v. 4, n. 104, 2024

International Journal of Health Science

Acceptance date: 16/12/2024

ROLE OF AN INTERNAL NASAL DEVICE (BEST BREATHE) IN HEADACHE PATIENTS

Carlos Mas Bermejo
MD, DDS, PhD, Bachelor of Medicine and Surgery Universidad de Murcia 1982 España Specialist in Stomatology Universidad de Murcia 1982 España, Professor of Master and Expert in implant prosthetics and prosthetic rehabilitation and advanced esthetics, Director of Master and Specialist in Prosthetic Rehabilitation and Advanced Dental Aesthetics based on Dental Sleep Medicine

Carlos Mas Gómez
CBCT and EXCEL Data. DDS, Degree in Dentistry (Universidad Europea de Madrid) 2014, Master in Aesthetics and Prosthetic Rehabilitation

Ambrosio Bermejo Fenoll
Article Review, MD, DDS, PhD, Degree in Medicine and Surgery. Universidad de Zaragoza 1967. Medical Specialist in Stomatology. Universidad Complutense de Madrid 1969, Doctor of Medicine and Surgery. Universidad de Valencia 1981, Professor of Oral Medicine at the Faculty of Medicine and Dentistry of the Universidad de Murcia. deceased

Antonio Francisco Bravo
Statistical analysis, Statistician

Keypoints: Question: Does the placement of an internal nasal dilator have any effect on patients with primary headaches? **Findings:** In this case-control study involving 200 patients (108 with headaches and 92 without headaches) we found, after placement of an internal nasal device during sleep, a significant improvement in oxygen saturation, in both groups, being higher in patients affected by headache, **Significance:** The use of the internal nasal dilator lowers the respiratory effort and facilitates nocturnal nasal breathing, because it avoids the collapse of nasal nares, facilitating nasal breathing during sleep. It can be useful in nasal breathing therapy used during the control and resolution phase of patients with OSAHS. By improving oxygen saturation in patients with headaches, it may decrease the symptomatology.

Abstract: Importance: Many headaches are diagnosed as primary (migraine and tension headaches), whose treatment is palliative. They could be related to sleep disordered breathing and chronic intermittent hypoxia. If this is so, some primary headaches should be included in the group of secondary headaches. **Objective: To** analyze the influence of nocturnal internal nasal dilator on oxygen saturation levels in patients with and without headaches. To investigate the possible relationship between primary headaches and sleep disordered breathing. We performed a 3D study of the airways by cone beam computed tomography (CBCT) and evaluated oxygen saturation levels before and after the use of the nocturnal internal nasal dilator. **Design, location and participants:** Observational case-control study carried out from September 2017 to September 2018 in a dental clinic specialized in prosthetic rehabilitation in Murcia (Spain). From the initial number of patients (400), 200 (n=200) were selected. They were fitted with an internal nasal dilator, measuring oxygen saturation before placement, one week and one month after placement. The patients were classified into two groups, CP primary headaches (n= 108) and GC control group (n= 92) who were first visits who came to the clinic for study due to problems of missing teeth and temporomandibular joint (TMJ) dysfunction and did not have headaches.**Interventions:** All were given a subjective functional and sleep test (Epworth test). We performed a muscle examination (cranio-cervical and craniomandibular palpation), temporomandibular joint (TMJ) and dental examination, and a 3D scan using cone-bean computed tomography (CBCT) to explore the patency of the airways. **Results and main measurements:** In the descriptive study of clinical variables of the patients with headaches, tension headaches were observed in 64 (59%). Both in the functional or subjective tests and in the muscular exploration there was a statistically significant association between the group of patients with headache and the presence of symptoms (muscular, articular, dental, poor sleep and mouth breathing) so that the percentage of patients with symptoms was significantly higher than in the control group. On examination by cone-bean computer tomography (CBCT), variables such as the presence of turbinate hypertrophy, septal deviation and the decrease in the oro-pharyngeal space showed significant differences between the two groups, being higher in patients with headaches. After placement of the nasal dilator, a significant increase in saturation was observed in patients with headache at one week and one month after its use, and the patients improved their headache. **Conclusions and development:** By improving oxygen saturation and improving inspiratory flow limitation with the use of the internal nasal dilator some headaches improve, reducing the dose and time of palliative pain medication. Therefore, they would not be primary headaches or of unknown origin but secondary ones.

Keywords: Primary headaches, secondary headaches, tension-type headache, Migraine, trigeminal autonomic cephalalalgias, func-

tional somatic syndromes, mouth breathing, chronic intermittent hypoxia, sleep disruption, inspiratory flow limitation, upper airway resistance syndrome, snoring, nasal resistance, internal nasal dilator, external nasal dilator

INTRODUCTION

Breathing is the most important function of the human body. It sustains life by providing oxygen necessary for metabolism and eliminating carbon dioxide. It influences physiological regulation, psychological and homeostatic function of various systems such as the autonomic nervous system, circulatory system, chemical regulation, metabolism and can affect postural stability (1) The mission of the nasal passages is to prepare the air reaching the lungs by filtering particles, tempering and humidifying (2) Nasally inhaled air also transports nitric oxide from the maxillary sinuses to the lungs. It reduces vascular resistance causing vasodilation and bronchodilation, favoring homeostasis thanks to increased oxygenation (3,4,5) There are works that relate hypoxia and headache that appears in exposure to altitude or mountain sickness (6) Based on the latest international classification of headache disorders published in 2018 (7) it includes primary headaches or headaches of unknown origin (migraine, tension and trigeminal) whose treatment is palliative pain. It also includes secondary headaches or headaches of known origin, among which we highlight, with section 10, those attributed to homeostasis disorders, which include, among others, those secondary to hypoxia and/or hypercapnia, sleep apnea and high altitude headache or mountain sickness. With nº 11 it groups headaches secondary to facial pain due to disorders in the skull, nape of the neck, eyes, ear, sinuses, teeth, mouth and other facial and cervical structures.

Headaches represent a major health and social problem due to the high consumption of drugs. They generate an enormous work absenteeism in the adult population, being the most prevalent neurological pathology in world health, with 46% for general headache, 42% for tension type, 11% for migraine and 3% for cluster (8) and respiratory sleep disorders. On the other hand, the prevalence of OSAHS in our consultations is increasing, knowing that there are many undiagnosed, is why we propose a literature review, using as a database PubMed, 30 years, (from 1989 to 2019) and using as keywords: Primary headache, tension-type headache, migraine, trigeminal autonomic cephalalalgias, functional somatic syndromes, mouth breathing, chronic intermittent hypoxia, sleep disruption, Inspiratory flow limitation, upper airway resistance syndrome, snoring, nasal resistance, internal nasal dilator, external nasal dilator 875 citations were obtained and manually reviewed. Most of the articles were in English.

The prevalence of OSAHS (9) in the general adult population is strikingly high, ranging from 9% to 38%, being higher in men and increasing with age. Mild OSAHS (≥ 5 AHI) is from 9 to 38%, moderate OSAHS ≥ 15 events /hour, in adults was from 6 to 17% reaching 49% in older ages.

Primary headaches have been included, within the somatic functional syndromes, along with irritable bowel syndrome, chronic fatigue, fibromyalgia, anxiety, depression, bruxism, temporomandibular dysfunction and attention deficit hyperactivity disorder. These patients have polysomnographic signs of increased upper airway resistance syndrome (SARVAS) (12). It is considered a mild variant of obstructive sleep disordered breathing and is characterized by airway collapsibility due to nasal obstruction. It was described by Guilleminault et. al (13) whose characteristics are: inspiratory flow limitation, increased sleep onset latency period (insomnia), apnea and hypopnea index <5, minimum oxygen saturation >92%, predominance of respiratory effort related to micro arousals (RERAS) and frequent sleep cycle disturbance (14).

In the pathogenesis of SARVAS, one of the most frequent causes is the collapse of nasal valves or nares (15). It causes increased nasal resistance to the passage of air flow. Among the sleep breathing problems are simple snoring, upper airway resistance syndrome (SARVAS) and sleep apnea and hypopnea syndrome (SAHOS). Clinically, the collapse of the nasal wall during inspiration is called dynamic obstruction, while the narrowing of the nasal valve is called static obstruction. An alternative to surgical procedures to repair an obstructive nasal valve may be represented by nasal dilators which can be external or internal (16,17), the latter used in this study confirm that the activation of the dilator muscle is directly related to airway narrowing and reducing resistance in patients with obstructive sleep apnea (18).

The use of the internal nasal dilator (IND) in collapsed nares is relatively new. The first data are from 1990, being very popular in the Olympic Games of Atlanta 1996, where they were used by US athletes. They were nasal strips called external nasal dilators (19, 20). They have been used as a nonpharmacologic therapy to reduce snoring and daytime sleepiness. Most existing studies with internal nasal dilators (IND) explore their effect on snoring, achieving significant reduction in snoring time and improvement in sleep quality (16). Its effect was studied by Polysomnography, obtaining a significant decrease in the frequency and severity of breathing obstruction, lowering the rate of apneas, snoring noise and raising the minimum oxygen saturation (19,20,21).

OBJECTIVES

The aim of this study is to test whether there is a relationship between patients with primary headaches and chronic intermittent hypoxia and the effect on oxygen saturation when an internal nasal dilator (Best Breathe®) is placed.

MATERIAL AND METHOD

We conducted a retrospective retrospective descriptive longitudinal observational study, endorsed by the Ethics Committee of the Morales Meseguer Hospital in Murcia, in accordance with the ethical principles **(Annex 1).**

Patients were recruited by means of an advertisement in a regional health newspaper (Salud 21) offering a free study to patients diagnosed with primary headache by their neurology specialist. In addition, and as a control, the same number of patients who attended the dental clinic during the same period of time were selected. Inclusion criteria: Equal or older than 12 years of age, with headaches diagnosed by a neurologist or family physician and who signed the informed consent form (IC) and wished to commit to participating in the study. Exclusion criteria**:** under 12 years of age, without headaches or not signing the IC or missing appointments during the process. The criteria for patient withdrawal and substitution were performed according to the protocol and in observance of the principles of the Declaration of Helsinki (Seoul 2008 update), Good Clinical Practice (GCP) and other applicable regulatory standards. A patient has the right to leave the study at any time and for any reason, without prejudice to his/her future medical care by the physicians or the institution. A patient may be required to leave the study at the request of the investigator for any of the following reasons:

- Serious adverse event(s) (AAG).
- At the discretion of the investigator.

- Violation of inclusion criteria.
- In any case, the reasons for exit should be recorded in the data collection notebook (CRD) and in the patient's clinical history. Those patients who exit the study as a result of an adverse event should be followed up until complete resolution of the event or until its evaluation as chronic or stable by the investigator. Patients who exit the study will not be replaced or substituted.

- All patients recruited must be identifiable throughout the study, although in the computerized database, their data will be dissociated and with keys for identification.

Out of 400 patients, 200 volunteer patients were selected, 70% (n=140) of whom were female and 30% (n=60) male, ranging in age from 12 to 91 years with an average of 43.9 years (SD=16.4).

In the experimental group of 108 patients (54%) all had primary headaches (83 women and 25 men) 64 were tension headaches, 38 migraines, and 6 cluster. In the control group there were 92 volunteer patients without headaches (46%) who came to the clinic for dental problems. Of these, 57 were women and 35 men **(Figure 1).**

STUDY DESIGN

We conducted an observational, descriptive, analytical, prospective, case-control study, whose independent variables were airway obstruction (nasopharynx, oropharynx and hypopharynx) and chronic intermittent hypoxia and headache as dependent variables.

EXPLORATION AND COMPLEMENTARY EXAMINATIONS

Data collection and examination were carried out in the facilities of a dental clinic specializing in functional oral prosthetic rehabilitation, located in Murcia, directed by a physician specializing in stomatology.

- The participant was specifically informed that he/she could leave the study at any time (**Annexes 2 and 3).**
- Subjective functional test **(Appendix 4)** with questions related to muscular problems, temporomandibular joints, dental problems, sleep, breathing, and dry mouth with two possible answers: Yes or No. This reflects the subjectivity of the patient in the face of functional problems. The patients who answered positively to the functional test were selected for the study.
- The selected patients underwent the following tests:
- Functional test **(Annex 5)**
  - Cranio-cervical and cranio-jaw muscle examination by palpation, looking for muscle knots or painful areas, instructing the patient to indicate from 0 to 10 the intensity of pain, understanding 0 as absence of pain and 10 as pain of maximum intensity. In patients with headaches, a specific headache test was used.
  - Examination of the temporomandibular joints by palpation, auscultation and measurement of range of motion.
  - Examination of the condition of teeth and their occlusion by means of wear pattern and occlusal analysis
  - Examination of mucous membranes for signs of xerostomia (dry mouth, chapped lips, canker sores).
  - Respiratory examination: we performed a breathing test where the patient was told to breathe in and out by plugging one of the two nostrils and to say where he/she breathed with less resistance.
  - The data were recorded on the functional examination sheets.
- Study of oxygen saturation (O2) by pulse oximetry (Appendix 6), which is the noninvasive measurement of oxygen carried by hemoglobin inside the blood vessels. It is performed with a device cal-

led a pulse oximeter or saturation meter. In our study it was the SpO2t brand of Criticare System. We performed 3 measurements, one per minute, using in the study the mean

- Airway examination (**Annex 7)**
  - KODAK 9500 cone-bean computer tomography (CBCT) and Window Dental Imaging Kodak software were used to analyze the images looking for anatomical alterations in the airways related to the lack of patency.
  - The position when taking the scan could be seated or standing, all chose standing.
  - We observed airways in Sagittal, Frontal and Axial planes **(figure 2).**
- After performing the tests, we provide all patients with an internal nasal device (IND) of the nostrils or nares, whose commercial name is Best Breathe®, whose mission is to reduce air passage resistance by facilitating nasal breathing and lip sealing (**Figure 3**). Its use at night favors a correct re-education of nasal breathing and consequently avoids harmful mouth breathing secondary to the obstruction of the passage of air through the nose. It therefore contributes to lip sealing during inspiration during sleep,
- They are trained in the placement of the device. The pulse oximetry, functional examination and functional test are repeated one week and one month after the use of the dilator. The differences before and after its use will be analyzed,
- The data were dumped into an Excel table by the principal investigator for further statistical analysis.

STATISTICAL METHOD

Statistical analysis was performed with SPSS 25.0 for Windows. The differences considered statistically significant are those whose $p < 0.05$.

For the descriptive analysis of the qualitative variables, we obtained the number of cases present in each category and the corresponding percentage; and for the quantitative variables, the values: minimum, maximum, mean and standard deviation.

Comparison between groups of qualitative variables was performed using the Chi-square test. For the comparison of means, the Student t-test was used for two groups, once the assumptions of normality (Kolmogorov-Smirnov test) and homogeneity (Levene test) had been checked.

The multivariate logistic regression model was performed to determine the effect of the variables sex, scan results, facial type, tongue palate space and functional examination on the course of headache. The linear mixed model has been performed to determine if the proposed treatment has an effect on the evolution of saturation. For this purpose, the *"time"* effect was studied (measurements of saturation: baseline, at one week and at one month) also introducing in the model the independent variables of group, turbinate hypertrophy, nostril, oropharynx, crossbite and maxillary width to adjust the effect of these on the evolution of saturation.

RESULTS

As shown in the flow chart **(Table 1)** of the 400 patients (282 with headaches and 118 without headaches) 200 patients were selected (108 with headaches and 92 control without headaches) of which 70% (n = 140) were female and 30% (n = 60) male, aged between 12 and 91 years with an average of 43.9 years (SD = 16.4).

Of the headache patients, 25 are men and 83 are women.

International Journal of Health Science ISSN 2764-0159 DOI https://doi.org/10.22533/at.ed.159410424131213

Table 2 shows the descriptive description of the clinical variables of the patients with headache in which it is observed that 59.3% present TE type headache and 69.4% are located in the temple (temporal muscle). In relation to the number of headache attacks suffered in the last month, 41.1% stated having had more than 20 and in 48.6% of the cases of moderate intensity.

In the functional examination (**Table 3**), the percentage of patients with headaches presenting symptoms was significantly higher than that of patients without headaches, except for joint symptoms, where the percentage of patients presenting symptoms was significantly lower than that of patients without headache or controls, since the clinic specializes in temporomandibular dysfunction.

With respect to the results of the functional test **(Table 4),** the results showed that there is a statistically significant association between the group and the presence of the symptoms in such a way that the percentage of patients with headache presenting symptoms was significantly higher than that of patients without headache, except for joint symptoms where the percentage of sick patients presenting the symptom was significantly lower than that of healthy patients.

Table 5 shows the descriptive of the scan results according to the group, as well as the results of the tests performed to compare the scan results between patients with and without headache. The variables that showed statistically significant differences between the groups were turbinate hypertrophy and alterations in the nasal fossa and oropharynx. The presence of turbinate hypertrophy was higher in the group of patients with headaches (76.9%) than in patients without headaches (60.9%), and the presence of septal deviation was higher in the group of patients with headaches (76.9%) than in patients without headaches (57.6%). With respect to oropharyngeal narrowing, the percentage of patients with headaches with presence of oropharyngeal narrowing (78.7%) was higher than in patients without headaches (56.5%).

The baseline oxygen saturation of patients with headache (94.05) was significantly lower than that of patients without headache (96.59). No statistically significant differences were observed between the groups for the rest of the variables. descriptive and comparative study of the craniofacial structure variables according to group.

In the course of a headache, oropharyngeal narrowing showed a significant and direct effect (OR = 3.39; $p < 0.001$) such that patients with oropharyngeal narrowing are 3.39 times more likely to have headaches than patients without oropharyngeal narrowing. With respect to functional examination, patients with muscle symptoms are 28.89 times more likely to have headaches than patients without these symptoms (OR = 28.89; $p < 0.001$). Conversely, patients without joint (TMJ) symptoms are 5 times more likely to have headaches than patients with these symptoms (OR = 3.39; $p < 0.001$). The remaining variables did not show a statistically significant effect.

The results of the mixed effects model showed that the time effect was statistically significant (F (1;192) = 4.911, $p = 0.028$), indicating that the saturation values increased significantly during the study, independently of the group. However, there was a significant effect of the interaction of group and time (F (1;192) = 6.552, $p < 0.001$), which tells us that the passage of time influenced differently, depending on whether one participated in the intervention group or not. In the group of patients with headache, saturation increased significantly at one week and one month with respect to the baseline measurement, and no statistically significant change was observed between one week and one month, the same as in the control group, although to a lesser extent.

A statistically significant association was observed between improvement in oxygen saturation and the absence of headache in patients with headaches ($\chi 2(1) = 31.86, p < 0.001$). Thus, in 82.7% of patients with no headache there was improvement in oxygen saturation versus 28.6% of those with pain (Table 6).

DISCUSSION

The literature relates primary headaches (PH) to sleep problems, suggesting that they share anatomical and physiological characteristics. There are study groups that express how patients with primary headaches have a high risk of developing sleep apnea (22). We investigated whether there is a relationship between primary headaches or headaches of unknown origin and secondary headaches attributed to hypoxia. In the descriptive analysis of our study, of 108 patients with headaches, 76% were women (83 women and 25 men) and 24% were men, with tension headache being the most prevalent (59.3%) and its most frequent localization in the temporal and frontal areas, with an intensity between moderate and severe. Our prevalence data are very similar to those of other studies (23,24).

With respect to the functional examination, the presence of pain on palpation of the cranio-mandibular and cranio-cervical muscles (P<0.001), presence of dental wear (P=(0.009), mouth breathing (0.002), poor sleep (P<0.001) and signs of xerostomia or dry mouth (P=0.001) are significant. This reflects a possible relationship of respiratory problems during sleep with headaches. These data are related to other studies that reflect the presence of muscle pain and trigger points in 43-92% of patients with tension headaches, with the most affected muscles being the temporal, trapezius and frontal muscles (25).

Many patients with headaches end up undergoing imaging studies that are not necessary (26). The upper airway study by short beam computed tomography (CBCT) shows significant turbinate hypertrophy (P=0.014), septal deviation (P=0.004) and oropharyngeal narrowing (P=0.001) in patients with headaches, These results are very similar to other studies that explore by CBCT patients with sleep disordered breathing that observe a narrowed upper airway volume compared to controls (27,28). The narrowing or obstruction of the upper airway, partial or total, causes mouth breathing during wakefulness and/or sleep causing respiratory disturbances during sleep as occurs in increased upper airway resistance (SARVAS) (29).

One of the most common causes of airway obstruction is collapsed nares, the classification of which is given in Professor Duran Von Arx's book (30). Internal nasal dilators produce a higher peak nasal inspiratory flow than external nasal dilators or nasal strips (31). In a systematic review, the results indicate that external nasal dilator strips and internal nasal dilators effectively relieve nasal valve obstruction and may be an alternative to surgical intervention in some patients (32,33) In our study we provided patients with an internal nasal dilator (NIDD) (Best breathe®) to both headache sufferers and controls and measured its effect on hypoxia and symptoms. We measured oxygen saturation in both headache and non-headache sufferers and observed mild hypoxia (94.05%) on average in headache sufferers and normoxia (96.59%) in controls. We gave them an internal nasal dilator for nocturnal use and measured saturation again at one week and one month. In the group of patients with headache, saturation increased significantly at one week and one month with respect to the baseline measurement, and no statistically significant change was observed between one week and one month, the same as in the control group, although to a lesser extent.

In the course of a headache, oropharyngeal narrowing showed a significant and direct effect (OR = 3.39; $p < 0.001$) such that patients with oropharyngeal narrowing are 3.39 times more likely to have headaches than patients without oropharyngeal narrowing.

The results of the mixed effects model showed that the time effect was statistically significant (F (1;192) = 4.911, p = 0.028), indicating that the saturation values increased significantly during the study, independently of the group.

A statistically significant association was observed between improvement in oxygen saturation and improvement in headache in patients with headaches ($\chi 2(1)$ = 31.86, $p < 0.001$). Thus, in 82.7% of patients with no headache there was an improvement in oxygen saturation compared to 28.6% of those with headache ($\chi 2(1) = 31.86$, $p < 0.001$).

Other authors have studied the effect of internal nasal dilators (IND) on fatigue in athletes, where the use of IND has been shown to reduce the perception of fatigue. These dilators are designed to temporarily facilitate inspiratory breathing, reducing transnasal resistance and improving inspired airflow in healthy individuals and in subjects with nasal congestion (34).

The association of headache and chronic exposure to hypoxia in people living in high altitude mountains has been described many years ago and it is suggested that it may be involved in the pathophysiology of migraine (35, 36). In addition, there are papers examining the efficacy of normobaric and hyperbaric oxygen therapy in the treatment and prevention of migraine and cluster headache (37). In the latter study, 81% of participants developed headache six hours after the onset of normobaric hypoxia (equivalent to a simulated altitude of 4500 m).

A recent review study concludes the possible connection between hypoxia and migraine and possibly cluster. There is a possible link between hypoxia and migraine and perhaps cluster headache, but the pathophysiological mechanism is currently unknown. Hypoxia provocation models have yielded interesting results that suggest a novel approach to further study the mechanism underlying hypoxia and primary headaches.(38)

Regarding poor sleep quality, our results show a very significant (P<0.001) ratio of cephalgic mouth breathers (86.1%) in relation to the non-cephalgic control group (56.5%), which explains a poorer sleep quality in cephalgic patients (88.9%) than in non--cephalgic patients (45.1%). This is also reported in other studies (40) which point out that inadequate sleep can contribute to increased sensitivity to pain and increased frequency of headaches. Respiration is the most important function of the human body, providing the oxygen necessary for internal or cellular respiration, responsible for metabolism to obtain energy and eliminate water and CO_2. When oxygen is low (hypoxia) it is detected by the respiratory centers causing hyperactivity of the vegetative nervous system, responsible for multiorgan dysfunction secondary to a disorder in cellular respiration.

Could headache be an alarm signal for lack of oxygen in our brain? If our organism lives in a constant limitation of inspiratory flow (airway obstruction, overweight, etc.) the result would be chronic intermittent hypoxia and chronic intermittent hypercapnia whose result would be the hyperactivity of the sympathetic nervous system which could affect cellular respiration and give way to organic dysfunctions and symptoms secondary to chronic low oxygen concentration.

The use of the nasal dilator can play an important role in patients with upper respiratory obstructions and headaches, by favoring nasal breathing, decreasing the respiratory effort by increasing the inspiratory flow. Therefore, it favors the passage of air through the nostrils preparing the air to be filtered, tempered and with the necessary humidity. It is also important that it incorporates nitric oxide from the maxillary sinus mucosa, whose action is vasodilator and bronchodilator among others, improving gas exchange in the alveoli. This means an improvement in oxygen saturation, which will favor internal or cellular respiration.

CONCLUSIONS

The present study shows the relationship between patients diagnosed with primary headaches (migraine, tension, cluster) and airway obstruction and hypoxia. It also shows the improvement of oxygen saturation in headache patients and the improvement of symptoms.

Therefore, the use of the Best Breathe® internal nasal dilator can be used to perform nasal breathing therapy, in the protocol for the control and resolution of sleep disordered breathing (snoring, increased airway resistance and sleep apnea and hypoapnea syndrome).

We believe it would be interesting to conduct further studies that could analyze the possible relationship between headaches and patients with sleep disordered breathing.

CONFLICT OF INTEREST

No conflicts of interest

ACKNOWLEDGMENTS

I would like to thank Best Breathe for their support in providing us with the necessary material for this study.

To thank Dr. Frank Spear and Dr. Jeff Rouse, Dr. Kevin Kwiecien, Dr. Gary DeWood, Dr. Ricardo Mitrani and Trisha O'Heir and the entire Spear Education team for providing me with an update on sleep disordered breathing and functional stomatologic problems. Without them I would not have been able to do this work. Thank you from the bottom of my heart

Of course, I would like to thank all my clinical team and those who have collaborated or helped to make this study a reality.

REFERENCES

1. Courtney R The functions of breathing and its dysfunctions and their relationship to breathing therapy. International J of Osteopathic Medicine 2009; 12: 78-85.

2. Lees N. Soni N, Respiratory Phisiology in book Clinical Intensive Care Medicine (2014) p 41-69 https://doi.org/10.1142/9781848163898_0003

3. Lundberg J.O. Weitzberg E. Nasal Nitric in man. Thorax 1999; 54:947-952

4. Scadding G. Nitric oxide in the airways Curr Opin Otolaryngol Head Neck Surg 2007;15:258 – 263.

5. Gaston B, Reilly J, Drazen JM, et al. Endogenous nitrogen oxides and bronchodilator S-nitrosothiols in human airways. Proc Natl Acad Sci USA 1993; 90:10957 – 10961.

6. Carod-Artal F.J. High-altitude headache and acute mountain sickness. Neurologia 2014; 29 (9): 553-540

7. International Headache Society (IHSL) headache classification committee. The International Classification of Headache Disorders, 3rd edition. Cephalalgia. 2018; Jan; 38(1): 1–211.

8. Stovner LJ, Hagen K. Jensen R, Katsarava Z, Lipton R, Scher The global burden of headache: a documentation of headache prevalence and disability worldwide. Cephalalgia 2007; 27: 193-210

9. Senaratna C.V et al. Prevalence of obstructive sleep apnea in the general population: A systematic review. Sleep Med Rev 2017 Aug ;34:70-81. doi: 10.1016/j.smrv. 2016.07.002. Epub 2016 Jul 18.

10. Suzuki K. Miyamoto M., Miyamoto T. Numao A. Suziki S. Sakuta H. Sleep apnoea headache in obstructive sleep apnoea syndrome patients presenting with morning headache: comparison of the ICHD-2 and ICH-3 beta criteria. The Journal of Headache and Pain 2015; 16:56 1-7

11. Goksan B, Gunduz A, Karadeniz D, Agan K, Tascilar FN, Tan F et al Morning headache in sleep apnoea: clinical and polysomnographic evaluation and response to nasal continuous positive airway pressure. Cephalalgia 2009; 29(6):635–641

12. Gold AR, Dipalo F, Gold MS, et al.: The symptoms and signs of upper airway resistance syndrome: a link to the functional somatic syndromes. Chest 2003,;123:87–95.

13. Guilleminault C. Stoohs R, Clerk A, Cetel M Maistros P A cause of daytime sleepiness: the upper airway resistance syndrome Chest 1993; 104:781-7

14. Terán Santos J. Síndrome de Resistencia aumentada de la vía aérea

15. superior ¿Una entidad especifica? Arch. Bronconeumol. 2002; 38 (8):348-50

16. Kerr P, Millar T. Buckles P. Kryger M. The importance of nasal resistance in obstructive sleep apnea syndrome. J Otolaryngol. 1992; 21(3):189-195

17. Gelardi M Et al. Internal and external nasal dilator in patients who snore: a comparison in clinical practice, Acta Biomed. 2019 ;11; 90(2-S): 10-14

18. Herulf M, Lundberg J.O.N., Weitzberg E. Nostril widening improves arterial oxygenation: a role for nasal nitric oxide? Respiratory Medicine 1999; 93 134-135

19. Pierce R. et al. Upper airway collapsibility, dilator muscle activation and resistance in sleep apnoea Eur Respir J. 2007 30 (2): 1-20 doi:10.1183/09031936.00063406.

20. Höijer U, Ejnell H, Hedner J, et al. The Effects of Nasal Dilation on Snoring and Obstructive Sleep Apnea. *JAMA Otolaryngology-Head & Neck Surgery.* 1992;118(3):243-247.

21. Ellegård E. . Mechanical nasal alar dilator. Rhinology 2006;44 (4):239-248

22. Bahammam AS, Manfreda TR., Kryger MH. Upper airway resistance syndrome: effect of nasal dilation, sleep stage, and sleep position Sleep 1999; 1;22(5):592-598

23. Yin JH, Chen SY, Lin CC, et al. Increased risk of sleep apnoea among primary headache disorders: a nationwide population-based longitudinal study. *Postgrad Med J*. 2019;95(1120):72–77. doi:10.1136/postgradmedj-2018-136220

24. Toom K, et al: The prevalence of primary headache disorders in the adult population of Estonia. Cephalalgia 2019. 39 (7): 883-891

25. Luvsannorov O. et al Primary headache disorders among the adult population of Mongolia: prevalences and associations from population-based survey. The journal of headache and Pain 2019 20;114: 1-9

26. Abboud J et al Musculoskeletal physical outcome measures in individuals with tension-type headache: A scoping review. Cephalalgia 2013; 33 (16)1319-1336

27. Rizzoli, Paul et al. Headache. The American Journal of Medicine, 2018 Volume 131, Issue 1, 17 – 24

28. Mouhanna-Fattal C et al. Evaluation of upper airway volume and craniofacial volumetric structures in obstructive sleep apnoea adults: A descriptive CBCT study Int Orthod 2019; 17 (4): 678-686

29. Pepin J.L. Guillot M. Tamisier R. Levy P. The Upper airway Resistance Syndrome. Respiration 2012;83:559-566

30. Echarri P, Carrasco A. Emma Vila EB. Protocolo de exploración interdisciplinar orofacial para niños y adolescentes: manejo y codificación. En Prof. Dr. Jose Duran Von Arx. Estimuloterapia en ortodoncia: Control etiopatogénico y de la recidiva. 1ª Edición (Madrid); Ed. Ripano 2010 p165-174

31. Lekakis G, Dekimpe E, Steelant B, Hellings PW Managing nasal valve compromise patient with nasal dilator: Objetiv vs subjective parameters Rhinology 2016 Dec 1; 54(4):348-354

32. Kimbell J.S. Frank-Ito DO. Mechanical Nasal Dilators for the Management of Nasal Obstruction. *JAMA Facial Plast. Surg.* 2016;18(5):389–390.

33. Engstrøm M. et al Sleep quality, arousal and pain thresholds in tension –type headache: A blinded controlled polysomnographic study. Cephalalgia 2014 34 (6)

34. Linde M. et al. Migraine associated with altitude: results from a population- based study in Nepal European J. of Neurology 2017 (24) 1055-1061455-463

35. Gelardi M Et al. The role of an internal nasal dilator in athletes Acta biomed 2019. 90(s-2) 28-30

36. Broessner G, Rohregger J, Wille M, et al. Hypoxia triggers high-altitude headache with migraine features: A prospective trial. Cephalalgia 2016; 36: 765–771.

37. Bennett MH, French C, Schnabel A, et al. Normobaric and hyperbaric oxygen therapy for the treatment and prevention of migraine and cluster headache. Cochrane Database System Rev. 2015; 12: CD005219.

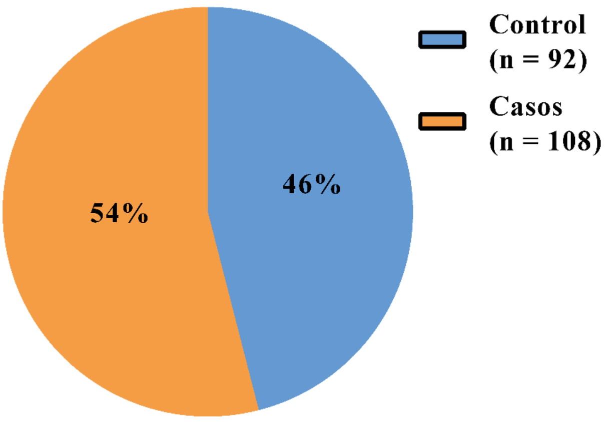
38. Britze J., Arngrim N., Schytz HW, Ashina M. Hypoxic mechanisms in primary headaches Cephalalgia 2017 37(4) 372:384

39. Kiyohara N, Badger C, Tjoa T, Wong B. A comparison of over-the-counter mechanical nasal dilators. JAMA Fac Plast Surg 2016; 18: 385-9.

FIGURES

FIGURE 1

The final study sample consisted of 200 patients, 70% (n=140) of whom were women and 30% (n=60) men, aged between 12 and 91 years, with an average of 43.9 years (SD=16.4). Figure 1 shows the distribution of patients according to the group to which they belonged.



Distribution of patients according to group.

TABLE 1

Table 1 shows the descriptive description of the clinical variables of the patients with headache in which 59.3% present TE type headache, 69.4% are located in the TEMP. In relation to the number of headaches suffered in the last month, 41.1% stated having had more than 20 and in 48.6% of the cases of moderate intensity.

	n (%)	*Mean (DT)*
Headache type		
MY	38 (35,2)	
TE	64 (59,3)	
CLU	6 (5,6)	
Location		
TEMP	75 (69,4)	
FRONT	54 (50,0)	
PARI	15 (13,9)	
CERVI	58 (53,7)	
MAXI	34 (31,5)	
Headaches		9,1 (10,6)
< 10	33 (30,8)	
10-20	30 (28)	
>20	44 (41,1)	
Intensity		3,8 (3,8)
Slight	7 (6,7)	
Moderate	51 (48,6)	
Serious	47 (44,8)	

Table 1. Descriptive clinical variables in patients with headache

TABLE 2

Table 2 shows the descriptive of the functional examination performed according to the group, as well as the results of the Chi-square tests performed to test the association between the symptoms of the examination and the group. The results showed that there is a statistically significant association between the group and the presence of the symptoms in such a way that the percentage of ill patients presenting the symptoms was significantly higher than that of healthy patients, except for joint symptoms where the percentage of ill patients presenting the symptom was significantly lower than that of healthy patients. **In the functional examination (Table 2), the percentage of ill patients presenting symptoms was significantly higher than that of healthy patients, except for joint symptoms, where the percentage of ill patients presenting symptoms was significantly lower than that of healthy patients.**

Functional exploration	**Total, *n (%)***	**Group, *n (%)***		**p-value**
		Control	**Cases**	
Symptoms Muscular				**< 0,001**
No	38 (19,8)	35 (38,9)	3 (2,8)	
Yes	159 (82,8)	55 (61,1)	104 (97,2)	
Articular Symptoms				**< 0,001**
No	133 (69,3)	49 (53,3)	84 (77,8)	
Yes	67 (34,9)	43 (46,7)	24 (22,2)	
Tooth wear				**0,009**
No	24 (12,5)	17 (18,5)	7 (6,5)	
Yes	176 (91,7)	75 (81,5)	101 (93,5)	

Oral Respirator				**0,002**
No	22 (11,5)	17 (18,7)	5 (4,6)	
Yes	177 (92,2)	74 (81,3)	103 (95,4)	
Sleep (Sleeps poorly)				**< 0,001**
No	52 (27,1)	44 (48,4)	8 (7,4)	
Yes	147 (76,6)	47 (51,6)	100 (92,6)	
Xerostomia				**< 0,001**
No	47 (24,5)	33 (36,3)	14 (13)	
Yes	152 (79,2)	58 (63,7)	94 (87)	

Table 2. Functional examination results according to group

TABLE 3

Functional test	Total, *n (%)*	Group, *n (%)*		p-value
		Control	Cases	
Symptoms Muscular				**< 0,001**
No	40 (20,8)	37 (40,2)	3 (2,8)	
Yes	160 (83,3)	55 (59,8)	105 (97,2)	
Articular Symptoms				**< 0,001**
No	76 (39,6)	48 (52,2)	28 (25,9)	
Yes	124 (64,6)	44 (47,8)	80 (74,1)	
Tooth wear				**0,032**
No	43 (22,4)	26 (28,3)	17 (15,7)	
Yes	157 (81,8)	66 (71,7)	91 (84,3)	
Oral Respirator				**< 0,001**
No	55 (28,6)	40 (43,5)	15 (13,9)	
Yes	145 (75,5)	52 (56,5)	93 (86,1)	
Sleep (Sleeps poorly)				**< 0,001**
No	62 (32,3)	50 (54,9)	12 (11,1)	
Yes	137 (71,4)	41 (45,1)	96 (88,9)	
Xerostomia				**< 0,001**
No	59 (30,7)	39 (42,9)	20 (18,5)	
Yes	140 (72,9)	52 (57,1)	88 (81,5)	

Table 3. Functional test results according to group

TABLE 4

Table 4 shows the descriptive of the scan results according to group, as well as the results of the tests performed to compare the scan results between patients without and with headache. **The variables that showed statistically significant differences between the groups were turbinate, nostril and oropharyngeal hypertrophy.** The presence of **turbinate hypertrophy** was higher in the group of patients with headaches (76.9%) than in patients without headaches (60.9%), the presence of **septal deviation** was higher in the group of patients with headaches (76.9%) than in patients without headaches (57.6%). With respect **to oropharyngeal narrowing**, the percentage of patients with headaches with presence of oropharynx (78.7%) was higher than that of patients without headaches (56.5%).

SCANNER	Total, *n (%)*	Group, *n (%)*		p-value
		Control	Cases	
Turbinate hypertrophy				**0,014**
No	61 (31,8)	36 (39,1)	25 (23,1)	
Yes	139 (72,4)	56 (60,9)	83 (76,9)	
Septum deviation				**0,004**
No	64 (33,3)	39 (42,4)	25 (23,1)	
Yes	136 (70,8)	53 (57,6)	83 (76,9)	
Maxillary width	29,85 (3,15)	29,85 (3,15)	29,59 (3,32)	**0,205**
Oropharyngeal Narrowing				**0,001**
No	63 (32,8)	40 (43,5)	23 (21,3)	
Yes	137 (71,4)	52 (56,5)	85 (78,7)	
Sinusitis				**0,616**
No	149 (77,6)	67 (72,8)	82 (75,9)	
Yes	51 (26,6)	25 (27,2)	26 (24,1)	
Crossbite				**0,271**
No	117 (60,9)	50 (54,3)	67 (62)	
Yes	83 (43,2)	42 (45,7)	41 (38)	

Table 4. Scanner results by group

TABLE 5

The baseline saturation of patients with headache (95.95) was significantly lower than that of patients without headache (96.59). There were no statistically significant differences between the groups for the remaining variables. Table 5 shows the descriptive and comparative analysis of the variables according to group.

	Total	Group		p-value
		Control	Cases	
Basal saturation, *mean (SD)*	96,24 (1,78)	96,59 (1,75)	94,05 (1,77)	**0,012**
TYPE TF, *n (%)*				0,499
Dolic	94 (49,0)	45 (48,9)	49 (45,4)	
Meso	78 (40,6)	37 (40,2)	41 (38)	
Braqui	28 (14,6)	10 (10,9)	18 (16,7)	
Tongue palate space, *n (%)*				0,439
No	62 (32,3)	26 (28,3)	36 (33,3)	
Yes	138 (71,9)	66 (71,7)	72 (66,7)	

Table 5. Descriptive and comparative variables of **craniofacial structure** according to group

The result of the multivariate logistic regression model to determine the **effect of the variables sex, scan results, type of TF, tongue-palate space and functional scan on the course of headache** is shown below, the result of which is shown in Table x. Oropharynx showed a significant and direct effect (OR = 3.39; $p < 0.001$) such that patients with oropharynx were 3.39 times more likely to have headaches than patients without oropharynx. With respect to functional examination, patients with muscle symptoms are 28.89 times more likely to have headaches than patients without these symptoms (OR = 28.89; $p < 0.001$). In contrast, patients without atrial symptoms are 5 times more likely to have headaches than patients with these symptoms (OR = 3.39; $p < 0.001$). The remaining variables did not show a statistically significant effect on the course of headache.

TABLE 6

To determine the possible association between the improvement in oxygen saturation and the absence of headache, the Chi-square test was performed, the result of which showed that there is a statistically significant association between both variables ($\chi2(1) = 31.86$, $p < 0.001$). Thus, 82.7% of patients with no headache had improved oxygen saturation compared to 17.3% with no improvement and no pain.