



**Abbreviations:** CDC: Centers for Disease Control and Prevention; HRQoL: Health Related Quality of Life; ICD 10: International Classification of Diseases, Tenth Revision; MEPS: Medical Expenditure Panel Survey; MCS: Mental Component Scores; PCS: Physical Component Scores; OLS: Ordinary Least Squares; SF12-12 item Short Form Survey

## Background

The Centers for Disease Control and Prevention (CDC) estimates 37.3 million Americans-about 11.3% of the US population, suffer from diabetes mellitus [1]. The disease had a diagnosis incidence of

and the extent to which patient level characteristics impact HRQoL in those with complications of neuropathy. We hypothesize that though anticonvulsant therapy improves patient quality of life, the poor quality of life of diabetic patients suffering from neuropathy persists despite anticonvulsant therapy, and patient’s quality of life measures remain lower than the general diabetic patient population after controlling for patient specific characteristics.

This study evaluates the quality of life of diabetic patients on anticonvulsant therapy, using the 12 item Short Form Survey (SF-12) physical component scores (pcs) and mental component scores (mcs) to estimate the gap in HRQoL in optimally treated diabetic neuropathy patients in comparison to the general diabetic population. This study explores the potential to improve the quality of life for patients with diabetic neuropathy, and the extent to which differences in person-level characteristics contribute to poor health-related quality of life.

## Methods

Given the need for a deeper understanding of the extent to which modifiable and non-modifiable patient characteristics explain differences in patient reported HRQoL, and how quantifying such differences can inform more robust treatment and intervention policies, we employed the Blinder Oaxaca decomposition analysis to assess and better understand the contribution of patient-level factors to poor HRQoL among diabetics on anticonvulsant therapy on controlling for characteristics such as age, gender, employment, physical activity, and comorbidity. We employed data from the 2020 Medical Expenditure Panel Survey (MEPS) for the analysis after merging and weighting the prescribed medicines, conditions, and condition-event linkages, with the Full-Year Consolidated data. We used univariate and bivariate analyses to examine subgroup differences among diabetics on anticonvulsants and non-anticonvulsant diabetic patient cohorts. We measured HRQoL using patient pcs and mcs scores, with multivariate linear regressions evaluating the magnitude of the variation in HRQoL between both cohorts, on controlling for patient specific characteristics. Finally, we employed a decomposition analysis to identify the explained and the unexplained portions of difference in patient HRQoL.

## Study cohort

We identified diabetic patients using the international classification of diseases (ICD) 10 classification code E11 diagnosing patients with diabetes mellitus. We also identified a sub-cohort of diabetic patients on anticonvulsant therapy, pooling their mcs and pcs scores to compare with scores from diabetic patients who were not on anticonvulsant therapy. Patient characteristics evaluated include age, gender, employment, insurance status, physical activity, and presence of other comorbidities.

## Statistical analysis

We obtained summary statistics using univariate and bivariate analyses comparing demographic characteristics of diabetics with and without anticonvulsant treatment. Multivariate regression analysis quantified the significance of differences in mcs and pcs scores between both cohorts. We decomposed post regression estimation weights using the Blinder Oaxaca decomposition to examine the relative contribution of factors in explaining the average differences in mcs and pcs scores between the two groups. We employed STATA SE 18.0 statistical software in analyses with a p-value of < 0.05 set to determine the level of significance with a 95% confidence interval.

## Results

The total number of diabetic patients sampled in the MEPS 2020 dataset was 34,815. Of these 624 were on anticonvulsant treatment. Gabapentin was the most common anticonvulsant medication taken, with 76.6% of all the diabetics prescribed anticonvulsants taking gabapentin. Table 1 shows the characteristics of both the anticonvulsant and non-anticonvulsant diabetic patient cohorts.

Table 2 presents the results from the ordinary least squares (OLS) regression output. The physical component scores and the mental component scores of patients HRQoL were the outcome variables. Our results show how likely these differ across cohorts. Diabetic patients on anticonvulsant therapy had lower pcs and mcs scores ( $\beta = -5.24$ ;  $P < 0.001$ ,  $\beta = -3.151$ ;  $P < 0.01$ ) respectively, demonstrating an overall lower HRQoL.

Table 3 presents the results of the decomposition which show a mean predicted pcs score of 33.21 for diabetics on anticonvulsant medication and 39.45 for the general diabetic population, yielding a

pcs score disparity of 6.24 on controlling for age, gender, body mass index, employment status, presence of comorbidity, and limitations in physical activity. In general, about 5.05-unit pcs change in HRQoL are unexplained by the patient specific characteristics. We see that after controlling for the observed covariates, about 80.93% of the disparity in pcs scores are unexplained and may be intrinsic to the effects of the disease complication. The mean predicted mcs scores were 46.58 and 47.79 for diabetics on anticonvulsant medication and controls, respectively.

