PRELIMINARY RESULTS OF A U.S.-BASED STUDY TO VALIDATE THE ACUTE BRONCHITIS SYMPTOM SEVERITY SCALE

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OBJECTIVE: To evaluate the psychometric characteristics of the Acute Bronchitis Symptom Severity Scale (ABSS).

METHODS: The ABSS is a seven-question, bronchitis specific, instrument. Responses are measured on a scale of 0–4. The total score is calculated as the mean of the seven responses with higher scores indicating greater distress. The ABSS was pilot tested as a part of a US-based prospective, naturalistic study to patients with acute exacerbation of chronic bronchitis at the pre-treatment visit, each day of the first five days of therapy with any antimicrobial agent, and at the test-of-cure visit (TOC, 18–21 days post therapy). Item and total scale performance, internal consistency (Cronbach’s alpha), construct validity (correlation with St. George’s Respiratory Questionnaire or SGRQ subscale), and responsiveness to change over time (based on clinician evaluation and patient’s perceived treatment efficacy) were examined.

RESULTS: Twenty-seven patients were enrolled at four study sites in the US. Mean age was 57.4 (±14.5) years; 74% were female. No floor or ceiling effects were seen. Consistent with an improvement in acute bronchitis symptoms over time, mean item and total score values declined from baseline to TOC. Cronbach’s alpha at each time point ranged from 0.70 to 0.88, exceeding the reliability guideline of 0.70 for a new measure. At TOC, the correlation between the ABSS total score and SGRQ activity subscale score was strong (0.60). The 18 patients considered clinically cured or improved at day 5 reported a mean ABSS score change, from baseline, of −0.90. Patients who considered the treatment moderately effective at day 5 (n = 11) reported an average change score of −0.87, while those who considered the treatment very effective (n = 3) improved by a score of −1.50.

CONCLUSIONS: Preliminary results from this pilot test with US-based patients suggest the instrument is valid, reliable, and sensitive to change over time.

THE ASSOCIATION BETWEEN HEALTH RELATED QUALITY OF LIFE AND ADHERENCE TO THERAPY IN HEPATITIS C

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For many conditions the overall impact of treatment on health related quality of life (HRQL) involves a tradeoff between improvement in the condition being treated and unwanted side effects. When the net HRQL result is too negative, patients have difficulty tolerating medication and may fail to adhere or discontinue treatment.

OBJECTIVE: We investigated the association between reduced HRQL due to interferon treatment and premature treatment discontinuation for chronic hepatitis C.

METHODS: A pooled secondary analysis of patients (n = 1441) across three international, multicenter, open-label, randomized studies that compared peginterferon α-2a with interferon α-2a. Health-related quality of life was assessed using the SF-36 Health Survey. The Fatigue Severity Scale (FSS) was used to measure the impact of disabling fatigue. Logistic regression analysis was used to examine the association between changes in health-related quality of life and treatment discontinuation.

RESULTS: Reduction from baseline in HRQL scores was a significant predictor of in-treatment SF-36 scores (P < 0.001). The odds of discontinuing treatment early were 48% higher in the quartile of patients with the greatest worsening of fatigue scores than in the lowest quartile. The odds ratios for treatment discontinuation among patients with worsening of SF-36 domain and summary scores ranged from 1.09 (physical function) to 3.56 (role limitations-emotional).

CONCLUSION: The impact on health-related quality of life is an important consideration in optimizing treatment of patients with chronic hepatitis C. HRQL assessments during treatment may offer physicians a method for monitoring the risk of premature discontinuation.

PRESCRIBING DECISIONS IN A UTILITY MODEL

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OBJECTIVE: To build a utility-based model comparing physicians’ prescribing practices for acute sinusitis, assuming that utility is a function of repeat visits, second prescriptions and call-backs.

METHODS: An algorithm is applied to data from an open-label, multicenter, randomized trial, which documents call back times, office visits and second prescriptions for 792 Acute Bacterial Sinusitis patients treated with Amoxicillin clavulanate 875 mg, Levofloxacin 500 mg or Moxifloxacin 400 mg. The marginal effect of fewer call-backs, office visits and second prescriptions, using utility as a function of these, is represented by a decision tree. Probabilities from the trial are used. Utilities range from highest (1.00) when the patient does not call back or get a second prescription, to lowest (0.25), when the patient calls back/comes back for a visit. Intermediate utilities range in decreasing order from call-back/no action, to no call-back/second prescription, to