Author’s response to reviews

Title: Paranasal sinus air suction for the treatment of acute migraine – A randomized, double blind, pilot Study

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Thank you for your reviews

Reviewer reports:

Romina Moavero (Reviewer 1):

Background (and consequently the abstract) are not well organized. For instance, the Authors discuss the prevalence of migraine in adulthood, and its place among the causes of disability in adulthood, but they perform a study on migraine in adolescents. Epidemiology should be discussed in this age range.

I have added epidemiology of migraine in adolescents to the introduction part

Overall the paper is too long and it should be significantly shortened. There are more limitations than expressed. Some more information should be given on the accessibility of the device and eases to use. It should be stated whether this technique is used and approved for conditions other than migraine, both in pediatric age and in adulthood. Some more data on safety would be useful.
This is a pilot study and I have added that to the manuscript. I have added these to the limitations. The safety of this technique will be studied in another subsequent study.

The text should be revised by an English native speaker.

Thank you. Revision done

Catello Vollono (Reviewer 2): Comments to the Authors

Dear Authors, Dear Editor,

this is an interesting study evaluating the efficacy of paranasal air suction as symptomatic treatment of migraine.

In the present study, the Authors assessed a non-pharmacologic therapy in acute migraine.

The therapeutic method assessed is interesting and probably without relevant side effects.

The availability of alternative therapies, particularly in young subjects, is an important topic. The authors reported their findings in a relatively clear presentation.

Certain major revisions are needed and may help the strength of their efforts. Subsequently, I have several concerns regarding the methods as well as the results and the interpretation of their findings.

1. The Authors should explain more extensively how the perception of suction was similar in the control group and in treated group. In my opinion, the perception of the suction is important for the 'placebo effect'.

We have one the following methods to reduce the placebo effect.

None of subjects were told that this procedure was a therapy for migraine in order to prevent placebo effects of the procedure. The control group was tested by keeping the same type of a nasal suction tube close to the nostrils. The appearance of the nasal air suction tube end of placebo group is similar to the test group. They were also asked to close and open the nostrils in a similar manner. However they were not exposed to air suction procedure though they were made to hear the sound of the air sucker. They were given the same instructions as the test group.
All these measures were taken to provide similar perception to both groups to reduce placebo effect.

2. Single measurement of both pain intensity drop and tenderness over sinuses only 60 seconds after the application of the device are poor predictive of real efficacy of the treatment. Data on pain relief (at 30, 60, 120 minutes) and on recurrence (at 24 hours) would be needed, as the observation period is too short to establish the efficacy.

This is done as a pilot study and our main aim was to evaluate the effect of paranasal sinus air suction for immediate relief of migraine headache. In fact, first we observe effect of air suction to reduced acute migraine headache that is not reduced even by new drug within very short period of time. Significant pain relief within very short period of time means significant pathophysiological recovery effect that done by modern drugs. The effect of latter sustained for more than 24 hours. On this background, we are conducting another research to assess how long beneficial effects/pain relief last long after air suction procedure using multiple measurements over 24 hours. This was added the limitations.

Consensually, I suggest that the Authors change in this way, the discussion and the conclusion of the study.

Have changed accordingly

4. The Authors could discuss more extensively how the paranasal suction is able to discriminate sinusitis from migraine and if they used other methods to exclude the diagnosis of sinusitis or turbinate hypertrophy.

This is done as a pilot study and our main aim was to evaluate the effect of paranasal sinus air suction for immediate relief of migraine headache. In this study we excluded patients with sinusitis after consulting an Ear nose and throat (ENT) surgeon have also assisted in confirmation migraine and exclude sinusitis patients who have been tested by taking history and clinical examination. We are planning to conduct a separate research to see the efficacy of this method to discriminate sinusitis from migraine.

5. The Authors could take in account and discuss that other mechanisms to interpret effectiveness (for example presser modifications).

I have added this to the discussion part.
6. No data on safety or side effects are reported.

This is done as a pilot study and our main aim was to evaluate the effect of paranasal sinus air suction for immediate relief of migraine headache. Since this method was not used before we were unable to find data on safety or side effects in literature. However, a second study is undergoing to evaluate the safety, side effects and efficacy of a portable low grade air pressure suction device that can be used in a day to day life.