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From case-series to a placebo-controlled n-of-1 'clinical trial' of topical analysics in the treatment of peripheral neuropathic pain: How to enhance the level of evidence of a case-report?

Tase 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.

Biography

As a medical student, David J. Kopsky wanted to expand his knowledge in the medical field and got skilled as an MD in acupuncture and hypnotherapy. He gained experience in READE, the Amsterdam Rehabilitation Centre in treatment and research. Together with Jan Keppel Hesselink, he founded the Institute for Neuropathic Pain, committed to the slogan: "pain free without side effects". Keeping this slogan in mind, the use of topical analgesics was born. Since 2010 he published many publications on topical analgesics and set up double-blind randomized placebo-controlled trials to objectify its effects. Since 2016 he is patent holder of patents related to the topical formulations of phenytoin in the treatment of pain. He founded the company Topical Innovations BV to develop topical analgesics on a global scale.

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