Multidisciplinary behavioral therapy reduces rumination

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Study protocol with statistical analysis plan 2024-9-10

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Background

Rumination is a disorder of the gut-brain interaction characterized by repetitive regurgitation of ingested food that is followed by remastication and swallowing or spitting but without preceding retching or nausea (1, 2). The Rome IV rumination criteria include symptom onset six months prior to diagnosis and persistent symptoms for the last three months (3). Rumination is caused by subconscious but volitional contractions of the abdominal muscles resulting in intragastric pressure peaks of $\geq$ 30 mmHg that can be detected by performing esophageal high-resolution manometry using a solid test meal (4).

Biofeedback can reduce rumination by teaching the patients to control abdomino-thoracic muscle activity by following electromyography during eating. This has been proven in both open and randomized, placebo-controlled studies (5-6). Behavioral therapy consisting of diaphragmatic breathing exercises has been shown to reduce rumination in an open setting (7). We have used habit-reversal therapy with diaphragmatic breathing exercises successfully at our center to treat patients with supragastric belching (8). Our case report shows that rumination could be reduced by combining diaphragmatic breathing with abdomino-thoracic muscle relaxing exercises performed by a physiotherapist (9).

Data from randomized studies show that multidisciplinary therapy performed by a group comprising gastroenterologists, dietitians, hypnotherapists, psychiatrists and biofeedback physiotherapists is superior to standard gastroenterologist therapy in improving symptoms, psychological state, quality of life and costs in functional gastrointestinal disorders. The difference maintains up to 12 months of follow-up (10, 11).

We wanted to test the efficacy of a multidisciplinary, behavioral approach in treating patients with rumination in the present study. This study was approved by the Ethics Committee of Helsinki University Hospital (HUS/2118/2021) and by the Helsinki University Hospital Abdominal Center (HUS/23/2022). The study was registered at Clinical Trials as study number NCT05232097.

Objective

The primary objective was a reduction of $\geq$2 of the rumination score measured by question 32 of the Rome IV diagnostic questionnaire for adult functional disorders (Rome IV) at baseline and at the 6-month control. Secondary objectives were improvement of HRQoL and functional capacity scores, reduction of anxiety and depression scores, and disappearance of intragastric pressure peaks in esophageal manometry at the 6-month control.

Patients

We recruited rumination patients from gastroenterology outpatient clinics to our study at the Helsinki University Hospital during the study period of Jan. 1, 2022, to Dec. 31, 2023.

The inclusion criteria for the study included age between 15-70 years, Finnish as the native language, fulfillment of the clinical Rome IV rumination criteria, a rumination score of $\geq$ 6 in the Rome IV diagnostic questionnaire for adult functional disorders (rumination occurring most days a week),

previous gastroscopy, esophageal manometry and MII-pH. We aimed to recruit patients, who had previously had esophageal manometry performed with intragastric pressure increases ≥ 30 mmHg immediately preceding the rumination experienced by the patient, suggestive of rumination. Patients with only a clinical diagnosis of rumination syndrome were also accepted in the study, because previous to our study, Nutridrink instead of a solid meal was used when performing standard esophageal manometry in our institution and thus might not always detect rumination

The exclusion criteria comprised large hiatal hernia, severe esophagitis, previous fundoplication, eating disorder, BMI under 14, pregnancy, significant cognitive disorder, and any other condition hindering outpatient visits.

Study protocol

At the baseline visit, cases were checked to ascertain whether they fulfilled the inclusion or exclusion criteria. Previous conditions, investigations, use of medications, and symptoms were registered. All patients obtained written information about the study, about the behavioral and functional nature of rumination, and its therapy including diaphragmatic breathing excercises and thoracic and abdominal muscle relaxations. Written consent was obtained from all patients.

From the baseline visit the patients were referred to the speech therapist for five one-hour sessions, and to the physiotherapist for two one-hour sessions and to the psychologist´s and the dietitian´s consultation.

Symptoms, HRQoL, depression, anxiety, and functional capacity were evaluated by questionnaires given to the patients and weight were defined at onset of the study and at the 6-month control. Esophageal manometry with a pancake meal (191 kcal) was performed at the 6-month control. The study protocol is displayed in the figure below (Figure 1).

Questionnaires

Symptom severity was evaluated by the Rome IV questionnaire for adult functional disorders (12). The question 32 of the Rome IV diagnostic questionnaire for adult functional disorders scores the rumination frequency as follows: ”In the last 3 months, how often did food come back up into your mouth after you swallowed it ?, 0 = never, 1= fewer than 1 day a month, 2 = 1 day a month, 3 = 2-3 days a month, 4 = 1 day a week, 5 = 2-3 days a week, 6 = most days, 7 = every day, 8 = multiple times per day or all the time”.

Depression was evaluated by the Beck Depression Inventory (BDI), anxiety by the Beck Anxiety Inventory (BAI), HRQoL by the 15D, a 15-dimensional measure of health-related quality of life and functional capacity by the World Health Organization disability assessment schedule 2.0 (WHODAS 2.0) (13-16). The patients filled out the questionnaires at home and mailed them to the hospital.

Behavioral therapy

The therapy comprised psychoeducation about the nature of rumination as a behavioral disorder and means of dealing with the symptom including diaphragmatic breathing exercises and guided eating performed by the speech therapist, and mind-body oriented physiotherapy, all aiming at habit reversal.

The patients were first taught the mechanisms of rumination at the speech-therapist visits. We considered it essential for the study's success for the patients to understand the functional nature of rumination. The next step was to teach them diaphragmatic breathing and to relax abdominal muscles. Finally, the patients were trained to apply these exercises during meals and to continue them at home.

The mind-body oriented physiotherapist approached the patients to improve body awareness – which consists not only of sensing position and movement of the body in space – but also of sensing the internal state of the organs – and to understand that signals from the stomach entering conscious awareness are modified by mental processing. The physiotherapist also encouraged the patients to freely express their concerns and worries during sessions to enhance abdominal and thoracic muscle relaxations. The physiotherapy consisted first of manual therapy of the tensed regions of the neck, chest and abdomen, and of relaxation exercises, and imagery training to find one's inner refuge, all aiming to reduce overexcitement and achieve body and mind relaxation. Second, breathing exercises to relax the thoracic and abdominal muscles were performed at the therapy sessions. Third, the patient was guided to practice imagery training, relaxation exercises, and breathing exercises at home.

Psychologist and dietitian consultations

The patients were referred to a psychologist for assessment of psychiatric symptoms. The psychologist's consultation included psychoeducation about how stress and anxiety affect rumination symptoms, and how to improve the stress and anxiety management to enhance rehabilitation of the rumination syndrome. We considered it reasonable to consult a psychologist trained in functional behavioral disorders first rather than sending all patients directly to the psychiatrists. A referral to a psychiatrist was recommended in the case of more severe psychiatric conditions.

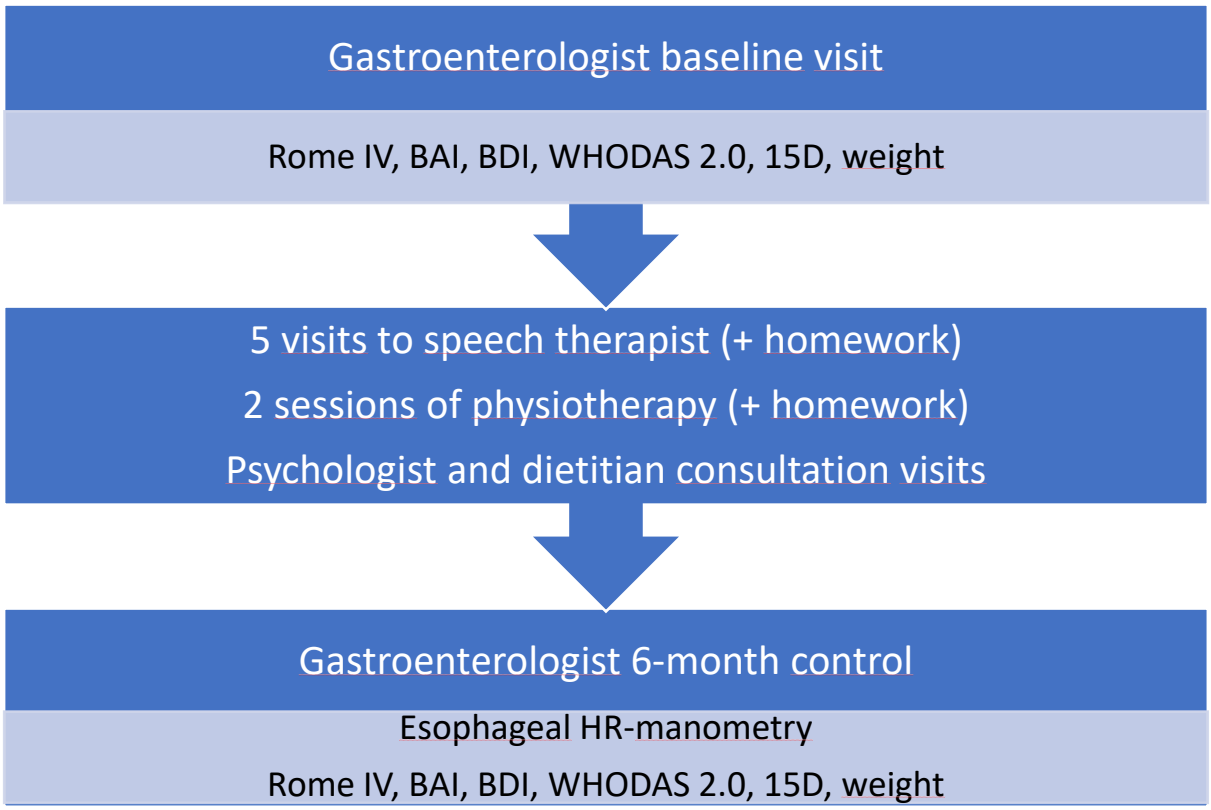
The patients were referred to a dietitian trained in functional behavioral disorders for psychoeducation, to evaluate food and meal and related mental threats, and to ensure a sufficient diet. The primary goal of the dietitian's psychoeducation was to ensure that patients did not have negative expectations regarding food or nutrients. It is common in functional diseases that patients develop learned experiences and expectations that become self-predictive. The dietitian interviewed the patients to discover which food products the patients avoided due to them provoking rumination or other gastrointestinal symptoms such as diarrhea, to learn if rumination played a role in managing anxiety, and to discern if the patients had lost weight prior to or during the study. No special diet instructions or foods were recommended to be avoided due to rumination. The dietary goal was to normalize eating.

Statistical analysis

SPSS softtware was used to perform the statistical analysis. The question 32 of the Rome IV diagnostic questionnaire for adult functional disorders was used for the sample size calculation.The hypothesis was that the mean (± standard deviation) self-perceived frequency of rumination at baseline would be 6 ± 2 (most days a week) because this was the inclusion criteria for the study and the symptom improvement after therapy would be $\geq$2 resulting in the score of 4 ± 2 (once a week) at the 6-month control. Using the Sample Size Calculator of ClinCalc.com the number of patients required was 8 to obtain 80% power and significance of $P < 0,05$. The non-parametric Wilcoxon's signed rank test and Mann-Whitney test for the analysis of related samples were used for the

comparison of differences in the distributions of variables between the baseline and the 6-month control except for the 15 dimensions of HRQoL which were analyzed by the paired samples t-test. The independent samples t-test was used to compare the mean 15D results of the patients at baseline with those of age-standardized general Finnish population. Apart from the manometry and 15D results which are displayed as means and standard deviations, all other results are displayed as medians and interquartile ranges.

Figure 1.



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