

Neuromodulation based on physiological data

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ABSTRACT

The rapid evolution of neuromodulation techniques includes an increase in research into stimulation paradigms guided by patient's neurophysiology in order to increase efficacy and responder rates. In fields such as Parkinson's disease, treatment personalization and target engagement have been shown to be effective, and closed-loop paradigms have been successfully implemented in cardiac defibrillators. In psychiatry, promising avenues for physiologically informed neuromodulation are being investigated. Transcranial Magnetic Stimulation (TMS) has shown some promise in terms of

matching stimulation frequency to individual brain rhythms. Matching the phase of those rhythms may improve neuroplasticity even further, as when TMS is combined with Electroencephalographic (EEG) recordings.

Key Words: *Electroencephalographic*

INTRODUCTION

The use of resting-state EEG and event-related potentials to demonstrate connectivity between stimulation sites and connected areas may be beneficial. Today, psychiatrists can use these techniques to diagnose underlying sleep disorders, epilepsy, or lesions as contributing factors to depression. These technologies may also be useful in determining the patient's brain network status prior to making treatment decisions. Ongoing research with invasive recordings could lead to the identification of mood biomarkers and network structure in the future. One major limitation is that biomarker research may be hampered by the internal heterogeneity of psychiatric disorders as defined by current DSM-based classifications. New approaches are being developed and may be validated in the near future [1]. Neuromodulation therapies and technologies are rapidly expanding. Neuromodulation devices, particularly those that deliver electrical current to neuronal tissue, can deliver a wide range of stimulation parameters. These technologies can also target specific anatomical targets. This opens up the possibility of tailoring therapy to a patient's specific needs. Neurophysiological biomarkers such as Electroencephalography (EEG) or Local Field Potentials (LFPs) offer the possibility of better personalizing or even automating the selection of stimulation parameters or physiological stimulation targets. In other fields, medical devices that automatically adjust therapy are currently available. An implantable cardio defibrillator, for example, employs several sensors to ensure that a patient receives defibrillation only when necessary.

Similarly, wearable insulin pumps controlled by glucose sensors have significantly improved the lives of diabetics. In some psychiatric cases, EEG is currently used to rule out underlying neurological conditions such as epilepsy, tumours, or other neurological disorders. EEG-based sleep staging can also be used to diagnose and treat sleep disorders that interact with mood state, such as identifying obstructive sleep apnea that is causing treatment-resistant depression or fatigue [2]. Although the evidence quality remains low, EEG-based biofeedback is frequently used in patients with attention deficit disorders. There is also considerable interest in further development; for example, biomarkers for Autism Spectrum Disorder have been accepted for evaluation as potentially valid clinical trial metrics by the FDA biomarker programme. Success stories in adaptive systems to restore health are generally based on an understanding of physiology dynamics, ranging from signals that correlate to symptoms to stimulation response times [3]. Diabetes' artificial pancreas, cardiac pacemakers, and ventilators all show how this understanding, often with non-linear systems, can yield meaningful results. When the mapping is not understood, the results are more modest, as evidenced by the current similarities between open loop and adaptive epilepsy systems. These successes were also the result of technological advancements, and the timelines for medical innovation necessitate a focus on meeting meaningful milestones in order to maintain interest and investment [4]. A key opportunity is to use the existing technological infrastructure as a platform to systematically investigate physiological dynamics and refine therapies. Therapy platforms allow access to the neural network

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of interest, as well as data collection and algorithmic prototyping that can take advantage of a digital infrastructure. Another advantage of platforms is that they enable cost-sharing among disease states and the sharing of best practices among investigative teams. The NIH BRAIN and SPARC initiatives have assisted in the development and distribution of platforms in collaboration with industry [5]. When investigating sensing and adaptive systems, it is critical to design for safe operating modes and limits in order to avoid over- or under-stimulation of patients. Control frameworks for implementing these control limits have been developed by engineers and are now being used in research systems and shared as best practices. For example, the ability to detect abnormal stimulation results, such as the onset of epileptiform after-discharges caused by excessive stimulation, and to automatically reduce stimulation can help to ensure patient safety for novel therapy approaches.

The field of physiologically-informed neuromodulation is rapidly evolving and will improve both therapy efficacy and patient management efficiency. Patient stratification research is still important, and it will most likely provide early value in terms of enriching patient populations for clinical trials. Such predictive biomarkers will need to be highly sensitive and selective in order to be used in clinical decision making. With the current low sensitivity/specificity, withholding therapy from a patient based on biomarker analysis is not clinically justified, especially for non-invasive therapies like TMS. Such predictions will become increasingly important for higher-risk therapies as patients and physicians weigh risks and benefits. Machine learning may lead to the discovery of potentially very complex algorithms that can be used to personalize treatments for patients. More high-quality multimodality datasets will be needed to discover and develop new paradigms, and clinicians and researchers will need new skills to interpret such research findings and avoid subtle methodological pitfalls. Physiology-informed neuromodulation is already being used in clinical trials, and more specific applications to personalize treatment will follow.

TMS treatment power is now chosen for each patient based on motor threshold measurements, which are frequently based on EMG. EEG-based and cardiac-guided treatment location and protocol selection is rapidly evolving and could be clinically applicable in the coming years. The use of phase-informed therapy has the potential to improve both invasive and non-invasive neuromodulation for a variety of brain disorders. In addition, depending on the state of the brain networks, phase-related synchrony metrics may allow stimulation parameters to change. These technologies could eventually lead to real-time closed-loop interventions that can adjust neurostimulation to keep these biomarkers within a target range.

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