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Letter to the Editor

The Efficacy of acetyl-L-carnitine and Palmitoylethanolamide in Traumatic Lower Back Pain should be Tested by Appropriately Designed Studies

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Letter to the Editor

We read with interest the article by Cominacini *et al*. on a single-center, observational, single-arm longitudinal study on the effect of the fixed combination of acetyl-L-carnitine (ALC), palmitoylethanolamide (PEA), alpha-lipoic acid (ALA), Boswellia serrata, vitamin E, and vitamin B6 over a period of 56 days in 48 patients with traumatic low back pain [1]. This combination was found to reduce neuropathic pain, as measured by the Neuropathic Pain Scale (NPS) and the Visual Analogue Scale (VAS), and to improve physical health status according to SF-36 [1]. The study is promising, but some uncertainties should be clarified.

The first point is that it was not a single drug that was tested, but a combination of several drugs [1]. Therefore, it is impossible to say which of the drugs administered or which combination of them was truly effective. To test the effect of a drug on neuropathic pain, it is generally recommended to test each substance individually rather than as a cocktail.

The second point is that the dosages of the individual active ingredients in the cocktail were not adjusted to body weight. It is therefore conceivable that some obese patients did not experience any pain relief simply because the individual components were relatively underdosed. We should therefore know whether pain relief correlated with body weight.

The third point is that the effect of the study cocktail may also depend heavily on the type of trauma that caused the lower back pain. We should know how many of the patients included suffered a car accident, a fall, a sports accident, or trauma from heavy lifting. The response to the study cocktail may also depend on the injured structure. How many patients had soft tissue damage (tears or strains to muscles, tendons, joint capsules, or ligaments), herniated discs, or nerve compression (pinched nerves causing pain, tingling, or weakness)?

The fourth point is that the use of painkillers other than opioids was not restricted. It is therefore conceivable that the pain relief in some patients was simply due to taking a higher dose of non-steroidal anti-inflammatory drugs (NSAIDs) and not to taking the study drug. Therefore, the type of painkillers and their dosages should have been included in the study.

The fifth point is that no information was provided about liver and kidney function. Since serum levels of the administered drugs can depend heavily on liver and kidney function, we should know how many patients had kidney or liver dysfunction and therefore may have been overdosed. Did those with impaired metabolism or excretion of the study drugs perform better on the NPS and VAS scales than those with normal metabolism of the study drugs?

Finally, the study design used (single-center, single-arm, no control group, non-randomized, non-blinded) is unsuitable for testing the efficacy of the prescribed drugs. The gold standard for testing drug efficacy is the randomized, double-blind, placebo-controlled crossover study [2].

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