PELVIC FLOOR MUSCLE EXERCISE AND PHYSICAL THERAPY MAY IMPROVE SYSTEMIC SCLEROSIS-ASSOCIATED FECAL INCONTINENCE

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Abstract
Gastrointestinal involvement in systemic sclerosis (SSc) is observed in up to 90% of patients. Resolution of some of these gastrointestinal complications is challenging without the support of physical therapy and rehabilitation. One of these complications, SSc-associated fecal incontinence, which can be devastating for those affected, is seen in up to 39%. Studies focusing on fecal incontinence and its treatment are scarce. The hypothesis presented herein suggests that pelvic floor muscle exercise, biofeedback therapy, and neuromodulation methods might be effective and safe treatment strategies for patients affected by this debilitating complication.

Keywords: Fecal incontinence, Exercise therapy, Systemic sclerosis, Physical therapy


INTRODUCTION
Physical therapy has been part of the management of rheumatological diseases, and therefore it has been recently included in the updated recommendations. Comprehensive treatment strategies, including physiotherapy, exercise therapy, cognitive rehabilitation and psychological therapies, in conjunction with medical therapies, allow patients not only to maintain their optimal physical condition but also to improve their health status [1,2]. Systemic sclerosis (SSc) is an autoimmune disease characterized by abnormal cutaneous and internal organ fibrosis causing musculoskeletal and organ dysfunction [3]. In SSc patients, the physical therapy and rehabilitation approach should be personalized and based on the affected organ systems such as the orofacial, hand, pulmonary, cardiovascular, and gastrointestinal organ systems. Even though several studies have investigated the efficacy of exercise and rehabilitation in orofacial-musculoskeletal involvement, research evaluating interventions to improve dysfunction related to internal organ involvement remains scarce [4].

Gastrointestinal involvements, consisting of microstomia, dysphagia, hoarseness, gastroesophageal reflux disease, nausea, vomiting, diarrhea, constipation, internal anal sphincter dysfunction, fecal incontinence and malabsorption, have been reported in up to 90% of SSc patients. Some of these complications are difficult to overcome without the support of physical therapy and rehabilitation [5]. One of these complications, SSc-
associated fecal incontinence, which is observed in up to 39% of SSc patients, has particularly been found to be associated with decreased social interaction, impaired psychological status, and reduced quality of life [6-8]. The mechanisms underlying fecal incontinence are explained by lower resting anal sphincter pressure, poor compliance and distensibility of the rectum, and an impaired recto-anal inhibitory reflex, all of which are caused by the accumulation of collagen in the smooth muscle of the internal anal sphincter [8,9].

Dietary modification, antidiarrheal agents, and suppositories can be used as initial conservative therapies. However, there are limited data regarding available treatment strategies outside the bounds of this conservative approach [8,9]. Collins et al. performed a case-controlled study that investigated the effect of anorectal biofeedback therapy. The therapy consisted of education about anatomy, toilet training, a detailed description of the feedback display, anal squeeze exercises, and rectal sensory retraining and was given once-weekly sessions of 30-60 minutes duration for 6 weeks. This study reported improvements in symptoms, anorectal physiology, and quality of life [8]. Another study conducted by Kenefick et al. demonstrated that sacral neuromodulation might be an effective treatment in female SSc patients with fecal incontinence who are not responsive to either conservative or behavioral therapies [10]. Unfortunately, both studies of Collins et al. and Kenefick et al. have limitations. Firstly, the sample size was rather small to draw robust conclusions and the study population consisted of predominantly female patients. Secondly, the long-term effects of the therapies were not reported. Lastly, but not least, the lack of a sham control group prevented the clinicians from ruling out a placebo effect. Even though the data in this area is lacking, biofeedback and sacral pacer treatments have been included in the treatment algorithms developed by international experts [11].

Therefore, more studies, especially larger, randomized, prospective, controlled, and well-designed trials, are needed to tailor appropriate and more effective treatment approaches. In addition, pelvic floor muscle training, which is a well-known exercise for individuals with urinary and fecal incontinence, has never been studied in SSc patients.

HYPOTHESIS
Physical therapy and rehabilitation programs containing pelvic floor muscle training, pelvic floor and anorectal biofeedback therapies, and neuromodulation methods (sacral nerve stimulation, posterior tibial nerve stimulation) might be safe, effective, and logical treatment strategies in patients with SSc-associated fecal incontinence. Among these strategies, pelvic floor muscle training is regarded as the least expensive and the most practical approach.

STUDY DESIGN
As outlined in evidence-based points to consider, randomized-controlled studies are needed [12,13]. Based on the current hypothesis, the following suggestions should be addressed in the research agenda:

- To design a prospective randomized, sham controlled, double-blind study to investigate the impact of pelvic floor muscle training on SSc-associated fecal incontinence and to evaluate its short-term and, importantly, its long-term effects
- To design a prospective study to compare the effects of pelvic floor muscle exercise, biofeedback therapy, and neuromodulation methods on SSc-associated fecal incontinence.

After setting a research question and defining a hypothesis, the first step should be deciding the study design. Thereafter, a sampling method has to be identified and sample size should be estimated. Despite the insufficient data related to SSc-associated fecal incontinence, many studies investigating fecal incontinence caused by a range of etiologies can be reviewed to determine the appropriate sample size. During this process, defining outcome variables plays an important role in interpreting the results in line with scientific evidence. Therefore, outcome measures should be reviewed and the objective and validated variables, which evaluate gastrointestinal tract involvement and treatment efficacy, should be chosen [13-15]. Furthermore, intervention methods should be determined.

Identifying inclusion and exclusion criteria is a challenge in SSc owing to the heterogeneity in disease characteristics. Demographic data including age, sex, disease-related variables (disease duration, disease subset, disease severity and activity, and organ involvement) need to be obtained. In particular, other gastrointestinal tract involvements other involvement, other than SSc-associated fecal incontinence should also be investigated through careful patient questioning and examination. Even though disease duration is one of the most important concerns in building the study population, any disease duration seems allowable to investigate the treatment approaches in SSc with gastrointestinal tract involvements [12,13]. Inclusion
criteria might be developed in line with the preference of the authors. Concomitant diseases and medications that affect the gastrointestinal system and confound the results should be evaluated. Participants with these confounding factors need to be excluded from the study.

After assessment of eligibility, randomization and allocation concealment should be performed based on the Consolidated Standards of Reporting Trials (CONSORT) statement [16]. The study duration should be designed, taking into consideration the long-term effect of the treatment [13]. Statistics plays an important role in designing, improving, analyzing, and presenting the study. A study without a well-designed methodology can lead to errors and wrong conclusions that might be difficult to correct. Therefore, the researchers and authors should be aware of how important statistical analysis is in every step of the study [15].

CONCLUSION
Given the scarcity of published evidence, the present hypothesis aimed at addressing the question of the whether physiotherapy and exercise therapy would be beneficial in patients with SSc-associated fecal incontinence. Well-designed randomized-controlled studies are warranted to prove the effect of pelvic floor muscle training on fecal incontinence. Additionally, prospective comparative studies, which show the differences or similarities among pelvic floor muscle exercise, biofeedback therapy, and neuromodulation methods, are needed.

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REFERENCES
Резюме
Поражение желудочно-кишечного тракта при системном склерозе (СС) наблюдается у 90% пациентов. Разрешение некоторых из этих желудочно-кишечных осложнений является практически невозможным без физиотерапии и реабилитации. Одним из таких осложнений является недержание кала, обусловленное СС. Недержание кала встречается почти у 39% пациентов и может иметь разрушительные последствия. Исследования, посвященные недержанию кала и его лечению, немногочисленны. Представленная в статье гипотеза предполагает, что упражнения для мышц тазового дна в совокупности с методами биологической обратной связи и нейромодуляции могут составить эффективную и безопасную стратегию лечения пациентов, у которых наблюдается данное осложнение.

Ключевые слова: недержание кала, лечебная физкультура, системный склероз, физиотерапия.