

## **55** PSYCHOMETRIC VALIDATION OF THE PORTUGUESE FOR PORTUGAL VERSION OF THE SATISFACTION FOR PATIENTS IN CROHN'S DISEASE QUESTIONNAIRE (SPACE-Q?)

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**BACKGROUND/PURPOSE:** Crohn's disease is a chronic inflammatory bowel disease that highly impacts patients' lives. It requires continuous treatment with, for example, anti-tumor necrosis factors (anti-TNFs). Patients' satisfaction with their anti-TNF treatment may have impact on their quality of life.

The <u>Satisfaction</u> for <u>PA</u>tients in <u>Crohn's diseasE</u> <u>Questionnaire</u> (SPACE-Q®) is the first questionnaire aiming to assess patients' satisfaction with their anti-TNF treatment for severe Crohn's disease. It was recently validated in French language. The objective of the VISION international study was to assess the psychometric properties of the Portuguese, Greek, Canadian English and Canadian French versions of SPACE-Q®. This report discloses the Portuguese results.

**METHODS:** Patients with severe Crohn's disease were asked to complete SPACE-Q® at 3 time points: inclusion (before starting anti-TNF, either naive or switch); week 12; week 13. Psychometric assessment of SPACE-Q® included clinical validity (against Harvey–Bradshaw score), concurrent validity (against Treatment Satisfaction Questionnaire for Medication [TSQM]), internal consistency reliability, test–retest reliability, and responsiveness (against the patient global impression of change [PGIC]).

**RESULTS:** Eight investigators recruited 59 patients, and all patients completed SPACE-Q®, at least at one of the 3 planned time points. Anti-TNF treatment was prescribed to 50 patients (e.g. due to lack of response to corticosteroids and/or immunosuppressors), and a new anti-TNF treatment to 9 patients (e.g. due to lack or loss of response to previous anti-TNF treatment).

No robust conclusion could be taken regarding the clinical validity against Harvey–Bradshaw score, due to small sample sizes of patients with "very severe disease", and with "inactive disease". However, SPACE-Q® scores were found to be different in the expected direction according to the level of severity of Crohn's disease based on Harvey-Bradshaw score: worse SPACE-Q® scores were reported by patients with more severe disease.

Concurrent validity against TSQM was confirmed, as low correlations were observed for scores measuring different concepts (e.g. SPACE-Q® "Symptoms transition scale" score and the TSQM "Convenience" score [r=0.13]), while moderate correlations were observed for scores measuring similar concepts (e.g. SPACE-Q® "Expectation toward efficacy" score and the TSQM "Effectiveness" score [r=0.65]).

Internal consistency reliability was confirmed for all psychometric dimensions, except for "Anal symptoms transition scale", which had a Cronbach's  $\alpha$  lower than the recommended 0.70 threshold.

It was not possible to assess test-retest reliability and responsiveness, as sample sizes in each longitudinal subgroups were too small.









**Conclusion:** The Portuguese for Portugal version of the SPACE-Q® is a valid and reliable instrument to measure satisfaction with anti-TNF treatment in patients with severe Crohn's disease. Results of the international study will be soon disclosed.

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