



Clinical Use, Quality of Life and Cost-Effectiveness of Spinal Cord Stimulation Used to Treat Patients with Failed Back Surgery Syndrome

Luciana Scalone¹, Lorenzo Giovanni Mantovani¹, Angelo Lavano²,
Amedeo Costantini³, Gianpaolo Fortini⁴, Furio Zucco⁵

¹Research Centre on Public Health, University of Milan Bicocca, Monza, Italy

²Università Magna Grecia, Catanzaro, Italy

³Department of Anesthesia and Intensive Care, Regional Pain Unit, University Hospital SS. Annunziata, Chieti, Italy

⁴Azienda Socio Sanitaria Territoriale dei Sette Laghi, Varese, Italy

⁵Azienda Ospedaliera Salvini, Garbagnate Milanese, Garbagnate, Italy

Waszak et al. [1] published a literature review regarding the clinical use, quality of life, and cost-effectiveness of spinal cord stimulation (SCS) to treat failed back surgery syndrome (FBSS) patients. As the authors did not specify the aims of their review, we inferred them based on their conclusions, namely cost-effectiveness of SCS remains unclear and evidence regarding the role of SCS in FBSS is controversial. After reading their reported conclusions and methods, we were unable to understand the criteria and reasons for which they did not include the study of Zucco et al. [2], who assessed the effects, cost-effectiveness, and cost-utility of SCS for FBSS patients, which would contribute in achieving more robust conclusions regarding the value of this technique in such patients. In particular, we analyzed the selection criteria specified in the review; however, the reported criteria did not help in clarifying the reasons for excluding the study by Zucco et al., although the article can be found in PubMed using the combined keywords specified. The authors stated that the articles were selected based on the Preferred Reporting

Items for Systematic Reviews (PRISMA) statement checklist. However, in this checklist [3], we do not note any criteria regarding article selection that clarify the reasons for excluding the study. Finally, the authors of the review specify that “reports on FBSS and SCS needed to have a rigid protocol, inclusion criteria and follow-up strategy” however they do not explain further their meaning, although Zucco et al. used all the methodological data required in the Consolidated Health Economic Evaluation Reporting Standards [4]. In the paragraph that focused on the cost-effectiveness of SCS, Waszak et al. commented on some studies: a Canadian study in which the Markov model was used and a systematic review and economic model that included three randomized controlled trials (RCTs) on neuropathic pain and eight on ischemic pain. They also criticized most of the trials because the trials involved small sample sizes. To note, the authors did not include the economic evaluations conducted by Taylor et al. [5], which were based on the results of the Prospective Randomised Controlled Multicentre Trial of the Ef-

Received May 10, 2017; Accepted 20-May 20, 2017

Corresponding author: Luciana Scalone

CESP, Research Centre on Public Health, University of Milan Bicocca Via Cadore, 48, Monza I-20900, Italy

Tel: +39-(0)39-2333097, Fax: +39-(0)2-700536422, E-mail: luciana.scalone@unimib.it

fectiveness of Spinal Cord Stimulation (PROCESS) RCTs conducted in Europe, Canada, Australia, and Israel. Furthermore, the authors mentioned that “RCTs that model routine practice may not fully represent the real effects of a technology” and commented on an observational study that showed that SCS was not cost-effective in a US Workers’ Compensation Population. Correctly, they also stated that “research on cost-effectiveness strongly depends on features of a healthcare system;” hence, evidence from different healthcare systems in different countries should be considered. For example, the PRECISE study was conducted in a routine clinical practice setting within the Italian healthcare system and involved 80 patients, i.e., a sample population larger than that of previously conducted RCTs regarding the same topic [6,7]. This study results show that in clinical practice, SCS can be a value-for-money option for patients with FBSS and characteristics similar to the participants in the PRECISE study. Regardless of this study results, we wonder whether the review by Warszak et al. is methodologically outstanding. Thus, we believe that the conclusions of this review should be cautiously considered.

Conflict of Interest

No potential conflict of interest relevant to this article was reported.

References

1. Warszak PM, Modric M, Patujev A, et al. Spinal cord stimulation in failed back surgery syndrome: review of clinical use, quality of life and cost-effectiveness. *Asian Spine J* 2016;10:1195-204.
2. Zucco F, Ciampichini R, Lavano A, et al. Cost-effectiveness and cost-utility analysis of spinal cord stimulation in patients with failed back surgery syndrome: results from the PRECISE study. *Neuromodulation* 2015;18:266-76.
3. Liberati A, Altman DG, Tetzlaff J, et al. The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate healthcare interventions: explanation and elaboration. *BMJ* 2009;339:b2700.
4. Husereau D, Drummond M, Petrou S, et al. Consolidated Health Economic Evaluation Reporting Standards (CHEERS): explanation and elaboration: a report of the ISPOR Health Economic Evaluation Publication Guidelines Good Reporting Practices Task Force. *Value Health* 2013;16:231-50.
5. Taylor RS, Ryan J, O’Donnell R, Eldabe S, Kumar K, North RB. The cost-effectiveness of spinal cord stimulation in the treatment of failed back surgery syndrome. *Clin J Pain* 2010;26:463-9.
6. Kumar K, Taylor RS, Jacques L, et al. Spinal cord stimulation versus conventional medical management for neuropathic pain: a multicentre randomised controlled trial in patients with failed back surgery syndrome. *Pain* 2007;132:179-88.
7. North RB, Kidd DH, Farrokhi F, Piantadosi SA. Spinal cord stimulation versus repeated lumbosacral spine surgery for chronic pain: a randomized, controlled trial. *Neurosurgery* 2005;56:98-106.