The Validity of Patient-led Self- screens for Identifying Malnutrition in Inflammatory Bowel Disease

by

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Abstract

Background: Malnutrition is common in Inflammatory Bowel Disease (IBD) and is associated with significant morbidity and mortality. Identification of high-risk patients using a sensitive and reliable screen is the first step to dietitian referral for nutritional assessment and intervention.

Aim: The primary goal of this study was to determine the validity of patient led self-screens and health-care practitioner (HCP) screens against a dietitian-led nutritional assessment to detect malnutrition in outpatients with IBD. Our secondary objectives were to: i) determine the inter-rater reliability of patient-led self-screens compared to HCP screening and ii) determine the prevalence of malnutrition assessed by a range of assessment tools - subjective global assessment (SGA), body mass index (BMI), mid-arm muscle circumference (MAMC) and handgrip strength (HGS).

Methods: Patients were prospectively recruited from IBD outpatient clinics in Edmonton and Calgary. Patients completed 4 self-screening questionnaires: abridged Patient-generated Subjective Global Assessment (abPG-SGA), Malnutrition Universal Screening Tool (MUST), Canadian Nutrition Screening Tool (CNST) and Saskatchewan IBD-Nutrition risk (SaskIBD-NR) tool, followed by independent nutrition screening performed by a HCP. A dietitian blinded to the results of the screens carried out a gold standard nutritional assessment using the SGA (primary assessment modality), BMI, MAMC and HGS. We identified the proportion of patients in each category, sensitivity and specificity

against SGA (dietitian-led malnutrition assessment) using contingency tables, and agreement between patient-led self-screen and HCP-led screening using kappa statistics (inter-rater reliability).

Results: A total of 204 IBD outpatients (131 Crohn's (CD) and 73 Ulcerative colitis (UC)), 50.5% female, were assessed. According to Harvey-Bradshaw Index and partial Mayo scores, 12.8% of CD and 11.3% of UC patients had moderate to severe disease activity. The most common symptoms affecting dietary intake were diarrhea (21%), poor appetite (20%), pain (18%), and fatigue (18%). Of the 4 screening tools, the abPG-SGA and SaskIBD-NR tool showed the best predictive values (sensitivity of 89% and 70%; specificity of 75% and 81%, respectively) compared to dietitian-led SGA assessment. All self-screens demonstrated a moderate inter-rater agreement with the HCP-led screening ($p < 0.001$). According to dietitian-administered nutritional assessment, the prevalence of malnutrition in our IBD outpatients was 3%, 18%, 22% and 31% according to BMI, SGA, MAMC and HGS, respectively.

Conclusion: The abPG-SGA and SaskIBD-NR tools are promising nutrition screening tools in an IBD outpatient setting. They are valid and can be completed by patients in the waiting room during the clinical visit. With the high sensitivity and high negative predictive value for malnutrition detection, the majority of patients who screen at risk of malnutrition with these tools would be appropriately referred for further assessment. Future clinical practice should integrate these tools into routine IBD nutrition screening and assess the ability of the screening tools to predict clinical outcomes.

Preface

This thesis is an original work by Tannaz Eslamparast. The research project, of which this thesis is a part, received research ethics approval from the University of Alberta Research Ethics Board, project name "The Validity of Patient-led Self- screens for Identifying Malnutrition in Inflammatory Bowel Disease", No. Pro00073470, May 29, 2017. Some of the research conducted for this thesis forms part of a research collaboration, led by Dr. Maitreyi Raman at the University of Calgary, with Dr. Puneeta Tandon being the lead collaborator at the University of Alberta. No part of this thesis has been previously published.

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Table of Contents

APPENDICES:

LIST OF TABLES

LIST OF FIGURES

LIST OF ABBRIVIATION

5-ASA: 5- Aminosalicylates

abPG-SGA: Abridged Patient-Generated Subjective Global Assessment

AND: Academy of Nutrition and Dietetics

ASPEN: American Society for Parenteral and Enteral Nutrition

BAPEN: British Association for Parenteral and Enteral Nutrition

BIA: Bio-Impedance Analysis

BMI: Body Mass Index

CD: Crohn's Disease

CNST: Canadian Nutrition Screening Tool

CT: Computed Tomography

DXA: Dual-Energy X-ray Absorptiometry

ESPEN: European Society of Clinical Nutrition and Metabolism

FFMI: Fat Free Mass index

GI tract: Gastrointestinal tract

HBI: Harvey–Bradshaw Index

HCP: Health Care Practitioner

HGS: Hand Grip Strength

IBD: Inflammatory bowel disease

IMM: immunomodulators

LOS: Length of Hospital Stay

MAC: Mid-Arm Circumference

MAMC: Mid-Arm Muscle Circumference

MIRT: Malnutrition Inflammation Risk Tool

MNA: Mini Nutritional Assessment

MST: Malnutrition Screening Tool

MUST: Malnutrition Universal Screening Tool

NPV: Negative Predictive Value

NCCH: Nutrition Care in Canadian Hospitals

NRI: Nutrition Risk Index

NRS-2002: Nutrition Risk Screening

PPV: Positive Predictive Value

RCT: Randomized Clinical Trial

REE: Resting Energy Expenditure

SaskIBD-NR: Saskatchewan IBD – Nutrition Risk Tool

SGA: Subjective Global Assessment

SMI: Skeletal Muscle Mass Index

TSF: Triceps Skinfold

UC: Ulcerative Colitis

CHAPTER 1: INTRODUCTION

1.1 Brief Introduction

Inflammatory bowel disease (IBD), including Crohn's disease (CD) and ulcerative colitis (UC), is a spectrum of chronic, idiopathic inflammatory disorders affecting the gut mucosa with intestinal and systemic manifestations (1, 2). IBD represents a public health challenge in the 21st century, with increasing incidence in both developed and developing countries (3). Over 1.5 to 2 million North Americans and Europeans suffer from IBD (4). In 2015, a predictive model estimated the prevalence of IBD to be 0.6% of the general Canadian population and projected to increase to 0.9% by 2025 (5). IBD is proposed to occur as a consequence of multiple etiologic factors that include genetic predisposition, environmental exposures and immunological defects (1, 2). IBD symptoms may include severe diarrhea, intestinal bleeding, abdominal pain, malabsorption, weight loss and fatigue, with a wide range of clinical complication such as abscesses, strictures, fistulas and extra-intestinal manifestation and intestinal cancers (6).

Malnutrition is a frequent complication in patients with IBD, even when the disease is in remission. Malnutrition is estimated to be present in up to 85% of hospitalized patients with active IBD and in up to 42% of patients in clinical and endoscopic remission (7-9). Malnutrition is a strong predictor of poor clinical outcomes in IBD including increased rates of infection, longer hospital stays, prolonged recovery time after surgery and higher health care costs (10, 11). Malnutrition is under-detected and under-treated in IBD patients since nutrition risk screening is not common practice in routine clinical care (12, 13). In other populations, patient-led nutrition screening tools such as the malnutrition universal screening tool (MUST), abridged patient-generated subjective global assessment (abPG-SGA) and malnutrition screening tool (MST) have been shown to be valid and efficient means of detecting those at high-risk of malnutrition (14-17). In IBD, other studies have demonstrated that the patient-led MUST had moderate to excellent agreement with a health care practitioner (HCP)-administered MUST screen (18, 19). To date however, patient-led self-screens have not been compared to dietitian-administered nutritional assessment.

American Society for Parenteral and Enteral Nutrition (ASPEN) supports use of the subjective global assessment (SGA) - The recommended malnutrition assessment by the European Society of Clinical Nutrition and Metabolism (ESPEN) requires the determination of fat free mass, which we did not have available to us as part of this study. Therefore, we chose the ASPEN determination of malnutrition based on SGA. The purpose of the present study was to examine the validity of patient-led nutrition risk self-screens for identifying malnutrition in outpatients with IBD.

1.2 Statement of the Problem and Purpose of the Thesis

Due to the increased risk of malnutrition in patients with IBD, the ESPEN guideline for clinical nutrition in IBD recommends nutrition risk screening to identify patients at high risk of malnutrition at the time of IBD diagnosis and at routine intervals (20). Although many nutrition screening tools are available, and despite the high prevalence of malnutrition in IBD, nutrition screening is infrequently performed. This may be due to inadequate awareness of the detrimental effects of malnutrition in IBD, lack of knowledge of the best nutritional screening tools in this patient population, and challenges with implementing nutrition screening in busy clinical settings. The possibility of nutritional self-screening (i.e. patients screening themselves) has received little attention so far in IBD. Patient engagement through a valid and reliable nutrition self-screening tool could facilitate advancement of a nutrition care plan leading to appropriate self-referral to registered dieticians for further care.

Preliminary data support the feasibility, reliability and validity of nutritional self-screens in patients with gastrointestinal diseases, including IBD outpatients (16, 18, 19). However, in the studies conducted in IBD populations, the sample sizes were small (n=154, n=80), and only one nutrition screening tool, the MUST, has been studied as a patient-led self-screen to identify risk of malnutrition in this patient population (18, 19). Importantly, neither of these studies compared nutrition self-screens to the malnutrition assessment determined by a dietitian using SGA. The specific aims of current study were to evaluate the validity of different patient-led screens including MUST, abPG-SGA, Saskatchewan

IBD–Nutrition Risk Tool (SaskIBD-NR), and Canadian Nutrition Screening Tool (CNST) for detecting risk of malnutrition in outpatients with IBD.

1.3 Objectives

The study focused around the following objectives:

1.3.1 Primary Objective

1. To evaluate the sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) of the patient-administered and HCP-administered screens (MUST, abPG-SGA, CNST and SaskIBD-NR) compared to dietitian-administered nutritional assessment using SGA in outpatients with IBD

1.3.2 Secondary Objectives

1. To determine the inter-rater reliability between the patient-administered self-screens (MUST, abPG-SGA, CNST and SaskIBD-NR) and HCP-administered screens (MUST, abPG-SGA, CNST and SaskIBD-NR) in outpatients with IBD.

2. To determine the prevalence and predictive factors of malnutrition according to dietitian-administered nutritional assessment methods including SGA, body mass index (BMI), mid-arm muscle circumference (MAMC) and hand grip strength (HGS) in outpatients with IBD.

1.4 Hypotheses

Hypothesis 1: The primary hypothesis is that a patient-led self-screen will prove to be a valid nutritional screening tool with high sensitivity, specificity, PPV and NPV to identify risk of malnutrition in outpatients with IBD.

Hypothesis 2: The secondary hypothesis is that a patient-led self-screen will provide a good level of agreement ($\kappa \geq 0.41$) with HCP-administered screen to identify malnutrition in outpatients with IBD.

1.5 Significance of the Study

In this study, we assessed the performance characteristics of malnutrition "self-screens" against the ASPEN -recommended dietitian-administered SGA. This will inform the potential implementation of the self-screen into IBD clinics in Edmonton, Calgary, and beyond for timely referral of at-risk patients for in-depth malnutrition screening and interventional therapy. This work will potentially allow us to move towards our vision of developing an Alberta-wide IBD Nutrition screen and standardized intervention clinical care pathway. This will provide a robust data set for our primary as well as secondary outcomes, thereby increasing the generalizability of the results.

CHAPTER 2: LITERATURE REVIEW

This literature review will serve to: i) introduce the overview of the characteristics, epidemiology, pathophysiology and potential complications of IBD including disease-related malnutrition in this population, ii) describe screening and the current methods used in the screening of nutritional status and how they are correlated with nutritional assessment and clinical outcomes in patients with IBD and iii) focus on the rationale behind self-screens by reviewing literature examining the use of patient-led self-screen in IBD compared to dietitian-administered nutrition assessment and HCP-administered screens.

2.1 Overview of IBD

The intestine is a vital organ in the gastrointestinal (GI) tract required to perform essential metabolic functions which include nutrient digestion and absorption, metabolism, fluid and electrolyte balance, bile and waste excretion and immunological functions (21). Inflammatory bowel disease (IBD) is a chronic, idiopathic inflammatory disorder which causes a significant disruption of intestinal and extra-intestinal functions by affecting the immune system in gut mucosa (1). IBD primarily comprises two major categories: crohn's disease (CD) and ulcerative colitis (UC) with a characteristically relapsing and remitting courses (2).

Classically, the pathology of CD is characterized by discontinuous patchy mucosal disease with skip lesions and transmural inflammation that can involve the entire GI tract. The ileum is affected most frequently, either in isolation, or in combination with the colon. (22). Conversely, in UC, inflammation is confined to the mucosa and submucosa starting in the rectum and extending to the proximal segments of the colon with minor impact on nutrient absorption (23).

2.1.1 Epidemiology of IBD

IBD is a public health challenge in the 21st century. Epidemiological studies have reported an accelerating incidence and prevalence of IBD in industrialized countries (e.g. Canada,

USA, New Zealand and western Europe) (24). Over 1.5 to 2 million North Americans and Europeans suffer from IBD (4). Outside the western world, newer epidemiological studies suggest the occurrence of a rapid rise in disease incidence in much of the newly developed or developing countries including Africa, Asia, South America, and Eastern Europe where societies have become more westernised (24-27). In North America, the incidence of CD ranges from 3.1 to 14.6 per 100,000 person-years, and UC from 2.2 to 14.3 per 100,000 person-years (28).

After three decades of a rapidly rising incidence in industrialized countries, the prevalence of IBD exceeds 0.3% of the population, translating into a huge disease burden in these regions (3). The prevalence of CD ranges from 26 to 322 per 100,000 persons, and for UC from 37 to 505 per 100,000 persons, with the highest reported values observed in Europe, and North America (3, 28). In 2015, a predictive model estimated that the prevalence of IBD was 0.6% of the general Canadian population and could increase to 0.9% by 2025 (5). Although, the prevalence of IBD in newly developed countries is still much lower than industrialised countries, given the increasing incidence observed in these countries it is expected to rise sharply (3).

2.1.2 Pathogenesis of IBD

IBD has a complex pathogenesis. The exact mechanism remains unclear. Accumulating evidence proposes that IBD is caused by an inappropriate inflammatory response to alteration in the composition of the gut flora in a genetically susceptible host (1). A number of risk factors have been identified as potential risk factors for developing IBD, including age, gender, race, genetics, smoking history, physical activity, dietary composition and frequent use of food additives and exposure to antibiotics. Among these factors, alteration in the traditional eating habit to a ‘western style diet’ is associated with an increased risk of developing CD and possibly UC. This may be related to an alteration in the composition of gut flora which is assumed to trigger immunological responses resulting in IBD (29).

In IBD, the gut is unable to appropriately down-regulate the inflammatory responses to potential pathogens, therefore, the mucosal immune function and the intestine remain

chronically inflamed, beginning a cascade of inflammatory events including excessive production of proinflammatory cytokines, uncontrolled activation of macrophages, bacteria- and virus-meditated autophagy (29-31).

2.1.3 Clinical Complications of IBD

The clinical and histopathological presentation of IBD varies depending on the location and severity of disease. Both CD and UC are lifelong diseases, with potentially disabling symptoms such as diarrhea (bloody or non-bloody) associated with chronic or recurrent abdominal pain (6). Other symptoms include fatigue, arthralgia, nausea, malabsorption, anorexia, weight loss, and malnutrition, which are more common during IBD flare-ups (2, 6). Beyond the gastrointestinal complications, extra-intestinal symptoms occur in 25 to 40% of patients with IBD. Almost every organ can be influenced, but most commonly sites involve the skin (erythema nodosum and pyoderma gangrenosum), eye (episcleritis, uveitis, and iritis), joints (sacroiliitis and ankylosing spondylitis) and liver (primary sclerosing cholangitis, fatty liver, and autoimmune liver disease). These symptoms can be present with or without active intestinal disease (32).

2.2 Malnutrition in IBD

The ESPEN guideline defines malnutrition as “a state resulting from lack of uptake or intake of nutrition leading 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” (33). There is no internationally accepted definition for operationalizing the definition of malnutrition perhaps explaining the wide range of malnutrition prevalence in chronic diseases. In IBD, malnutrition leads to an increased risk of complications resulting in increased morbidity and mortality rates and decreased quality of life (12, 13).

Malnutrition, suboptimal nutritional status and weight loss may be present at any stage of IBD (34). Rates of malnutrition range between 20-85% for hospitalized patients with active inflammation and 12-42% of patients in clinical and endoscopic remission depending

largely on the criteria used to define malnutrition (7-9). The prevalence of malnutrition is higher in patients with CD than UC, up to 83% in the former, and 68% in the latter (7, 8, 13, 35). Pathophysiologically, the higher prevalence in CD makes sense given the colon only involvement and fewer direct malabsorptive effects than in UC (36). The etiopathogenesis of malnutrition in IBD is multifactorial and strongly related to disease severity/activity, disease duration and the extent of inflammatory response which accelerates the catabolic state in the body (37).

2.2.1 Etiopathogenesis of Malnutrition in IBD

A combination of factors contributes to etiopathogenesis of malnutrition in IBD. Suboptimal food and energy intake is one of the most important contributing factors to malnutrition in IBD patients resulting from either self-imposed dietary restrictions, taste change and loss of appetite. This may be meditated by GI symptoms such as anorexia, nausea, vomiting, diarrhea and abdominal pain during disease flare-ups (38-40), or fasting due to hospitalization or procedures (35). Malabsorption and increased nutrient loss is also linked to release of inflammatory cytokines within inflamed gut mucosa, and is strongly associated with an alteration of epithelial function, loss of epithelial integrity, bacterial overgrowth and translocation, and disease activity (41, 42).

Existing data propose increased resting energy expenditure (REE) as another reason for impaired nutritional status in IBD patients. Studies on energy metabolism in IBD have reported contradictory results; some have shown that the energy requirements did not show any significant differences compared to healthy controls (43, 44); whereas others indicated an increased (45-47) or even decreased REE (48). This discordance may be rationalized in several ways, including: i) a rise in metabolic activity at times of flare-ups compared to remission courses (49, 50); ii) a reduction in physical activity in the acute phase of IBD offsetting the increase in REE (46).

Drug-nutrient interactions can also have a significant impact on the absorption and utilization of nutrients in IBD patients. Sulfasalazine and methotrexate are folic acid antagonists and long-term treatment is a risk factor for anemia and hyperhomocysteinemia

(51). Glucocorticoids suppress intestinal calcium, zinc and phosphorus absorption and alter utilization and metabolism of vitamin D and C and the above mentioned minerals, resulting in alteration in bone structure and metabolic bone disease (52, 53). Moreover, the use of long-term parenteral nutrition can leads to gut atrophy arising from complete bowel rest, resulting nutrient deficiencies through impaired absorption of vitamin A, D, E and minerals (51, 53).

Another important mechanism for malnutrition in IBD is bowel resection, usually associated with a reduction in absorptive capacity of nutrients, fluid and electrolytes. In particular, resection of the distal ileum in patients with CD can affect the absorption of vitamin B12 and bile acids, while colonic resection can significantly decrease the absorption of vitamin K and impair water and electrolyte reabsorption (53-56). Post-operative malnutrition is frequently observed in both patients with CD and UC and has been correlated with worsened surgical complications (11, 57).

2.2.2 Prognostic Implications of Malnutrition in IBD

Malnutrition is associated with a worse prognosis and increased risk of clinical and surgical complications such as a higher infection rate and decreased quality of life (11, 58). Patients with IBD and malnutrition have a 2-fold higher length of hospital stay (LOS) compared to those patients without malnutrition (11.9 days versus 5.8 days, $p < 0.00001$) (11). CD increases the risk of "severe" hospitalization by three-fold (OR 3.67, 95 % CI: 3.20 – 4.22; $p < 0.001$), severity defined as requiring non-elective bowel surgery or hospitalization longer than 7 days (59). IBD also increases costs, in one study, the average hospital costs for malnourished patients were two times that of patients without malnutrition ($45,188 vs. $20,295, $p < 0.0001$) (11).

Numerous studies have linked malnutrition to adverse post-operative outcomes (36, 60, 61). In one study of CD, malnourished patients with weight loss > 10% within 6 months of surgery had an increased risk of postoperative intra-abdominal septic complications such as clinical anastomotic leakage, intra-abdominal abscess and postoperative peritonitis ($p = 0.001$) (60, 61). In another series of patients undergoing colorectal resection, malnutrition

was a predictive factor for infectious complications attributed to a reduction in cellular and humoral immune responses (62, 63).

Similar to other chronic diseases (64-68), malnutrition also increases in-hospital mortality in IBD (2.7% in malnourished compared to 0.5% in well-nourished) (11), with an in-hospital mortality rate of 2.5 fold (95% CI: 1.93-3.24) for IBD with severe malnutrition compared to those without (69).

2.3 What Is Screening?

The World Health Organization defines screening as a simple procedure evaluating a large number of individuals to identify those who are perceived to be at risk of a particular disease, but do not yet have symptoms (70). A screening test predicts the likelihood of an individual having or developing a particular disease or condition which requires special intervention and management (71). In some cases such as breast cancer screening, the screen may identify those patients at an early stage of cancer (72). However, in other cases, screening may detect a condition which can be managed before developing an illness or disability, such as newborn metabolic screening (73).

Although there are many different screening tests frequently used in the health care system, not all screening tests have benefited the system and patients equally. Some screening tests can lead to over- and/or misdiagnosis and create a risk of false results (74). An ideal screening tool has good sensitivity in addition to acceptable specificity to detect the maximal number of affected individuals without needing to send all patients on for a confirmatory assessment (75).

2.3.1 Nutritional Screening

The current guidelines focus on different aspects of nutrition risk to define nutritional screening. The ASPEN definition focuses on the detection of "potential malnourished patients" (76), whereas the ESPEN guideline suggests a much wider definition of nutrition screening by identifying patients who are "at nutritional risk" (77). Considering both

guidelines, nutrition screening is a process to identify early determination of patients at risk of malnutrition who require further nutritional assessment (78). In 2006, the ESPEN guideline defined nutrition risk as a probability of better or worse clinical outcome from disease or surgery due to nutritional and metabolic factors (77). Various nutritional screening tools are available to screen patients for malnutrition in clinical setting. These screening tools are designed to be administered rapidly, by a variety of clinical and nonclinical individuals, to evaluate risk of malnutrition in those patients who would benefit from subsequent referrals for comprehensive nutritional assessment and therapy (79, 80).

Given the above-mentioned information, it is reasonable that the best tool to employ should be sensitive to detect positive cases who benefit from intervention including special diets, nutrition support, monitoring and counselling before malnutrition becomes clinically manifested. In this regard, the majority of screening tools combine similar parameters including unintentional weight loss and difficulties in eating (loss of appetite or reduced food intake) (33). A positive answer to these screening questions indicates a need for further nutritional evaluation performed by a trained healthcare professional (dietitian, physician) (33).

2.3.1.1 Nutritional Screening in Chronic Diseases

Several nutrition screening tools have gained acceptability due to their feasibility in different clinical care settings. The ESPEN and BAPEN (British Association for Parenteral and Enteral Nutrition) guidelines recommend Nutritional Risk Screening 2002 (NRS-2002) and MUST tools, respectively, to detect malnutrition in elderly care, hospital and community settings (79). Other malnutrition screening tools including abPG-SGA, malnutrition screening tool (MST) and CNST has been validated in oncology outpatient and inpatient, elderly and community rehabilitation settings (17, 81, 82). **Table 1** outlines the main available nutrition screening tools and their components.

Table 1 Summary of nutrition screening tools

Screening tool	Parameters					Care settings
	Weight loss	BMI	Poor appetite/ Food intake	Food restriction	Others	
abPG-SGA	*		*		Symptoms affecting food intake, physical activities	Oncology outpatient and inpatient settings
MUST	*	*	*		Acutely ill and there has been or is likely to be no nutritional intake for > 5 days	Outpatient clinics, hospital wards, in home and community care settings
CNST	*		*			Hospital
MST	*		*			Hospital, oncology outpatient and community care settings
NRS-2002	*	*	*		Severity of disease	Hospital
NRI	*				Serum albumin	Hospital, oncology and elderly care settings
MNA-SF	*	*	*		Psycho. stress Acute disease Neuropsycho. problems, Mobility	Elderly (home-care programs, nursing homes, and hospitals)
MIRT	*	*			CRP	Outpatient setting
IBD- specific screening tool						
SaskIBD-NR	*		*	*		IBD outpatient setting

Abbreviations: *abPG-SGA* abridged patient-generated subjective global assessment; *MUST* malnutrition universal screening tool; *CNST* Canadian nutrition screening tool; *MST* malnutrition screening tool; *NRS* nutrition risk screening; *MNA-SF* mini-nutritional screening-short form; *IBD* inflammatory bowel disease; *SaskIBD-NR* Saskatchewan IBD-nutrition risk; *MIRT* malnutrition inflammation risk tool; *CRP* C-reactive protein

The predictive value of NRS-2002 has been documented by conducting a retrospective study of 128 randomized clinical trials (RCTs) of nutrition support which reported a higher likelihood of beneficial clinical outcomes in patients fulfilling risk criteria compared to those who did not (79). This tool is mostly suited to acute care; a study by Kondrup et al showed that 99 % of patients could be screened easily using the NRS 2002 (83). It is important to note that the NRS 2002 has been validated to identify those patients who would benefit from nutrition intervention, not for categorizing them based on their risk of malnutrition.

MUST has been evaluated in varied health care settings such as outpatient clinics, hospital wards and in home and community care settings (84). It strongly predicts the LOS, quality of life, morbidity, and mortality in hospitalized and outpatients (84, 85). In a multicenter study in 1146 inpatients and outpatients, the validity of MUST and NRS-2002 were assessed in the light of the new ESPEN consensus definition of malnutrition. MUST was found to have a very high sensitivity and specificity for both inpatients and outpatients (sensitivity = 96.0% for outpatients and 100% for hospitalized), while the NRS-2002 showed lower sensitivity for both outpatients (50%) and inpatients (61%) (86).

The abPG-SGA is a screening tool derived from the full version of the PG-SGA. The PG-SGA was specially developed for patients with cancer (87). It is comprised of two sections: i) a self-administered nutritional history completed by patients which includes 4 domains of changes in body weight, food intake, symptoms affecting dietary intake, and functional capacity (abPG-SGA); and ii) a clinician assessment of the disease status and its relation with metabolic demands, nutritional requirements and physical examinations to identify malnutrition. The latter clinician assessment section is removed from the abPG-SGA version. In a study in chemotherapy outpatients the accuracy of the abPG-SGA was evaluated compared to SGA - the abPG-SGA had a sensitivity of 94% and specificity of 78% and was established as a valid, practical and reliable tool for identifying malnourished patients in an oncology setting (17). The abPG-SGA also showed high sensitivity in oncology inpatients and outpatients with cancer cachexia (88). Other studies have

associated a high abPG-SGA score with decreased HGS, BMI and FFM, elevated CRP increased LOS and mortality rate in patients with cancer (88, 89).

In a cross-sectional study, the MST was investigated for validity within a community rehabilitation setting. The MST showed high sensitivity (72%) and specificity (84%) with acceptable positive and negative predictive value compared to the SGA (82). MST also showed a good to excellent sensitivity of 83-100% in populations of residential care patients, frail elderly patients at risk of hospital readmission and oncologic patients compared to SGA (90-92).

The CNST is a new nutritional screening tool which showed promising results in its first validity assessment study (sensitivity (91.7%) and specificity (74.8%)), and a strong prediction of clinical outcomes (LOS, 3-day admission and mortality rate) in hospitalized patients (81).

2.3.1.2 Nutritional Screening in IBD

According to the current ESPEN guideline for Clinical Nutrition, it is recommended that since IBD patients are at increased risk of malnutrition, they should be screened regularly for malnutrition with a validated screening tool (20). Screening may be required more frequently among patients with active disease. As routine malnutrition screening is not commonly performed as a part of IBD clinical care, this may lead to under-recognition and under-treatment of malnutrition in this population (93, 94).

Although a number of nutritional screening tools have been validated in a variety of patient populations such as surgical and oncologic populations, there is limited evidence for a validated screening tool in the IBD population. Some of the currently available nutritional screening tools that have been studied in IBD include MUST, NRS 2002, Nutrition Risk Index (NRI), Malnutrition Inflammation Risk Tool (MIRT) and SaskIBD-NR tool (95-99).

Although MUST has not been validated specifically in IBD population, it has been verified as an easy, quick, reproducible, and internally consistent tool (84, 85), qualities which are required in busy IBD clinics. According to the MUST, a range of 15.5% to 60% of IBD patients were categorized at high risk of malnutrition (96, 99). A few IBD studies examining the relationship between MUST and nutritional status reported that MUST had a significant correlation (OR = 0.934, $p = 0.014$) with skeletal muscle index (SMI) and a fair inter-rater reliability ($\kappa = 0.53$) to fat free mass index (FFMI) in hospitalized patients (95, 100). Similarly, NRS- 2002 also showed a significant correlation with SMI (OR=0.928, $p = 0.008$) (95), and reported a range of 20 to 67.5 % of IBD inpatients with risk of malnutrition (94, 96).

MIRT a newly developed nutritional screening tool specifically developed for patients with inflammation (98, 99). MIRT was significantly correlated to SGA ($r = 0.394$, $p = 0.005$) (98). SaskIBD-NR tool is a nutritional screening tool developed specifically for IBD outpatient population. The SaskIBD-NR tool classified 19% of IBD patients at high or medium risk of malnutrition with a significant and high agreement with the registered dietitian and gastroenterologist assessments ($\kappa = 0.83$, $p < 0.001$). It also demonstrated very good sensitivity (82.6%; 95%CI: 61.2 - 95) and excellent specificity (97.7%; 95%CI: 91.9 – 99.7) in identifying IBD patients at nutritional risk (99).

2.3.1.3 Nutritional Screening and Clinical Outcomes in IBD

There is limited evidence associating screening tools with clinical outcomes in IBD patients. Guerra et al. (58) found that malnutrition screening including ‘MUST’ and NRS have a similar ability to predict hospitalisation costs compared to the ASPEN and Academy of Nutrition and Dietetics (AND) recommended nutritional assessment. A recent Canadian study examined the ability of MUST to predict disease activity in outpatients with IBD. Study findings showed a strong association between a moderate to high MUST score (≥ 2) and increased disease activity score in patients with CD. In UC patients, the same

association was found only in patients at high risk of malnutrition but it was not significant (101), however, the study did not examine outcomes over nutritional risk longitudinally. In 2017, Takaoka et al showed that a significant association between the SGA and NRS 2002 and length of hospital stay, however this association was not significant with the MUST ($p = 0.314$). None of these tools were correlated with intestinal resection (96).

MIRT was significantly associated with disease flares ($p = 0.030$), disease complications ($p = 0.015$), CD-related surgery ($p = 0.006$) and history of hospitalizations ($p = 0.003$) in outpatients with CD. MIRT showed a tendency towards an association with the Crohn's disease activity index (CDAI) (98). There is no available study examining the association between SaskIBD-NR tool and clinical outcome.

Besides the abovementioned screening tools, there are other nutritional screening tools such as abPG-SGA, MST and CNST that have not been studied in IBD patients. However, evidence from other patient populations showed an association between these nutritional screening tools and poor clinical outcomes (102-105).

2.3.2 Nutritional Assessment

Confirmation of nutrition risk is achieved through nutritional assessment. Nutrition assessment is the gold standard tool to define nutritional status, and is used to identify modifiable factors to inform an appropriate nutrition intervention (78). The assessment is administered by a dietitian or a nutritional support team and is of greater complexity than a screen (106). In general practice, the nutritional assessment is most commonly performed using the SGA, anthropometric measurements including BMI, triceps skinfold (TSF), mid-arm circumference (MAC), MAMC, and biochemical tests such as albumin and prealbumin. Other assessment methods include measures of body composition such as bioimpedance analysis (BIA) and dual-energy X-ray absorptiometry (DXA) (107).

SGA is a clinical method recommended by ASPEN to assess undernutrition independent of clinical setting (78). In their recent guideline, the ASPEN and AND Consensus Statement recommended 6 constructs (insufficient energy intake, unintended weight loss, loss of subcutaneous fat, loss of muscle mass, fluid accumulation, a decline in functional status as measured by HGS) that had the strongest association with adult malnutrition in routine clinical practice (108). The authors suggested that identification of two or more of these characteristics provided evidence of malnutrition (108). The recent recommendation by ESPEN provides a consensus-based minimum set of criteria for diagnosis of malnutrition including two criteria: i) a low BMI (<18.5 kg/m^2); ii) the combination of unintentional weight loss AND at least one of either reduced BMI (<20 or <22 kg/m^2 in individuals younger and older than 70 years, respectively) or a low FFMI (< 10^{th} percentile) (33). Unintentional weight loss could be >5% weight over 3 months or >10% indefinite of time.

Alteration in muscle strength may also serve as a useful assessment method for early detection of malnutrition (109). An assessment method based on an objective measure of physical strength and function may be valuable (110), especially in conditions where weight measurement is not a reliable and accurate assessment method (111). HGS is commonly used for assessment of skeletal muscle function across clinical settings (112). As a quick, user-friendly and cost-effective tool HGS has the capacity to detect improvement in nutritional status following supplementation (111). Data supports that functional assessment tools may decline earlier than changes in body composition (112, 113).

2.3.2.1 Nutritional Assessment in IBD

In the IBD population, several assessment methods have been used to evaluate a patient's nutritional status: clinical (SGA), anthropometric (BMI, TSF, MAC and MAMC) and body composition (FFMI) (114). The ideal tool remains unknown. A research study in 2010 compared different methods of nutritional assessment in 75 patients with CD using SGA, BMI, MAMC, MAC, TSF and HGS, and found that the BMI was not an effective tool to

diagnose malnutrition in this population. Conversely, the HGS detected a high prevalence of impaired nutritional status in patients with CD in remission compared to other assessment methods (115). Later, in 2017 another study with a larger sample size that included both UC and CD patients reported only 4% of patients with malnutrition according to the SGA, rising to 7% and 11% when classifying malnutrition according to the ESPEN guideline for malnutrition diagnosis (cut points of BMI and FFMI, respectively) (114). A recent study showed a significant correlation between SGA and SMI in IBD patients (95).

2.3.2.2 Nutritional Assessment and Clinical Outcomes in IBD

In a study in 333 IBD patients, malnutrition was diagnosed using the ESPEN consensus definition (weight loss, BMI and FFMI), SGA and HGS. The univariate analysis showed that history of abdominal surgery due to IBD was more frequent in patients with malnutrition than in well-nourished patients [37% vs 19%, $p < 0.01$] (114). Moreover, clinical activity [52% vs 27%, $p < 0.001$], and combination therapy (immunosupressors plus anti-TNF) [44% vs 27%, $p < 0.05$] were more frequent in malnourished patients than well-nourished patients. They also demonstrated that malnourished patients avoided some food groups to prevent a flare [82% vs 69%, $p = 0.05$], and during a flare [98% vs 83%, $p < 0.01$] more frequently than well-nourished patients (114). Another study in IBD found that SGA also did not significantly predict the need for surgery ($p = 0.071$). However, the same study found that SGA did predict length of stay in hospitalized patients ($p = 0.008$) (96). In CD patients, SGA did not show any correlation with the duration of disease or any other clinical outcomes (98).

Other nutritional assessment methods such as computed tomography (CT) and BIA were also applied to assess loss of skeletal muscle mass (sarcopenia) in IBD population. The results showed that decreased SMI (sarcopenia) had a significant correlation with need for surgery (intestinal resection) ($p = 0.003$) (95, 116). A significant correlation was also found between sarcopenia and major postoperative complications (OR = 9.24, $p = 0.04$) (116).

An adverse correlation was found between skeletal muscle percent and major and overall postoperative complication in CD patients (117).

2.4 Facilitating the Screening to Assessment Process by Using Self-Screening

Self-screening is not a new concept in medicine. By helping HCP to provide an early referral for a comprehensive assessment and intervention (16, 118, 119), self-screening has been utilized across disease processes including, cancer, gastroenterology diseases and diabetes. In theory, it would be desirable if patients could reliably screen themselves with ease and without interfering with the routine process of clinical care in a busy clinic, increasing the rate of risk screening in health care system.

2.4.1 Self-Screening for Malnutrition

Nutrition risk self-screening is a well-known concept in clinical care, particularly in cancer care (17, 88). Abridged PG-SGA is one of the validated self-screening tools frequently used in cancer patients (described in more detail in the methods section below). In a study conducted in oncology outpatients, the abPG-SGA yielded a sensitivity of 94% and specificity of 78%, which was slightly lower than full version of PG-SGA administered by both patient and HCP (97% sensitivity, 86% specificity). In their conclusion, abPG-SGA was suggested as an informative, practical and valid tool for detecting malnutrition in cancer patients (17). In addition, in a prospective cohort study in 207 advanced lung and gastrointestinal cancer patients, a higher score of abPG-SGA (≥9 vs 0 to 1) showed a significant association with biological marker of cancer cachexia ($p < 0.05$), decreased anthropometric and physical measurements such as BMI (22.5 *vs.* 27.1 kg/m^2), fat mass (14.4 *vs.* 26 kg), hand grip (24.7 *vs.* 34.9 kg) and leg strength, longer LOS (greater than 12%) and increased mortality (88).

Other validated nutrition screening tools such as MUST and MST have been employed as self-screening tools in different clinical settings. In a study of 205 outpatients in UK, the 3-category classification (low, medium, high) of MUST showed 90% agreement ($\kappa = 0.70$,

p = 0.001) between patient-led and HCP-administered screen; this agreement increased when the 2-category classification of MUST (low risk, medium and high risk) used to screen patients (93%; κ = 0.78, p = 0.001) (15). This finding is consistent with previous work by McGurk et al (16) demonstrating perfect agreement (κ = 1.00) between self-screen and HCP-led MUST screen in gastroenterology outpatients.

A recent study in an ambulatory cancer care setting studied MST as a nutrition self-screen, and found 'almost perfect' agreement (κ = 0.96) between patient-led and dietitian-administered MST with high inter- and intra-rater reliability which reported MST as a reliable, user friendly screening tool in this population (14). Another study on patients attending oncology clinics showed that the categories of abridged PG-SGA tool was well correlated with BMI, and total and appendicular fat mass measured by DXA, but not with lean mass (88).

2.4.2 Malnutrition Self-Screening in IBD

In IBD, the patient-administered MUST was in excellent agreement with a HCP-led MUST screen (18); while another study in IBD patients reported moderate agreement (κ = 0.486, p < 0.001) between patient-led and HCP-led MUST screen, with 100% agreement in scoring for medium to high risk of malnutrition (19). These two studies were consistent with studies in other populations where patient-administered screening tools such as MUST, abridged PG-SGA and MST were shown to be valid and efficient means of detecting those at high-risk of malnutrition (14-16).

Notably, to date, patient-led self-screens have not been compared to the ASPEN-recommended assessment of malnutrition (SGA) administered by a dietitian. The purpose of the present study was to examine the validity of patient-led self-screens for identifying malnutrition in patients with IBD.

CHAPTER 3: MATERIAL AND METHODS

3.1 Overview of Study Design

"The Validity of Patient-led Self-screens for Identifying Malnutrition in Inflammatory Bowel Disease" was a cross-sectional study conducted at the University of Alberta in Edmonton and the University of Calgary in Calgary, Alberta, Canada, from May 2017 to March 2018. Patients meeting eligibility criteria completed self-screens, and were screened and assessed for nutritional status by a HCP and dietitian, respectively.

3.2 Ethics Approval

Ethical approval was obtained from the Health Research Ethics Board at the University of Alberta and the University of Calgary (Identifier: Pro00073470). Oral and written informed consent was obtained from all patients prior to their participation in this study.

3.3 Participants

A convenience sample of eligible patients was recruited from the IBD outpatient Clinics at the University of Alberta and the University of Calgary. Patients were screened for inclusion and exclusion criteria.

3.4 Inclusion Criteria

Outpatients with age 18 years and older, and those with diagnosis of IBD (CD or UC) as per standard diagnostic criteria.

3.5 Exclusion Criteria

Patients were excluded from enrolment if they were pregnant or had chronic renal failure on dialysis, chronic pulmonary disease on home oxygen, congestive heart failure with an EF <40%, and inability to provide informed written consent due to physical or mental impairment and or had English language difficulties.

3.6 Patient Evaluation

Patients meeting study eligibility were provided with an information sheet (**Appendix A1)**, which outlined the purpose, procedures, risks and possible benefits involved with participation in this study. The patient's written informed consent was obtained. Informed consent included access to patient's electronic medical charts.

3.6.1 General Data Collection

General data collection sheets (**Appendix A2**) included demography, clinical history and disease activity/severity data either completed by a HCP (a medical student or research assistant) through an interview or obtained from patient's chart review.

i. Demography and Clinical History Data

Baseline evaluations administered at the IBD outpatient clinics were gathered about each patient (**Appendix A 2-1**):

a) Demographics – age, sex, ethnicity

b) Alcohol intake – estimate daily or weekly frequency/quantity

d) Smoking

e) History of hospitalization in past 12 months

f) History of abdominal surgery

g) Co-morbidities

h) Medications and supplements

ii. Grading Disease Activity/Severity of IBD

Patients were assessed for their severity of disease. They completed the first two sections of the Harvey–Bradshaw Index (HBI) and the Partial Mayo Scoring Index (Mayo) forms for CD and UC, respectively, and then a HCP completed the evaluation and classified patients according to their severity of disease.

Disease severity was assessed in three primary domains: impact of disease on patient (clinical symptoms, patient reported outcomes, quality of life, fatigue, and disability); disease course (such as structural damage, number of flares, perianal disease, history of

intestinal resection, and extraintestinal manifestations); and measurable disease burden (extent, location, and severity of bowel inflammation at a given time). The HBI and Mayo forms used in this study are presented in **Appendix A 2-2.**

3.6.2 Nutritional Screening and Assessment Methods

After obtaining the demographic and disease activity data, nutritional screening was performed in two phases:

1. Patient Self-screens – Eligible patients were provided with a single instruction sheet following four self-screens. The patients were initially asked to complete self-screens independently.
2. HCP screen – after the self-screening process, the HCP measured patient's height and weight, calculated BMI, and completed the nutritional screening tools (abPG-SGA, MUST, CNST and SaskIBD-NR) for each patient.
3. Dietitian - Once the nutrition screening (patient-led and HCP-led) were completed, the dietitian (blinded to patient and HCP screen data) performed a complete nutritional assessment to evaluate the patient's nutritional status for indications of malnutrition.

The detailed description of each method and tool used for nutritional screening and assessment are described in the following section:

3.6.2.1 Nutritional Screening Tools

For nutritional screening, a commonly used screening tool (MUST), a Canadian nutrition screening tool (CNST) and an IBD-specific screen (SaskIBD-NR) were selected for detecting the risk of malnutrition in this patient population. The abPG-SGA also selected for the nutrition screening process in the study due to its unique design including symptoms affecting food intake which are severely compromised in the majority of IBD patients (2, 120).

The categories and principle of each tool are described below:

i. Malnutrition Universal Screening Tool (MUST)

MUST was developed in the UK by the Malnutrition Advisory Group to identify patients at risk of malnutrition, who could benefit from further nutritional intervention (84). The nutritional risk is assessed through calculation of BMI, assessment of unintentional weight loss in the last 3-6 months, and the presence of any acute disease, in which there was an insufficient food intake calculated for a period equal to or greater than 5 days. The total score ranges from 0 to 2, indicating the presence of a mild, moderate, or severe risk of malnutrition (low risk = 0, moderate risk = 1, and severe risk = 2) (84). The MUST form is shown in **Appendix A 3-1**.

ii. Canadian Nutrition Screening Tool (CNST)

In the Nutrition Care in Canadian Hospitals (NCCH) Study conducted by the Canadian Malnutrition Task Force, the CNST was developed which is validated in hospitalized patients (81, 121). The CNST is a quick, two-item questionnaire including weight loss and poor food intake in which a ‘‘yes’’ answer for both questions classifies the patient at nutrition risk who requires a referral to a dietitian for further nutritional assessment (**Appendix A 3-2**).

iii. Saskatchewan IBD–Nutrition Risk (SaskIBD-NR)

The SaskIBD-NR Tool was recently developed screening tool by a Canadian research group specifically for the IBD population (99). The SaskIBD-NR Tool evaluates four components: gastrointestinal symptoms, weight loss in past one month, poor food intake, and food restrictions (99). The SaskIBD-NR Tool is presented in **Appendix A 3-3**.

iv. Abridged Patient-Generated Subjective Global Assessment (abPG-SGA)

The abridged PG-SGA contains four main domains including weight loss history, dietary intake, symptoms affecting food intake and activities and function. The total score provided by this screening tool is gained from the sum of scores in each domain and provides a global rating system which is described as follow:

a. Score 0 to 1 indicates no nutritional support is required and the patient just needs routine re-evaluation for planning future care plan;
b. Score 2 to 3 means patients and their families need to be educated for nutrition aspects of their disease by a health professional such as a nutritionist, dietitian or a nurse based on the signs and symptoms assessment and laboratory results;
c. Score 4 to 8 shows that nutritional support should be provided by the dietitian in conjunction with physicians or nurses based on patient's symptoms;
d. A Score ≥ 9 indicates a crucial need of urgent nutritional support and symptom management.

Patient with higher abPG-SGA scores demonstrate the greatest risk of malnutrition. Similar to the SGA, the abPG-SGA global rating also classifies a patient's nutritional status into three categories of "well-nourished or anabolic" (abPG-SGA A), "Moderately or suspected of being malnourished" (abPG-SGA B), or "Severely malnourished" (abPG-SGA C). (122). The abPG-SGA form is present in **Appendix A 3-4**.

3.6.2.2 Nutritional Assessment

Based on the ASPEN and ESPEN guidelines, patient's nutritional status was assessed by using multiple assessment methods. The primary assessment method for defining malnourished or not was the SGA. BMI, MAMC, and HGS were added as secondary assessment methods. These methods were structured as described below:

v. Subjective global assessment (SGA)

SGA consists of five parts (**Appendix A 4-1**): unintentional weight change, change in food intake, change in appetite (e.g., decreased or increased appetite, early satiety), gastrointestinal symptoms (e.g., diarrhea, nausea, vomiting), and physical markers of malnutrition such as the detection of muscle wasting and subcutaneous fat loss, ascites and peripheral edema. SGA classified patient's nutritional status into three categories: class A (well nourished), class B (mild or moderately malnourished), or class C (severely malnourished). Although, the SGA was not developed specifically for patients with IBD, the existing evidence suggests sufficient validity, reliability, and prognostic value for its use in this patient population (114, 115, 123).

vi. Anthropometric measurements

All patients underwent measurements of weight and height. Body weight was measured to the nearest 0.1 kg. Height was recorded to the nearest 0.1 cm by using a stadiometer. Each individual's BMI was calculated by using the following formula: BMI = weight (in kg)/ height (in m^2). The other anthropometric measurements include triceps skinfold thickness (TSF) and mid-arm circumference (MAC) in order to calculate the mid-arm muscle circumference (MAMC) (124). MAMC was calculated by using the following formula: MAMC = avg. (MAC in cm) – [3.14 × avg. (TSF in mm)] (**Appendix A 4-2**).

MAMC below the 10^{th} percentile was considered as a cut-off for both moderate/severe malnutrition as previously defined by Alberino et al (66). The results were compared to normality tables in percentiles based on age and sex, according to Frisancho (125).

vii. Hand-grip strength (HGS-Functional assessment)

HGS was measured in the dominant hand by using a Jamar® Hydraulic Hand dynamometer (model 2010, Sammons Preston Rolyan, Bolingbrook, Illinois), and where this was not possible (patients with arthritis or other secondary diseases), the patient's non-dominant hand was used and this detail was recorded. The best of 3 consistent attempts was recorded, allowing a recovery of ≥1 min between attempts (**Appendix A 4-3**).

Our results were compared to normality tables in percentiles for Canadian male and female aged of 6 to 79, according to Canadian Health Measures Survey (126). As previously done, the 5^{th} percentile was utilized as a reference point for abnormally low hand-grip strength (127).

3.7 Sample Size

The primary objective of the study was to test the difference in the estimated prevalence of correctly identified malnourished subjects at the patient-led and HCP-led screening tools vs. the dietitian-administered nutritional assessment method (SGA). Considering an estimated prevalence of malnutrition in outpatients with IBD of 30%, an average value from previous studies (RW.ERROR - Unable to find reference:1078), to estimated sensitivity and specificity with 10% margin of error with a confidence interval of 95% and

a significance level of 5%, a sample size of 186 patients was determined. A final sample of 200 participants was set as practically feasible to account for potential dropouts or missing data.

3.8 Statistical Analysis

The predictive values of patient-led and HCP-led nutrition screening versus dietitian-administered SGA were estimated through the evaluation of sensitivity (percentage correctly identified as malnourished), specificity (percentage correctly identified as well nourished), positive and negative predictive values (likelihood that the presence or absence of malnutrition is correctly predicted by the tool). For this analysis only two levels of risk were considered for screening tools and SGA, aggregating patients with a moderate or high risk of malnutrition (for screening tools) and with moderate or severe malnutrition (for SGA) within a single level of risk. Since the present study is a screening study, it necessitates a sufficiently high degree of sensitivity (129). According to previous studies validating screening tools (81, 99, 130, 131), in this study, the degree of sensitivity was defined: 85% and greater indicating high sensitivity and 65 to 85% indicating satisfactory sensitivity. A screening tool with sensitivity lower than 65% was not considered a sensitive tool to screen malnutrition in IBD outpatients.

Inter-rater reliability (agreement) between the screening methods administered by patients and HCP was also predicted by the kappa (κ) statistic. The value of κ varies from 0 to 1, with values less than 0.2 indicating poor, 0.21–0.4 fair, 0.41– 0.6 moderate, 0.61–0.8 substantial, and more than 0.8 almost perfect concordance (132).

Distributional assumptions were tested. Continuous variables are presented as mean ± SD or as median ± interquartile range (IQR), as appropriate. Categorical variables were described based on frequencies and percentages. Cochran's test was used for comparison of different methods for identifying the risk of malnutrition. The Pearson's chi-square test or Fisher's exact test was used to evaluate the association between categorical variables. The Student's t-test was used to compare the continuous variables in relation to IBD types and malnutrition categories.

Contingency tables classifying the screening tools and the SGA (B and C combined as malnourished) results were established to determine the criterion validity of the tool (sensitivity, specificity, PPV and NPV). Inter-rater agreement was assessed using the Kappa coefficient. Univariate and multivariate logistic regression analysis was used to identify independent predictors of malnutrition. Statistical significance was reported as $p < 0.05$. Statistical analysis was performed using SPSS statistical software (SPSS Inc. Wacker Drive, Chicago, IL, USA).

CHAPTER 4: RESULTS

4.1 Flow of Patients through Selection Process

Two hundred and four IBD (131 CD and 73 UC) outpatients were consecutively recruited. Out of 344 IBD patients approached to participate to the study, 140 did not meet the inclusion criteria, declined to participate or did not complete the study survey. Individual patient data were available and analyzed for all 204 patients completed nutritional screening and assessment. **Figure 1** shows the flow of patients through the study.

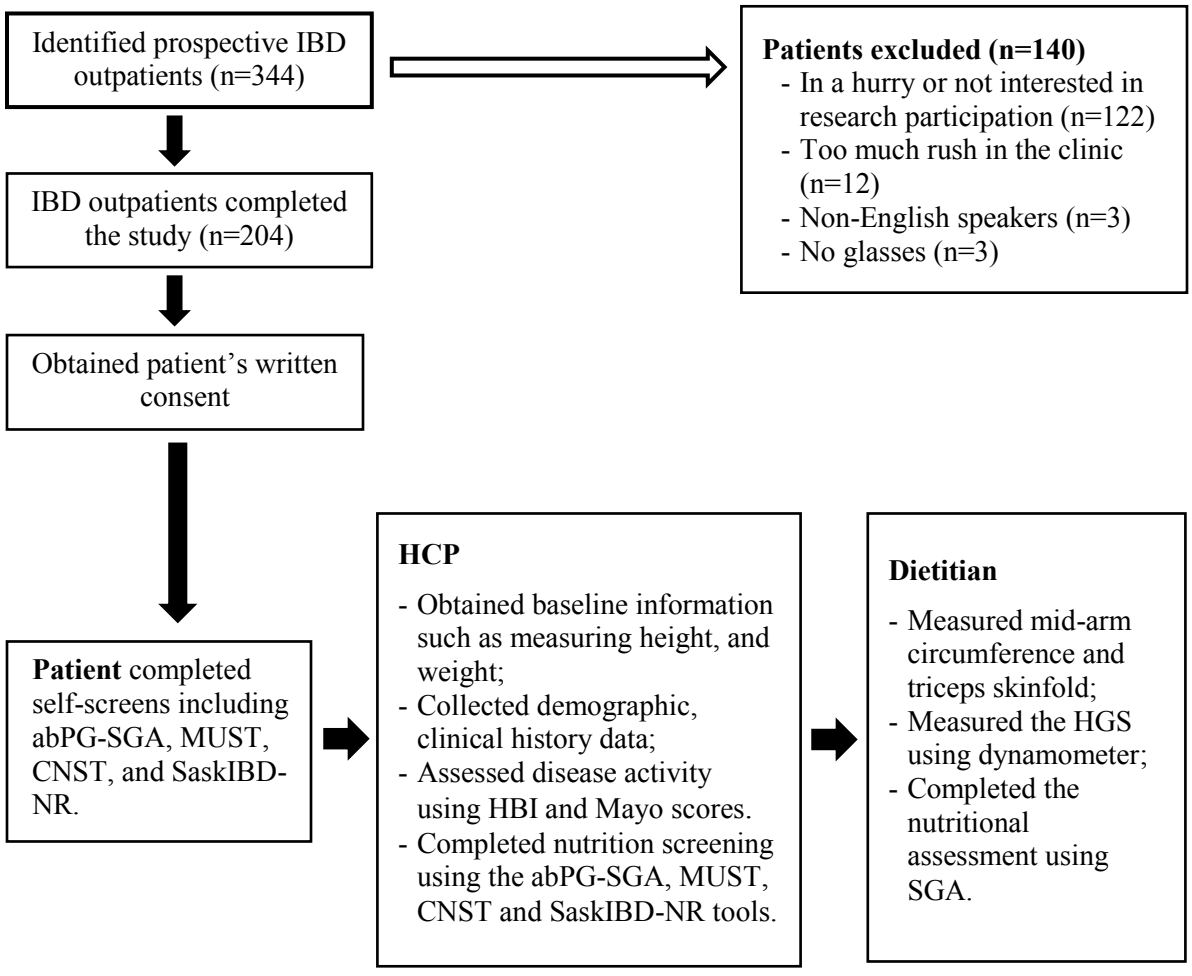

Figure 1 IBD patient malnutrition screening flow chart through the study

4.2 Patient Characteristics

The participants included 131 (64%) CD and 73 (36%) UC patients, half of them were female (50.5%), 89% were Caucasian. The baseline patient characteristics of the study population is summarized in **Table 2**. The mean age for all participants was 42.32 ± 15.6 years [range = 18 - 86]. Based on the HBI and partial Mayo scores, 12.8% of CD and 11.3% of UC patients had moderate to severe disease activity. Seventy-two percent had a history of abdominal surgery due to IBD, and 17 % were current smokers. The most common symptoms affecting dietary intake in this population were diarrhea (21 %), poor appetite (19.6%), pain (18 %), and fatigue (17.7 %). The only demographic/ clinical characteristics that were significantly different by IBD status (UC versus CD) were smoking status and the number of IBD-related surgeries - those with CD were more likely to be a current smoker and have more surgeries compared to UC patients ($p < 0.001$). In addition, the use of biologic and immunomodulators was significantly higher in CD patients compared to UC, while in UC, the use of 5-ASA was significantly higher than CD patients. Patients with CD consumed more supplements than UC patients, however, this association did not reach statistical significance for the subgroup.

Table 2 Demographic and clinical characteristics of the study participants

Characteristics	Total IBD (n= 204)	CD (n= 131)	UC (n=73)	*P*-value†
Age, *year*s	42.3 ± 15.6	38.8 ± 15.7	44.3 ± 15.3	0.934
Sex, *n (%)*				0.163
Male	101 (49.5)	61 (46.6)	40 (54.8)	
Female	103 (50.5)	70 (53.4)	33 (45.2)	
Ethnicity [Caucasian], *n (%)*	182 (89)	121 (92.4)	61 (83.6)	0.216
Current smoker, *n (%)*	34 (16.7)	29 (22.1)	5 (6.8)	0.017*
Current alcohol drinker, *n (%)*	143 (70)	93 (71)	50 (68.5)	0.920
Hospitalization history for IBD in past 12 months, *n (%)*	39 (19.3)	22 (17.1)	17 (23.3)	0.185

History of abdominal surgery related to their IBD, *n (%)*	77 (39.1)	74 (58.3)	3 (4.3)	< 0.001*
Treatment of IBD, *n (%)*				
5-ASA	49 (24)	17 (13)	32 (43.8)	0.000*
IMMs	88 (43.1)	65 (49.6)	23 (31.5)	0.009*
Biologics	127 (62.3)	89 (67.9)	38 (52.1)	0.019*
Steroids	36 (17.6)	23 (17.6)	13 (17.8)	0.554
Supplements	124 (60.8)	85 (64.9)	39 (53.4)	0.073
Disease activity, *n (%)*				0.485
Remission	119 (69.6)	78 (71.6)	41 (66.1)	
Mild	31 (18.1)	17 (15.6)	14 (22.6)	
Moderate	17 (8.3)	11 (10.1)	6 (9.7)	
Severe	4 (2)	3 (2.8)	1 (1.6)	
Symptoms affecting dietary intake, *n (%)*				0.520
Diarrhea	43 (21.1)	28 (21.4)	15 (20.5)	
No appetite	40 (19.6)	28 (21.4)	12 (16.4)	
Pain	37 (18.1)	24 (18.3)	13 (17.8)	
Fatigue	30 (14.7)	20 (15.3)	10 (13.7)	
Nausea	28 (13.7)	18 (13.7)	10 (13.7)	
Early satiety	19 (9.3)	14 (10.7)	5 (6.8)	
Vomiting	14 (6.9)	9 (6.9)	5 (6.8)	

Data are presented as mean ± SD and n (%), using an unpaired t-test and a chi-squared test, respectively, to test for differences by IBD groups.

†*P*-values represent differences between subgroups UC and CD only.

Abbreviations: *IBD* inflammatory bowel disease; *CD* Crohn's disease; *UC* ulcerative colitis*; 5-ASA* 5-aminosalicylates; *IMMs* immunomodulators.

4.3 Primary Objective: Validity of Nutritional Self-Screening and HCP-led Screening Compared to Dietitian-administered Assessment

All patients were able to screen themselves. Patients classified themselves at moderate to high risk of malnutrition in 39% of cases using abPG-SGA, 32% SaskIBD-NR, 21% MUST and 11% using CNST. From the results derived from HCP-led screening, 36% of patients were at medium to high risk of malnutrition screened by abPG-SGA, 28% SaskIBD-NR, 21% MUST and 9% using CNST.

The ability of the screening tools to predict assessment result is summarized in **Table 3**, with the abPG-SGA and SaskIBD-NR having better test characteristics than the MUST and CNST tools for detecting the risk of malnutrition in IBD patients.

Table 3 Comparison of sensitivity, specificity, PPV and NPV of dietitian-administered SGA with patient-led and HCP-led screening tools

Screening tools	Sensitivity	Specificity	PPV	NPV
Patient-led *(%)*				
abPG-SGA	89.2	71.9	41.3	96.8
SaskIBD-NR	67.6	75.4	37.9	91.3
MUST	51.4	85.6	44.2	88.8
CNST	29.7	92.8	47.8	85.6
HCP-led *(%)*				
abPG-SGA	89.2	75.4	44.6	96.9
SaskIBD-NR	70.3	80.8	44.8	92.5
MUST	59.9	88	52.4	90.7
CNST	32.4	95.8	63.2	86.5

Data are presented as frequency n (%) using a chi-squared test

Abbreviations: *HCP* health care practitioner; *abPG-SGA* abridged patient generated-subjective global assessment; *SaskIBD-NR* Saskatchewan IBD- Nutrition Risk; *MUST* Malnutrition universal screening tool; *CNST* Canadian nutrition screening tool; *PPV* positive predictive value; *NPV* negative predictive value.

4.4 Secondary Objective1: Inter-Rater Reliability between Self-Screening and HCP-led Screening

Table 4 presents a comparison of the risks of malnutrition as identified by self-screens and the HCP-led screens. To summarize, the HCP-led screens demonstrated that the abPG-SGA and SaskIBD-NR classified more patients at medium and high risk of malnutrition as compared to the other two tools. There was a moderate agreement between the patient-led and HCP-led abPG-SGA, MUST and SaskIBD-NR, as determined by the κ statistic ($p < 0.001$).

Table 4 Risk of malnutrition obtained from patient-led self-screens and HCP-led screening tools, and the inter-rater reliability between these two screening methods

Screening tools		**HCP-led screening**[†]		Inter-rater reliability
Patient-led self-screens[†]		no or low risk	Medium to high risk	Kappa (95% CI)
abPG-SGA	no or low risk	108 (83.1)	16 (21.6)	0.60 (0.49 – 0.72)
	Medium to high risk	22 (16.9)	58 (78.4)	
SaskIBD-NR	no or low risk	121 (82.9)	17 (29.3)	0.51 (0.37 – 0.64)
	Medium to high risk	25 (17.1)	41 (70.7)	
MUST	no or low risk	148 (91.4)	13 (31)	0.59 (0.46 – 0.74)
	Medium to high risk	14 (8.6)	29 (69)	
CNST	no or low risk	147 (90.2)	12 (28.4)	0.49 (0.45 – 0.51)
	Medium to high risk	19 (9.2)	26 (67.6)	

[†] Data are presented as frequency n (%) using a chi-squared test

Abbreviations: *HCP* health care practitioner; *abPG-SGA* abridged patient generated-subjective global assessment; *SaskIBD-NR* Saskatchewan IBD- Nutrition Risk; *MUST* Malnutrition universal screening tool; *CNST* Canadian nutrition screening tool.

4.5 Secondary Objective2: Prevalence and Predictive Factors of Malnutrition

Table 5 shows the results obtained for the dietitian-administered nutritional assessment. The mean BMI was 26.4 ± 5.5 kg/m^2, of which 7 patients (3.4 %) were underweight, 83 (40.7 %) were normal, 114 (56 %) were overweight and obese (37.3% overweight; 18.6% obese).

Of the 204 IBD patients who underwent nutritional assessment, 18% had SGA grade B or C. BMI was below 18.5 kg/m^2 in 3% of patients, while 22% of the patients had MAMC below the 10th percentile, and 31% had HGS below the 5th percentile, according to sex and age **(Table 5)**. Fifty-one percent of the patients met at least one criteria for malnutrition. Across tools, the prevalence of malnutrition was higher in patients with UC compared to CD, however the difference was not statistically significant.

Table 5 Values obtained in the dietitian-administered nutritional assessment according to the different methods employed

Parameters	IBD (n = 204)	CD (n = 103)	UC (n = 73)	*P*-value[†]
Height[‡], *cm*	170.6 ± 9.8	170.9 ± 10.3	170.2 ± 8.8	0.609
Weight[‡], *kg*	77 ± 17.5	76.6 ± 17	77.8 ± 18.5	0.646
BMI[‡], *kg/m^2*	26.4 ± 5.5	26.2 ± 5	26.8 ± 6	0.406
Nutritional assessment methods, *n (%)*				
SGA (B + C)	37 (18.1)	20 (15.3)	17 (23.3)	0.109
BMI (<18.5 kg/m^2)	7 (3.4)	4 (3.1)	3 (4.1)	0.487
MAMC (< 10th % tile)	44 (21.6)	25 (19.1)	19 (26)	0.164
HGS (< 5th % tile)	63 (30.8)	39 (30.5)	23 (31.5)	0.408

[†]*P*-values represent differences between subgroups Crohn's and UC only.

[‡]Data are presented as mean ± standard deviation. [a] 2 missing data; [b] 1 missing data

Abbreviations: *BMI* body mass index; *SGA* subjective global assessment; *MAMC* mid-arm muscle circumference; *HGS* handgrip strength.

When defined by SGA, on multivariate analysis, the independent predictors of malnutrition were disease activity and sex, male gender being protective. Male gender and lower BMI increased the risk of having an abnormal MAMC. Male gender and >10% weight loss in the last 6 months increased the risk of having an abnormal HGS.

Malnourished participants identified by SGA and MAMC were more likely to have a lower BMI than those who were well nourished (p = 0.044 and 0.003, respectively), but there was no association in those diagnosed using HGS.

The result of univariate and multivariate analyses of the risk factors predicting malnutrition using SGA, MAMC and HGS are summarized in **Table 6**. In univariate analysis, all variables including age, sex, IBD type, smoking and alcohol intake status, history of hospitalization and abdominal surgery, severity of disease, BMI, consumption of supplements, IBD medications, weight loss, food restriction, and presence of gastroenterology symptoms were tested and those variables with statistically significant association in the univariate analysis were presented in the table. A potential limitation of this section is that we may be underpowered to have 6 variables be statistically significant on the multivariable analysis. This needs to be confirmed in subsequent studies.

Table 6 Unadjusted and adjusted odds ratio in univariate and multivariate analyses for the predictors of abnormal malnutrition assessment in IBD patients

	Univariate analysis		Multivariate analysis[†]	
Risk factors	OR (95% CI)	*P*-value[‡]	OR (95% CI)	*P*-value
SGA				
Age	1.032 (1.009-1.056)	0.007	1.023 (0.993-1.054)	0.142
Sex (male)	0.309 (0.141 - 0.679)	0.003	0.360 (0.139 – 0.930)	0.035*

Hospitalized for IBD in past 12 months	2.896 (1.309 - 6.408)	0.009	2.629 (0.954 - 7.250)	0.062
History of abdominal surgery	2.875 (1.056 – 7.823)	0.039	1.579 (0.482 – 5.167)	0.451
BMI	0.923 (0.853 – 0.998)	0.044	0.919 (0.844 – 1.001)	0.052
Disease activity	4 (1.474 – 10.858)	0.007	2.760 (1.924 – 8.239)	0.045*
MAMC				
Sex (male)	3.066 (1.494 – 6.293)	0.002	4.163 (1.895 – 9.145)	< 0.001*
BMI	0.844 (0.773 – 0.922)	< 0.001	0.814 (0.737 – 0.899)	< 0.001*
HGS				
Sex (male)	1.702 (1.205 – 8.848)	0.013	2.003 (1.247 – 8.869)	0.017*
>10% weight loss in past six months	7.891 (1.306 – 39.027)	0.012	7.532 (1.443 – 39.036)	0.017*

[†]In the multivariate analysis, all variables including age, sex, IBD type, smoking and alcohol intake status, history of hospitalization and abdominal surgery, severity of disease, BMI, consumption of supplements, IBD medications, and weight loss symptoms were tested and those variables with statistically significant association in the univariate analysis were presented in the table.

[‡] Only those risk factors with a significant association with malnutrition were presented in the table.

Abbreviations: *BMI* body mass index; *SGA* subjective global assessment; *MAMC* mid-arm muscle circumference; *HGS* handgrip strength.

CHAPTER 5: DISCUSSION

We are aware of only two published studies which have evaluated the self-screening tools in IBD – both studies utilizing the MUST. These studies focused on feasibility and reliability of the patient-led MUST compared to a HCP-led MUST (18, 19). The present study is the first to examine the validity of patient-led self-screens compared to a dietitian-administered nutritional assessment for identifying the risk of malnutrition in outpatients with IBD. Our results suggest that the patient-led abPG-SGA and SaskIBD-NR are valid and accurate tools in detecting patients at risk of malnutrition. We also present novel data around the inter-rater agreement between the patient-led and HCP-led screening tools, as well as the prevalence and predictive factors of malnutrition (based on nutritional assessment tools) in our study population.

5.1 Validity of Self-Screens Compared to Dietitian-Administered Nutritional Assessment

For any screening and diagnostic tool, a compromise between sensitivity and specificity is observed. As discussed above, nutritional screening is the initial approach for detecting nutrition risk, thus, a screening tool ideally optimizes sensitivity; and further nutritional assessment goes on to confirm the diagnosis of malnutrition. In regard to our primary objective, we determined that the patient- and HCP-led abPG-SGA and SaskIBD-NR can accurately detect malnourished or at risk of malnourished patients with good sensitivity and specificity compared to dietitian-administered nutritional assessment. The sensitivity was only fair to negligible for patient-led and HCP-led MUST and CNST in our study population.

To our knowledge, there are no previous reports in the literature evaluating the implementation of abPG-SGA in an IBD population. Existing data in other clinical populations report an excellent sensitivity (93.8%) and good specificity (78%) for detection of malnutrition in oncologic patients in an outpatient setting (17). Similar finding was made in other study in chemotherapy outpatients, reporting high sensitivity (80.4%) and

specificity (72.3%) of abridged version of PG-SGA for evaluating nutrition risk compared to full version of PG-SGA undertaken by accredited practicing dietitian in Australia (130).

In this study both patient and HCP-led abPG-SGA showed a high sensitivity of 89% and specificity of 72% and 75%, respectively. This high predictive value is likely related to the comprehensive evaluation that the abPG-SGA provides – including not only important information on specific symptoms that can adversely affect food intake (2, 120) but also a patient's functional status and activities. In addition to providing a nutrition screen, this information is of practical value for providing solutions to barriers to intake in the overall development of an appropriate nutrition care plan. Why did the abPG-SGA not detect all patients (ie) why was the sensitivity not 100%? On looking at the data, we suspect this may be related to the way that the question regarding symptoms was worded in the abPG-SGA – it asks for symptoms that affect food intake. Of the 37 patients who were not picked up as being malnourished by the abPG-SGA (but were found to be malnourished by the dietitian led SGA assessment), 9 of them did not mark any abnormalities in the section related to the symptoms affecting food intake (e.g. diarrhea, nausea, vomiting, etc.). On dietitian questioning, 25 of these patients had symptoms. Therefore, although these symptoms may not have kept the patient from eating, they can still cause malabsorption and then accelerate malnutrition in this patient population (8, 20).

In the second position, the SaskIBD-NR tool was suggested as an acceptable self-screening tool for malnutrition assessment in IBD population with satisfactory predictive validity (self-screens: 68% sensitivity and 75% specificity; HCP-led screens: 70% sensitivity and 81% specificity). This finding was consistent with result of previous work by Haskey et al reporting sensitivity of 82.6% and specificity of 97.7% compared to the registered dietitian and gastroenterologist assessment (99). We hypothesize that the high sensitivity and specificity can be attributed to two important components of this IBD-specific screening tool – the scoring of GI symptoms and food restriction in this population. Food restriction and specific avoidance of food are very common in IBD patients and multiple studies discussed this issue in IBD which can lead to malnutrition (35, 53, 114). In our study, 57% of malnourished patients had been restricting a certain food or food group from their diet

and 70% had experienced one of the GI symptoms for greater than two weeks. Food restriction is not a part of the other screening tools. Uniquely therefore, the SaskIBD-NR tool by considering these parameters was able to detect malnutrition risk with better sensitivity and specificity compared to MUST and CNST that do not take these factors into account.

We found a poor sensitivity (51%) but high (86%) specificity for patient-led MUST screening compared to dietitian-nutritional assessment. There is no previous IBD study examining the validity of patient- led MUST compared to dietitian assessment. However, in studies conducted in other patient populations with acute conditions, MUST showed high sensitivity and specificity compared to assessment methods. In a study in a radiation oncology setting, a high predictive value (80% sensitivity and 89% specificity) was found for MUST with a relatively high capacity to effectively detect patients at nutritional risk in this population (131). Similarly, another study in patients undergoing cardiac surgery, MUST showed high sensitivity of 74% compared to low FFMI measured using BIA (133). The poor sensitivity of patient-led and HCP-led MUST in IBD studies may be related to the value of BMI reported in these patient population. Of the 43 patients who were not classified themselves as a at moderate/high risk of malnutrition by the MUST (but were found to be malnourished by the dietitian led SGA assessment), 24 (84%) of them had "normal" or "overweight/obese" BMI. Therefore, MUST misclassified these patients as not at risk of malnutrition, and they might not refer for further assessment and their poor nutritional status would be masked by their normal or overweight/obese BMI. Hence, the MUST might not be a sensitive and that since we had a high proportion of obesity, this may present some limitations for our group of patients.

Another possible reason for the fair sensitivity could attributed to a small number (11/43; 26%) of our patients who were at risk of malnutrition assessed by MUST, answering "they are acutely ill and would not be able to have nutritional intake for more than 5 days". None of these patients scored positive for this question during the dietitian assessment. This is consistent with the result of a study in gastroenterology outpatients assessing the

practicality of a self-screening MUST versus screening undertaken by a trained health professional (15). The situation of no food intake for more than 5 days is unlikely to apply to non-hospitalized patients. In addition, as the patient should have both conditions (being acutely sick and no or low food intake for more the 5 days) in order to be scored positive, the likelihood of this in outpatients is very low.

CNST is a two-question screening tool evaluating patient's recent weight loss and reduced food intake. In the present study, we found very low sensitivity and specificity between patient-led and HCP-led CNST and dietitian-administered assessment. There is no previous study used this screening tool in IBD outpatients. The only study conducted in hospitalized patients (30% of patients recruited from a GI ward) reporting good sensitivity (91.7%) and specificity (74.8%) between two groups of interviewers (untrained nursing personnel and diet technicians) (81). We hypothesize this discordance may be attributed to two reasons. First, CNST is mainly developed for an inpatient setting, and since our study population was outpatients, and the majority of them (88%) were in remission or had mild disease activity they might not present severe weight loss or poor eating at the time of screening. Therefore, CNST may not be sensitive to measure the small magnitude of changes observed in outpatients. Accordingly, the majority of malnourished patients were misclassified as well-nourished according to this screening tool (26/75 (70%) of patients). In the present study, the screening tool was compared to dietitian administered nutritional assessment methods to make sure that those who identified as malnourished or at risk of malnutrition were accurately diagnose with malnutrition; however, in the previous work by Laporte et al (81), both diet technician and untrained nursing personnel conducted the same screening and did not compare their results with nutritional assessment (81).

Each of the tools used for screening for malnutrition in the current study has potential benefits and limitations in an IBD outpatient population. The abPG-SGA is an accurate and simple screening tool for detecting malnutrition risk in IBD outpatients. One important advantage of this tool is that the presence of symptoms affecting food intake particularly diarrhea, poor appetite, abdominal pain are very common in patients with IBD and can

adversely affect patient's nutritional status (35, 37). Our findings above suggest that this specific series of question may benefit from some modification as it refers to the influence of symptoms on intake, not just the presence of symptoms alone. This hypothesis requires testing in a larger group of patients. An important advantage of the abPG-SGA tool is that the patient's physical activity is taken into account. Existing data demonstrates an inverse association between physical activity and the development of IBD, suggesting a protective role of physical activity for IBD-related diseases (134, 135). A possible limitation of the abPG-SGA is that it only scores weight change (as opposed to BMI) in its grading system and has no compensatory measures for already underweight patients upon screening. Thus, if one compares a morbidly obese patient with identical symptoms and relative weight loss to a patient who is already underweight, these patients could obtain similar scores (88, 136). However, due to high correlation between the percentage of weight loss and risk of malnutrition and clinical outcomes (137, 138), this disadvantage may be covered by other aspects of the screening. Moreover, the high sensitivity and specificity of the abPG-SGA indicates that it strongly predicts patient's nutritional status as defined by nutritional assessment methods.

The SaskIBD-NR tool is another screening tool which showed an acceptable predictive value in IBD outpatients. One of the unique features of this IBD-specific screening tool is the presence of questioning about food restriction on its evaluation. Prolonged restricted diets are prevalent in IBD and associated with malnutrition (139, 140). The question regarding to GI symptoms is similar to the abPG-SGA but is not limited to symptoms that affect intake. The SaskIBD-NR tool has the same potential limitation as abPG-SGA mentioned above regarding the use of percentage of the weight loss instead of current weight/BMI in order to capture patients with a very low BMI at baseline.

Two other screening tools employed in the study, MUST and CNST, were associated with suboptimal sensitivity for screening patients for risk of malnutrition. This finding may be explained by the nature of population we were screening - outpatient clinical setting in which the majority of patients were in remission or had mild disease activity. The MUST

and CNST screens have been shown a better predictive value in inpatients where magnitude of symptoms and weight change much larger (81, 86, 102, 131). Thus, in our study were not as sensitive.

5.2 Inter-rater reliability between Self-Screens and HCP-led Screens

In regard to our secondary objective, the present study showed that IBD outpatients were able to self-screen by using abPG-SGA, SaskIBD-NR, MUST and CNT, with minimal instruction from the HCP. All self-screens (abPG-SGA, MUST, SaskIBD-NR and CNST) used in the present study had a moderate inter-rater agreement (κ = 0.6, 0.59, 0.51, and 0.49, respectively) with HCP-led screening. The presence of a good to moderate rate of agreement demonstrates that both patients and HCPs without specific nutrition knowledge were able to correctly interpret the questions in the same way as each other, probably reflecting that the questions were user-friendly, clear and interpretable by non-healthcare professionals.

Among the employed self-screening tools in the current study, only MUST has been previously studied in IBD population (18, 19, 99). Compared to previous studies, our result is similar to that found in British study (19) reporting a moderate level of agreement (κ = 0.486) between patient-led and HCP-led MUST in IBD outpatients. However, our results showed a lower level of agreement than the excellent agreement (κ = 0.83) previously reported by Sandhu et al (18) in outpatients with IBD. Both abovementioned studies were conducted in same clinical settings (academic IBD outpatient clinics) as the present study with similar study design; however, we acknowledge that our patient-led self-screening processes were different than the published study by Sandhu et al. In our cohort more than 40% of patients used estimated weight in their self-evaluation. This highly depends on memory and might not represent their accurate and actual weight in the day of assessment. In the Sandhu study patients were provided with electronic weight scale in their clinic room so they completed the MUST using actual measured weight. In Keetarut study, authors did not mention if providing a weight scale for the patient-led screening process.

SaskIBD-NR tool is a newly developed screening tool for IBD outpatients. There is only one study which utilized this tool and reported a significant agreement ($\kappa = 0.83$) between the screening tool and registered dietitian/gastroenterologist assessment (99). We found a moderate agreement between this tool and HCP-administered screening. The minor discrepancies may be because in our study, 8 out of 26 (31%) of patients who scored themselves for the first question of SaskIBD-NR tool (Have you experienced nausea, vomiting, diarrhea or poor appetite for greater than two weeks?), did not score positive for this during either HCP screening or dietitian assessment. One possible reason could be that these patients had been experiencing some of these symptoms but for shorter than two weeks, as came out during the dietitian assessment.

Although there is a lack of evidence on examining the inter-rater agreement between two raters (patient, HCP or dietitian) using abPG-SGA and CNST in the IBD population, studies in other populations reported a good inter-rater agreement using these tools. In an Australian study in 189 adult hospitalized patients, sixteen dietitians showed good inter-rater reliability using PG-SGA (intraclass correlation coefficient = 0.901; p <0.001) (141). The study that first defined and used CNST in hospitalized patients reported an excellent agreement ($\kappa = 0.78$) between CNST administered by untrained nursing personnel and diet technician (81).

Taken together, the self-screens showed a moderate agreement with the HCP-led screens with better predictive value through HCP screening when comparing with dietitian assessment. This could be due to an error in self-reported weight and height through self-screening, while the HCP measured patient's actual weight and height and used in their evaluations. We recommend the clinic staff or the patient measure the patient's height and weight in clinic and utilize those readings for the screen.

5.3 Prevalence of Malnutrition in IBD

There is unfortunately no standardized definition of malnutrition, not only in IBD but also in broader literature. This is evident from the varied range of definitions and methods available in the literature (33, 78, 108). One of the secondary assessment tools used to define malnutrition in our study population was BMI. The prevalence of malnutrition based on BMI cut-off of < 18.5 kg/m^2 was low at only 3%. This finding is almost the same as previous reports using BMI to define the prevalence of malnutrition in IBD patients in remission (114, 115, 142). Although BMI is a simple tool used as an indicator of chronic protein-energy status (143), a BMI based definition of malnutrition has limitations, even in broader population of non-IBD patients (144, 145). BMI cannot accurately assess the muscle mass/function which is the most objective evaluation of malnutrition assessment (112, 146). Also, unless it is very low, BMI alone is not sufficient to determine the malnutrition because even with a "normal" or "overweight/obese" BMI, muscle mass can be abnormal (147). In our study, 41 (20.8%) and 58 (29.4%) out of 197 patients with BMI ≥ 18.5 kg/m^2 were classified as having abnormal low muscle mass (MAMC) and low grip strength (HGS), respectively. We also found that 84% of patients with normal or overweight/obese BMI were malnourished through dietitian assessment (SGA), which is consistent with Aydin et al (144) who showed that a patient can be malnourished even when the BMI is in normal range and that the SGA can identify malnutrition before the BMI drops below 20 kg/m^2. For this reason (unless it is very low), it is advisable not to use the BMI alone to evaluate a patient's nutritional status.

We know the prevalence of obesity is increasing in society (148). Obesity is also becoming increasingly prevalent amongst patients with IBD (149). A systematic review on body composition in patients with IBD reported that many IBD patients had disturbances in fat mass and lean mass compared to healthy matched population, despite only 5% being underweight by BMI criteria (150). In a study in IBD patients, malnutrition was mainly associated with loss of body mass cell without any impact on BMI but accompanied by further muscle mass depletion (151). Multiple studies in adult and children with IBD have reported that BMI does not correlate well with lean mass, even in remission (115, 152,

153). Thus, as discussed above, using BMI alone can mask underlying muscle abnormalities and patients with normal and overweight/obese BMI may be incorrectly classified as being well nourished, and not referred to a dietitian for further malnutrition assessment and intervention (154).

The SGA is a simple method used to detect malnourished patients that utilizes subjective parameters in its evaluation, correlates well with nutritional intake, percentage of weight loss and severity of the underlying medical and surgical conditions, and predicts hospital related complication and prolonged LOS (96, 155). SGA was considered our primary malnutrition assessment measure. In our study population, 18% of IBD patients were classified malnourished according to SGA grade B or C. This result is similar to previous work by Bin et al. (115) who performed SGA assessment in CD patients in clinical remission. A recent Spanish study in an IBD outpatient setting found a malnutrition prevalence rate of 7% based on SGA (114) which was lower than the value obtained from our results. On the other hand, a study conducted in hospitalized patients reported that 37.5% of CD patients were severely malnourished according to SGA (94). This discrepancy can be due to differences in the clinical setting and underling patient factors including severity of disease and comorbidities. Multiple studies reported a high correlation between the SGA and other measures of nutritional status assessments that are felt to be more objective such as anthropometric parameters (BMI and weight loss), serum albumin and total protein (155-157) and an adequate intra- and inter-observer reliabilities in identifying those patients who were subsequently found to be malnourished by the SGA (158-160). The subjective nature of the SGA may be a disadvantage. Objective assessment methods even done at baseline or that consider changes in body composition and muscle function may give a better understanding of the patient's nutritional status, used alongside SGA evaluation (161, 162). However, a recent study showed a significant correlation between SGA and SMI in IBD patients (95). Further analysis is required to see if the addition of muscle mass/function measures are superior to or may improve the ability of the SGA to predict clinical outcomes.

In the literature, MAMC has been suggested as a reliable indicator of nutritional status and an important measure of skeletal muscle mass due to its good correlation with creatinine-height index, and grip strength and its predictive ability for postoperative complications (RW.ERROR - Unable to find reference:1079). In the present study, 22% of IBD patients were classified as malnourished based on MAMC below the 10th percentile. This finding was lower than the prevalence of malnutrition in previous studies of 29% of CD patients in clinical remission (115) and in another study, 42.5% of CD and 22.1% of UC outpatients (128). This contrast may be attributable to the mean value of TFS (19 ± 4.7 cm) and MAC (32 ± 4.5 cm) - two components of MAMC calculation - reported in our study which were higher than those values found in the previous studies (115). Anthropometric measurements such as TSF, MAC and MAMC also have their limitations for the assessment of body composition given their reliance on operators to carry these out (161, 164).

The HGS is a validated, non-invasive and practical clinical method for the measurement of muscle function (113, 163, 165). Consistent with a study of Crohn's patients in clinical remission reporting HGS as a more sensitive tool than other methods for detecting clinical nutrition outcomes (115), our study also found that the patients were more likely to be labeled as malnourished (31%) when assessed by the HGS below 5th percentile (115). Why the increased prevalence as compared to the other assessment tools? Several studies have identified muscle performance measures as more sensitive for the detection of muscle abnormalities than muscle mass assessment (112, 113, 166). Within the clinical chain of malnutrition, muscle function is affected earlier than muscle mass. Lopes et al (167) reported specific abnormalities in skeletal muscle function including an increased muscle fatigability and an altered pattern of muscle contraction and relaxation in patients with malnutrition, greater than the loss of muscle mass over the course of study. Moreover, a short-term starvation in obese, healthy women showed a significant lower HGS, slowing of the maximal relaxation rate and decrease muscle force, while no measurable changes observed in anthropometric indices including estimated body fat mass and creatinine-height index which is generally associated to the muscle mass (168). There are limitations to the handgrip strength including limited consensus on protocols for measurement such as

posture, allowance for hand size and dominance, joint position, frequency of testing and time of day, and training of the assessor. Moreover, inconsistencies in the use of maximum or mean value of handgrip strength as a summary measure limit comparison of results between studies (RW.ERROR - Unable to find reference:1080). Taken together, muscle strength measures being more sensitive than muscle mass measures through early reflection of nutrition deprivation, before changes in body composition parameters can be detected (169, 170).

In the present study, a higher but not statistically significant difference in the prevalence of malnutrition was observed between patients with UC and CD. Previous studies on prevalence of malnutrition in IBD population reported discordant results; some studies in outpatient settings have shown that malnutrition was more common in CD patients than UC (13, 128, 142); whereas other indicated a similar prevalence of malnutrition in patients with UC and CD (11, 151). One possible reason for this discrepancy can be attributed to each study using different definitions and assessment methods to define malnutrition in their populations. Generally, we expect a higher rate of malnutrition in CD patients on the whole, assuming that the small bowel involvement with impaired absorptive function and intestinal loss of nutrients will have a greater impact on patient's nutritional status (54, 171, 172). We believe that the non-significant higher prevalence of malnutrition in UC patient than CD found in our study was most likely due to the CD population being younger and consuming more supplements, with fewer comorbidities than UC patients, results similar to those shown by Neguyen et al (11) reporting that their UC population was older and with more comorbidities.

Taken together, it has been shown that muscle function is a sensitive indicator of nutritional status in patients, as functional changes occurs before abnormalities in body composition and anthropometric indices of malnutrition are observed. In outpatients with IBD mainly in remission or with mild disease, the BMI showed the lowest number of malnourished patients (3%), and HGS the highest number of patients with compromised nutritional status (31%). Give the subjective nature of SGA, in future work we will evaluate whether the

addition of an objective, sensitive and easy-to-use tool such as HGS improves the prediction of clinical outcomes in IBD.

When malnutrition is diagnosed, the first recommendation is to optimize oral nutrition supplementation. In the lack of sufficient oral feeding, enteral and parenteral nutrition should be considered as supportive therapies. To choose an optimal route of nutrition support in IBD patients, several factors should be evaluated including the patient's ability to eat liquid and solid food, patient's nutritional status, the absorptive capacity of GI tract and the main therapeutic goals for nutrition support including supportive care, management of malnutrition and indication or maintenance of remission (78). According to the ESPEN guideline, in IBD outpatients - the majority of patients in remission or with mild disease activity do not require a specific diet. There is some evidence to support a Mediterranean-style diet rich in vegetable fibre and fruit (provided there are no known strictures) (20). For those IBD patients with sarcopenia or features of sarcopenia (diminished muscle mass, strength and /or performance), the guideline recommends prescribing adequate protein intake, in addition to exercise (20, 173).

5.4 Predictors of Malnutrition in IBD

In present study, we found that the low HGS and decreased MAMC in our study population was associated with male sex and severe weight loss in the past six months. Several previous studies in IBD patients found that male sex has been associated with reduced muscle strength and disturbed body composition (174-176). In one study of IBD patients within 6 months of diagnosis, Geerling et al (174) found a deterioration of body composition largely in male patients with UC compared with healthy controls. This data was in line with the previous work in which low body fat and muscle strength measured by both DXA and anthropometry was found in male patients with long-standing CD in remission (176). In another cross-sectional study in 137 patients with IBD recruiting from both inpatient and outpatient settings, male patient showed altered body composition profile and were more sarcopenic compared to female patients (18% *vs.* 5%) (177). One plausible mechanisms for a higher prevalence of low muscle mass and strength can be

explained by the higher rate of comorbidities in male patients compared to female. Previous studies showed that a presence of an underlying medical illness such as diabetes, stroke, hypertension, dyslipidemia and heart disease was associated with decreased muscle mass and strength (178, 179). In the present study, we found that the male patients with IBD had more hypertension (20.8% *vs.* 8.7%), dyslipidemia (8.9% *vs.* 6.8%), and diabetes (3% *vs.* 1%) compared to female patients. Other possible explanations for the sex differences in muscle mass and function may be sex-related biological differences including hormonal effects, immune system responses, genetic factors, physical function and muscle capacity (173, 180-182). However, the main mechanism of this sex differences in muscle mass and strength has not been fully understood.

We also showed that the prevalence of malnutrition assessed by the SGA was associated with female sex and severity of disease independently of age, BMI, history of hospitalization and abdominal surgery. Interestingly, the SGA assessment showed a completely contrary result with the abovementioned results. Indeed, males were at lower risk of being classified malnourished by the SGA. Similarly, Valentini et al (151) demonstrated that female patients with UC seemed to be more malnourished according to SGA, BMI and plasma albumin value. The possible reason for this disagreement might be due to the subjective nature of the SGA which limits the assessment to the questions provided in this tool. As well, it is possible that muscle mass and muscle function may have greater sensitivity value in male patients. This requires further evaluation. Our result showed that the female patients had more moderate/severe disease activity (16% *vs.* 8%; *p* value = 0.048) and presented higher GI symptoms affecting food intake (diarrhea: 26% *vs.* 16%, *p* value = 0.048; nausea: 20.4% *vs.* 6.9%, *p* value = 0.004; anorexia: 25.2% *vs.* 15.9, *p* value = 0.04) compared to their male counterparts. Moreover, the female patients reported significantly lower food intake (35% *vs.* 15.8%; *p* value = 0.001) and decrease appetite (28.2% *vs.* 10.9%; *p* value = 0.002) compared to the male IBD patients. Therefore, the female patients were scored for change in food intake, change in appetite, and gastrointestinal symptoms in the SGA through dietitian assessment. However, further research should be performed to contribute to a better understanding of malnutrition assessment in IBD population.

5.5 Future Directions

In the current study we also collected data on cross-sectional imaging with CT in this patient population as a potential gold standard for nutritional assessment. Future studies will compare the screening tools to that as well as to clinical outcomes such as hospitalization, need for surgery and survival rate. Longitudinal studies with more patients in both inpatient and outpatient settings are needed to study the validity of nutritional self-screens in patients, so that the real significance of these results are confirmed. In addition, given the compromised body composition and nutritional status of IBD patients, high quality interventional studies with assessment of sarcopenia and malnutrition on other clinical outcomes are required. Although further work is required, given the impact of malnutrition on this population, nutrition education should be adopted and encouraged with the goal of preventing or modifying nutritional deficiencies and improving clinical outcomes.

5.6 Strength and Limitation

The strength of this study include the use of multiple nutrition screening and assessment methods to identify malnutrition by examining different aspects of patient's nutritional status.

The present study also had some limitations that should be acknowledged. One of these limitations was that the results may not be applicable to the entire group of IBD outpatients because we were unable to assess whether the nutritional status of those patients who participated in the study was different from that of those who did not, which introduces sample bias. In the current study, 140 out of 344 IBD outpatients did not meet the inclusion criteria, declined to participate or did not complete the study survey demonstrated selection bias. In addition, the study population was limited to two quaternary care centers with focused IBD outpatient clinics which does not cover the vast majority of GI practices across Alberta. It remains to be seen whether these tools will have similar test characteristics in a more expanded population of patients. This will require further

evaluation. The other limitation was that we were not able to record the time and patient preferences to complete self-screens in our study, which may play an important role in choosing an appropriate screening tool in busy outpatient settings.

5.7 CONCLUSION

Given the increasing prevalence of malnutrition in IBD patients, self-screening could help prevent malnutrition and its consequences by detecting patients who are malnourished or at risk of malnutrition and in need of intervention. Indeed, considering that IBD predisposes patients to malnutrition through multiple mechanisms, outpatient clinics propose an important opportunity to bridge the gap between achievable and potential benefits of malnutrition screening in this population. In the present study the abPG-SGA and SaskIBD-NR are promising nutrition screening tools in patients with IBD. They are accurate and valid and can be completed by patients in the waiting room. With the high sensitivity and high negative predictive value for malnutrition detection, the majority of patients who screened at risk of malnutrition would be appropriately referred for further assessment. Future validation and implementation studies will allow us to integrate these tools into routine IBD nutrition screening.

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APPENDICES
Appendix 1 (A1): Information Sheet and Consent Form

UNIVERSITY OF ALBERTA

Division of Gastroenterology
Department of Medicine

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INFORMATION SHEET

THE VALIDITY OF PATIENT-LED SELF-SCREENS FOR IDENTIFYING MALNUTRITION IN IBD

INVESTIGATORS:

P. Tandon, MD, FRCPC	U of A,	Division of Gastroenterology	492-9844
M. Ma, MD, FRCPC	U of A,	Division of Gastroenterology	
T. Eslamparast, MSc	U of A,	Division of Gastroenterology	492-9844
K. Kroeker, MD	U of A,	Division of Gastroenterology	
A. Montano-Loza MD	U of A,	Division of Gastroenterology	
R. J. Bailey, MD	RAH,	Division of Gastroenterology	

BACKGROUND: Many people with inflammatory bowel disease are malnourished. This can lead to poor clinical outcomes, including worsened disease control, weakness and an increased risk of death. Although we believe this is important to do, we do not currently have a system in place to screen all patients with inflammatory bowel disease for malnutrition. In other patient populations, a malnutrition "self-screen" – a short questionnaire completed by a patient provides an accurate assessment of malnutrition risk. The purpose of this study is to compare the data gathered from these short patient-led "self-screens" to a nutrition assessment performed by a health care practitioner. In addition we will be getting simple measures of your arm muscle mass and hand-grip strength to see if these improve our ability to assess malnutrition.

DESCRIPTION OF THE STUDY: You have been asked to be in this study because you have a history of inflammatory bowel disease and you are currently being seen in the IBD clinic. If your doctors decide that you meet the inclusion criteria for the study, we will approach you to review this information sheet with you and determine if you would be willing to participate. If you decide to participate, we will take 5 minutes to go through this consent form and answer any questions you have. For another 10-15 minutes we will ask you to fill out four short nutrition "self-screening" questionnaires and do a nutrition screening and assessment on you including a measure of your muscle mass in your arm using a tape measure and a measure of your muscle strength using a hand-grip tool. Participation in this study will not interfere with your treatments.

RESEARCH PROCEDURES

Testing will be carried out on one day only.

We will perform the following tests on you at the University of Alberta Hospital or the IBD clinic, depending where you are being seen in clinic or admitted.

Test Day 1.

Nutritional status evaluation:

1) Ten minutes nutrition self-screens to assess your nutrition status – abridged Patient-generated subjective global assessment (abPG-SGA), the Malnutrition Universal screening tool (MUST), the Canadian Nutrition Screening Tool (CNST) and the Saskachwen IBD-Nutrition Risk (SaskIBD-NR).
2) Your height and weight will be measured
3) Five minutes nutrition screens performed by the health care practitioner - Doing all of them will allow us to compare which is the most accurate. These include the abPG-SGA, MUST, CNST and SaskIBD-NR.
4) Testing hand-grip strength using a tool that you squeeze with your hand
5) Ten minutes nustritional assessment administered by a dietitian – Subjective global assessment (SGA)
6) Circumference of your upper arm taken using a tape measure
7) Triceps Skinfold Thickness of your upper arm to assess how much fat tissue you have in your arm

We will get information about your disease severity, your medications, when you had your last CT scan or MRI of the abdomen (so we can assess muscle mass based on that) and your clinical outcomes from your electronic medical health records including Netcare.

POSSIBLE BENEFITS: This study will help us to identify a quick and acceptable tool to screen our patients with inflammatory bowel disease for malnutrition. It will also allow us to identify the relationship between nutritional status and important clinical outcomes. The information gathered may allow us to improve our care of our patients. You may not personally derive benefit by participating in this study.

POSSIBLE RISKS: There are no risks to the nutritional assessment measures (height, weight, arm and leg circumference measurements, triceps skinfold thickness, hand-grip strength). It is not possible to know all of the risks that may happen in a study, but the researchers have taken all reasonable safeguards to minimize any known risks to a study participant.

Do I have to take part in the study?: Being in this study is your choice. If you decide to be in the study, you can change your mind and stop being in the study at any time, and it will in no way affect the care or treatment that you are entitled to.

What happens if I am injured because of this research: If you become ill or injured as a result of being in this study, you will receive necessary medical treatment, at no additional cost to you. By signing this consent form you are not releasing the investigator(s), institution(s) and/or sponsor(s) from their legal and professional responsibilities.

CONFIDENTIALITY: During the study we will be collecting health data about you. We will do everything we can to make sure that this data is kept private. No data relating to this study that includes your name will be released outside of the study doctor's office or published by the researchers. Sometimes, by law, we may have to release your information with your name so we cannot guarantee absolute privacy. However, we will make every legal effort to make sure that your health information is kept private. The study doctor/study staff may need to look at your personal health records held at the study doctor's office, and/or kept by other health care providers that you may have seen in the past (i.e. your family doctors). We will also access your electronic medical records to collect some additional health information about you. Any personal health information that we get from these records will be only what is needed for the study. During research studies it is important that the data that we get is accurate. For this reason, your health data, including your name, may be looked at by people from the University of Alberta. By signing this consent form you are indicating that you are giving your permission for the study doctor/staff to collect, use and disclose information about you from your personal health records as described above. After the study is done, we will still need to securely store your health data that was collected as part of the study. At the University of Alberta, we keep data stored for 5 years after the end of the study. If you leave the study, we will not collect new health information about you, but we will need to keep the data that we have already collected

CONTACTS: Please contact the following investigator listed below if you have any questions and concerns. P. Tandon, MD FRCP(C) (492-9844).

If you have any questions or concerns about your rights as a pariticpant, or how this study is being conducted, you may contact the University of Alberta's Research Ethics Office at 780-492-2615. This office has no affiliation with the study investigators.

CONSENT FORM

THE VALIDITY AND ACCEPTABILITY OF PATIENT-LED SELF-SCREENS FOR IDENTIFYING MALNUTRITION IN IBD AND CIRRHOSIS

INVESTIGATORS:

P. Tandon, MD, FRCPC	U of A,	Division of Gastroenterology	492-9844
M. Ma, MD, FRCPC	U of A,	Division of Gastroenterology	
T. Eslamparast, MSc	U of A,	Division of Gastroenterology	492-9844
K. Kroeker, MD	U of A,	Division of Gastroenterology	
A. Montano-Loza MD	U of A,	Division of Gastroenterology	
R. J. Bailey, MD	RAH,	Division of Gastroenterology	

1) Do you understand that you have been asked to be in a research study? Yes No

2) Have you read and received a copy of the attached Information Sheet? Yes No

3) Do you understand the benefits and risks involved in taking part in this research study? Yes No

4) Have you had an opportunity to ask questions and discuss this study? Yes No

5) Do you understand that you are free to refuse to participate or withdraw from the study at any time? You do not have to give a reason and it will not affect your care. Yes No

6) Has the issue of confidentiality been explained to you? Do you understand who will have access to your health records including personally identifiable health information? Yes No

7) Do you want the investigator to inform your family doctor that you are participating in this research study? If so, please provide your doctor's name: _____ Yes No

Who explained this study to you? _____

I agree to participate in this study. Yes No

_____ _____

Signature of Research Participant Date of Signature

_____ _____

Printed Name Printed Name

I believe that the person signing this form understands what is involved in the study and voluntarily agrees to participate.

_____ _____

Signature of Investigator or designee Date of Signature

Appendix 2 (A2): General Data Collection Sheet

A 2-1 Demography and Clinical Data Sheet

Title of Project: The validity of patient-led self-screens for identifying malnutrition in IBD

Principal Investigator: Dr. Puneeta Tandon MD Phone: 780 492 9844

Co-Investigator(s): Dr. Karen Kroeker MD

Research coordinator: Tannaz Eslamparast, MSc

Baseline Data Collection Sheet - IBD

Patient General Information **Study ID: _____**

Patient Name	_____ _____ _____ First Last M.I.
Gender	[ ] Male [ ] Female
Date of Birth	_____/_____/_____ Year /Month /Day
Date of Baseline Visit	_____/_____/_____ Year /Month /Day

Patient Comorbidity Information:

Heart attack / MI	[ ] Yes [ ] No **If YES,** Date (if known):
Prior angioplasty or stent	[ ] Yes [ ] No
Prior cardiac surgery	[ ] Yes [ ] No **If YES,** Specify type(s):_____
Diabetes (type I or II)	[ ] Yes [ ] No **If YES,** [ ] Type I [ ] Type II [ ] End-organ damage [ ] Insulin-dep
Hypertension	[ ] Yes [ ] No
Dyslipidemia	[ ] Yes [ ] No
Peripheral vascular disease	[ ] Yes [ ] No
Stroke	[ ] Yes [ ] No **If YES,** [ ] Hemiplegia
Cerebrovascular disease (other than stroke):	[ ] Yes [ ] No **If YES,** Specify type(s): _____
Other neurologic disease (e.g. Parkinson's)	[ ] Yes [ ] No
Cirrhosis	[ ] Yes [ ] No
Gastro-intestinal disease (e.g. reflux, ulcer, hiatal hernia)	[ ] Yes [ ] No **If YES,** Prior GI bleed [ ] upper or [ ] lower
Pulmonary hypertension	[ ] Yes [ ] No **If YES,** PAPs (if known): _____mmHg
Emphysema / COPD (chronic obstructive lung disease)	[ ] Yes [ ] No **If YES,** [ ] Mild [ ] Moderate [ ] Severe FEV1 (if known): _____ [ ] HomeO2
Asthma	[ ] Yes [ ] No
Arthritis (rheumatoid or osteoarthritis)	[ ] Yes [ ] No
Congestive Heart Failure (CHF)	[ ] Yes [ ] No
Back disease (e.g. degenerative disc, spinal stenosis, severe chronic back pain)	[ ] Yes [ ] No
Visual impairment (e.g. cataracts, glaucoma, macular degeneration)	[ ] Yes [ ] No
Hearing impairment	[ ] Yes [ ] No

Dementia	[ ] Yes [ ] No
Depression	[ ] Yes [ ] No
Anxiety / Panic attacks	[ ] Yes [ ] No
Malignancy	[ ] Yes [ ] No
HIV/AIDS	[ ] Yes [ ] No
Falls (in past year)	[ ] Yes [ ] No **If YES,** How many _____
Psychological stress or acute disease	[ ] Yes [ ] No

IBD:

- Crohn's disease
- Ulcerative colitis

Describe the extent of involvement.
Complete the Harvey Bradshaw Index (attached) for Crohn's disease or the Mayo Risk Score for Ulcerative Colitis (attached).

History of IBD Complications

- Need for hospitalization for IBD in the past 12 months?
- Month of last hospitalization in the past 12 months?

Current Medications (Prescriptions, Herbal, OTC, Supplements)		
Drug Name	Dosage (mg)	Frequency

Medical and Surgical History

Average Alcohol Intake: (#drinks/week)

☐ Never ☐ Current_____

☐ Used to drink _____ How many months of abstinence? _____

(at peak drinking amount)

Smoking History:

☐ Never ☐ Current_____ ☐ Ex-Smoker_____

A 2-2 Disease Activity Index Sheets

A 2-2-1 Harvey-Bradshaw Index (HBI) — Assessment for Crohn's Disease Activity

Division of Gastroenterology

University of Alberta

RE:
DOB:
Date: _____

Modified Harvey Bradshaw Index

Assessment for Crohn's Disease Activity

Patients, please complete Questions 1, 2 & 3.

Base your answers on how you felt yesterday.

1. **General Wee-being** (see description)
   - ☐ Very well = 0
   - ☐ Slightly below Par = 1
   - ☐ Poor = 2
   - ☐ Very Poor = 3
   - ☐ Terrible = 4

   ☐

2. **Abdominal Pain** (see description)
   - ☐ None = 0
   - ☐ Mild = 1
   - ☐ Moderate = 2
   - ☐ Severe = 3

   ☐

3. **Number of Liquid or Soft Stools per day** (Yesterday)

   ☐

Physician, please complete Question 4

4. **Additional Manifestations**
   - ☐ None = 0
   - ☐ Arthalgia = 1
   - ☐ Uveitis = 1
   - ☐ Erythema Nodosum = 1
   - ☐ Aphtous ulcer = 1
   - ☐ Pyoderma gangrenosum = 1
   - ☐ Anal Fissure = 1
   - ☐ New Fistula = 1
   - ☐ Abscess = 1

   ☐

Total Harvey Bradshaw Index Score:

[sum of all above items]

☐

Remission = < 5
Mild Disease = 5-7
Moderate Disease = 8-16
Severe Disease > 16

1. General Well-being Description

General well-being includes fatigue in the overall rating and how you feel today. Record the worst you have felt today. Compare yourself to someone else of your age, how would they rank their general well-being? Below are some descriptors to help you rank your category of general well-being.

- **Very Well:** General health is not generally a problem. You're feeling very good or great and under control.
- **Sliently Below Por:** You're getting through things but feeling below par and not normal. Something overall is preventing you from saying "I feel wonderful". You're feeling good but not great. You can work, socialize, and function on a day to day basis.
- **Poor:** Your symptoms bother you. You occasionally miss work, school, or social activities. You have some embarrassing moments with fecal incontinence. You have diarrhea, abdominal pain, fatigue, and basically just feeling unwell, but you are still able to function. You're getting through the day, doing all your normal stuff but it is a struggle.
- **Very Poor:** You're getting through a part of the day, but can't do your normal stuff. You can't attend social events in evening. You sometimes leave home from work early. You feel pretty bad and are not doing much activity – only those absolutely necessary. Your symptoms interfere with life considerably, you don't go out or are fearful when out, you miss a lot of school or work. Fecal incontinence happens several times per week.
- **Terrible:** You're unable to function. You can't manage the basics and you're almost bedridden. This is the worse you have ever been. You're not working.

2. Abdominal Pain Description

Abdominal pain may include cramping and discomfort. It does not have to be just "pain" as we know it. Below are some descriptors to help you rank your category of abdominal pain.

- **Mild:** You're aware that the abdominal pain is there but it does not interfere with your life and continue with activities such as work and pleasure. You feel and hear rumbles, gurgles, and cramps.
- **Moderate:** You're aware of your abdominal pain and must alter your activities to manage the pain (ie. Lie down to rest, postpone shopping trips until later, and take Tylenol). The pain interferes with your life and daily activities. You may have to miss work or pleasure activities on occasion.
- **Severe:** Your abdominal pain causes you to stop all activity. You are frequently in bed because of the pain, you call in sick to work and cancel all activities.

A 2-2-2 Partial Mayo Scoring Index (Mayo) - Assessment for Ulcerative Colitis Activity

Division of Gastroenterology

University of Alberta

RE:
DOB:
Date: _____

Partial Mayo Scoring Index

Assessment for Ulcerative Colitis Activity

Patients, please enter number of daily bowel motions you would have when in remission or before your diagnosis or symptoms of ulcerative colitis began. **This number will be <u>Your Normal:</u>**

Patients, please complete Questions 1 and 2.

1. Stool Frequency (based on the past 3 days)

- ☐ Normal number of stools = 0
- ☐ 1-2 stools more than normal = 1
- ☐ 3-4 stools more than normal = 2
- ☐ 5 or more stools more than normal = 3

☐

2. Rectal Bleeding (based on the past 3 days)

- ☐ No blood seen
- ☐ Streaks of blood with stool less than half the time = 0
- ☐ Obvious blood with stool most of the time = 1
- ☐ Blood alone passed = 2

☐

<u>Physician, please complete Questions number 3.</u>

3. Physician's Global Assessment (to be completed by Physician)

- ☐ Normal (sub score are mostly 0) = 0
- ☐ Mild Disease (sub score are mostly 1) = 1
- ☐ Moderate Disease (sub score are mostly 1 to 2) = 2
- ☐ Severe Disease (sub score are mostly 2 to 3) = 3

☐

The physician's Global Assessment acknowledges the Sub scores, the daily record of abdominal discomfort and functional assessment and other observations such as physical findings, and the patient's performance status.

Total Partial Mayo Index Score [sum of all above items] ☐

Remission = 0-1
Mild Disease = 2-4
Moderate Disease = 5-6
Severe Disease = 7-9

Version June 2009

Appendix 3: Nutritional Screening Tools

A 3-1 Malnutrition Universal Screening Tool (MUST)

Step 1

Calculate your body mass index (BMI)

A. Measure your weight in pounds _____
B. **Estimate or measure** your height in feet and inches _____
C. Use the chart to estimate your BMI

If your BMI is less than 18.5, you score 2 point.

If your BMI is 18.5 - 20, you score 1 point.

If your BMI is greater than 20, you score 0 point.

Score ☐

Step 2

Calculate your weight loss score.

A. What is your current weight? _____ pounds
B. Estimate how much weight you have lost in the last 3 - 6 months? _____ pounds
C. Use the chart to estimate your percentage of weight loss

If less than 5%, your score is 0 point.

If 5 – 10% weight loss, your score is 1 point.

If greater than 10% weight loss, your score is 2 points.

Score ☐

Step 3

Do you feel acutely sick right now? ☐ No ☐ Yes

Has your intake of food been poor for the last 5 days **or** likely to be poor for the next 5 days?

☐ No ☐ Yes

If you answered **yes** to **both** questions then score 2 points. Otherwise your score is 0 point.

Score ☐

Step 4

Add scores together

Overall score: ☐

0 = Low risk of malnutrition

1 = Moderate risk of malnutrition

2 or greater = High risk of malnutrition

Example of Charts Used for MUST

(adopted from: Cawood et al. Am J Clin Nutr.2012;96(5):1000-1007)

Step 1 Chart Example Section

- Find your height in one of the white columns on the left of the table
- Read across the same row as your height to find the weight range your weight today falls into
- Look to the top of the coloured column for your score (score 0, 1 or 2)
- Write your score for Step 1 on the nutrition tool.

HEIGHT		Weight (kg)		
		Score 0	Score 1	Score 2
1.46m	4' 9½"	more than 42.60 kg	39.40 - 42.60 kg	less than 39.40 kg
1.47m	4' 10"	more than 43.20 kg	40.00 - 43.20 kg	less than 40.00 kg
1.48m	4' 10¼"	more than 43.80 kg	40.50 - 43.80 kg	less than 40.50 kg
1.49m	4' 10½"	more than 44.40 kg	41.10 - 44.40 kg	less than 41.10 kg
1.50m	4' 11"	more than 45.00 kg	41.60 - 45.00 kg	less than 41.60 kg
1.51m	4' 11½"	more than 45.60 kg	42.20 - 45.60 kg	less than 42.20 kg
1.52m	5' 0"	more than 46.20 kg	42.70 - 46.20 kg	less than 42.70 kg
1.53m	5' 0¼"	more than 46.80 kg	43.30 - 46.80 kg	less than 43.30 kg
1.54m	5' 0½"	more than 47.40 kg	43.90 - 47.40 kg	less than 43.90 kg
1.55m	5' 1"	more than 48.10 kg	44.50 - 48.10 kg	less than 44.50 kg
		SCORE 0	SCORE 1	SCORE 2

Step 2 Chart Example Section

Only complete this step if you have lost weight without trying in the last 3 months

- Find your weight before you lost weight (3 months ago) in the white column
- Read across the row to find the weight range your weight today falls into
- Look to the top of the coloured column that your weight is in to find your score for Step 2 (score 0, 1 or 2)
- Write your score for Step 2 on the nutrition tool.

WEIGHT 3 MONTHS AGO		Weight (kg)		
		Score 0	Score 1	Score 2
30kg	4st 10lb	more than 28.5 kg	27.0 - 28.5 kg	less than 27 kg
31 kg	4st 12lb	more than 29.5 kg	27.9 - 29.5 kg	less than 27.9 kg
32 kg	5st 1lb	more than 30.4 kg	28.8 - 30.4 kg	less than 28.8 kg
33 kg	5st 3lb	more than 31.4 kg	29.7 - 31.4 kg	less than 29.7 kg
34 kg	5st 5lb	more than 32.3 kg	30.6 - 32.3 kg	less than 30.6 kg
35 kg	5st 7lb	more than 33.3 kg	31.5 - 33.3 kg	less than 31.5 kg
36 kg	5st 9lb	more than 34.2 kg	32.4 - 34.2 kg	less than 32.4 kg
37 kg	5st 12lb	more than 35.2 kg	33.3 - 35.2 kg	less than 33.3 kg
38 kg	6st	more than 36.1 kg	34.2 - 36.1 kg	less than 34.2 kg
39 kg	6st 2lb	more than 37.1 kg	35.1 - 37.1 kg	less than 35.1 kg
40 kg	6st 4lb	more than 38.0 kg	36.0 - 38.0 kg	less than 36.0 kg
		SCORE 0	SCORE 1	SCORE 2

A 3-2 Canadian Nutrition Screening Tool (CNST)

Ask the patient the following questions (two yes answers indicates nutrition risk)

Have you lost weight in the past 6 months WITHOUT TRYING to lose this weight? *If the patient reports a weight loss but gained it back, consider it as NO weight loss.*	**□ YES** **□ NO**
Have you been eating less than usual for MORE THAN A WEEK?	**□ YES** **□ NO**

A 3-3 Saskatchewan IBD – Nutrition Risk Tool (SaskIBD-NR)

Nutrition screening item	Score
1. Have you experienced nausea, vomiting, diarrhea or poor appetite for greater than two weeks?	☐ no symptoms = 0 ☐ two symptoms = 1 ☐ ≥3 symptoms = 2
2. Have you lost weight in the last month without trying? **IF YES**, how much weight have you lost?	☐ no = 0 ☐ unsure = 1 ☐ yes = see below ☐ <5 lbs = 0 ☐ 5-10 lbs = 1 ☐ 10-15 lbs = 2 ☐ >15 lbs = 3
3. Have you been eating poorly because of a decreased appetite?	☐ no = 0 ☐ yes = 2
4. Have you been restricting any foods or food groups?	☐ no = 0 ☐ yes = 2

Total score: ☐

0 - 2 = Low Risk

3 - 4 = Medium Risk

≥ 5 = High Risk

A 3-4 Abridged Patient-Generated Subjective Global Assessment (abPG-SGA)

History Boxes 1-4 are designed to be completed by the patients.

Patient ID Information

1. Weight

In summary of my current and recent weight:

I currently weigh about _____ pounds.
I am about _____ feet _____ tall.

One month ago I weighed about ___ pounds.
Six months ago I weighed about ___ pounds.

During the past two weeks my weight has:
□ decreased □ not changed □ increased

Box 1 ☐

2. Food Intake: As compared to my normal intake, I would rate my food intake during the past month as:

□ Unchanged
□ More than usual
□ Less than usual

I am now taking:

□ Normal food but less than formal amount
□ Little solid food
□ Only liquids
□ Only nutritional supplements
□ Very little of everything
□ Only tube feedings or only nutrition by vein

Box 2 ☐

3. Symptoms: I have had the following problems that have kept me from eating enough during the past two weeks (check all that apply):

□ No problem eating
□ No appetite, just did not feel like eating
□ Nausea □ vomiting
□ Constipation □ diarrhea
□ Mouth sores □ dry mouth
□ Things taste funny or have no taste
□ Problem swallowing □ Feel full quickly
□ Pain; where? _____ □ Fatigue
□ Other** _____

** Examples: depression, money, or dental problem

Box 3 ☐

4. Activities and Function:

Over the past month, I would generally rate my activity as:

□ Normal with no limitation
□ Not my normal self, but able to be up and about with fairly normal activities
□ Not feeling up to most things, but in bed or chair less than half the day
□ Able to do little activity and spend most of the day in bed or chair
□ Pretty much bedridden, rarely out of bed

Box 4 ☐

Appendix 4: Nutritional Assessment Tools

A 4-1 Subjective Global Assessment (SGA)

Medical History			A	B	C
WEIGHT	Usual weight……	Current weight……			
Wt change past 6 months	Amount weight loss…….	% weight loss…….			
0-<5% loss			*		
5-10% loss				*	
>10% loss					*
Weight change past 2 weeks		Amount…….			
No change; normal weight			*		
Increase to within 5%			*		
Increase (1 level above)			*	*	
No change, but below usual wt				*	
Increase to within 5-10%				*	
Decrease					*
DIETARY INTAKE					
No change; adequate			*		
No change; inadequate				*	
Change	**Duration of change**……...				
Suboptimal diet				*	
Full liquid				*	
Hypocaloric liquid					*
Starvation					*
Intake borderline; increasing			*		
Intake borderline; decreasing				*	
Intake poor; no change				*	*
Intake poor; increasing				*	
Intake poor; decreasing					*
GASTROINTESTINAL SYMPTOMS					
	Frequency (never, daily, no. of times/week)	Duration (<2wk, >2wk)			
Nausea	……	……..	Mild	Moderate	Severe
Vomiting	……	…….	Mild	Moderate	Severe
Diarrhoea	……	……...	Mild	Moderate	Severe
Anorexia	……	……...	Mild	Moderate	Severe
None; intermittent			*		
Some (daily >2 week)					
All (daily >2 week)				*	
					*
FUNCTIONAL CAPACITY					
No dysfunction	Duration of change ……..		*		
Difficulty with ambulation/normal activities				*	
Bed/chair-ridden					*
Change past 2 week					
Improved			*		
No change				*	
Regressed					*

Physical examination	A	B	C
SUBCUTANEOUS FAT			
Under the eyes	Slightly bulging area		Hollowed look, depression, dark circles
Triceps	Large space between fingers		Very little space between fingers, or fingers touch
Biceps	Large space between fingers		Very little space between fingers, or fingers touch
MUSCLE WASTING			
Temple	Well-defined muscle/flat	Slight depression	Hollowing, depression
Clavicle	Not visible in Males; may be visible but not prominent in females	Some protrusion; may not be all the way along	Protruding/prominent bone
Shoulder	Rounded	No square look; acromion process may protrude slightly	Square look; bones prominent
Scapula/ribs	Bones not prominent; no significant depressions	Mild depressions or bone may show slightly; not all areas	Bones prominent; significant depressions
Quadriceps	Well rounded; no depressions	Mild depression	Depression; thin
Calf	Well developed		Thin; no muscle definition
Knee	Bones not prominent		Bones prominent
Interosseous muscle between thumb and forefinger	Muscle protrudes; could be flat in females		Flat or depressed area
OEDEMA (related to malnutrition)	No sign	Mild to moderate	Severe
ASCITES (related to malnutrition)	No sign	Mild to moderate	Severe
OVERALL SGA RATING	**A**	**B**	**C**

A 4-2 Muscle Mass Assessment (MAMC)

Muscle Mass Measurement				**[on the patient's right side]**
	Trial 1	Trial 2	Trial 3	**Average**
Mid upper arm circumference (MAC) (cm)				
Triceps Skinfold (TSF) (mm)				
Mid arm muscle circumference (MAMC) ***use average values**	= avg. ($MAC_{[cm]}$) – [3.14 × avg. ($TSF_{[mm]}$)] **= _____ cm**			

A 4-3 Hand Grip Strength (HGS) Assessment

Handgrip Strength (kg)				**[on the patient's dominant hand]**
Dominant hand: [ ] Right [ ] Left	**Right Hand**		**Left Hand**	
	Trial 1:		Trial1:	
	Trial 2:		Trial 2:	
	Trial 3:		Trial 3:	
	Average:		Average:	
	Max:		Max:	

Does the patient have any hand injury, sore wrist, nerve related problems or carpal tunnel that would prevent them from performing the handgrip strength test to their full ability? Yes [ ] No [ ]