HEALTH-RELATED QUALITY OF LIFE AMONG PATIENTS WITH VENOUS LEG ULCER

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OBJECTIVES: To assess the health-related quality of life (HRQoL) among patients with venous leg ulcer and providers. METHODS: A prospective, observational, multi-center study was conducted among 112 patients with VLU in the US (76 patients) and the UK (36 patients) between 2007 and 2008. Patients completed the generic health status measure, the EuroQol (EQ-5D) Questionnaire and a disease-specific health-related quality of life measure, the Charing Cross Leg Ulcer Questionnaire at study baseline and at the end of the study. Patients were provided routine medical care for their ulcer for a study period of 12 weeks or until all their ulcers healed. Analyses were conducted to assess the change in HRQol scores over the study period among all patients, among patients with all ulcers healed (healed patients) and among patients with at least one ulcer not healed (non-healed patients). RESULTS: The mean age (SD) of VLU patients was 61.9 (13.7) years in the US and was 70.9 (13.9) years in the UK. A total of 51.3% of VLU patients in the US were males while 36.1% in the UK were males. At baseline, the mean (SD) EQ-5D index score was 0.6628 (0.2402) for US patients and 0.6206 (0.3413) for UK patients. There was a statistically significant improvement in EQ-5D index scores over the study period among the US healed patients (p < 0.01) but not for US non-healed patients or UK patients. Among all patients, the Charing Cross Leg Ulcer Questionnaire showed that patients’ social interaction (p < 0.01) and emotional status (p < 0.01) were significantly improved during the study period. CONCLUSIONS: VLU results in a significant negative impact on patients’ health status. Treatments for VLU that promote ulcer healing are likely to result in significant improvements in patients’ health-related quality of life. EU-08-1532. © 2008 ER. Squibb & Sons, LLC. 1 The EuroQol Group. www.euroqol.org; accessed 01/02/2007 2 Smith J, et al. Measuring the quality of life in patients with venous leg ulcers. J Vasc Surg 2000;31:642-9.

VALIDATION OF THE SINONASAL OUTCOME TEST-16 (SNOT-16) IN PATIENTS WITH ACUTE BACTERIAL SINUSITIS

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OBJECTIVES: To document the psychometric properties and estimate a minimal important difference (MID) for the Sinonasal Outcome Test-16 (SNOT-16) in patients with acute bacterial sinusitis. METHODS: Secondary psychometric analysis was undertaken on data from a phase III trial to evaluate the efficacy and safety of moxifloxacin over 5 consecutive days in the treatment of acute bacterial sinusitis (N = 374). Trial patients also completed the RAND SF-36, the Activity Impairment Assessment (AIA) and a global rating of change. The SNOT-16 has 16 items and is scored as a uni-dimensional measure of symptoms of rhinosinusitis. Internal consistency and construct validity (against SF-36 and AIA) were assessed at baseline. Sensitivity and MID were assessed by comparing test of cure data against baseline using statistical methods (effect size (ES), standardised response mean (SRM); and standard error of measurement (SEM) and 1/2 standard deviation (1/2SD)) and anchor methods against the smallest change on the global rating of change. Missing data were imputed using last observation carried forward. RESULTS: Internal consistency (α = 0.874) and construct validity (SF-36 Role Function r = -0.44, Vitality r = 0.45, Social Function r = 0.48, Pain r = 0.51, AIA r = 0.67 all P < 0.001) were confirmed. The SNOT-16 was sensitive (ES = 1.68; SRM = 1.36). The MID estimated by the anchor method was ~0.85; but MID was lower by distributional estimates (SEM = 0.21, 1/2SD = 0.29). CONCLUSIONS: The study confirms the good psychometric properties of the SNOT-16 in patients with acute bacterial sinusitis and demonstrates the sensitivity and MID for this measure. The 3 MID estimates were widely separated and the higher anchor based estimate was settled on.

VALIDATION OF THE ACTIVITY IMPAIRMENT ASSESSMENT IN PATIENTS WITH ACUTE BACTERIAL SINUSITIS

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OBJECTIVES: To document the psychometric properties and estimate a minimal important difference (MID) for the Activity Impairment Assessment (AIA) questionnaire in patients with acute bacterial sinusitis. The AIA has previously been validated in people with uncomplicated urinary tract infections. METHODS: Secondary psychometric analysis was undertaken on data from a phase III trial to evaluate the efficacy and safety of moxifloxacin over 5 consecutive days in the treatment of acute bacterial sinusitis (N = 374). Trial patients also completed the RAND SF-36, the Sinonasal Outcomes Test-16 (SNOT-16) and a global rating of change. The AIA has 5 items and is scored as a uni-dimensional measure of the impact of disease on an individual’s work or regular activities. Internal consistency and construct validity (against SF-36 and SNOT-16) were assessed at baseline. Sensitivity and MID were assessed by comparing test of cure data against baseline using statistical methods (effect size (ES), standardised response mean (SRM); and standard error of measure-