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From case-series to a placebo-controlled n-of-1 clinical trial of topical analgesics in the treatment of peripheral neuropathic pain: How to enhance the level of evidence of a case-report?- David Kopsky- Institute for Neuropathic Pain

David Kopsky and Jan M Keppel Hesselink

Institute for Neuropathic Pain, Netherlands

Case reports have been identified as relevant and important elements in advancing medical scientific knowledge. At our Institute for Neuropathic Pain, we treat patients suffering from symmetrical peripheral neuropathic pain, often resistant to most therapies. Since 2010, we have developed a number of compounded topical formulations containing classical co-analgesics such as ketamine, baclofen and phenytoin in treatment-resistant patients and reported the results in case-reports and case-series. We were able to optimize dose and formulations based on the feedback given by the patients. Most of our patients reported a quick analgesic effect, within 20-30 minutes after applying analgesic creams. Case-reports or case series are seen as the lowest level of evidence; therefore, we adapted our approach to the n-of-1 ‘clinical trial’, seen as the ultimate strategy for individualizing medicine. This is possible for symmetrical neuropathic pain states, as a patient can compare the analgesic response on treatments (or placebo) between both feet. We developed first a single-blind placebo-controlled responder test, and currently are designing a double-blind placebocontrolled response test. These tests helped us to better identify responders and exclude placebo responders. Using a placebo in a practical setting however is not done frequently, and the ethical justifications of using such placebo will be presented, as well as the results of single-blind and double-blind response test evaluating the safety and efficacy of phenytoin cream in peripheral neuropathic pain. The above serves to underline the importance of case-reports in the emergence of new insights in medicine.

Subsequent to creating skin creams containing set up co-analgesics for off-mark use in fringe neuropathic torment, our underlying methodology was to begin by endorsing one of those creams to patients; for example, amitriptyline 10% cream for the treatment of PDN. One to about fourteen days after the fact a subsequent meeting was masterminded and patients detailed one of the accompanying – an extensive decrease in agony, once in a while a slight decrease in torment, or no reaction by any means. We additionally checked for and recorded any neighborhood or fundamental antagonistic occasions.