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Poor Health-Related Quality of Life Associated with Diabetic Patients on Anticonvulsant Medication: A Blinder-Oaxaca Decomposition

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Abstract

This study evaluates the potential to improve the quality of life for diabetic patients with comorbidities that warrant adjunctive anticonvulsant medication treatment. It explores the extent to which differences in person-level characteristics contribute to poor health related quality of life (HRQoL), and the gap in HRQoL in optimally treated diabetic neuropathy patients.

It employs a retrospective cohort design utilizing data from the Medical Expenditure Panel Survey (MEPS) to estimate HRQol in patients with diabetes mellitus. It applies the mental component scores (mcs) and the physical component scores (pcs) from the 12 item Short Form Survey (SF12) questionnaire to estimate differences in patient overall health and quality of life among diabetics on anticonvulsant medication. A Blinder Oaxaca regression decomposition analysis performed from post linear regression quantified how much of the difference between mcs and pcs scores are explained by patient characteristics such as age, gender, race, employment, and other chronic conditions among diabetic patients on anticonvulsant medication in comparison to the general diabetic patient population.

The results reveal that ceteris paribus, diabetic patients on anticonvulsant therapy were more likely to have lower pcs and mcs scores ($\beta=-5.24$; $P<0.001$, $\beta=-3.151$; $P<0.01$) respectively, demonstrating an overall lower HRQoL. About 80% of the difference in pcs scores were unexplained by observed patient characteristics and may be intrinsic to disease complication or gaps in treatment. The study shows how modifiable and non-modifiable patient characteristics explain health status differences, and how addressing patient needs depends on implementing robust treatment and intervention policies both within and beyond the healthcare sector.

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 5.9 cases per 1,000 persons in 2019 [2], and the total cost of managing it and its associated complications stood at $237 billion in 2017 [3]. One of the disabling complications of diabetes is neuropathy and neuropathic pain. It negatively affects the patient's quality of life, with chronic pain being the major cause of suffering [4] Treatment usually comprises pain management and tighter glycemic control. The mainstay of treatment for diabetic neuropathy are anticonvulsants, with gabapentin, pregabalin, and topiramate being the most employed. These medications slow disease progression and improve pain control when matched with better glycemic control [5], leading to improved quality of life [6]. The extent of this improvement, however, is unclear and varies from patient to patient.

Inasmuch as objective and empirical patient management are hallmarks for patient care, patient experience and quality of life reports are useful evaluations of subjective treatment effectiveness. Such patient perspectives of care are obtainable using health related quality of life measures that provide insight for clinicians to better understand specific patient needs [7]. This enables finer calibration of treatment and management strategies to better suit these needs. It becomes very important in diabetic neuropathy where patients feel the range and extent of disease severity, and treatment directly impacts coping with daily life activities. Patient reported quality of life measures can therefore be useful guides to evaluating patient wellbeing and treatment impact. Patient-reported outcome measures also continue to form important key performance indicators in disease management, patient care, and health systems quality metrics.

Unfortunately, research shows that healthcare providers often under-detect and underestimate patient symptomology and disease severity, and there is discordance in clinician evaluations and patient self-reporting of symptoms and disease severity [8]. This discordance could affect disease management, symptom control, treatment adherence, recovery, and survival. The phenomenon is more common in chronic disease conditions that impact patient quality of life.

Given this discordance in provider and patient perspectives on treatment outcomes, there is need to better understand how patient health related quality of life (HRQoL) differs among diabetic patients,

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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. The 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 link files, 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

Table 1: Summary statistics.

	Diabetic (Not on anticonvulsant)			Diabetic (On anticonvulsant)					
	n	**%**		**n**	**%**		**Total**	**%**	**p-value**
Gender									≤ 0.018
Female	17,759	51.94		354	56.73		18,113	52.03	
Male	16,432	48.06		270	43.27		16,702	47.97	
Total	34,191	100		624	100		34,815	100	
Race									≤ 0.001
White	24,442	71.49		508	81.41		24,950	71.66	
Black	6,487	18.97		77	12.34		6,564	18.85	
Native ameri	611	1.79		12	1.92		623	1.79	
Asian	1,268	3.71		15	2.4		1,283	3.69	
Multi-race	1,383	4.04		12	1.92		1,395	4.01	
Total	34,191	100		624	100		34,815	100	
Limitation in physical functioning									≤ 0.003
no	13,255	58.94		176	51.01		13,431	58.82	
yes	9,235	41.06		169	48.99		9,404	41.18	
total	22,490	100		345	100		22,835	100	
Health insurance coverage									≤ 0.001
private	14,437	42.22		191	30.61		14,628	42.02	
public	19,052	55.72		429	68.75		19,481	55.96	
uninsured	702	2.05		4	0.64		706	2.03	
total	34,191	100		624	100		34,815	100	
Co-condition									≤ 0.001
no	1,271	5.62		48	13.48		1,319	5.75	
yes	21,332	94.38		308	86.52		21,640	94.25	
total	22,603	100		356	100		22,959	100	
Employment									≤ 0.001
no	23,004	67.8		476	77.65		23,480	67.98	
yes	10,925	32.2		137	22.35		11,062	32.02	
total	33,929	100		613	100		34,542	100	
Continuous variables									
	n	mean	sd		n	mean	sd		
age	34,191	62.94	13.04		624	62.29	11.93		
bmi	24,370	32.83	7.674		425	31.81	9.189		
mcs	25,654	49.1	11.14		445	45.49	12.1		
pcs	25,666	39.05	12.49		445	33.13	11.53		

Table 2: OLS regression pcs and mcs.

VARIABLES	(1) pcs	(2) mcs
Diabetic (1=anticonvulsant)	-5.243***	-3.151**
	-1.373	-1.471
age	-0.0784**	0.0740**
	-0.0341	-0.0366
Gender (1=male)	0.202	0.52
	-0.855	-1.109
Race (reference white)		
black	-2.451*	-1.167
	-1.272	-1.491
Native american	-0.622	-9.725*
	-2.109	-5.579
asian	-1.759	2.03
	-2.29	-1.505
Multiple race	-2.436	-6.597*
	-1.947	-3.769
bmi	-0.155***	-0.160**
	-0.0506	-0.0787
Other co-condition	0.822	-1.564
	-1.376	-1.6
Employment (1=yes)	3.785***	
	-1.068	
Lack physical activity (1=yes)	-11.12***	
	-1.153	
Insurance coverage (ref private)		
Public only	-3.842***	
	-0.923	
uninsured	-7.955**	
	-3.827	
Constant	54.88***	51.51***
	-3.5	-4.4
Observations	16,219	16,219
R-squared	0.428	0.058

*** p<0.01, ** p<0.05, * p<0.1. Standard errors in parentheses

Table 3: shows the Blinder Oaxaca decomposition.

VARIABLES	(1) pcs	(2) pcs	(3) pcs	(4) mcs	(5) mcs	(6) mcs
age		0.0981	1.903		-0.11	0.173
		-0.156	-7.663		-0.171	-6.856
gender		0.0475	-0.99		0.0395	2.183
		-0.0999	-1.541		-0.109	-1.492
bmi		-0.404	-2.728		-0.29	3.213
		-0.318	-3.897		-0.309	-4.517
Existing co-condition		0.2	-4.400*		0.0971	-5.665*
		-0.238	-2.466		-0.242	-2.982
employment		1.02	-0.151			
		-0.617	-0.844			
Lack physical activity		0.229	-0.783			
		-0.707	-1.487			
group_1	39.45***			47.79***		
	-0.881			-0.776		
group_2	33.21***			46.58***		
	-1.752			-1.448		
difference	6.240***			1.21		
	-1.715			-1.337		
explained	1.191			-0.264		
	-1.344			-0.486		
unexplained	5.049***			1.474		
	-1.213			-1.288		
Constant			12.2			1.57
			-10.52			-8.303
Observations	7,304	7,304	7,304	7,304	7,304	7,304

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 the general diabetic population respectively. The difference in mcs scores were, however, not statistically significant suggesting the complication has a more physical strain on patients than mental.

Discussion

Our findings draw attention to valuable patient perspectives of the care diabetics receive, as obtained from HRQoL measures, and how these vary across complications involving diabetic neuropathy. These measures can provide clinician's insight to better understand gaps in specific patient needs and to respond by tailoring interventions that address these needs. Prior studies involving diabetic patient reported outcomes show that patient HRQoL improves with treatment [9]. This study suggests that disease related disparities exist for patients with complications, especially diabetic neuropathy despite treatment, and the improvements in HRQoL needs closer attention. This is because the improvement obtained by anticonvulsant treatment leaves gaps in patient physical wellbeing, such that patients do not enjoy higher levels of HRQoL, nor match the levels of the general diabetes patient population. We find that about 80% of this gap is not due to patient individual characteristics but rather to the disease and gaps in management. These gaps can be narrowed through more intensive and engaging treatment interventions. Caregivers must continue to seek opportunities to modify patient treatments for better outcomes and higher quality of life [10].

The results from the pooled regression weights show that the patients exhibit lower physical component scores unexplained by individual patient characteristics alone and are intrinsic to the complication. This becomes more important when we consider that the patients were receiving treatment but continued to experience the observed lower pcs scores, suggesting current treatments for diabetic neuropathy may not be optimum. Care providers need to probe deeper when engaging with patients to fully grasp the gaps in care and discern opportunities to optimize treatment interventions.

The findings from this study are strengthened by the use of a nationally representative data set, the national MEPS survey. The post-decomposition methodology helps identifies the unexplained gap in HRQoL between the two cohorts by examining the extent to which individual level factors contributed to patient reported quality of life. The study limitations include the single year (MEPS 2020 data) consideration or measures hence the study has no longitudinal arm to observe the long-term effects of treatment on the gap in HRQoL across the cohorts. The study also was unable to adjust for severity of symptoms of diabetic neuropathy as this may help understand how the gap in HRQoL distributes across disease severity. The decomposition technique identifies the explained and unexplained gap in HRQoL but does not unravel the intrinsic or disease related reasons and mechanisms by which these gaps manifest.

Care providers and treatment policy makers managing diabetic neuropathy can re-position their approach to better serve patients by providing useful intervention that maximize treatment impact and improve care pathways and patient wellbeing, especially as it relates to

physical components of care.

In such chronic conditions, an assessment of patient HQRoL as affected by disease complications will help highlight the gaps in treatment and better inform treatment approaches. There is therefore a need to better understand patient perspectives of care received, as obtainable using health related quality of life measures. The measures provide better insight to clinicians on management strategies and specific patient needs. Further research is needed to explore the intrinsic causes of the observed gaps in patient reported outcome measures for diabetic neuropathy.

Conclusion

Our findings show that individual characteristics do not completely explain differences in HRQoL among diabetic patients in general and diabetics with secondary complications needing anticonvulsant treatment. We see that even though anticonvulsant treatment helps, it does not fully restore patient's quality of life to the level obtainable in the general diabetic population. This calls for further research in this area to help identify more ways to improve the quality of life for patients with diabetic neuropathy. New interventions are needed which may include newer ways of disease management, newer therapies, as well as expanded care models that encompass non-health sector interventions if we are to improve both the physical and mental aspects of overall patient quality of life.

This study ascertained the extent to which HRQoL differences are explained by modifiable and non-modifiable patient characteristics and informs robust intervention policies needed to encompass patient needs both within and beyond the healthcare sector.

Ethical Approval

Not applicable. This project utilized secondary data consisting de-identified publicly available data. It does not include interaction with human subjects and there was no access to identifiable private information.

Availability of Data and Materials

The Medical Expenditure Panel Survey (MEPS) data utilized for this study is publicly available and can be downloaded from the MEPS website: https: //meps.ahrq.gov/mepsweb/

Competing Interests

No competing interests.

Authors' Contributions

This manuscript was researched and written by the author indicated

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Authors' Information

The author is a registered pharmacist with a PhD in health policy with interests in health economics and outcomes research, real world evidence and patient reported outcomes.

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