PLACEBELL
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TITLE: **BASELINE PAIN MEASUREMENTS AS PREDICTORS OF THE PLACEBO RESPONSE IN NEUROPATHIC PATIENTS**

Abstract

In analgesia randomized clinical trials (RCTs), the magnitude of the placebo response has a negative influence when testing the statistically significant superiority of active compounds compared to placebo. In chronic pain, meta-analyses have already highlighted the baseline pain amongst the many parameters correlated with the placebo response.

One of the objectives of this study was to investigate the relationship between the placebo response and the baseline pain intensity collected by the average pain intensity (API), the brief pain inventory (BPI), etc. Eighty-eight patients with peripheral neuropathic pain were enrolled and blindly given a placebo in addition to their regular analgesic treatment during 4 weeks. The multiple endpoints (placebo responses) were estimated as the pain differences between baseline and the end of the treatment, computed with the API, BPI, etc.

As expected, the baseline pain measures were significantly correlated between each other and with their respective placebo response (API-baseline correlated with API improvement, etc). To go further in the prediction, we combined the baselines in a global pain intensity scale which turned not to be correlated with any placebo responses. However, this scale can be used to estimate if a patient has over-evaluated his baseline pain which then correlated with the multiple endpoints. Indeed, a patient with an over-estimated baseline pain has more chances to show a pain improvement.

Those results challenge the classical view of the baseline pain in the placebo response. An alternative use of the multiple baseline measurements could then help to predict the placebo response, a major confounding factor, in RTCs

Authors

Alvaro Pereira, PHD; Samuel Branders, PHD; Christian Dualé, MD PHD; Fréderic Clermont, PHD; Pierre Gramme, MS; Chantal Gossuin, PHARMD; Dominique Demolle, PHD