Blood Pressure Monitoring in People with Spinal Cord Injury

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In a collaboration in the framework of the Eurostars IMPULSE project, CSEM, Onward Medical and ·NeuroRestore are working on the development of a sensor for the closed-loop control of blood pressure for people with spinal cord injury. We present hereafter a preliminary analysis on the feasibility of the approach, by comparing CSEM's blood pressure monitoring technology with invasive measurements acquired in people with spinal cord injury.

Millions of people with spinal cord injury (SCI) suffer from hemodynamic instability, characterized by unstable blood pressure (BP), and usually treated with slow-acting drugs. However, these drugs cannot adequately address transient episodes. Both the absence of effective therapies and monitoring options to address these instability episodes make the condition difficult to manage and hamper recovery after SCI, reducing quality of life and increasing the risk of stroke and heart disease.

In the context of the Eurostars project IMPULSE, CSEM is collaborating with Onward Medical and ·NeuroRestore to develop a solution to monitor hemodynamic instability in people with SCI. Prior to this collaboration, CSEM has developed a cuff-less BP monitoring technology based on photoplethysmography (PPG). EPFL has developed a therapeutic concept based on spinal cord stimulation to alleviate hemodynamic instability [1]. Onward Medical has developed the cutting-edge clinical ARC^{IM} platform, which enables the delivery of this therapeutic concept. The goal of the IMPULSE project is to develop a sensor integrated with the ARC^{IM} system for long-term, user-friendly monitoring of hemodynamic biomarkers relevant to SCI. These developments will lead to the closed-loop "IMPULSE system" neuroprosthesis.

CSEM's BP monitoring technology has proven its capability to accurately track rapid BP changes induced by fast-acting drugs in operating rooms during induction of general anesthesia [2], and circadian BP variations in patients undergoing 24-hour ambulatory BP monitoring [3]. However, to date it was not tested in individuals with autonomic dysfunction, such as people with SCI. Thus, the first phase of the IMPULSE project is to evaluate the BP trending ability (i.e., the ability to track BP changes) of CSEM's BP technology in people with SCI. This report presents preliminary results of this investigation.

PPG signals were acquired in two individuals with SCI participating in the EPFL-sponsored HemON clinical study (ClinicalTrials.gov identifier: NCT05111093) during their stay in the post-operative, step-down unit of the Lausanne University Hospital (CHUV, Switzerland). Reference BP was measured invasively by means of a radial arterial line. The data were acquired in five recording sessions of 1h50min ±3 min. From the PPG signals – acquired at the upper arm – non-invasive BP was estimated using CSEM's BP technology and was compared for trending ability to the invasive reference. This was done by focusing on rapid BP changes, critical for detecting hemodynamic instability episodes such as events of orthostatic hypotension or autonomic dysreflexia in people with SCI. To that end, systolic BP changes of at least 20 mmHg occurring over a time span no longer than 3 minutes were identified both in the invasive and non-invasive BP traces. Similarly, changes of at least 10 and 13.3 mmHg were identified in the diastolic and mean BP traces, respectively. The invasive and non-invasive BP changes were then compared through four-quadrant analysis [4]. The concordance rate (CR), the percentage of BP changes showing a concordant direction of change between both methods, was assessed. The agreement on the estimated amplitude of the changes was also assessed. Finally, to evaluate the quality of the PPG signal – critical for a reliable PPG-based BP estimation – the number of cardiac harmonics distinguishable in the PPG spectrum was assessed. It is generally considered that a BP-related waveform is practically perfectly reconstructed using its 20 first harmonics [5].

Four-quadrant analysis revealed a CR of 95% on systolic BP, and of 94% on both diastolic and mean BP. An average absolute difference of 11.9 mmHg, 5.1 mmHg, and 7.0 mmHg, respectively, was found between the amplitudes of the systolic, diastolic, and mean BP changes assessed by both methods. Finally, the number of harmonics averaged at 11.4.

This preliminary feasibility study reveals a good trending ability of the PPG-based BP estimation method, with an average CR of 94%. This suggests that a cuff-less PPG sensor placed on the upper arm can reliably detect the vast majority of potentially deleterious BP changes in individuals with SCI. The slight imprecision observed on the estimation of the amplitude of the changes is hypothesized to be due to the sub-optimal number of cardiac harmonics found in the PPG signals, linked with motion artefacts and occasional insufficient sensor tightening. There is therefore still room for improved BP precision, as PPG data quality was not optimized in the present data.

As part of the feasibility phase of the IMPULSE project, this preliminary analysis has shown promising results and confirms that rapid BP changes may indeed be reliably tracked using a PPG sensor at the upper arm in people with SCI. It has also revealed the importance of PPG signal quality on the precision of the estimated BP. Integration of the PPG-based BP estimation method in the IMPULSE sensor and confirmation of these findings in a larger sample size are next steps planned in the project. If confirmed, the IMPULSE sensor in conjunction with the use of closed-loop control of BP through an ARC^{IM} spinal cord stimulation has the potential to drastically revolutionize the quality of life of people with SCI.

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