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Research Article

Kinetic Oscillation Stimulation of Nasal Mucosa as Treatment for Non-allergic Rhinitis. A Pilot Study

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Abstract

Introduction: Patients with persistent symptoms for non-allergic rhinitis (NAR) often relay on medical treatment and/or surgical approach. Kinetic oscillation stimulation (KOS) seemed in a few studies to have a positive effect and reduces symptoms for NAR. This pilot study aims to demonstrate effect of KOS in objective and subjective assessment in Danish patients.

Method: Fifteen patients with NAR were included and values for nasal inspiratory peak flow (NIPF) , subjective score using SNOT22 and VAS score for pain and patients allover judgement were registered. KOS treatment was offered two times with two weeks interval.

Results: Significant change of SNOT22 and NPIF was only present after two treatments. From patients allover judgement there were nine who felt improvement or satisfied but one of these also wanted minor surgery giving a success rate of 53%. The treatment was accepted of all patients with no pain but with minor or moderate discomfort.

Conclusion: Kinetic Oscillation Stimulation , KOS, of nasal mucosa showed significant effect after second treatment when evaluating sino-nasal-outcome test ,SNOT22 and nasal inspiratory peak flow, NPIF. Patients tolerated the treatment without major discomfort and the patients all over judgement of effect was 53% and was regarded as satisfactory in this pilot study. The result seems to justify further research for which is giving some proposals.

Keywords: Kinetic Oscillation Treatment; Non-allergic Rhinitis; Nasal Congestion; Clinical Trial

Introduction

Rhinitis is a common nasal disorder characterized by the presence of nasal congestion, rhinorrhea, sneezing and nasal itching which can adversely impact the quality of life. The most common form are allergic, infectious and non-allergic rhinitis (NAR). The non-allergic rhinitis is often diagnosed by exclusion criteria with the predominate feature symptom such as nasal congestion and postnasal drainage. Symptoms are often perennial. The medical treatment for NAR is often nasal corticosteroid [1], but also nasal anti-cholinergic, nasal antihistamin and capsaicin [2]. From a recent Cochrane review the evidence was regarded as low or very low for the use in NAR [1]. In some patients the surgical option of turbinate surgery is offered for nasal congestion. With these different treatments available a considerable number of patients still experience insufficient effect. A non-invasive method have been developed as an alternative to the methods mentioned above and have been presented as Kinetic Oscillation Stimulation (KOS) and have been reported to be a safe treatment and have a positive effect on NAR [3-5]. The idea behind KOS treatment was that applying mechanical oscillating pressure on the nasal mucosa might impli-

cate stimulation of the nervous system of nasal mucosa. A study found an effect of KOS on the autonomic balance with pronounced heart-rate independent reduction on heart rate variability [6], and have also been used in a study on the effect on migraine [7]. The primary objective of the this pilot study using KOS treatment in patients with NAR was to evaluate the effect in a specified population with objective as well as subjective scores and the patients allover judgement including registration of any pain or discomfort before deciding a large scale study and implementation in daily practice.

Material and Method

Included were 6 females and 9 males. Median age was 53 years (27-66 years). All the included have had symptoms during several months and have tried topical steroid without sufficient effect on symptoms. Vasomotor rhinitis was defined as the presence nasal airway obstruction and secretion of varying degree over time and from side to side and where no cause from medical disease or any external cause as well as any skeletal and polypoid structural causes was present that might explain the symptomatology. The test persons had to accept withdrawal of any topical steroid treatment and not to take any medications for the nose during the test period.

Excluded were patients who have had previous nasal operation, airborne allergic rhinitis, pregnancy, and age under 18 years. Treatment was performed using a Chordate Medical Rhinitis Controller Unit. A catheter A100 with a small ballon at the one end was placed in the nasal cavity and connected to the unit that delivered an oscillating pressure with a mean of 65 mBar and a frequency of 68 hz. The balloon was lubricated with medical glycerine and placed in the nasal cavity fixated by the patient holding it in place. The stimulation was given 10 min on each side and was given 2 times with 2 weeks interval.

At entrance all patients had an ENT examination including video nasal endoscopy. Each patient completed the SNOT22 questionaire, the translated Danish version, at baseline and two weeks after each treatment. SNOT22 includes 11 questions each giving 0-5 score points, with 5 meaning worse score. Peak nasal inspiratory flow (PNIF) was measured with medium face mask during forced maximal inspiration, Clement Clarke Intl. LTD, Harlow UK and the best of three measurements was used. Any pain was evaluated as visual analog scale score (VAS), 0-10 where 10 was worst pain and if no pain any nuisance caused by the treatment was registrated as none, slight, moderate or severe.

The patients signed acceptance to the participation and storage of data according to current legislation and that they could refrain from the study at any time and be offered other treatment for the nose, that might include small surgical intervention for the purpose of volume reduction of nasal turbinate. Data were evaluated with non-parametric statistics. Wilcoxon test, Man Whitney test and Spearmanns correlation test was used where appropriate. The significance level was $p<0,05$. Data collection was reported to the Danish Data Protection Agency. The Ethical considerations are in accordance with the Helsinki Declaration 1975 and revision 2008.

Results

At the primary visit the score for nasal congestion and runny nose together showed a median score of 7 (range4-9) out of 10 possible. From that it seems likely that it was the right persons with typical symptoms of moderate or severe vasomotor rhinitis that we wanted to treat with KOS. From the 15 patients included there were 6 patients who only had one treatment and 9 patients had two treatments, both groups on their own desire.

The total SNOT22 score at baseline was median 34 (range 17-71), after 1st treatment median 27 (range 12-70), after 2nd treatment median 30 (range 8-61). There was no significant change of the total SNOT22 score after the first treatment compared to the pre -treatment score. After the second treatment the total SNOT22 score showed significant change compared to pre treatment scores ($p < 0,01$). When SNOT22 was divided into two groups, nasal symptoms (question 1-4, 6 and7) and the remaining questions regarded as mostly general symptoms the scores from each of these groups showed no significant change after one treatment but a significant change after two treatments (Table 1). To estimate the burden on the total score from the primary nasal symptoms and the general symptoms the percentage of maximal score was evaluated after two treatments. Nasal symptoms changed from 42,9% of maximal

at entrance to 37,1% and general symptoms changed from 25,3% to 17,3%, but with great interindividual variation. Highest score for general symptoms combined with lowest nasal score was 63% against 34% respectively , and the highest nasal score combined with lowest general score was 88% against 25%. This finding might indicate that nasal symptoms is not always followed by the same degree of wellbeing. Meanwhile, correlation analysis from all the observations between nasal symptoms and general symptoms before and after treatments did show a significant correlation, (R = 0,506, p < 0,01).

Nasal inspiratory peak flow (NIPF) was at baseline median 110 (range 50-180) l/min, after one treatment 120(50-220) and after two treatments 150(50-205). Paired comparison showed only significant improvement after two treatments (p < 0,05).

The patients overall subjective evaluation of the treatment was evaluated after one and two treatments. Among the 6 patients who had one treatment , 3 felt improvement and satisfied and 1 patient wanted minor operation as previously stated and 2 patients did not want further treatment. Among 9 patients who had two treatments there were 6 patients that felt improvement or satisfied, but 1 with improvement wanted minor surgical intervention. Three patients were not satisfied and wanted minor surgical intervention. All together 8 patients were satisfied and stayed by that, and 5 patients ended up with minor surgery on the turbinates and 2 patients wanted to continue their medical treatment (Fig 1) At baseline using two sample test there was no difference in total SNOT22 score between those who felt improvement and those who did not. There seems not to be any specific characteristics among patients that might indicate that they may gain benefit of KOS.

Regarding evaluation of any pain or discomfort during the treatments they were evaluated with VAS score for pain (range 0-10 with 10 as the worse possible) and in case of no pain they had to grade any nuisance as either none, slight, moderate or severe. All 15 patients made this evaluation after the first treatment (at the first visit) and at the time of the second treatment. From that 30 treatments were evaluated. Vas score was 0 in 21 treatments, score 1-2 in 7 treatments and 4-5 in 3 treatments. In VAS score 0 any nuisance was graded as none, slight, moderate or severe. Non or slight or moderate was registrated in 18 treatments and severe in 3.

	Median (RANGE)	Mean (SD)	P
SNOT22			
Baseline	34 (17-71)	39,9 (17,3)	
1st treatment (n = 15)	27 (12-70)	35,2 (18,7)	ns
2nd treatment (n = 9)	30 (8-61)	33,2 (18,6)	P < 0,01
NOSESYMPT.			
Baseline	15 (6-31)	16,5 (6,2)	
1st treatment (n = 15)	14 (5-31)	14,4 (6,9)	ns
2nd treatment (n = 9)	13 (5-28)	14,9 (7,7)	P < 0,05
GENERAL SYMPT.			
Baseline	19 (5-47)	23,3 (14,5)	
1st treatment (n = 15)	17 (5-51)	21,3 (14,1)	ns
2nd treatment (n = 9)	13 (0-39)	18,9 (12,9)	P < 0,01

Table 1

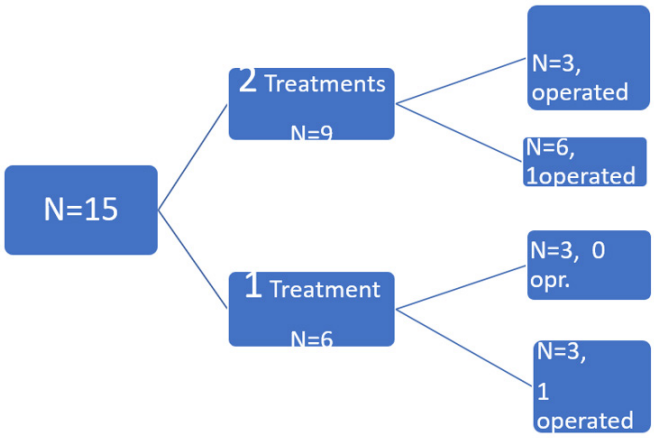

Figure 1

Discussion

The KOS treatment is a rather new method in the treatment of non-allergic rhinitis and the literature is sparce. In recent studies treatment effect was present eight weeks after KOS treatment judged from changes in two subjective score systems including the SNOT22 score [3-5], and evaluation of two different pressure amplitudes. In one study it was found that symptom relief was already present after one treatment and was even better after 2 weeks [3].

In other studies the PNIF did not show improvement after 4 weeks nor after 24 weeks [3,4]. In the present study we found significant effect on PNIF after the second treatment and SNOT22 improved also after 2 treatments both as a total score but also for splitting up the SNOT22 into two parts, the nasal score and the general scores for partly quality of life or wellbeing. At baseline the nasal scores was median 7 out of 10 possible indicating that we have included the right population. The good correlation between the nasal scores and the general scores seems to indicate that the improvement of the total SNOT22 score was a result of improvement of both segments of the questionnaire. This might also indicate that improvement of the general scores is not a result of a kind of placebo effect but more a reflection on the improvement of nasal complaints. The treatment was generally well accepted without pain but not surprisingly with minor or moderate nuisance in most cases which is in accordance with other studies [5]. We used placement of the catheter by the investigater and the patient fixed it in place with hand. Patient administrated catheter have been found just as good in another study [5]. Different amplitude of the balloon pressure have been tried without clinical significant difference [4]. In the present study we used the high amplitude pressure but same frequency.

Conclusion

After two KOS treatments objective as well as subjective improvement was found in patients with non allergic rhinitis. From the patients allover judgement nine of fifteen were improved but one of these wanted supplementary operation given a success ratio 53%. These findings together with previous studies may justify for further research. Uniform measuring methods and subjective questionnaires are important. Defining the number of treatments needed, the interval between treatments and duration of the effect of treatment are relevant parameters in future studies.

Conflicts of Interest

None.

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