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Reply to the Letter by Lévêque et al. Entitled 'Simultaneous Deep Brain Stimulation/Motor Cortex Stimulation Trial for Neuropathic Pain: Fishing with Dynamite?'

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We thank Lévêque et al. [1] for their pertinent comments on our paper 'Simultaneous trial of deep brain and motor cortex stimulation in chronic intractable neuropathic pain' [2]. Lévêque et al. raised substantial concerns about our study protocol and concept regarding the application of deep brain stimulation (DBS)/motor cortex stimulation (MCS), the application of a preoperative repetitive transcranial magnetic stimulation (rTMS) study before moving to MCS/DBS and the risks associated with DBS. We intend to clarify the issue in the following paragraphs.

We agree with Lévêque et al. that the efficacy of MCS is correlated with rTMS [3, 4]. We already enjoyed the French references in their letter with much interest, and we did, indeed, perform preoperative rTMS in all patients listed in the paper as a step to evaluate possible relationships with long-term outcomes of MCS. However, the result of rTMS in our series was disappointing, and we did not document that in the article. This kind of preoperative assessment has already been described: the pharmacological classification of pain, degree of motor impairment, sensory changes in the painful zone or response to rTMS. We think we need a more sophisticated evaluation with the preoperative rTMS technique and its results [5]. We performed almost all the preoperative trials previously mentioned during the last 10 years; however, we are not yet satisfied. In our opinion, the discrepancy between the preoperative rTMS results and the MCS long-term outcome might be due to interpretation of the rTMS study and the methods of outcome measurement in chronic pain. Fortunately, there are some papers regarding the relationship between rTMS and MCS outcome [3, 4], and we will keep an eye on them.

Regarding the double-blinded studies of DBS/MCS stimulation efficacy, we accept the opinion of Lévêque et al. to some degree. However, in our opinion, true double-blinded stimulation in a clinical setting of an implanted electrode would be impossible. Although most authors mentioned that most patients did not feel any stimulation-induced sensation with MCS [5], we [6, 7] and Katayama et al. [8] reported a sensation of vibrating paresthesia in patients who responded nicely to an initial trial MCS period. Furthermore, it is inevitable that thalamic DBS always produces a paresthesia if the lead lies in the sensory thalamus.

We sincerely agree that our study of simultaneous DBS/CMS has only a weak significance in the determination of the efficacy of DBS/MCS because of the limited number of patients included and the open-labeled observation. However, we think that we had a case that favorably responded to thalamic DBS rather than MCS. Indeed, the fate of thalamic DBS has been continually reported to be poor. However, we think that thalamic DBS or intracranial DBS for intractable pain may revive [9]. We feel the problem is that we still do not know who will respond more favorably to a particular treatment such as DBS/MCS and why some patients with central pain respond and some do not. In line with this, the efficacy of MCS for the trigeminal neuropathic pain, which was once reported as one of the best indications of MCS, was questioned recently [10]. Thus, we performed a limited simultaneous trial, though invasive, to see if there were candidates who were best treated with thalamic DBS and if a comparison of the dual efficacy of DBS/MCS suggested any synergistic response.

We think that the important issue in the treatment of severe, intractable neuropathic pain stems from the limitation of our current understanding of the classification of pain: central or peripheral, etc. and a mere interpretation of pain outcome following surgical treatment with a 30–50% reduction on the visual analogue scale or the numeric rating scale (NRS). We understand that this would be what Lévêque et al. are concerned about.

We currently define the long-term MCS treatment as successful when the patient achieves a significant mean reduction in the NRS score of at least 30% compared to the baseline. The reason for considering a 30% mean reduction in the NRS score as a successful outcome is the lack of consistency across studies regarding the method used to evaluate the outcome, as is pointed out by Fontaine et al. [5] and others [4, 11–13]. For example, a pain relief of 40% has been considered a good outcome by some authors, while others have required an improvement of >50% [5]. It has been suggested that this kind of variability in the outcome measurements used in clinical trials hinders the evaluation of the efficacy and effectiveness of the treatments following the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials guidelines [11].

According to these guidelines [11], a 30% reduction in pain is considered a moderately important change and is equal to 'much improved' as measured by the Patient Global Impression of Change scale [12, 14], and it is now commonly used in the subjective evaluation of clinical trials for various kinds of pain treatment [12]. The problem associated with the mere description of 'more than 40–50% pain relief' in the evaluation of the efficacy of a specific treatment has already been reported [4, 5]. For example, Sears et al. [13] documented that 29.4% of the patients with failed back surgery syndrome reported a 50% or greater reduction in pain after spinal cord stimulation with paddle leads at a mean follow-up of 3.8 years. However, 70.6% of the same group of patients reported

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that they were satisfied with the surgery to the point of undergoing it again for the same outcome. This discrepancy between the visual analogue scale or the NRS-11 outcome and overall satisfaction has been reported in spinal cord stimulation studies as well as in studies of MCS for chronic pain by Nuti et al. [15].

I again thank Lévêque et al. for their deep consideration and kind concerns regarding our small study.

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Erratum

In our article 'Motor cortex stimulation for trigeminal neuropathic or deafferentation pain: an institutional case series experience' which appeared in *Stereotactic and Functional Neurosurgery* [Raslan et al., Stereotact Funct Neurosurg 2011;89:83–88, DOI: 10.1159/000323338], we incorrectly referred to the stimulation pulse width in milliseconds (ms). The correct duration of the pulses should be in microseconds (μs). We regret the error and hope that this correction of our units of measurement will allow others to replicate these clinical protocols.