

Evaluation of Health-Related Quality of Life in Patients Treated with RBX2660 (microbiota suspension) for Recurrent *C. difficile* Infection

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Purpose: Recurrent *C. difficile* infection (CDI) is a debilitating condition known to have major effects on both patient physical and mental health. Little is known about the quality of life aspects of this chronic condition. We report on changes in health-related quality of life (HRQOL) as assessed with the Short Form 36 (SF-36) in patients enrolled in the PUNCH CD phase 2 safety assessment of RBX2660 (microbiota suspension) for recurrent CDI.

Methods: A total of 34 patients (mean age 66.8 years, 67.6% female) at 11 centers in the US received at least one treatment with RBX2660 via enema. RBX2660 is a next generation version of fecal transplantation consisting of a suspension of live-human derived intestinal microbes. Total efficacy at 8 weeks was 87.1%. Participants were asked to complete the SF-36 questionnaire at the follow-up visits scheduled at: 7, 30, and 60 days after the last treatment. The SF-36 is scored from 0 to 100; a higher score indicates better HRQOL. The results of a 60-day interim analysis are reported here.

Results: The mean SF-36 score on the mental health component increased from 43.6 (SD: 13.9) at baseline to 51.3 (SD: 11.2) at 60 days; mean improvement from baseline to 60 days was 7.7 (SD: 12.2). The mean score on the physical health component increased from 44.9 (SD: 10.3) at baseline to 46.0 (SD: 11.1) at 60 days; mean improvement of 1.1 (SD: 10.6). All comparisons were based on paired data, n=29. Mean mental health scores improved steadily at the interim follow-ups at 7 and 30 days. Improvement on the physical health component scores was more modest at 7-day follow-up and then plateaued.

Conclusions: SF-36 scores reported in a phase 2 study of RBX2660 (microbiota suspension) for recurrent CDI show the magnitude of impact the condition has on HRQOL. The improvement in mental health scores vis-à-vis physical health scores in this first prospective multicenter study of microbiota restoration therapy for recurrent CDI suggest that the psychological impact of the disease may be underappreciated and should be considered in the development of an individual care plan.

This research was funded by Rebiotix Inc., Roseville, MN

Subject Category: F. Colon

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