Background: Subcutaneous (SC) delivery of biologic therapies is typically self-administered via a prefilled syringe or an auto-injector. Auto-injector devices are designed to offer a more convenient and more consistent administration of the drug product. The Subcutaneous Administration Assessment Questionnaire (SQAAQ) is a novel, 12-item, self-administered questionnaire that assesses ease of use of SC delivery devices and patient confidence while using the device to administer an injection of drug. This study aimed to establish evidence of the content validity of the SQAAQ among patients with moderate to severe ulcerative colitis (UC).

Methods: A cross-sectional, US-based, qualitative study using a semi-structured discussion guide was conducted using online focus groups and one-on-one telephone interviews among adolescent (12–17 yrs) and adult (18 yrs+) participants with CD. The SQAAQ is appropriate for inclusion in CD clinical trials for SC treatment devices with adult and adolescent patients.

Results: Twenty-four patients (adults, n=16; adolescents, n=8) participated in the interviews. Thirteen adults and 3 adolescents experienced moderate disease severity (reported by clinicians). Adult and adolescent groups contained an equal proportion (50%) of male and female participants. Adults had a mean age 50.3 years (range 27.0–75.0), adolescents with mean age 15.6 years (range 14.0–17.0). Overall, two-thirds (n=16, 67%) of patients were white, and the mean duration for CD diagnosis was 8.0 years (range 1.0–23.7). Ten (42%) patients had been on SC treatment for a mean 4.5 years (range 0.2–16.9), all self-administered. Seven (29%) patients had been receiving intravenous treatment for a mean 2.1 years (range 0.2–5.4). The SQAAQ was found to be conceptually relevant, understandable and usable by adults and adolescents with CD. Notably the measurement concepts were confirmed as relevant by patients who currently used SC treatment devices. The patients with no SC experience (n=7, 29%), understood the item wording, responded with ease and perceived self-efficacy (n=3 items).

Figure 1. Features of the SQAAQ

Easy for me to learn how to use
Easy for me to unlock
Easy to hold in my hand when I inject my dose
Easy to inject my dose
Easy to know that my dose is complete
Easy to store the device in the refrigerator
Easy to remove needle shield/cover
Easy to pick up
Overall, easy to use
The device is stable against my skin during the injection
I am confident in my ability to use the device
I am confident my dose is complete

Conclusion: Patient feedback confirms content validity of the SQAAQ and provides strong evidence that the concepts included in the SQAAQ are important to and well-understood by adults and adolescents with UC.

Figure 1. Conceptual Framework - SQAAQ

11 ENTERAL NUTRITION THERAPY IS ASSOCIATED WITH FEWER READMISSIONS AND DEATHS AMONG MALNOURISHED INPATIENTS WITH INFLAMMATORY BOWEL DISEASE

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Background: Malnutrition is a common complication observed in hospitalized patients with inflammatory bowel disease (IBD). Enteral nutrition therapy can be used to support the nutritional needs of inpatients with IBD. However, evidence on the impact of enteral nutrition on clinical outcomes is equivocal. This study assesses post-hospitalization outcomes associated with enteral nutrition therapy amongst inpatients with IBD in a large nationwide database.

Methods: We conducted a retrospective propensity score-matched study among IBD inpatients diagnosed with protein-calorie malnutrition using the Nationwide Readmissions Database from 2010–2015. ICD9 codes associated with each admission were used to identify patients who received enteral nutrition. Using propensity score matching, patients who received enteral nutrition were matched with patients who did not receive enteral nutrition based on the following variables: age, sex, elective admission, patient income, teaching hospital, and hospital urban or rural locality. Primary endpoints included 30-day readmissions, 90-day readmissions, 30-day mortality and 90-day mortality.

Results: Among the 1,588 IBD patients (822 Crohn’s disease, 755 ulcerative colitis, 11 unclassified IBD) with protein-calorie malnutrition, patients who received enteral nutrition (n=794) had fewer 30-day readmissions (OR 0.73; 95% CI 0.55 – 0.96) and 90-day readmissions (OR 0.77; 95% CI 0.61 – 0.97). None of the patients (0%) in the enteral nutrition group died on a subsequent admission within 30 days of discharge, compared to 6 patients (0.8%) in the control group (p=0.027). Inpatient mortality within 90 days of discharge did not differ significantly between the two groups (0.8%, enteral nutrition vs. 1.6%, control; p=0.086).

Discussion: Enteral nutrition therapy amongst IBD inpatients with malnutrition was associated with lower odds of readmission and 30-day mortality, but not 90-day mortality. The findings of our study support the use of enteral nutrition in IBD inpatients and motivate the need for prospective studies assessing the impact of enteral nutritional support in IBD inpatients.