Randomized Controlled Trial to Evaluate a BCI-Supported Task-Specific Training for Hand Motor Recovery after Stroke

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Abstract—Motor Imagery (MI) was proposed to enhance motor recovery after stroke. It has been suggested that EEG-based Brain Computer Interfaces (BCI) operated by MI can provide monitoring and reinforcement of such task-specific training. A BCI rehabilitation device was specifically developed in our laboratory for recovery of hand function after stroke. Here we report the validation of this device, conducted in accordance with the guidelines to demonstrate the efficacy of novel rehabilitation interventions. The validation procedure of such BCI application was designed as a rehabilitation stage II pilot trial with two endpoints: primarily, to demonstrate the efficacy this BCI-based MI training as an adjunctive intervention in post-stroke rehabilitation and, secondarily to foster the transfer of BCI technology into clinical practice.

I. INTRODUCTION

MOTOR Imagery (MI) was proposed to enhance arm motor recovery after stroke. Yet, unambiguous evidence are currently available about the efficacy of such covert motor practice [1], [2]. EEG-based BCIs operated by MI can provide a valuable method to support mental motor practice by allowing direct monitoring of the patient’s adherence to such task-specific training. Furthermore, BCI paradigms based on neurofeedback mechanisms offer a unique strategy to favor activity-dependent plasticity [3]. For this reasons a BCI-driven rehabilitation device was developed to encourage recovery of hand function after stroke [4]. As such, the implemented BCI-based rehabilitation device requires two actors: the patients who is provided with an enriched visual feedback congruent with his MI task (imagery of affected hand movements), and the therapist who monitors patient’s performance by means of the instant BCI feedback of the patient’s EEG sensorimotor rhythm modulation occurring over the stroke lesioned hemisphere (see Fig. 1). Here we report the validation of this BCI technology format that was conducted in accordance with the guidelines to demonstrate the efficacy of new motor rehabilitation interventions and to foster their translation to clinical practice.

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Fig. 1. Training session with the novel EEG-based BCI system. In this session, two actors take part: the patient and the therapist. The patient is trained to gain control of the visual hand representation by imagining hand movements and receives as a feedback the congruent movements of the represented hand. The therapist is fed back with the real-time movement of a cursor on a screen that is actually controlled by the patient EEG relevant feature.

II. MATERIAL AND METHODS

Eighteen first-ever unilateral cortical/subcortical stroke patients, (mean age 60 ±9; time form event less than 6 months) were consecutively recruited at the Fondazione Santa Lucia, upon their admission for post-stroke rehabilitation treatment. Exclusions criteria were: concomitant chronic disabling pathologies, orthopedic injuries that could impair reaching or grasping, severe spasticity, Mini-Mental State Examination score < 24 and cognitive deficits needing for rehabilitation after a neuropsychological evaluation. Patients were randomly assigned to the BCI-based MI training group (BCI; n=9) or MI control group (CTRL; n=9) group. The MI intervention in both groups lasted 4 weeks, with weekly training sessions (3 times per week) according to standardized practices as an “add-on” to usual care. The study design was a stage 2 (“Development-of-Concept Trials”) pilot study of phase III trials for motor interventions [5]; according to such design, the CTRL group underwent a task-related active intervention training, with similar timing and setting as in the BCI group; namely CTRL patients were asked to perform MI of the stroke affected hand in the presence of a therapist, but without the BCI feedback. For both groups, the trained MI tasks were grasping and finger extension of the stroke affected hand; these movements were performed in separate
runs (each run consisted of 20 subsequent trials of grasping or extension); in the BCI group, patients were given continuous feedback on their sensorimotor EEG reactivity by the therapist, and received discreet positive reward at the end of each successful trial (i.e. the visual representation of their own affected hand performing the imagined task).

Functional pre- and post- intervention assessments were performed by an expert physician who was concealed to allocation.

The primary outcome measure was the arm section of the Fugl-Meyer scale (arm F-M). A minimal clinically important difference for this scale (MCID) was described to 7 points. Secondary outcome measures included the European Stroke Scale (ESS) and the arm MRC (arm section of the Medical Research Council Scale). Moreover, we quantified the parameter effectiveness for all the adopted functional scales, reflecting the proportion of potential improvement that could be achieved after the intervention. As for the BCI group, control features for the BCI system were chosen among central and centro-parietal electrodes on the affected hemisphere, at motor-related EEG frequencies (Alpha and Beta). Outcome measures for the BCI training were performance rates and $R^2$ values on control channels.

The study protocol was approved by the local Ethical Committee and patients signed the informed consent before entering in the study.

III. RESULTS

All recruited patients were able to complete the training except for one patient in the CTRL group, who dropped the study before completing the post-intervention assessment. Randomization was partially successful since no significant group differences at baseline were found on the primary (arm F-M) and secondary outcome measures (ESS, arm MRC) or other demographic factors (age, time from event). As for the side of the brain lesion, the BCI group was composed by 7 patients with right and 2 with left hemispheric stroke, while the CTRL group contained 8 left and 1 right hemispheric lesion.

Regarding the primary outcome measure arm F-M, a mean change of 9 (+45%) was observed exceeding the MCID of 7 with respect to an improvement of 5 (+9%) observed in control group. The effectiveness of outcome scale scores showed a clear trend of higher improvement for the BCI group with respect to the CTRL group, though statistically significant difference could be highlighted for MRC only (see Fig. 2).

As for the BCI group, all patients were able to complete the one-month BCI training with performance rates of 70% on average; control features were chosen among central and centro-parietal electrodes contralateral to the stroke lesion (sensorimotor area), at frequencies relevant for sensorimotor reactivity (alpha and beta); $R^2$ values on control channels were significantly increased at the end of the training ($p<0.05$).

![Fig. 2. Effectiveness results in the two patients groups. * indicates statistical significance ($p<.05$).]

IV. DISCUSSION

To our knowledge this is the first randomized controlled trial (RCT) carried out to evaluate the efficacy of the mental training of motor skills (motor imagery, MI) supported by an EEG-based BCI device to promote recovery of hand function after stroke. Our findings on clinical and functional scales highlight the possible efficacy of such BCI technology-based approach. Moreover, we were able to demonstrate that stroke patients can successfully master a specifically designed BCI device with control features extracted from the affected hemisphere; the increase in $R^2$ values indicates higher responsiveness of motor related EEG rhythms on the affected hemisphere. Also, we were able to record high satisfaction rates despite the time consuming procedures of a BCI session (the only drop-out was in the CTRL group).

V. CONCLUSION

These preliminary results on the efficacy of BCI-supported MI-training after stroke are encouraging. Key points to validate the clinical benefit of the BCI-supported MI practice in subacute stroke will be to open the randomization procedure adjusting for lesion side, and to enlarge the patients sample in order to consolidate the trend of higher effectiveness in the BCI group in a well powered Stage 3 (“Demonstration-of-Concept Trials”) trial [5].

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