

Evaluation of the effects of using the AirDreamer Cuscino Naturale on patients with chronic non-specific neck pain

Primary Investigator: Prof. Stefano Masiero

Sub-investigators: Dr. Marzia Alderighi, Dr. Giuseppe Gasparre, Mr. Alberto Rigato

University of Padua – Orthopaedic Rehabilitation Unit

Introduction

The incidence of neck pain in the general population is very high; about 30-50% of the adult population has suffered from cervical spine pain at least once in their life. [...]. In the United States, it is the fourth leading cause of chronic morbidity and disability [...]. Neck pain is one of the most common causes that leads patients to consult general practitioners or specialists [...]. In pathogenic terms, it can be related to work, traumatic events or everyday activities [...].

Even though the pain symptoms tend to resolve with the appropriate therapies in a large number of patients, 47% of individuals with neck pain report pain symptoms that may even last one year after onset [...]. About 23% of the total number of patients who resolve the acute episode of neck pain may relapse in the following months.

Although nowadays there are different therapeutic strategies for patients with neck pain, often the efficacy of these treatments is limited to the short post-acute period [...]. Nowadays, patient education has become a routine practice for the management of neck pain and associated disorders, despite the lack of scientific evidence to support this recommendation [...]. Since sleep accounts for one third of a person's life, high-quality sleep is also essential because it maintains the body's homeostasis, immunity, and health. Furthermore, sleep regulates daily life and cognitive and mnemonic abilities and it has been demonstrated [...] that quality of sleep is directly related to human health and quality of life.

Posture during night rest is closely linked to the quality of sleep. In particular, poor cervical posture at night increases biomechanical stress on cervical spine structures, producing neck pain and stiffness, headaches and other symptoms resulting in poor quality sleep [...]. As a result, choosing the right pillow has been shown to optimise posture during night rest and help facilitate high-quality sleep [...].

A critical factor for a pillow is adequate support for cervical lordosis [...] in order to keep the cervical spine in a neutral position. A neutral position of the cervical spine prevents loss of the physiological curve of the vertebral column and the cervical pain symptoms that may occur upon awakening, minimizing positions of the spinal segments at the extremities of the articular range [...]. In addition, proper cervical support can increase the contact area between the neck and the pillow so that the pressure exerted on the muscles can be evenly distributed [...].

Another key feature of a pillow is that it helps to reduce basal and head temperatures during sleep at night, as this has proven to be crucial for deep sleep [...].

In addition, [...] have shown that a pillow that helps reduce head temperature and can reduce sweating and body temperature and indirectly improve sleep quality. In order to provide useful tools in the activities of daily life and devices aimed at improving the quality of life of patients with chronic non-specific neck pain and related disorders, the objective of this study was to evaluate efficacy in terms of reducing pain symptoms and associated muscle contracture and improving the articulation of the cervical spine through the use, during night rest, of the AirDreamer Cuscino Naturale thanks to its breathability, thermoregulation, ergonomics and support.

The AirDreamer Cuscino Naturale is a class I medical device that combines properties of comfort and ergonomics, thanks to the elasticity and adaptability of the personalised inner support, with characteristics of breathability and thermoregulation that are guaranteed by the pillow's lining. The latter consists of Siberian goose down and millions of air chambers inside the barbs of the down used. During movements at night, they are able to eliminate the hot and humid air inside and take fresh and clean air from the outside maintaining a constant temperature. In addition, the hygroscopic chamber, inserted inside lining on the side on which the head rests, increases this mechanism, ensuring an adequate level of humidity throughout the rest period.

The combination of these elements (personalized inner support and lining) is believed to determine

the benefits of the AirDreamer Cuscino Naturale during night rest with a consequent positive impact on pain symptoms and on a subject's quality of life.

Purpose and objective of the study

To evaluate the efficacy of AirDreamer Cuscino Naturale use during night rest for a period of five weeks in a sample of 5 individuals with chronic non-specific neck pain in terms of reduction of cervical pain symptoms and associated muscle contracture, improvement of cervical spine articulation and subject posture, and impact on quality of life.

Materials and methods

Subjects

Five individuals with chronic non-specific neck pain who met the following inclusion criteria were recruited:

- 1) aged between 20 and 65 years;
- 2) chronic non-specific cervical pain (cervical pain symptoms lasting more than 3 months) with a VAS pain scale score ≥ 4 ;
- 3) use of the AirDreamer Cuscino Naturale for 5 consecutive weeks (ergonomic support with a height of 5 or 10 cm, chosen on the first day of use of the pillow and kept unchanged for the entire period of use) and simultaneous use of the same mattress for the entire period of study;
- 4) abstention from physical, sporting and/or recreational activities that may compromise or alter the clinical and instrumental evaluation on the day prior to the acquisition of the data. [...]

Results

As regards the cervical kinematics results, for each cervical movement task evaluated, a slight overall improvement in the mean value (calculated on the total values of the five subjects examined) of the cervical Range of Motion (RoM) before (T0) and after (T1) 5-week use of the Natural AirDreamer Cuscino Naturale during night rest was shown.

In addition, corresponding high standard deviation values were found. More specifically, the most significant improvements were recorded for the total active rotation movement (increased by an average value of $10^{\circ} \pm 8.6$ and, in detail, improved in four patients out of five and unchanged in one patient), for the total active inclination (average increase of $6.3^{\circ} \pm 6.6$; in detail, improved in three patients and substantially unchanged in two) and, finally, for flexion-extension actively performed by the patient (average increase of $5.6^{\circ} \pm 13.1$; in detail, improved in two patients, unchanged in two and worsened in one of the patients) [...].

In detail, the most significant results were highlighted for the values of the sagittal curves of the spine, which improved in three patients at T1 and remained substantially unchanged in two patients. The imbalance values, both of overall posture measured with respect to the barycentric upright plane and of trunk posture with respect to the vertical plane passing through S3, showed a high degree of variability between the five patients; specifically, the values in indifferent orthostasis relative to imbalance of the overall posture on the frontal plane in three patients out of five, and on the sagittal plane in two patients out of five, improved more significantly [...].

As regards pain symptoms, in all patients, T1 showed an average reduction in the Visual Analogue Scale (VAS) score of 3.2 and an improvement in the pain items of the pathology-specific Neck Pain and Disability Scale questionnaire, with evidence of an improvement also in the corresponding overall score in the five patients.

The clinical examination also revealed a concurrent reduction in muscle contracture (cervical paravertebral and trapezius muscles) associated with neck pain. Two patients who had reported a relapse in pain symptoms for about 1 month and headache/migraine upon waking up with associated neurovegetative symptoms reported, in one case, that they had presented a single episode of headache and, in the other case, that they had not presented any episode of headache during the 5 weeks of pillow use.

Finally, with regard to the assessment of the quality of life estimated with the SF-36, there was an overall improvement in values in most of the items analysed. All patients expressed a very high score in the degree of satisfaction and comfort of the Cuscino Naturale (average value 9.2 out of a minimum score of 0 and a maximum of 10).

Discussion

A correct distribution of loads and mechanical stress on the spine prevents the onset of pain symptoms linked above all to the activation of compensation mechanisms that cause biomechanical overloads and pain-relieving muscle contractures.

The pathogenesis of chronic non-specific neck pain is often found in the imbalance of the loads applied on the cervical spine. A correct posture, especially during night rest, reduces the mechanical stress on the cervical spine in order to avoid neck pain, stiffness and all the symptoms linked to bad rest.

Though with a small sample, a short-term follow-up and the absence of a control group, the data collected allow us to highlight an improvement in pain symptoms in all patients (average reduction of the Visual Analogue Scale score of 3.2) with a reduction in muscle contracture of the trapezius and cervical paravertebral muscles; an overall improvement in the quality of life of patients was also highlighted, as shown by an overall improvement in the T1 score of the pathology-specific Neck Pain and Disability Scale questionnaire and in most of the items relating to the SF-36 quality of life questionnaire. As far as SF-36 is concerned, the reduction of the score observed in some sections can be attributed to the fact that the questionnaire evaluates the overall quality of life of the subject in terms of physical health, general health and psychological-emotional health, aspects that can be influenced by a series of factors not necessarily linked to the pathology in question.

As regards the cervical kinematics results, for each cervical movement task evaluated, a slight overall improvement in the mean value of the cervical Range of Motion (RoM) after 5-week use of the AirDreamer Cuscino Naturale during night rest was shown. More significant improvements were found, respectively, for the total active rotation movement, total active inclination and, finally, flexion-extension actively performed by the patient, though without a significant reduction in the RoM of the compensation rotations associated with each movement. For the 3D evaluation of posture, contrasting results and a high intra-patient T0-T1 and inter-patient variability were recorded. In detail, the most significant results were highlighted for the values of the sagittal curves of the spine, which improved in three patients at T1.

The imbalance values, both of overall posture and of trunk posture, showed a high degree of variability between the five patients; specifically, the values in indifferent orthostasis relative to imbalance of the overall posture on the frontal plane in three patients out of five, and on the sagittal plane in two patients out of five, improved more significantly.

No patients resorted to pain medication during the month of pillow use. All patients expressed a high degree of satisfaction in terms of the comfort of the AirDreamer Cuscino Naturale.

Conclusions

The AirDreamer Cuscino Naturale has proven to be a valuable complementary tool to rehabilitation, physical and medical therapy in reducing and controlling pain in patients with chronic non-specific neck pain.