Scrambler therapy

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In neuropathies there are complex reactions that modify the homeostatic equilibrium of pain system. In such a context the Scrambler Therapy (ST5) interferes with pain signal transmission, by "mixing" a "non-pain" information into the nerve fibres.The aim of this study is to evaluate the effectiveness of ST5 in the treatment of neuropathic pain. The ST5 consists of a multiprocessor apparatus able to simulate 5 artificial neurons by the application of surface electrodes on skin pain areas. A total of 226 patients, all suffering from intense drug-resistant neuropathic pain, were recruited for this trial in 2004. Inclusion criteria: neuropathic pain, very high baseline visual analogue scale (VAS). Exclusion criteria: pacemaker users, neurolithic blocks or neurolesive pain control treatment. The treated neuropathic pain syndromes were: failed back surgery syndrome (FBSS), sciatic and lumbar pain post-herpetical (PHN), trigeminal neuralgia, post-surgery nerve lesion neuropathy, pudendal neuropathy, brachial plexus neuropathy, low back pain (LBP), others. The trial programme: 1 to 6 therapy sessions of 5 treatments, each one lasting 30 min. Pain intensity was evaluated using VAS before and after each treatment. The statistical significance of VAS was measured using the paired *t*-test. The total results show 80.09% of responders (pain relief >50%), 10.18% of partially responders (pain relief from 25% to 49%) and 9.73% of no responders (patients with pain relief <24% or VAS >3). The conclusion is draen that ST5 produced a statistically significant (P<0.0001) pain relief in all treated neuropathies.

Key words: **Scrambler therapy - Pain - Neuropathies.**

The pain system is characterized by a high level of information content. Specific receptors, mechanoceptors and multimodal receptors, respond indifferently to all painful stimuli; they are biological elements that are able to transduce a chemical, physical or mechanical event into specific pain information. The complex modifications activated by the nervous system in response to a painful stimulus are the focus of a wide variety of reactions designed also to re-establish conditions of homeostatic equilibrium that the pain information signals have provoked. In most cases, this equilibrium can be rapidly restored thanks to a series of reactions involving much of the biological sys-

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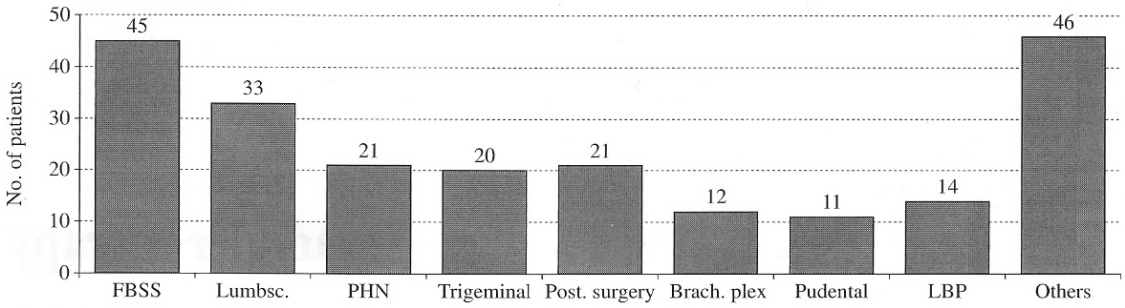

Figure 1.—Patients/pathology (total 226).

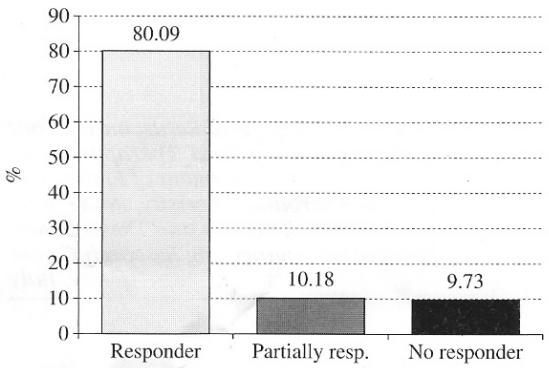

Figure 2.—Total percentage responses.

tem as a whole. However, there are situations in which this has not happened, either due to the impossibility of removing the cause, or due to intrinsic damage to the pain system itself (neuropathies). In such a context, complex reactions may modify the original information triggering the pain phenomenon (sensitization), thus setting up an iterative process that, in the case of chronic pain, and of neuropathic and visceral pain in particular, tends to render all known therapeutic strategies gradually (or completely) ineffective. The useful fact that emerges from all these scenarios is the central role of control exercised by information over the chemical-structural variations of the system. In this case, information is represented by the sequence of pulses generated by the activated nociceptor, pulses that "describe" the type of pain. Overall, this represents a good description of a cybernetic process: communication (pain information) and regulation (chemical feedback to modify perception and adaptive reactions). It may thus be reasonably assumed the possibility to control the lower levels of complexity of the pain system (the chemical reactions) by manipulating the "information" at higher levels. The incomplete knowledge characterizing the role of the chemical molecules involved in the pain phenomenon may conveniently be represented by the black box technique. This involves a model in which the input and output are known, but not the internal translation process that takes place inside the "box".

The research procedure adopted, therefore, allowed a comparatively complex system model, in which the biological variables were translated into cybernetic variables, extrapolating the role and the modality of the pain information, regardless of the biochemical aspects and its etiopathogenesis.

The approach actually adopted to respect the initial theoretical criteria (use of information as the active principle) was to replace the "pain" information with artificial "no-pain" information, in full respect of the information theory. Essentially, an artificial neuron was developed that behaves as a "Pain Scrambler". This system is able to interfere with pain signal transmission, by "mixing" a "no-pain" signal, into the transmission channel (the nerve fibres), for the purpose of masking the original pain information. The "no-pain" signal is still recognized as 'self' by the nervous system.[1, 2]

The aim of this study was to evaluate the effectiveness of Scrambler Therapy (ST5) in the treatment of neuropathic pain.

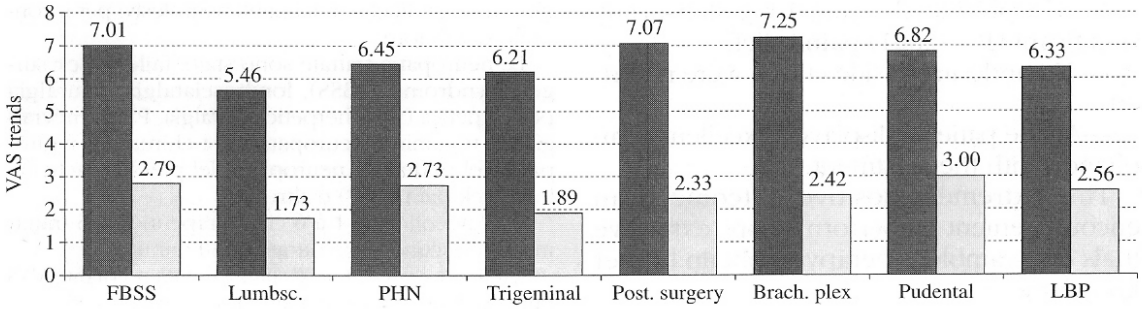

Figure 3.—VAS pre- and post-session.

Materials and methods

The ST5 consists of a multiprocessor apparatus able to simulate 5 artificial neurons that allow 5 pain areas in the same person to be treated simultaneously. The treatment is fully automated, including the dynamic parametrization required for the correct functioning of the method. This criterion ensures a very high degree of repeatability of the experimental data as it is not necessary to select the operating parameter manually except for the simple regulation of stimulus intensity, which is manually set at the perception threshold. Each treatment sessions lasts 30 min on average. Application is by means of disposable surface electrodes applied in the skin areas corresponding to the pain areas.

A total of 226 patients, all suffering from intense drug-resistant neuropathic pain, were recruited for the trial in 2004.

Inclusion criteria:

— neuropathic pain;

— very high baseline visual analogue scale (VAS) in drug treatment.

Exclusion criteria:

— pacemaker user;

— neurolithic blocks or neurolesive pain control treatment.

The trial programme was based on a series of therapy sessions: from 1 to 6 cycle of 5 treatments every 24 h.

Figure 1 shows the number of treated patients suffering from neuropathic pain syndromes: failed back surgery syndrome (FBSS) (45 patients), sciatic and lumbar pain (33 patients), post herpetical neuralgia (PHN) (21 patients), trigeminal neuralgia (20 patients), post-surgery nerve lesion neuropathy (21 patients), pudendal neuropathy (11 patients), brachial plexus neuropathy (12 patients), low back pain (LBP) (14 patients), others neuropathies (46).

The patients were stratified in 3 groups: responders patients - pain relief >50%, partially responders-pain relief from 25% to 49% and no responders patients - pain relief <24% or VAS >3.

Pain intensity was evaluated using VAS before and after each treatment. The statistical significance of VAS was measured using the paired t-test.

Results

Figure 2 shows total percentage responses: 80.09% of patients was responder, 10.18% was partially responder and 9.73% was no responder.

The VAS trends before and after the treatment sessions are shown in Figure 3: in FBSS the VAS decreases from 7.01 to 2.79; in lumbar and sciatic pain from 5.64 to 1.73; in PHN from 6.45 to 2.73; in trigeminal neuralgia from 6.21 to 1.89; in post-surgical pain syndrome from 7.07 to 2.33; in the damage of brachial plexus from 7.25 to 2.42; in the damage of pudendal nerve from 6.82 to 3; in LBP from 6.33 to 2.56.

All VAS values are statistically significant ($P< 0.001$.)

Conclusions

The following conclusions may be drawn from these results:

— ST5 produced a surprising statistically significant ($P < 0.001$) pain relief.

— No undesirable side effects were reported.

—All the patients displayed excellent compliance with the treatment.

This extremely positive outcome is an encouragement to perform more extensive trials of Scrambler Therapy to obtain further knowledge.

Riassunto

Scrambler therapy

Nelle neuropatie ci sono complesse reazioni che modificano l'equilibrio omeostatico del sistema del dolore. In questo contesto la Scrambler Therapy (ST5) interferisce con la trasmissione del segnale doloroso, inserendo un'informazione di "non dolore" nelle fibre nervose.

Lo scopo di questo studio è stato valutare l'efficacia della ST5 nel trattamento del dolore neuropatico.

La ST5 è un apparato multiprocessore capace di simulare 5 neuroni artificiali attraverso l'applicazione di elettrodi superficiali su aree cutanee dolenti.

Nel 2004 sono stati reclutati per lo studio 226 pazienti, tutti affetti da dolore neuropatico farmacoresistente. Criteri di inclusione: dolore neuropatico, scala visiva analogica (VAS) con valore iniziale molto alto. Criteri di esclusione: portatori di pacemaker, blocchi neurolitici o trattamenti neurolesivi per il controllo del dolore.

Le neuropatie trattate sono state: failed back surgery syndrome (FBSS), lombosciatalgia, neuralgia post-erpetica (post-herpetic neuralgia, PHN), nevralgia del trigemino, neuropatia post-chirurgica, neuropatia del pudendo, neuropatia del plesso brachiale, low back pain (LBP) e altre.

Il protocollo: da 1 a 6 cicli terapeutici di 5 trattamenti, ciascuno della durata di 30 minuti.

L'intensità del dolore è stata valutata mediante VAS prima e dopo ciascun trattamento. La significatività statistica della VAS è stata valutata usando il t-test.

I risultati totali mostrano un 80,09% di responders (riduzione del dolore >50%), 10,18% di parzialmente responders (riduzione del dolore compresa tra 25% e 49%) e 9,73% di non responders (riduzione del dolore<24% o VAS >3).

Sulla base dei risultati gli Autori concludono che la ST5 produce una riduzione del dolore statisticamente significativa (P<0,001).

Parole chiave: Scrambler therapy - Dolore - Neuropatie.

References

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