Abstract: PB3409

Title: PATIENT INTERVIEW–BASED CONTENT VALIDATION OF THE MYELOFIBROSIS SYMPTOM ASSESSMENT FORM VERSION 4.0 (MFSAF V4.0)

Abstract Type: Publication Only

Topic: Quality of life and palliative care

Background:

Patients with myelofibrosis (MF) often experience debilitating symptoms that negatively impact health-related quality of life and functioning. The MFSAF v4.0 is a 7-item questionnaire assessing the burden of MF symptoms, including fatigue, night sweats, pruritus, abdominal discomfort, pain under left ribs, early satiety, and bone pain. Each item is evaluated on an 11-point numeric rating scale (NRS) from 0 (absent) to 10 (worst imaginable). The MFSAF v4.0 was initially validated in patients with MF who were Janus kinase (JAK) inhibitor naive; therefore, it was unclear if the validity of the MFSAF v4.0 extended to patients with prior JAK inhibitor treatment.

Aims:

To evaluate the content validity of the MFSAF v4.0 in JAK inhibitor–experienced patients with MF via patient interviews.

Methods:

Qualitative interviews were conducted remotely by trained interviewers with 20 JAK inhibitor–experienced and symptomatic (MFSAF Total Symptom Score [TSS] ≥10) patients with MF from the US (n=5) and UK, Germany, Italy, Poland, and Spain (n=3 each). The interview began with a concept elicitation section to allow spontaneous reporting of important concepts prior to content validation of the MFSAF v4.0 items and NRS as relevant, important, and understandable to patients.

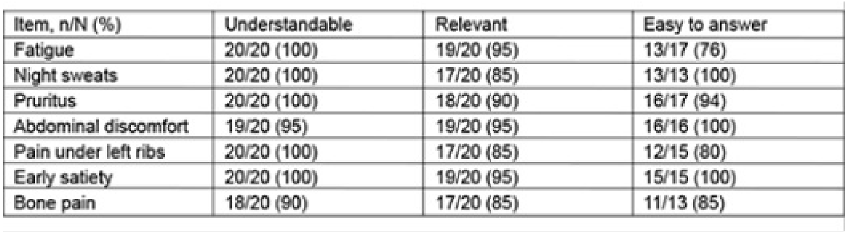
Results:

Mean patient age was 59.4 years; 50% were male, 55% had been diagnosed within the past year, 95% were on any treatment for MF, and 75% were anemic. On average, patients had 2.1 transfusions within the past 3 months. Mean MFSAF v4.0 TSS was 28.6.** The top spontaneously endorsed symptoms were tired (70%), bone/muscle pain (70%), fatigue (55%), night sweats (45%), and pruritis (45%), many of which are also items in the MFSAF v4.0. An additional 18 symptoms were spontaneously mentioned by patients prior to completion of the MFSAF v4.0. Many of these other symptoms were endorsed by ≤10% of patients (1 or 2 patients each), and 90% of patients felt that the measure represented their experience and did not recommend inclusion of additional symptoms after reviewing the measure.

Overall, patients showed a clear understanding of the MFSAF v4.0 (Table). No more than 3 patients (15%) mentioned that a given item was not relevant to their individual experience. Patients consistently felt that it was easy to select an answer on the response scale and were able to differentiate response options. When describing meaningful change in terms of NRS, patients most often suggested that an improvement of 2 to 4 points would be meaningful.

Summary/Conclusion: Based on the findings from this study, the MFSAF v4.0 is a content-valid measure for patients with MF and captures the most important concepts. All items are comprehensible and relevant, with the NRS endorsed as an appropriate response scale.

Funding: GSK (study #219695)



Item, n/N (%)	Understandable	Relevant	Easy to answer
Fatigue	20/20 (100)	19/20 (95)	13/17 (76)
Night sweats	20/20 (100)	17/20 (85)	13/13 (100)
Pruritus	20/20 (100)	18/20 (90)	16/17 (94)
Abdominal discomfort	19/20 (95)	19/20 (95)	16/16 (100)
Pain under left ribs	20/20 (100)	17/20 (85)	12/15 (80)
Early satiety	20/20 (100)	19/20 (95)	15/15 (100)
Bone pain	18/20 (90)	17/20 (85)	11/13 (85)

Keywords: Myelofibrosis