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Malnutrition in systemic sclerosis patients - protocol for a systematic review and meta-analysis

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ADMINISTRATIVE INFORMATION

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Review Stage at time of this submission - Data extraction.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 03 July 2023 and was last updated on 03 July 2023.

INTRODUCTION

Review question / Objective The aim of this systematic review and meta-analysis is to evaluate and assess the frequency and risk of manutrition in systemic sclerosis patients compared to healthy population in order to improve clinical care and gain new insights regarding nutritional status of systemic sclerosis patients. To this end, the proposed systematic review and meta-analysis will address the following question: How frequent is malnutrition, how high is the risk and how does it affect the prognosis and outcomes of systemic sclerosis patients?

Rationale According to the European Society for Clinical Nutrition and Metabolism (ESPEN) malnutrition is defined as "a state resulting from lack of intake or uptake of nutrition that leads to altered body composition (decreased fat free mass) and body cell mass leading to diminished physical and mental function and impaired clinical outcome from disease". Around 90% of patients that suffer from systemic sclerosis also have variable gastrointestinal involvement affecting the tract from mouth to anus. Most common symptoms are dysphagia and gastrointestinal reflux, fecal incontinence, malabsorption and malnutrition due to impaired upper limb function or dexterity and reduced oral opening. Even though malnutrition is not widely accepted as an independent mortality risk factor, a study on the Mexican population suggested that it represents an important and independent risk factor associated with mortality in systemic sclerosis.

Condition being studied Systemic sclerosis (SSc) is an immune-mediated disease with a prevalence of approximately 150–300 cases per million in the general population, with a lower prevalence noted

in Japan, Scandinavia, Taiwan, the UK, and India. It is primarily a connective tissue disease affecting mostly females with a reported ratio of 3:1 to 8:1, with mainly skin manifestations but very often a variable internal organ involvement. Skin fibrosis and the extent of skin fibrosis are used to stratify patients in two subsets - limited cutaneous (lcSSc) and diffuse cutaneous (dcSSc). Generally, patients with proximal involvement are classified as diffuse cutaneous subset, while those with restricted involvement on the limbs distal to the elbows or knees (with or without neck and face involvement) are classified as limited cutaneous subset. Around 90% of patients also have variable gastrointestinal involvement affecting the tract from mouth to anus. Most common symptoms are dysphagia and gastrointestinal reflux, fecal incontinence, malabsorption and malnutrition due to impaired upper limb function or dexterity and reduced oral opening.

METHODS

Search strategy PubMed: ("systemic sclerosis" OR scleroderma) AND ("nutritional status" OR malnutrition OR sarcopenia). Scopus: ("systemic sclerosis" OR scleroderma) AND ("nutritional status" OR malnutrition OR sarcopenia), filters: Review, Letter, Book chapter, Short survey, Editorial, Note, Conference paper Cochrane library: ("systemic sclerosis" OR scleroderma) AND ("nutritional status" OR malnutrition OR sarcopenia). Web of Science: ("systemic sclerosis" OR scleroderma) AND ("nutritional status" OR malnutrition OR sarcopenia), filters: Abstract, Meeting, Review Article, Patent, Case Report, Letter, Editorial Material, Book, Biography, Data Set, Reference Material.

Participant or population Systemic sclerosis patients (women and men) with appropriate healthy controls that have fullfilled MUST questionnaire, do not have multiple comorbidities or other immune diseases, and are older than 18 years will be included in this systematic review and meta-analysis, with no exclusions based on ethnicity or race.

Intervention Not applicable.

Comparator Not applicable.

Study designs to be included Observational (cross-sectional, case-control and longitudinal studies) and cohort studies.

Eligibility criteria All inclusion criteria were:• study design: cohort studies (prospective or retrospective) or observational studies (cross sectional, case-control);• studies including SSc patients;• studies directly assessing malnutrition by applying Malnutrition Universal Screening Tool (MUST) scoring;• a full version of the paper available online;• papers available in English. Accordingly, the exclusion criteria were: • comments, abstracts and conference abstracts, letters, notes, editorials, books, reviews, meta-analyses or case reports, clinical trials, randomized controlled trials;• studies that did not include patients with SSc;• studies in which malnutrition was not assessed by Malnutrition Universal Screening Tool (MUST) scoring in SSc patients;• papers that are not available online in full length or are not available in English.

Information sources Databases (Web of Science Core Collection, BIOSIS Citation Index, MEDLINE®, Current Contents Connect, Derwent Innovations Index, SciELO Citation Index, Data Citation Index, EMBASE) and a hand search of reference list of highly relevant articles in this topic.

Main outcome(s) Malnutrition Universal Screening Tool (MUST) scores in systemic sclerosis patients compared to healthy population.

Quality assessment / Risk of bias analysis To assess the risk of bias and the quality of the included studies the Newcastle-Ottawa Scale (NOS) was used. The NOS assessment has a maximum total score of 9 for case-control or cohort studies or a score of 10 for cross-sectional studies and comprises of three categories – Selection, Comparability and Exposure/Outcome (adjusted for study design accordingly). Studies scoring 0 to 3 points indicate a high risk of bias, studies scoring 4 to 6 points indicate a moderate risk of bias while studies scoring 7 or higher on NOS indicate a low risk of bias. The assessment was conducted by two reviewers (H.Đ. and E.K.) independently with all discrepancies resolved by discussion and consensus.

Strategy of data synthesis To evaluate the MUST scores in patients with systemic sclerosis in comparison to healthy controls, a random-effects meta-analysis model was applied with inverse variance weighting and mean difference (MD) with a 95% confidence interval (CI) was obtained. MD were considered significant if the P-value < 0.05 in the test for overall effect. Heterogeneity between studies was evaluated using the I2 index and significant heterogeneity between the studies was considered if the test for heterogeneity was significant (P-value < 0.05).

Subgroup analysis Subgroup analysis of medium risk and high risk groups of patients, according to the MUST scores, compared to the healthy controls are performed.

Sensitivity analysis The studies are not excluded due to the NOS assessment. The sensitivity analysis will not be conducted due to the design of included studies.

Country(ies) involved Croatia.

Keywords malnutrition; Malnutrition Universal Screening Tool; systemic sclerosis.

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