data quality and optical safety. The device is completely automatized for protocol standardization, battery operated and can be utilized remotely. We conducted a comprehensive validation of the platform ensuring VASCOVID's reliability and suitability for clinical use. Specifically, (Obj. 1) we compared its performances against a commercially available device and (Obj. 2) we evaluated its precision in-vivo. Finally, (Obj. 3) we compared the microcirculation in healthy subjects against ICU patients.

2. Methods

To address Obj.1, we utilized VASCOVID and an INVOS 5100C (Medtronic, Minneapolis, MN), a medical grade device based on spatially resolved NIRS. We placed the two devices alternately on palmaris lungus and brachioradialis muscles in a randomized order and performed two VOT, 30 minutes apart. For each instance, we computed DeO_2, ReO_2 and AUC for both StO_2 and BFI. We compared the two devices responses to the ischemic challenge by performing Wilcoxon signed-rank tests (significance at $p<0.05$). For Obj. 2, pertaining the assessment of the device precision, our goal was to identify the smallest meaningful alteration in both StO_2 and BFI while occluding the arterial blood flow at increments of 40, 60, 80 and 100% of the limb occlusion pressure, during both inflation and deflation. This pressure is defined as the point at which the PPG signal vanishes during limb occlusion. For

each occlusion interval (of 60 s duration) we calculated the coefficient of variation (CV = standard deviation/mean, %) in the last 15 s for both tissue oxygenation and blood flow. We then looked at correlation (Spearman's) between the absolute values and the dynamic range at 685 nm (most variable during VOT) and countrate (in kHz). Finally, as per Obj. 3, we included healthy subjects and critically ill patients within 24 hours from ICU admission. We performed a 3 minutes arterial occlusion and compared the responses to VOT in the two different population by means of Mann-Whitney U test (significance at $p<0.05$). The protocols were performed in accordance with the guidelines set forth by the local ethics committee and written informed consent was obtained from all participants prior to the start of the study.

3. Results

In pursuit of Obj.1, we enrolled 10 healthy young subjects. Comparing StO_2 measured by INVOS with respect to VASCOVID, we obtained significant higher values ($p=0.02$), along with elevated DeO_2 and ReO_2 ($p<0.001$), when measured on the same location. As an example, the Bland Altman plot in Fig. 1 a) illustrates 2.14% bias and distinct linear trend, highlighting the non-exchangeability of the two devices. Additionally, the CV for VASCOVID was 3.3 (5.0)% in the brachioradialis (palmaris longus) against the 6.1 (9.6)% for INVOS 5100C. For Obj. 2, we included 7 healthy young subjects, and we revealed a dependence of the calculated CV on mean values across the different inflation/deflation intervals. As anticipated, StO_2 exhibited smaller CV with higher 685 nm dynamic ranges (ρ=-0.5, $p<0.001$), and BFI displayed smaller CV with higher countrates (ρ = -0.41, $p=0.001$). Furthermore, a correlation was observed between computed StO_2 and its CV (ρ = -0.33, $p=0.007$). However, no significant associations were found between absolute StO_2 and the 685 nm dynamic range (ρ =0.08, $p=0.5$), countrate and BFI (ρ = -0.09, $p=0.46$), and CV BFI and BFI (ρ = -0.19, $p=0.15$). However, precision for StO_2 resulted better than 4% among all the StO_2 range [50% to 70%]. Future improvements, such as employing algorithms or components for fast dynamic range optimization, may lead to consistent precision across the measurement range. BFI variability was notably higher, particularly during full arterial occlusion (lower BFI), regardless of countrate, aligning with theoretical expectations. Moving to Obj.3, after careful data quality control, we included 30 controls and 74 ICU patients to the final data analysis. We observed significant lower values in the baseline of StO_2 ($p=0.006$), BFI ($p=0.03$) and MRO_2 ($p<0.001$) in ICU patients (Fig. 1 b). During the VOT we obtained smaller values of ReO_2, AUC StO_2 and BFI ($p<0.0001$). No significant differences are found in DeO_2 ($p=0.16$). Out of the 74 patients, 22 are septic with different degrees of severity. We observed lower reactivity in the sepsis population with respect to the general ICU patients (ReO_2 and AUC BFI), even though non-statistically significant.

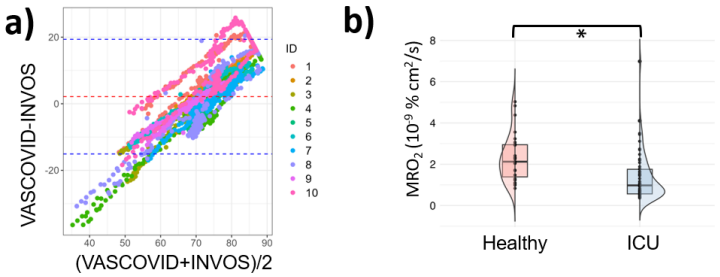


Fig. 1: a) Bland Altman plot displaying all subjects' StO_2 during VOT, for VASCOVID against INVOS; b) results for MRO_2 in healthy and ICU patients. (*) indicates $p<0.05$

4. Conclusion

These results highlight the ability of the platform to identify impairment in the microvasculature reactivity during VOT in a precise manner, displaying a low intersubject variability in the healthy population. These results are in line with the literature for StO_2. Moreover, VASCOVID provides information regarding tissue perfusion which is pivotal in hemodynamic interventions (e.g. resuscitation) in the intensive care, which still represent a missing piece [2].

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