Reviewer's report

Title: Upper airway stabilization by osteopathic manipulation of the sphenopalatine ganglion versus sham manipulation in OSAS patients: a proof-of-concept, randomized, crossover, double-blind, controlled study

Version: 0 Date: 17 Jul 2017

Reviewer: Nicolas Pinsault

Reviewer's report:

Comments to the Authors

The authors have prepared a manuscript that describes an experiment investigating the effects of active manipulation of the SPG. They announced a single-centre, randomized, crossover, double-blind study.

There are several issues that need to be addressed within the manuscript to be considered for publication.

Title: The title is appropriate for the manuscript.

Introduction:

P5: The authors stated that "It could therefore play an important role in control of upper airway stability.

Postganglionic parasympathetic blockade of the SPG by local anaesthesia" This claim needs direct evidence. The plausibility of a therapeutic approach without direct evidence.

P5: "Similar effects are observed during direct stimulation of the SPG by acupuncture [26]". The study mentioned is a PROTOCOL! Therefore it cannot be used to argue that « Similar effects are observed during direct stimulation of the SPG by acupuncture. »

P5: The study [27] is a pilot study. As its authors concluded: « All pilot studies warrant cautious interpretation of results. In a small study such as this, conclusions about effectiveness cannot be made. ». Therefore, this pilot study cannot be used to argue that: « Intraoral myofascial therapy of the SPG allows a muscle relaxation and a relief of pain in patients with temporomandibular dysfunction (as it is implied in the present claim).

P5: "Unpublished data from an osteopathy dissertation [29] also suggest reduction of snoring (reflecting upper airway instability during sleep) after osteopathic manipulative treatment (OMT) of the SPG." If this unpublished work is a rigorous methodological work, it is a priority to
publish it before to publish the present paper. Meanwhile, this work cannot be used to argue anything in an international scientific journal.

P5: "In the context described above, we proposed the hypothesis that OMT of the SPG could improve upper airway stability in OSAS patients". This hypothesis is based on anything substantial. Consequently, it is not justify testing it.

Method

I have several concerns concerning the method section.

My first concern is related to the design study. In fact, in my opinion this study is not a double-blind study, considering that the osteopath is not blind.

My second concern is related to the sample size calculation. I my opinion, the calculation made is wrong and should be based on the expected difference between conditions on raw primary outcome.

Results

2 patients were not reported due to lack of cooperation. This point is surprising and to be developed.

Considering the low number of subjects included, Individual results should be reported.

Discussion

Discussion is clear and concise.

References

Many references are difficult or impossible to find.
Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

No

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

Yes

Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.

No

Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

I recommend additional statistical review

Quality of written English
Please indicate the quality of language in the manuscript:

Acceptable

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