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ANTISECRETORY FACTOR – A CLINICAL INNOVATION IN MENIERE'S DISEASE?

ANTISECRETORY FACTOR AND MEDICAL FOOD – NOVEL THERAPY CONCEPTS

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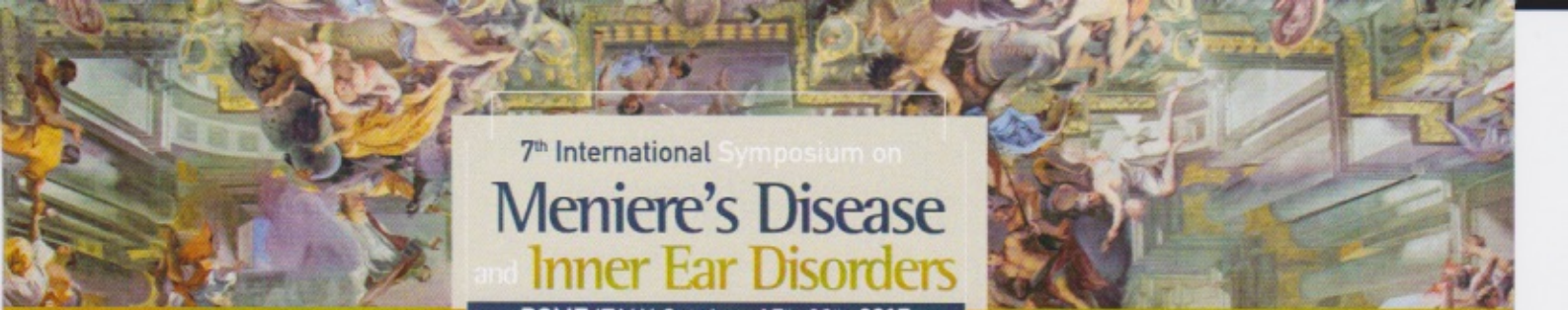
The antisecretory factor (AF) is a protein secreted in plasma and other tissue fluids in mammals. This 41-kDa protein provides protection against diarrheal diseases and intestinal inflammation. The endogenous plasma level of AF is increased by enterotoxins and also by certain food constituents. Based on these findings, AF-inducing medical and functional food and feed products have been developed. One of these products is named SPC, Specially Processed Cereals. Tests with this product showed it to be effective in reducing diarrhea in various animal species. In human clinical trials SPC stimulates the production of the AF protein in patients suffering from IBD, reduces their symptoms and improves their quality of life. In further clinical trials in Crohn's disease, secretory diarrhea and short bowel syndrome, SPC has been shown to exert both antisecretory effects (by inducing AF) and anti-inflammatory effects. Because of the effects on hyper-secretion in the GI tract, it was hypothesized that antisecretory treatment with SPC could be valuable in other instances where fluid imbalance is thought to play a role, such as MD. In an open pilot study, 24 MD patients received SPC for 14-30 days, and AF levels in plasma increased by 83 % in 20 of the 24 patients. The attacks of rotatory vertigo were reduced in 12 patients and in three of them hearing was normalized (Hanner et al, 2004). In a follow-up study, 51 adult patients with MD were included in a double-blind, placebo-controlled trial. 27 subjects were treated with SPC and 24 with control cereals for 3 months. The severity of MD was classified according to the AAO-HNS grading system. 14 of the 27 patients in the SPC group reported decreased vertigo, compared with 2 of 24 in the control group (Hanner et al, 2010). SPC is not a common dietary supplement. According to the EU Commission Directive 1999/21/EG of March 25, 1999, SPC is classified as a "Food for special medical purposes", i.e. food developed for specific patient Groups. SPC has been approved by the National Food Administration in Sweden, and the health claim that has been accepted is "For the nutritional treatment of disorders in connection with increased intestinal secretions".

ANTISECRETORY FACTOR-INDUCING THERAPY IMPROVES PATIENT-REPORTED FUNCTIONAL LEVELS IN MENIERE'S DISEASE

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OBJECTIVES: The aim of this study was to evaluate the effectiveness of specially processed cereal (SPC) as a suitable adjunctive treatment for Meniere's Disease. **METHODS:** We performed a randomized double-blinded, placebo-controlled, crossover study in a tertiary referral center of patients who had a diagnosis of Meniere's Disease based on the guidelines of the Committee on Hearing and Equilibrium of the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS). The main outcome measure was the AAO-HNS Functional Level Scale (FLS). **RESULTS:** Thirty-nine patients completed the study without any reported complications. The mean pretreatment FLS score for the entire study cohort was 3.8 (median, 4; range, 1 to 6). The overall FLS score improved significantly ($p < 0.001$), to 2.8 (median, 3), after SPC treatment. No patients showed worsening on the FLS during SPC or placebo treatment. Of the 39 patients, 23 showed improvement on the FLS, and no change was observed in the remaining 16. The median improvement on the FLS in these 23 patients was 2 points (mean, 1.7; range, 1 to 4). The mean FLS score after placebo cereal treatment was not significantly different from baseline ($p = 0.452$), but was significantly higher than that after SPC treatment (mean, 3.7; $p < 0.001$). The marginal difference observed between the baseline FLS score and the placebo FLS score was due to the fact that 5 patients reported 1-point improvements on the FLS after placebo treatment. Nevertheless, significantly fewer patients improved on placebo than on SPC ($p < 0.001$). **CONCLUSIONS:** Treatment with SPC appears to be well tolerated by most patients (91%) without any complications. More than half (59%) of the study cohort reported subjective improvement in functional level.



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SPC FLAKES IN PROPHYLAXIS OF MENIERE'S DISEASE

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Introduction: A raised endolymphatic pressure (hydrops) is the commonly accepted pathophysiological mechanism leading to MD. A disorder of fluid and ionic homeostasis has been postulated as a causal factor leading to hydrops, and among prophylactic measures in MD diuretics are widely suggested. Antisecretory Factor (AF) is a 41 kDa endogenous protein; in different studies demonstrated the constitutive capacity of modulating fluid and ionic transport through membranes. SPC-Flakes have been clinically shown to support cellular fluid balance stimulating the body's own production of protein AF. Purpose of our work was to assess a possible effect of SPC Flakes in prophylaxis of MD.

Material and Methods: Twenty five patients with definite MD have been included in the study, consecutively recruited in 2 University centres among those poorly responsive to betahistine 48 mg /day in the previous 3 months. During the next 3 months they underwent a combined therapy with betahistine and SPC Flakes (1 gr/Kg day). Exclusion criteria were ongoing therapies with calcium channel blockers, diuretics and drugs active on Central Nervous System (SSRIs and benzodiazepines among them). Main outcome was the number of vertigo spells (per month) in the 6 months before and in the 3 months of combined therapy. An Efficacy Index (EI) was calculated with the formula y/x per 100, where y is the number of vertigo spells (per month) during combined therapy and x the number of vertigo spells (per month) in the 6 previous months. Better results are expressed by lower rates.

Results: vertigo spells reduced from 1.8 ± 0.7 to 0.6 ± 0.3 per month ($p \leq 0.001$). Particularly, 8 subjects presented an EI lower than 25% (32%), 8 (32%) in the range between 25% and 50%, 5 (20%) in the range between 50% and 75% and 4 (16%) higher than 75%. Audiometric exam didn't demonstrate significant changes after combined therapy. Moreover, 4 subjects (16%) reported an overall reduction of the duration of vertigo spells.

Conclusions: our data confirm those of previous works reporting a significative reduction of vertigo spells during therapy with SPC Flakes. Above all, in our sample 16 out of 25 patients demonstrated a significative response to SPC Flakes.