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ADDITIONAL EFFECTS OF DULOXETINE IN RELATION TO EXERCISE ON SARCOPENIA ASSOCIATED WITH KNEE OSTEOARTHRITIS: A RANDOMIZED CLINICAL TRIAL

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BACKGROUND

The effects of duloxetine on sarcopenia are unknown in older adults with painful knee osteoarthritis (KOA) and lower physical performance, when added to standard exercise therapy. To study the additional effects of duloxetine on physical performance, muscle mass and muscle strength of individuals with KOA and lower physical performance treated with a home-based exercise program (HE).

MATERIALS AND METHODS

In a randomized, double-blind, placebo-controlled, 12-week trial, we assigned older adults with painful KOA and lower physical performance in a 1:1 ratio and blocks of 4 to receive duloxetine (60 mg/dL) or matching placebo, in addition to standard HE therapy. The primary endpoint at week 12 was a difference in physical performance of > 0.8 in short physical performance battery (SPPB) between groups. Secondary endpoints included 12-week changes in muscle mass by dual-energy X-ray absorptiometry (appendicular skeletal muscle mass index – ASMI), strength by knee extension maximal isometric voluntary contraction (KE) and pain by visual analog scale (VAS).

RESULTS

Between March 2017 and January 2020, 24 patients (12 per group) were included: 77.2% were women, 79.2% Caucasian, on average 64.3 ± 6.8 years of age. After 12 weeks, HE + placebo group performed more minutes of HE than HE + duloxetine group [692 (IQR 300 to 1,120) vs. 310 (IQR 210 to 543), $p = 0.015$] and both groups significantly improved SPPB [HE + duloxetine: 1.52 (CI95% 0.53 to 2.51) and HE + placebo: 2.00 (CI95% 1.23 to 2.77)], with no differences between them ($p = 0.456$). Only HE + duloxetine group improved the balance component of SPPB [0.27 (CI95% 0.01 to 0.54)] and pain VAS [-2.41 (CI95% -3.82 to -0.99)], while only HE + placebo group improved KE [11.8 kg (CI95% 4.3 to 19.2)] and ASMI [0.4 kg/m² (CI95% 0.0 to 0.9)]. Twelve-week variations in pain VAS and ASMI correlated only in HE + placebo group ($r_s = 0.821$; $p = 0.023$). Two individuals in each group withdrew from the study due to adverse events.

CONCLUSION

Duloxetine was not superior to placebo in increasing physical performance of KOA patients treated with home-based exercise. Duloxetine seems to have an additional benefit in relation to home-based exercise on pain and balance. Also, duloxetine appears to impair the benefits of exercise on strength and muscle mass, possibly by reducing the adherence to the home-based exercise program.

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