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Clinical Results of Kinetic Oscillation Stimulation (K.O.S.) in Non-Allergic Rhinitis

Monti G[1]*, Seccia V[2], Berrettini S[2], Picariello M[2], Gramellini G[3], Dragonetti AG[3], Marco Borin[3], Paolo Giocondo Castelnuovo[1] and Macchi A[1]

[1]ENT Clinic University of Insubriae Varese Asst-Settelaghi, Via Guicciardini, 9 Varese, Italy

[2]Otolaryngology, Audiology, and Phoniatric Operative Unit, Department of Surgical, Medical, Molecular Pathology, and Critical Care Medicine, Pisa University Hospital, Via Paradisa 2, 56124 PISA, Italy

[3]UOC Otorinolaringoiatria ASST GOM Niguarda, Milano, Italy

Corresponding author: Giulia Monti, Ent Clinic University of Insubria-Asst Settelaghi Varese, via Guicciardini, 9 Varese, Italy

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Abstract

Introduction: Rhinitis is a condition associated with an inflammatory response. Non-Allergic Rhinitis (NAR) describes a syndrome of chronic symptoms of nasal congestion and rhinorrhea, unrelated to a specific allergen.

Objective: Our study is about a new method of rhinitis therapy with Kinetic Oscillation Stimulation (K.O.S.). The aim of the study is to evaluate the response after treatment with K.O.S. in the various groups of vasomotor rhinitis.

Methods: All the patients underwent K.O.S. treatment after a period of suspension from topical and systemic steroid therapy and any other kind of therapy for the rhinitis. The active treatment, K.O.S., consisted of vibrations created using an oscillation which stimulates and rebalances his autonomic nervous system.

Results: The data show an improvement in the overall quality of life in treated patients. The study of the nasal cells was found to be important to classify patients in the various forms of rhinitis, and to tailor the best treatment. Moreover, the stratification of SNOT-22 according to the various cell types has highlighted how the differences between the various cell types played an important role on determining good outcomes. In NARMA and NARNE patients the treatment results were not satisfactory and not statistical significative, while in the other forms they were optimal.

Conclusions: The K.O.S. treatment could be used as a successful and alternative treatment for vasomotor rhinitis. We believe that the study should continue to increase the number of cases available and better typing the various patients.

Keywords: *Cytology, Rhinitis, Sympathetic Nervous system*

Introduction

Rhinitis is a condition related to inflammatory responses as allergic rhinitis but can also occur in the absence of a specific cause such as in the "vasomotor" rhinitis. Allergic rhinitis is an Ig E mediated condition; it affects approximately 25% of the population of European countries and is characterized by nasal itching, sneezing, rhinorrhea, and congestion [1,2]. Non-Allergic Rhinitis (NAR) involves chronic sneezing, congested nose, drippy nose, unrelated to a specific allergen, in fact the term is used to describe rhinitis symptoms associated with nonallergic, non-infectious triggers It represents till 10 to 18 % of idiopathic rhinitis and affects children and adults [1,2]. A diagnosis of NAR is made after an allergic cause is ruled out and it may require allergy skin or blood tests and nasal citology. The diagnosis of the specific type of rhinitis can be tricky. The study of the nasal cells has been shown to be a useful and easy diagnostic tool in the study of rhinitis. We can detect and measure the cell population in the nasal mucosa at a certain instant to better discriminate different pathological conditions and to evaluate the effects of various stimuli [3]. NAR are divided into numerous different subtypes with vasomotor rhinitis being the most common type. When associated to an inflammatory cellular infiltration, NAR can be subclassified into Non allergic Rhinitis eosinophils (NARES), Non allergic rhinitis eosinophil mast cell (NARESMA), Non-Allergic Rhinitis Neutrophils (NARNE), Non allergic Rhinitis Mast cell (NARMA) due to different type of inflammatory cell [4]. In vasomotor rhinitis, especially for non-IgE mediated rhinitis, cytological diagnostics has become key. Based on the cell types present on the nasal mucosa, many of these specific forms have acquired a nosologically dignity. Therefore, based on the cytological pattern, it is possible to diagnose eosinophilic rhinitis (nonallergic rhinitis with eosinophils - NARES), neutrophils (NARNE), mast cells (NARMA), and eosinophil-mast cell forms (NARESMA) as reported in the ARIA classification. Among all cases of rhinitis, these forms have an incidence of 13%, and their appropriate diagnosis is important for prognostic and therapeutic purposes. These different types of cellular rhinitis can be diagnosed by a cytological exam of nasal cells. Examination that is carried out

by taking cells at the level of the inferior turbinate. Material is affixed to a slide, fixed in the air, and colored with the May-Grunewald Geimsa method. The specimens are read under an optical microscope with a magnification of 100x. This method based on the cell type found at the sampling level allows to differentiate the various forms of rhinitis. The pathophysiology of nonallergic rhinitis is not a simple mechanism and must be discovered. An imbalance between parasympathetic and sympathetic inputs on the nasal mucosa can be the cause of the pathology. The etiology of vasomotor rhinitis is not well understood, it is probably associated with a dysregulation of sympathetic, parasympathetic, and nociceptive nerves innervating the nasal mucosa. This can increase vascular permeability and mucus secretion from the nasal glands. Mucous secretion is regulated by the parasympathetic nervous system, while the sympathetic nervous system controls vascular tone. To contribute to degranulate mast cell as well as the itching/sneezing reflexes the sensory neuropeptides and nociceptive type C fibers of the trigeminal nerve play an important role. The airflow is sensed by the nervous system. The nervous regulation by sympathetic and parasympathetic system is important to control all the function of the nose and the nasal cycle. An alteration of this control causes many functional alterations like a disfunction on the control of nasal flow, the temperature, the reflex, and so many cells can be recall in the alteration of this process: eosinophils, mast cell, neutrophil. These cells cause a cellular rhinitis in many patients [5]. The Kinetic Oscillation Stimulation (K.O.S.) treatment is based on kinetic oscillation (vibrations) and it works by stimulating the autonomic nervous system through its nerve endings in the mucosa of the nasal cavity. The underlying mechanism for this treatment effect is largely unknown, but an hypothesis is that it may be mediated through an alteration in autonomic balance (Juto & Hallin) [6]. The K.O.S. precise mechanism acting at the level of the mucosa is represented by the 50 Hz oscillation which regulates the nervous signal of the parasympathetic and sympathetic system operating at variable frequencies between 40 and 60 Hz. The alteration of these frequencies probably causes a dysfunction at the level of the nasal cycle.A particular catheter is inserted into one nasal cavity at time for 10 minutes to stimulate the nasal mucous membrane and the nervous system [6,7]. The idea behind the Kinetic Oscillation Stimulation (K.O.S.) treatment was that applying mechanical oscillations like naturally occurring turbulence would have a positive effect on the inflammatory condition on the mucosal surface layer [8,9].

Materials and Methods

A study was carried out and 90 patients evaluated in the centers of Varese, Pisa and Milan was enrolled. The average age of the patients is 39 years, 50 females and 32 males. All patients were evaluated before the procedure with an accurate medical history, a nasal endoscopy, a skin prick test, a nasal cytological examination, and compilation of SNOT-22.

It was used the SNOT-22 because it is the only validated tool that allows us to evaluate the quality of life of patients with chronic rhinosinusitis, which, considering the characteristics of vasomotor rhinitis, can be applied to this type of pathology. The patient's symptoms began from a period of 10 years to 1 with an average of 3,27 years. All 90 patients underwent K.O.S. treatment, after a period of suspension of topical and systemically therapy for the rhinitis. The device was inserted into the nasal cavity, and it is inflated to 50mbar (0,05 atm). Active treatment, K.O.S., consisted of mechanical vibrations created using regular pressure oscillation (increased and decreased) at a frequency of 50 Hz. All patients underwent nasal cytological examination. This one allowed us to classify the various patients in the different forms of vasomotor rhinitis (Table 1). We submitted a questionnaire, in this case we use SNOT 22, to determinate the quality of life to all the patients, before, after one month and after three months, in order to assess whether the therapy was satisfactory. All the patients underwent many types of therapy before K.O.S. treatment and the therapy were stopped 7-10 days before the treatment. We excluded patients with an allergic pathogenesis, with important anatomical problems such as deviation of the nasal septum, patients with chronic polypoid rhinosinusitis, and patients with coagulation alterations and serious related diseases. All patients were asked to stop using topical nasal therapy of any kind (topical steroids, nasal decongestant) in the seven weeks prior to the procedure; even those suffering from medical rhinitis were asked to discontinue topical vasoconstrictor therapy.

The study was approved by the ethical committee with N. IAR2015112.

Results

All patients completed the SNOT-22 questionnaire before treatment, after one month and after three months (Table 2). This cumulative data shows how there is an improvement in the overall quality of life in treated patients. The stratification of SNOT-22 (Table 3) according to the various cell types highlighted important differences between the various cell types. In NARMA and NARNE the result was not satisfactory, while in the other forms the results were optimal. A particular analysis must be done in the mast cell eosinophilic forms, NARESMA, where the result was only partial. Only 8 patients had no improvement on the nasal symptoms and exit from the follow up. The Table 4 analyzes the changing in the average of the symptoms, both dyspnea and rhinorrhea are decreased after the treatment, and the value is significative. The major results are on rhinorrhea. The cytological results show how the major result is the reduction of the value of eosinophils as reported in Table 5.

Table 1: Cytological Classification.

	NARES	NARESMA	NARMA	NARNE	NANIPER	Meidcamentous rhinitis
Patients	31	10	4	5	16	16

All the patients are divided in the various form of Non allergic Rhinitis Eosinophils (NARES), Non allergic Rhinitis Eosinophil and mast cell (NARESMA), Non Allergic Rhinitis mast cell (NARMA), Non Allergic Rhinitis Neutrophils (NARNE), Non Allergic non infections perennial Rhinitis (NANIPER), and Medicaments Rhinitis.

Table 2: Value of the SNOT 22 in all patients.

	Before-Treatment	After 1 month	After 3 months
Average	37,66	29,1	23,1

Snot 22: The value average of Snot 22 before the treatment and after one and three month shows how the improvement of quality of life of the patients.

Table 3: Snot 22 in all type of rhinitis before and post treatment.

Rhinitis	Pre-treatment	Post treatment (1 month)	Post Treatment (3 month)	P value
NARES	32	21	18	<0.03
NARESMA	35	30	20	n.s.
NARMA	38	38	36	n.s.
NARNE	39	48	49	n.s.
NANIPER	41	18	15	<0.01
MEDICAMENTOUS	41	20	18	<0.01

Snot 22 by different type.
Data is statistical significative p<0.001.
Average of snot 22 before treatment and after one and three month from the end of the treatment.
The only data statistical significative are in the Naniper, medicaments and Nares.

Table 4: Value of dyspnea and rhinorrhea.

Symptoms	pretreatment value	1 month value	3-months value	p
Dyspnea	4,15	0,9	0,4	p<0,001
Rhinorrhea	4,16	2,49	1,04	p<0,001

The first column is the value of the dyspnea pretreatment and after 3 month with a decrease of the grade, the second column is the rhinorrhea the decrease is more significative than dyspnea and statistical significative.
p < 0.001. The value of dyspnea and rhinorrhea is based on a VAS scale.

Table 5: Type of cells in nasal mucosa.

Type of cells	Pre-treatment	after 1 month	after 3 months	p
Eosinophils	1,88	1,5	1	p<0.001
Mast cells	2	1,8	1,7	N.S.
Neutrophils	2,57	2	2	N.S.

The value of the eosinophils is the only type of cells decreased with a statistical significance.
p < 0.001. The value of the cells is based on the number of cells on the specimen.

Discussion

Rhinitis is a pathology involving the nose that represents an excessive reaction of normal defensive functions, and they are mediated by neural activity; some rhinitis symptoms are exclusively produced by nervous system. High responses to environmental or endogenous stimuli occur because of a highest neural activity due to a pathologic inflammatory nature. This phenomenon is known as neural hyperresponsiveness and probably due to a central role of the nervous system. The parasympathetic innervation of the nasal airways originates from the facial nucleus of the brain stem and the superior salivatory nucleus. Paraganglion fibers follow the greater superficial petrosal nerve and the vidian nerve to synapse in the sphenopalatine ganglion. The post ganglionic fibers are distributed through the branches of the posterior nasal nerve to the nasal mucosa [10]. The sympathetic input in the human nose originates from preganglionic fibers in the thoracolumbar region of the spinal cord and relays in the superior cervical ganglion. Sympathetic stimulation induces vasoconstriction and increases nasal airway patency. The sympathetic activity can induce airway secretion through stimulation of serous cells even through there is no evidence that the glands receive sympathetic innervation [6]. A central reflex is the sneezing which targets are various respiratory and laryngeal muscles. Vasodilation with consequent nasal vascular congestion and airflow limitation can also be generated through neural stimulation. The sensorineural stimulus would lead to decreased sympathetic outflow in combination with increased parasympathetic discharge [6]. Nasal congestion that alternates between nostrils can be explained by an exaggerated form of nasal cycle. The non-allergic rhinitis should be associated with abnormalities in the neural control of the nasal function. This condition can be due to nasal hyperresponsiveness to irritants and to changes in environmental condition. Another mechanism could be an overinterpretation by the central nervous system [11,12]. The K.O.S. method proved its effectiveness in the treatment of vasomotor rhinitis. In our study we staged patients by dividing them into groups based on the outcome of the cytological examination. In this way we were able to obtain more data based on the effectiveness of K.O.S. therapy. We were able to identify the groups that responded better to the treatment compared to those less responsive. In detail, the cellular rhinitis characterized by the presence of mast cells (NARMA), neutrophils (NARNE), did not respond to treatment, probably due to an inflammatory status of the mucosa. In fact, the data were not statistical significative; patients with this pathology are unlikely to have any improvements. The patients who received the best benefit were those with negative nasal cytology, with a rhinitis medicamentosa followed by those with a NARES and NARESMA. The patients with NARESMA had a poor result with the K.O.S. treatment probably due to the presence of mast cells. The cytological examination of the nasal mucus has shown the reduction in the number of eosinophils during follow up, especially in the eosinophilic forms such as NARES. This data is statistically significant; instead of neutrophils and mast cell which numbers were unvaried after the treatment. The cytological analyses can help us in the patient targeting to give more prospective of success. The mechanism has yet to be known. This treatment effect may be explained by the active stimulation of sensory nerves and, directly or indirectly, by the autonomic nervous system involved in the nasal cavity. Other mechanism of action could be a balanced change in each of parts of the autonomic nervous system, sympathetic and parasympathetic nerves or in the nerve signal transmission itself. Treatment is easy to do, well tolerate, and no side effects were observed during the procedure or in the immediate post-treatment.

Conclusion

The study of the cytology of the nasal mucosa cell in the diagnosis of vasomotor rhinitis was important to identify the different forms of rhinitis, and to submit them to the best possible treatment. The correct classification of the different patients into the groups made it possible to clarify the criteria for using K.O.S. Moreover, we consider nasal cytology as an indispensable procedure before treatment with K.O.S. We believe that the study should continue to increase the number of cases available for further typing the various patients but K.O.S. must be considered as an alternative treatment for the NAR rhinitis.

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