Preview Abstract

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Kalinix® Night in real time treatment of obstructive sleep apnoea (OSA).

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Introduction. KaLinix is a smart, wearable, non-invasive medical device as an alternative to OSA treatment. The real-time nocturnal treatment mode is based on the detection of multisensory signals from the patient, predicts respiratory events and corrects them in real time by non-invasive external application of therapeutic electrical stimuli that open the upper airway (UA).

Objectives. To evaluate the efficacy and safety of Kalinix Night, in real-time treatment mode, in patients with moderate to severe OSA.

Methods. Nocturnal polygraphy was performed simultaneously with the kalinix Night device, comparing respiratory variables with pre-treatment baseline values. 3D/4D ultrasound was used to monitor UA changes.

Results. n=20; stimulation produced in 100% of patients an opening of the airway by 2.66 times in the area without discomfort. AHI improves between 63% and 8%. ODI improves between 66% and 13%. 75% have improved the duration of the event (apnea/hypopnea), shortening of event durations to 11 to 15 seconds in duration. This improvement is considered clinically relevant.

The hypnogram shows that kalinix stimulation pulses do not disturb the sleep architecture and can even improve it. Microarosals are not produced.

Reduced cardiac output during sleep, reducing the maximum heart rate by an average of 20%.

Most patients report no discomfort due to stimulation, better sleep and less fatigue.

Conclusions. The KaLinix Night improves apnoea and desaturation during the sleep. It would be indicated for all patients, especially those who do not adapt to traditional OSA treatments of choice such as CPAP, those who discontinue their use or as a booster therapy for other treatments.

Project promoter: Torytrans S.L.

Kalinix® Night in real time treatment of obstructive sleep apnea (OSA).

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AIMS

Kalinix® is a smart, wearable, non-invasive medical device that emerges as an alternative to conventional OSA treatment in those patients that do not tolerate CPAP.

The real time nocturnal treatment mode can predict respiratory events based on the detection of multisensory signals from the patient and corrects them in real time applying an electrical stimulus to the patient's upper airway (UA) muscles.

The aim of this study was to evaluate the efficacy and safety of Kalinix® Night in real time nocturnal mode in patients with moderate to severe OSA.

METHODS

- 20 patients with a previous diagnosis of OSA and poor tolerance to CPAP were selected.
- Polysomnography was performed simultaneously with Kalinix® treatment.
- We compared AHI, ODI, duration of the respiratory events and cardiac output with pre-treatment values.
- A 3D/4D ultrasound was used to monitor changes in the UA muscles.

RESULTS

- The electrical stimulus produced an opening of the upper airway by 2,66 times the diameter in every patient (20).
- The reduction of AHI was between 8 and 63%. The reduction of ODI was between 13 and 66%.
- 75% of patients reduced the duration of respiratory events (apnea/hypopnea).
- Kalinix® electrical stimulation does not interfere with the sleep architecture. No microarousal occurred due to the stimulus.
- Cardiac output during sleep was reduced, decreasing the maximum heart rate by an average 20%.
- No patient reported discomfort. Every patient claimed better sleep and less fatigue.

CONCLUSIONS

- ✓Kalinix® Night treatment improves AHI, ODI and cardiac output during sleep.
- ✓It reduces the duration of the respiratory events.
- ✓t could be indicated in those patients with poor tolerance to CPAP or as a booster therapy for other treatments.

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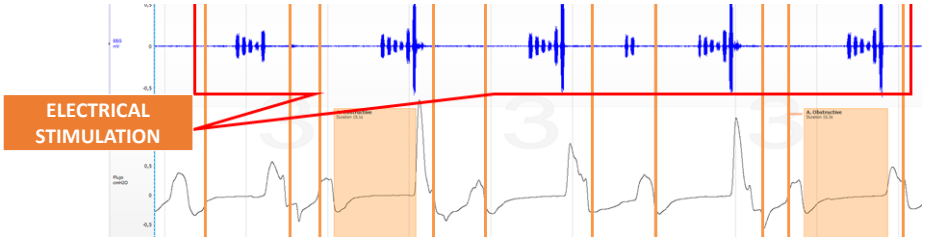

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Sleep and Breathing