METHODOLOGY

The Italian Consensus Conference on Pain in Neurorehabilitation: rationale and methodology

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On behalf of the Italian Consensus Conference on Pain in Neurorehabilitation (ICCPN)

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Fax +39 45 802 7276 Email stefano.tamburin@univr.it **Abstract:** Pain is very common in the neurorehabilitation setting, where it may not only represent a target for treatment but can also negatively influence rehabilitation procedures directly or through the side effects of painkillers. To date, there are neither guidelines nor consensus on how to assess and treat pain in neurorehabilitation. Because of the very scanty pieces of evidence on this topic, the Italian Consensus Conference on Pain in Neurorehabilitation (ICCPN) was promoted under the auspices of different scientific societies. This article illustrates the rationale, methodology, and topics of the ICCPN. The recommendations of the ICCPN will offer some information on how to deal with pain in neurorehabilitation and may represent the starting point for further studies.

Keywords: assessment, consensus conference, neurology, pain, rehabilitation, treatment

Introduction

A large number of studies document that chronic pain may have an adverse effect on physical, cognitive, and psychosocial functioning.^{1,2} Pain has recently received attention as a secondary complication and has been recognized as a common problem in patients undergoing neurorehabilitation, but its prevalence, severity, and psychosocial impact in this setting are still unknown.³

Spinal cord injury, traumatic brain injury, back pain, osteoarthritis, rheumatoid arthritis, multiple sclerosis, stroke, and limb amputation stand among the most common conditions that require inpatient and outpatient rehabilitation care. ⁴ Among these diseases, back pain and arthritis, where pain is the leading complaint, were found to cause the highest economic and social burden. ⁵ However, the impact of pain in the other common conditions listed above is largely unexplored.

Pain can negatively influence or even impede neurorehabilitation procedures,³ and most of the drugs used to treat pain, in particular neuropathic pain,⁶ may have an unfavorable side effect profile and may worsen neurological symptoms and cognition, with largely unknown consequences on recovery processes.

A very recent study explored the characteristics and impact of pain in people with stroke undergoing neurorehabilitation and reported that pain was present in 33% of the patients. Moreover, pain influenced rehabilitation treatment and outcomes in 25% of stroke patients and reduced attention during rehabilitation sessions in 16% of them, having a negative impact on the quality of life and eventually increasing the costs of the rehabilitation process.

A number of guidelines on pain management have been produced and regularly updated in recent years. For example, converging recommendations from different scientific societies help the neurologist or pain clinician to make the diagnosis, assess, 8,9 and treat neuropathic pain. 10–16 However, till now, how and to what extent such guidelines apply to the neurorehabilitation setting have not been explored.

The quality of scientific research on the rehabilitative approaches to treat pain is generally considered rather poor, which might be due to several reasons, including the low appeal of studies designed to explore the effect of a given rehabilitation treatment, the rather low impact factor of rehabilitation journals, and the difficulties in designing and conducting a randomized controlled trial (RCT) in rehabilitation.¹⁷ RCTs are mandatory for scientific evidence but are sometimes not feasible in the rehabilitation field because of the difficulties in designing true sham control conditions, in defining homogeneous patient groups, and in keeping equal duration and intensity of treatments among different centers.¹⁷

Because of the very scanty pieces of evidence on how to deal with pain in neurorehabilitation, the Italian Consensus Conference on Pain in Neurorehabilitation (ICCPN) was promoted by the Italian Society of Neurorehabilitation (Società Italiana di Riabilitazione Neurologica) and the Italian Society of Physical and Rehabilitative Medicine (Società Italiana di Medicina Fisica e Riabilitativa). This article illustrates the rationale, the methodology, and the topics of the ICCPN.

Methods

The methodology of the ICCPN was based on the Italian guidelines for organizing a consensus conference, ¹⁸ the Italian guidelines on stroke (Stroke Prevention and Educational Awareness Diffusion), ¹⁹ and the Consensus Conference on neuropsychological rehabilitation in adult patients. ¹⁷

Most of the current guidelines and evidence on the pharmacological and nonpharmacological treatment of pain may be difficult to transfer to the field of neurorehabilitation, and sound evidence is lacking for the majority of rehabilitative treatments of pain. For these reasons, we considered evidence derived from experimental, observational, case—control, and other types of studies, as well as the opinion of experts.

ICCPN task force

The ICCPN task force was composed of a promoter committee, a technical-scientific committee, and a jury. The task force of the ICCPN was formed by experts from

Società Italiana di Riabilitazione Neurologica, Società Italiana di Medicina Fisica e Riabilitativa, and from other Italian scientific societies interested in neurology, rehabilitation, and pain, including (in alphabetical order) the Italian Association for the Study of Pain (Associazione Italiana per lo Studio del Dolore), the Italian Association of Physiotherapists (Associazione Italiana Fisioterapisti), the Italian Society for the Study of Headache (Società Italiana per lo Studio delle Cefalee), the Italian Society of Clinical Neurophysiology (Società Italiana di Neurofisiologia Clinica), the Italian Society of Neurology (Società Italiana di Neurologia) and their study groups on neurosciences and pain (Neuroscienze e Dolore) and movement disorders (Accademia LIMPE - DISMOV), the Italian Society of Neuropsychiatry of the Infancy and the Adolescence (Società Italiana di Neuropsichiatria dell'Infanzia e dell'Adolescenza), the Italian Society of Pain Clinicians (Società Italiana dei Clinici del Dolore, FederDolore), the Italian Society of Palliative Care (Società Italiana di Cure Palliative), and the Italian Society of Rheumatology (Società Italiana di Reumatologia).

ICCPN topics and working groups

The topics of the ICCPN were divided into 27 working groups, which were incorporated into seven main paragraphs, three of which dealt with general issues and the remaining four dealt with specific clinical conditions that may be encountered in the neurorehabilitation setting. Common diseases with nociceptive pain were also included, because they may coexist with neurological conditions, especially in the elderly. The main paragraphs and working groups are listed as follows:

- 1. Diagnosing and assessing pain in neurorehabilitation (from translational research to the clinical setting): 1. translation research on pain; 2. neuropathic, nociceptive, and mixed pain; and 3. instrumental evaluation of pain.
- 2. The role of sex and psychosocial factors in pain in neuro-rehabilitation: 4. sex-related pain biomarkers; 5. the psychiatric comorbidity and the anthropological and cultural dimensions of pain; and 6. the psychological dimension of pain.
- 3. Pharmacological and nonpharmacological strategies in the integrated approach to pain in neurorehabilitation: 7. pharmacological, interventional, physical, and complementary therapies for the treatment of pain; 8. coping strategies, psychotherapy, and cognitive-behavioral therapies for pain; and 9. the role of the physical therapist.

- 4. Assessing and treating pain associated with stroke, multiple sclerosis, cerebral palsy, spinal lesions, and spasticity: 10. pain and spasticity; 11. pain in acute and chronic stroke; 12. pain in multiple sclerosis; 13. pain in spinal cord injury; and 14. pain in cerebral palsy and in pediatric patients.
- 5. Pain in degenerative, posttraumatic, infectious, and neoplastic central nervous system diseases: 15. pain in movement disorders; 16. pain in motor neuron disease; 17. pain in chronic disorders of consciousness and dementia; 18. pain in oncology and neurooncology; and 19. pain in neuroinfectious disease.
- 6. Pain in neuromuscular disorders and neuropathies: 20. pain in plexopathy, radiculopathy, and mononeuropathy; 21. deafferentation and phantom limb pain; and 22. pain in peripheral neuropathies.
- 7. Headache, low back pain, and other nociceptive and mixed pain conditions: 23. headache and facial pain; 24. low back pain and failed back surgery syndrome; 25. osteoarticular pain; 26. myofascial pain and fibromyalgia; and 27. chronic pelvic pain.

Each working group had a chairperson, and their members defined a number of questions to be answered by the ICCPN. Conflicts of interests were declared at the time of the formation of the groups, and the chairperson was chosen among those declaring no conflict of interests.

Bibliographic search and collection of papers

For the bibliographic search, the following search engines were used: Pubmed²⁰ Medline, and Embase²¹ Sets of specific and sensitive keywords or a combination of keywords were chosen, and the keywords of each group were checked centrally by a steering committee before launching the search. When possible, MeSH terms were used. The search was extended to a time period of 30 years and 20 years, respectively, for pharmacological and nonpharmacological studies. An example of the search strategy used by one of the working groups is reported in Table 1.

All the pertinent meta-analyses, guidelines, and reviews were considered, including the Cochrane Library²³ Meta-analyses were always collected and included. Previous guidelines and recommendations were sought from search engines and other sources, including national and international scientific organizations, patient organizations, and national or supranational health-related bodies. The conclusion of the ICCPN task force relied on quality-assured scientific data, and previ-

ous guidelines and recommendations were evaluated using the Appraisal of Guidelines for Research and Evaluation checklist²⁴ and eventually adopted in part or partially.²⁵ The conclusions of the reviews were critically evaluated on the basis of the scientific quality of the original papers,²⁵ which could serve as a source of additional data. Unpublished RCTs were searched on clinical trial registries^{26,27} or on pharmacological industries' websites. Data from nonrefereed journals, books, or other publications were considered only upon the judgment of the task force members.

Data evaluation and scoring of evidence

After bibliographic search and collection of papers, the full papers, including those in press, were read and data were collected from the papers themselves.²⁵ The evidence pertaining to each workgroup topic was evaluated and scored according to the Oxford 2011 Levels of Evidence.²⁸ These levels stipulate a gradient from the best (level 1) to the worst (level 5) evidence for systematic reviews, RCTs, cohort studies, case series, and mechanistic reasoning.²⁸ The bibliographic information, conclusions, and level of evidence of all the papers were tabulated in worksheets.

Proposal of the recommendations and evaluation by the jury

Each group prepared a final report with the defined questions and their answers, which were presented as recommendations with different grading strengths. The reports contained also summary tables and worksheets with tabulated data from original papers with levels of evidence. Each report included a structured summary with the main conclusions. Existing guidelines and/or consensus conferences prepared by other organizations, where appropriate, were adopted in part or whole with acknowledgment and respect for copyright. The format of each report was as follows: title, authors, structured abstract, objectives, background, search strategy, method for reaching consensus, results, recommendations, conflicts of interest, and references. The reports of all the groups were evaluated by the jury, and, when necessary, discussed with each group before preparing the final recommendations and strength grading.

The levels of the strength of recommendations were evaluated according to A, B, C, D, and good practice point score. 17,19 The top level was A and referred to high-quality RCTs, and the worst level was good practice point and referred to the best approach based on expert opinion, in the absence of any evidence from literature.¹⁷

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| Pubmed | Embase | Cochrane Database of Systematic Reviews |
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| (PDN OR "neuropathy" OR "brain injury" OR "multiple sclerosis" OR stroke OR "cerebral palsy" OR "postpolio syndrome" OR parkinson OR guillain-barre OR "nervous system diseases" [MeSH]) AND (rehabilitation* OR neurorehabilitation OR therapy) AND pain [Title/abstract] AND (psychotherapy [title/abstract] OR "cognitive therapy" [title/abstract] OR "group therapy" [Title/abstract] OR "family therapy" [Title/abstract] OR mindfulness [Title/abstract] OR biofeedback [Title/abstract] OR hypnosis [title/abstract] OR "cognitive-behavioral" [title/abstract] OR "psychodynamic" [title/abstract] OR "brief therapy" [title/abstract] OR "autogenic training" [title/abstract] OR "psychological treatment*" [title/abstract] OR "virtual reality" [title/abstract]) AND (trial OR review OR RCT OR "case reports" [publication type] OR "clinical trial" [publication type] OR "comparative study" [publication type] OR "cohort study*" OR "case-control" OR "efficacy" OR "pain reduction" OR "pain management" OR "panel study") | Neurologic disease'/exp OR "neurologic disease" AND pain:ab,ti AND (psychotherapy:ab,ti OR "cognitive therapy":ab,ti OR "behavioral therapy":ab,ti OR "cognitive-behavioral":ab,ti OR mindfulness:ab,ti OR hypnosis:ab,ti OR "brief therapy":ab,ti OR "psychodynamic therapy":ab,ti OR "acceptance therapy":ab,ti OR "autogenic training":ab,ti OR biofeedback:ab,ti OR "virtual reality":ab,ti OR "psychological treatment":ab,ti) | I: MeSH descriptor: [Nervous System Diseases] |
| | | 2: Pain and (psychotherapy OR "cognitive therapy" OR "behavioral therapy" OR "cognitive-behavioral therapy" OR "hypnosis" or biofeedback or "psychodynamic" OR "brief therapy" OR "acceptance therapy" OR "family therapy" OR "virtual reality") 3: I and 2 |

Writing and diffusion of ICCPN recommendations

The conclusions of the ICCPN will be written in English for publication in a peer-reviewed journal (expected time of publication: second half of 2016) and translated in Italian for a wider diffusion. In addition to the print copies, the conclusions will be made freely downloadable on a specific website and presented to national and international congresses. An audit on the ICCPN recommendations, including stakeholders (association of patients, health technology producers, health administrators), will follow their publication and diffusion.

Conclusion

The conclusions and recommendations of the ICCPN will represent a first step for answering the still open question of how to deal with pain in the setting of neurorehabilitation. Apart from offering some practical information on the evaluation and treatment of pain in this specific setting, they may represent the starting point for further studies, which hopefully will reach a high enough quality level to move from consensus conference conclusions to true guidelines.

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Disclosure

The authors report no conflicts of interest in this work.

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