Neurochirurgie 61 (2015) S117–S124

Disponible en ligne sur ScienceDirect www.sciencedirect.com

Elsevier Masson France EM|consulte www.em-consulte.com

Rapport : Douleurs lombaires postopératoires

A prospective study evaluating sleep quality in Failed Back Surgery Syndrome patients treated by multicolumn spinal cord stimulation: Study design protocol and presentation of the study population

Étude prospective évaluant la qualité du sommeil chez les patients atteints de Failed Back Surgery Syndrome (FBSS), implantés de stimulation médullaire multi-colonnes : présentation du design de l'étude et de la population incluse

O. Monlezun [a,*,b], K. Lode-Kolz [c], M. Roulaud [a,b], J. Paquereau [c], P. Ingrand [d], C. Veyrieras [a], C. Brandet [a], F. Guetarni [a], A. Prévost [a], B. Bataille [b], P. Rigoard [a,b], le groupe Estimet

[a] *Service de neurochirurgie, unité rachis et neurostimulation, N3Lab (Neuromodulation & Neural Networks), CHU de Poitiers, Poitiers University Hospital, 2, rue de la Milétrie, 86021 Poitiers cedex, France*
[b] *Department of neurosurgery, spine-neurostimulation unit, Poitiers university hospital, Poitiers, France*
[c] *Sleep center, Poitiers university hospital, Poitiers, France*
[d] *Faculty of medicine and pharmacy, Poitiers university hospital, Poitiers, France*

ARTICLE INFO

Article history:
Received 16 September 2013
Received in revised form 2 May 2014
Accepted 29 June 2014
Available online 22 September 2014

Keywords:
Sleep quality
Polysomnography
Actigraphy
Spinal cord stimulation
Failed back surgery syndrome
Chronic painleur chronique

ABSTRACT

Background and purpose. – One of the main consequences of chronic pain syndrome is major impairment of the quality of sleep. Chronic pain and insomnia are independently linked to significant reductions in quality of life and psychiatric morbidity. Recent studies have suggested the efficacy of spinal cord stimulation (SCS) for the treatment of the back pain component in failed back surgery syndrome (FBSS) patients using a multicolumn lead. The main aim of this pilot study is to assess the influence and potential benefits of SCS on sleep quality in refractory FBSS patients implanted with multicolumn SCS and enrolled in the French multicentre ESTIMET study.
Methods. – This is a single-centre, comparative, exploratory, pilot study. Sixteen FBSS patients enrolled in the ESTIMET study and implanted with multicolumn SCS will be monitored for 6 months after implantation. Sleep parameters will be recorded by polysomnography, Psychomotor Vigilance Test and Osler tests, actigraphy, sleepiness scales, and sleep quality testing. Sleep will be evaluated before (at the inclusion visit) and after SCS implantation (at the 6-month visit). Secondary objectives will also assess the impact of SCS lead programming (mono vs. multicolumn SCS) and the influence of position-adaptive stimulation at night on sleep quality.
Trial status. – The first patient of this ancillary study was enrolled on 21 May, 2012 and recruitment has now been achieved. Primary endpoint findings are expected to be available in 2015.
Conclusion. – By providing an analysis of the quality of sleep in chronic pain patients who are candidates for implanted neurostimulation, this new approach focuses on an important aspect of quality of life often overlooked in these poly-medication patients. It could show a real clinical benefit and underestimation of these analgesic innovative expensive techniques, where medico-economic analysis, would or would not promote access.

© 2014 Elsevier Masson SAS. All rights reserved.

* Corresponding author.
E-mail addresses: olivier.monlezun@chu-poitiers.fr, olivier.monlezun@gmail.com (O. Monlezun).

http://dx.doi.org/10.1016/j.neuchi.2014.06.006
0028-3770/© 2014 Elsevier Masson SAS. All rights reserved.

Mots clés :
Qualité du sommeil
Polysomnographie
Actigraphie
Stimulation médullaire épidurale
Douleur chronique

RÉSUMÉ

Description et objectifs de l'étude. – Une des principales conséquences d'un syndrome douloureux chronique est la dégradation de la qualité du sommeil. La douleur et l'insomnie sont indépendamment liées à des réductions significatives de la qualité de vie et de la morbidité psychiatrique. Des études récentes ont étudié l'efficacité de la stimulation médullaire épidurale (SME) pour le traitement du territoire douloureux lombaire, chez des patients souffrant de lombo-radiculalgies postopératoires (LRPO), grâce à l'implantation d'une électrode multi-colonnes. En revanche, il n'y a aucune donnée de disponible aujourd'hui sur l'interaction douleur chronique/qualité du sommeil et neurostimulation. L'objectif principal de cette étude pilote est d'évaluer l'influence et les avantages potentiels de la SME sur la qualité du sommeil chez les patients souffrant de LRPO, implantés d'une électrode multicolonnes et participant à l'étude française multicentrique ESTIMET.

Méthodes. – Il s'agit d'une étude pilote monocentrique, exploratoire et comparative. Seize patients souffrant de LRPO, inclus dans l'étude ESTIMET et donc implantés d'une électrode multicolonnes seront suivis pendant 6 mois après l'implantation. Leurs paramètres de sommeil seront enregistrés par polysomnographie (PSG), tests PVT et Osler, actigraphie, échelles de somnolence et tests sur la qualité de sommeil. Le sommeil sera évalué avant (lors de le visite d'inclusion) et après l'implantation de la SME (lors de la visite à 6 mois). Les objectifs secondaires évalueront également l'impact de la programmation de l'électrode (mono- vs multi-colonnes) et l'influence de la fonction adaptive stimulation de nuit sur la qualité du sommeil.

Statut de l'étude. – Le premier patient de cette étude ancillaire a été inclus le 21 mai 2012. Le recrutement est maintenant finalisé. Les résultats finaux devraient être disponibles d'ici début 2015.

Conclusion. – En proposant une analyse de la qualité du sommeil chez des patients douloureux chroniques candidats à une neurostimulation implantée, cette approche inédite s'intéresse à un aspect important de la qualité de vie souvent négligé chez ces patients poly-médicamentés. Il pourrait en ressortir un bénéfice clinique réel et sous-estimé de ces techniques antalgiques innovantes et coûteuses, dont l'analyse médico-économique, en favorisera ou pas l'accès.

© 2014 Elsevier Masson SAS. Tous droits réservés.

1. Background and introduction

1.1. Chronic pain and quality of sleep

One of the main consequences of a chronic pain syndrome is a major impairment of the quality of sleep. The hypothesis that nociceptive regulation may be disrupted by poor sleep quality is not a new concept [1]. In a prospective subjective sleep study versus control group, Van de Water et al. showed that subjects with chronic low back pain self-reported significantly poorer sleep quality [2]. According to Lautenbacher et al., the severity of pain increases with decreasing sleep quality, which could be linked to hyperalgesic responses [3,4]. However, sleep disorders also influence the perception of pain. Poor sleep quality and pain therefore interact to create a vicious circle, but it is currently unknown to what extent one parameter influences the other.

These sleep disorders result in an increased need for rest during the daytime due to lack of night time recovery. One assumption is that pain during sleep could cause interrupted sleep, possibly related to pain arousals. This induces less slow-wave sleep, the main form of recovery sleep, and larger amounts of light sleep, which is less effective. Patients with pain arousals may therefore spend more time in light sleep stages, increasing their total sleep time (TST). This pattern of sleep disorders could be similar to that observed in patients with obstructive sleep apnoea [5], who present a small amount of slow wave sleep and a large amount of light sleep, resulting in longer TST. Sleep disorders in chronic pain patients include insomnia characterized by sleep fragmentation related to arousals and awakenings associated with increased pain perception when changing position or prolonged recumbency at night [6]. The duration of rapid eye movement (REM) sleep may also be reduced and REM sleep stages may be replaced by light sleep, which is less efficient in terms of physical and psychological recovery [7]. The consequences of poor sleep quality on daytime functioning have been extensively documented and include significant irritability, low mood and possible progression to depressive syndrome [8]. Excessive daytime sleepiness and lower attention are factors associated with an increased risk of road and work accidents [9]. Sleep fragmentation could lead to poorer physical and cognitive performance [10], particularly memory disorders.

1.2. Spinal cord stimulation and Failed Back Surgery Syndrome

According to the French Society for the Management and Study of Pain (SFETD), the use of conventional spinal cord stimulation (SCS) should be recommended in patients with refractory Failed Back Surgery Syndrome (FBSS) presenting a dominant radicular component [11]. Recent studies have suggested the efficacy of epidural SCS for the treatment of the back pain component [12–19], using a new generation of SCS leads comprising stimulation of several columns. A large-scale, multicentre, prospective, randomised, controlled trial needed to be conducted to confirm these preliminary results and to assess the medico-economic value of multicolumn SCS.

Effectiveness and cost management of multicolumn spinal cord stimulation in neuropathic pain patients with failed back surgery syndrome (ESTIMET) study is the first randomised control trial (RCT) to be conducted in FBSS patients surgically implanted with multicolumn SCS. The design and protocol of the main medico-economic study are presented in a separate paper[1]. In this article, we present the first ancillary study, conducted simultaneously with the main ESTIMET study, focusing on sleep quality assessment in FBSS patients implanted with SCS.

[1] Roulaud M, Durand-Zaleski I, Ingrand P, Serrie A, Diallo B, Peruzzi P, et al. Multicolumn spinal cord stimulation for significant low back pain in failed back surgery syndrome: design of a national, multicentre, randomized, controlled health economics trial (ESTIMET study) (submitted for publication in Neurochirurgie [Hors-série]).

Download English Version:

https://daneshyari.com/en/article/3811621

Download Persian Version:

https://daneshyari.com/article/3811621

Daneshyari.com