Health-Related Quality of Life as Measured by the 12-Item Medical Outcomes Study Short-Form Among Adults With Community-Acquired Bacterial Pneumonia Who Received Either Leflamulin or Moxifloxacin in Two Phase 3 Randomized, Double-Blind, Double-Dummy Clinical Trials (LEAP 1 and 2)

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INTRODUCTION & PURPOSE

Health-related quality of life (HRQoL) is an important outcome in the assessment of new antibiotics and is a major component of the personal and community engagement quality domain in the Centers for Disease Control & Prevention’s National Health Interview Survey.1

Patients with pneumonia are a growing area of focus in antibiotic development and are a major component of the healthcare sector’s priority area for research and development.2-4

METHODS

Study Design and Population

A total of 2,035 patients were randomized to receive either leflamulin (LEF) or moxifloxacin (MOX), with a total of 914 randomized to LEF (454 patients) and 1,121 randomized to MOX (560 patients).5

Health-Related Quality of Life

The participant-reported 12-Item Medical Outcomes Study Short-Form Health Survey (SF-12)6 was administered to patients at baseline and test of cure (TOC). The SF-12 is a general survey that assesses HRQoL, which is measured by two domains: physical and mental health.7 The mental health domain includes emotional health, role emotional, vitality, social functioning, and general health.8

RESULTS

SF-12 domain and summary scores were evaluated at baseline and TOC.

Table 1. SF-12 Items and Scores

The greatest magnitude of improvements was observed in the domain of general health, which showed improvements of 15.6 points for LEF and 15.8 points for MOX

Table 2. Demographics and Baseline Disease Characteristics

CONCLUSIONS

Patients who received LEF had comparable improvements in HRQoL relative to those who received MOX

REFERENCES


2. Clinical and Laboratory Standards Institute. CLSI document M29-A3: Use of the 12-Item Medical Outcomes Study Short Form Health Survey (SF-12) to measure health-related quality of life in clinical trials of antimicrobial agents.

3. Lodise T, Colman S, Alexander E, Stein DS, Fitts D, Goldberg L, Schranz J. Health-Related Quality of Life as Measured by the 12-Item Medical Outcomes Study Short-Form Among Adults With Community-Acquired Bacterial Pneumonia Who Received Either Leflamulin or Moxifloxacin in Two Phase 3 Randomized, Double-Blind, Double-Dummy Clinical Trials (LEAP 1 and 2). Presented at IDWeek 2019; October 2–6, Washington, DC, USA.

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2. IDWeek 2019: October 2–6, Washington, DC, USA

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