VALIDATED MEASURES OF HEALTH RELATED QUALITY OF LIFE AND PRODUCTIVITY IN A POPULATION OF PATIENTS REPORTING CHRONIC CONSTIPATION

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**OBJECTIVES:** To quantify the effects of chronic constipation on health-related quality of life, work productivity, and activity impairment. **METHODS:** Data are taken from the 2005 U.S. National Health and Wellness Survey, an annual cross-sectional study of the health care attitudes and behaviors of adults (age 18+). Chronic constipation sufferers are defined as experiencing chronic constipation in the past twelve months, and non-sufferers have not experienced chronic constipation. Respondents who experience inflammatory bowel disease or irritable bowel syndrome are excluded from the analysis. Quality of life is defined using the SF-8. The Work Productivity and Activity Impairment (WPAI) scale is used to quantify productivity loss. Linear regression models are used to control for potential confounders including demographics, number of physical comorbid conditions, and experiencing psychiatric comorbid conditions. **RESULTS:** The sample includes 1,288 (3%) chronic constipation sufferers and 35,676 (97%) non-sufferers. Chronic constipation sufferers have significantly worse mean physical (40.08 versus 47.89, \(p < 0.001\)) and mental (42.13 versus 49.75, \(p < 0.001\)) quality of life than non-sufferers. Controlling for potential confounders, constipation sufferers have SF-8 physical summary scores that are 3.550 (\(p < 0.001\)) points lower and SF-8 mental summary scores that are 2.891 (\(p < 0.001\)) points lower than non-sufferers. Among respondents employed full-time, chronic constipation sufferers have significantly greater productivity loss due to absenteeism (8.35 versus 3.10, \(p < 0.001\)), presenteeism (29.36 versus 13.36, \(p < 0.001\)), and overall (25.54 versus 12.18, \(p < 0.001\)). Controlling for potential confounders, constipation sufferers have greater absenteeism scores (3.102 points higher, \(p < 0.001\)), presenteeism scores (7.782 points higher, \(p < 0.001\)), and overall work productivity loss (6.017 points higher, \(p < 0.001\)) than non-sufferers. Chronic constipation sufferers also experience greater activity impairment (48.71 versus 21.75, \(p < 0.001\)) than non-sufferers, and have activity impairment scores 11.708 higher (\(p < 0.001\)) after controlling for potential confounders. **CONCLUSION:** Chronic constipation has significant negative effects on physical and mental quality of life, work productivity, and activity impairment.
EGERTICAL REGRESSION MODEL. FIRST THE ESTIMATION PROCEDURE WAS VALIDATED THROUGH ESTIMATION OF THE MAUF FOR THE EQ-5D ATTRIBUTES BASED ON THE EXITING SPANISH TARIFF SCORES FOR THE INSTRUMENT. SECONDLY THE MAUF FOR THE SF-6D ATTRIBUTES WAS ESTIMATED REGRESSED ON THE EQ-5D TARIFF SCORES. WEIGHTS WERE RESCALED TO YIELD SCORES RANGING FROM WORSE POSSIBLE STATE (0) TO FULL HEALTH (1). RESULTS: ALL ESTIMATED ATTRIBUTE WEIGHTS WERE SIGNIFICANT AND GOODNESS OF FIT WAS REASONABLE (R2 = 0.799). SPANISH UTILITY VALUES FOR THE SAME HEALTH STATES ARE SIGNIFICANTLY DIFFERENT FROM THOSE USED IN THE UK: 0.7458 (0.208) VS. 0.7090 (0.143), P < 0.001. THE SHAPE OF UTILITY SCORES OBTAINED WITH THE SPANISH MAUF EXHIBITS A CUBE PATTERN AS COMPARED TO THE BRITISH. UTILITIES OBTAINED BY THE SPANISH MAUF ARE HIGHER FOR BENIGN HEALTH STATES WHILE SEVERE STATES ATTAIN LOWER UTILITIES. CONCLUSION: THE PROPOSED METHOD ALLOWS FOR A VALID AND RELIABLE ESTIMATION OF A MAUF BASED ON KROWN UTILITIES OF A CONCURRENT INSTRUMENT, AVOIDING THE NEED OF INCOMPLETE DESIGNS TO COLLECT PREFERENCES. EVIDENT DIFFERENCES BETWEEN CULTURE SPECIFIC SCORING SYSTEMS ENCOURAGE ADAPTING INSTRUMENTS TO THE TARGET CULTURE IN ORDER TO OBTAIN VALID MEASURES. SPANISH WEIGHTS FOR SF-6D ARE NOW AVAILABLE TO BE USED WITH EXISTING OR NEW SF-36V1 DATABASES.

IMPACT OF CERTOLIZUMAB PEGOL ON QUALITY-ADJUSTED LIFE-YEARS IN TWO INDUCTION AND MAINTENANCE TRIALS IN PATIENTS WITH ACTIVE CROHN’S DISEASE

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OBJECTIVES: The efficacy and safety of certolizumab pegol (CZP), a PEGylated anti-TNF, in patients with active Crohn’s disease (CD) have been demonstrated in two 26-week induction and maintenance trials, PRECiSE 1 (Sandborn et al., 2005) and PRECiSE 2 (Schreiber et al., 2005). This analysis evaluated the effect of CZP versus placebo on quality-adjusted life-years (QALYs) for each subject in these trials. METHODS: In PRECiSE 1, patients with active CD received double-blind CZP 400 mg (n = 331) or placebo (n = 328) every 4 weeks after induction. PRECiSE 2 began with an open-label induction period (CZP 400 mg at Weeks 0, 2 and 4). Patients who demonstrated a clinical response at Week 6 were randomised to receive CZP 400 mg (n = 215) or placebo (n = 210) every 4 weeks from Weeks 6 to 24. The EQ-5D was administered at each visit and converted into utility scores using an established algorithm (Dolan et al., 1995). An estimate of QALYs was made for each patient from the area under the utility curve during the randomisation period of each trial. Mean QALYs and standard deviation (SD) were calculated by treatment group and compared using a Wilcoxon Rank sum test. RESULTS: Over the 26-week PRECiSE 1 trial, the mean (SD) QALYs were 0.5456 (0.2993) for CZP and 0.4797 (0.3121) for placebo. Similarly, between Weeks 6 and 26 of PRECiSE 2, the mean (SD) QALYs were 0.4976 (0.2047) in the CZP group versus 0.4286 (0.2171) in the three injection followed by placebo group. A statistically significant gain in QALYs with CZP was observed in both trials: PRECiSE 1 0.0659 (p = 0.001); PRECiSE 2 0.0690 (p = 0.015). CONCLUSION: CZP improved both quality and quantity of remission and response period, as measured by QALYs, significantly more than placebo among patients with CD in two 26-week maintenance trials.