Reviewer's report

Title: Effect of exercise training and dopamine agonists in patients with uremic Restless Legs Syndrome: a six-month randomized, partially double-blind, placebo-controlled comparative study

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Reviewer: Gaetano La Manna

Reviewer's report:

The authors present a monocentric, randomized, partially double-blind, placebo-controlled study on hemodialysis patients with a diagnosis of restless syndrome, defined as the presence of one RLS episode per week excluding intra-dialytic episodes.

Patients were randomly assigned in three groups (2-1-1): A) exercise group (cycle ergometer 3-times/week B) dopamine agonists (DA; Ropinirole 0.25mg/day) C) placebo.

The patients' physical performance levels were assessed with specific tests (NSRI test, STS-5, STS-30, STS-60, two gait speed tests). The patients' body and regional fat and lean mass were measured by a DEXA system. Muscle size and composition were assessed with a CT system. The patients' subjective quality of life were evaluated by using a SF-36 questionnaires. The patients' depression levels were assessed by using the self-rating depression scale developed by Zung. Epworth sleepiness scale and a sleep diary were used to assess the daily sleepiness.

The authors observed that both exercise and DA intervention were equally effective in reducing RLS symptoms and depression score compared to placebo, as well as in improving quality of life, while DA were more effective in improving sleep score. The placebo group showed a significant worsening of depression score after 6 months. DEXA and CT showed that total lean body mass significantly increased after exercise training, while extramyocellular lipids significantly reduced after exercise.

The following are major criticism that may contribute to the revision of the manuscript.

1. This study compared the effect of dopamine agonist and physical exercise for restless syndrome in uremic patients in a randomized and placebo-controlled trial. The study design is clear also with a limited study population. Methods are appropriate and well described.

2. Polysomnographic study and ropinirole dosage were not performed, as the authors themselves admit in discussion.
3. Among the baseline characteristics residual renal function is not considered. In our experience this factor may contribute to symptoms onset.

4. Among the exclusion criteria (page 6) there should also be patients that refused to participate, in order to make the text congruent with figure 1.

5. The sentence from “The low dropout” to “hemodialysis unit” in the discussion session seems hypothetical and in some way redundant. We suggest to change or eliminate it.

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

'I declare that I have no competing interests