

Including the patient's perspective - A systematic literature review of Patient Reported Outcome Measures in chronic neuropathic pain clinical trials

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Introduction

Chronic neuropathic pain is characterized by a variety of somatosensory abnormalities and often accompanied by different co-morbidities leading to an overall heterogeneous clinical picture. Many neuropathic pain clinical trials do not or only insufficiently include the patient's perspective and focus mainly on pain intensity as primary outcome parameter. Comparability of outcome assessment is limited due to heterogeneous use of Patient Reported Outcome Measures (PROMs).

Definition of a standardized core set of outcome domains and PROMs would improve comparability of trials and treatment of neuropathic pain.

Aim

As a first step, this systematic literature review (SLR) aimed at identifying PROMs that have already been used in clinical trials on chronic neuropathic pain.

Methods

The MEDLINE, CENTRAL and Embase databases and reference lists of two published meta-analysis [2,5] were searched until April 2020. Only randomized controlled studies assessing treatment efficacy of drugs for chronic neuropathic pain published in English, German or French were included. Title, abstract and full-text screening were performed by three reviewers.

All PROMs were extracted and assigned to recommended IMMPACT/NeuPSIG domains: pain intensity, pain other aspects, physical functioning, emotional functioning, global improvement and satisfaction, adverse events, participant disposition [1,4].

Domains and PROMs were compared regarding the publication year of the studies and their methodological quality (high/moderate vs low [3]).

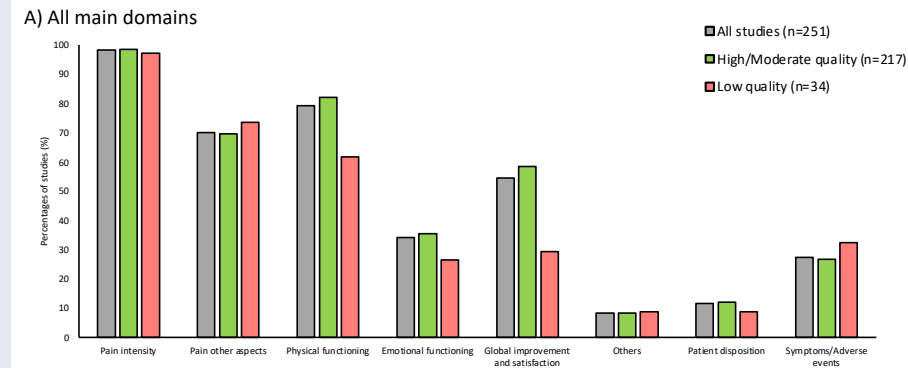
References

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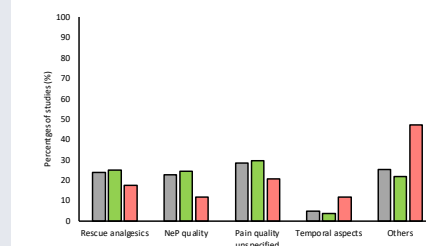
Results

- 251 of the 2693 identified articles were included in the analysis.
- 200 different PROMs were used, only 27 PROMs were recommended explicitly by IMMPACT and/or NeuPSIG.

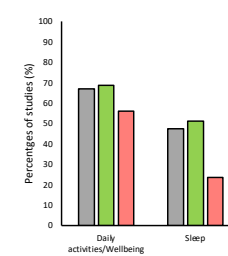
Figure 1. Percentages of studies assessing the different domains by at least one PROM.



B) 'Pain other aspects' subdomains

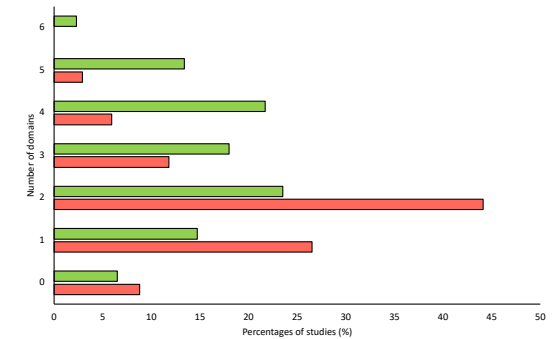


C) 'Physical functioning' subdomains



- While pain intensity was assessed by nearly all studies, the other (sub-) domains were assessed less frequently.
- The (sub-) domains 'physical functioning', 'global improvement and satisfaction' and 'neuropathic pain quality' were assessed more frequently in high/moderate quality studies and studies published after 2011. These studies also more often used the recently recommended PROMs.

Figure 2. Number of domains that were assessed by at least one recommended PROM.



- The number of domains was higher in high/moderate compared to low quality studies.

Conclusions

- ❖ Neuropathic assessment via PROMs in clinical trials has improved within last years.
- ❖ There is still a heterogeneous use of the single domains and PROMs even in studies with good methodological quality.
- ❖ The definition of standardized core set of outcome domains and PROMs relevant to both stakeholders and patients is needed to achieve better comparability of clinical trials and improve treatment of chronic neuropathic pain.

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