

Assessment of Health Related Quality of Life in Indian Generalized Anxiety Disorder Patients

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ABSTRACT

Introduction

Quality of life (QoL) is a broad concept that takes into consideration of both health related and non-health related aspects of life. Objective of the study was to assess QoL in patients suffering from generalized anxiety disorder (GAD).

Methods

This was a single-center prospective observational study. The inclusion criteria were patients with GAD, both genders, patients with age group 18-60 years, and patients willing to participate. A total of 352 patients were analyzed at the baseline visit. Health-related quality of life (HRQoL) data were collected for patients with GAD using the Short Form-12 Health Survey-version 2 (SF-12v2) and EuroQoL-5 Dimension (EQ-5D-5L) questionnaires.

Results

The mean scores for Physical Component Summary (PCS-12) and Mental Component Summary (MCS-12) of SF-12v2 in study were 47.68 ± 5.99 and 36.32 ± 4.78 respectively. It was observed that variables are generally associated with lower scores on MCS-12 than on PCS-12 in the analysis of the variables. EQ-5D-5L index score of female patients was lower than that of male patients (0.268 ± 0.105 versus 0.281 ± 0.119). EQ-VAS score for female patients was also lesser compared to that of male patients (52.0 ± 20.49 versus 57.5 ± 17.08) in EQ-5D-5L.

Conclusion

GAD has potential to decrease HRQoL significantly by affecting both physical and mental health status of the patients in SF-12v2 in addition to mobility, self-care, usual activities, pain/discomfort, and anxiety/depression in EQ-5D-5L.

INTRODUCTION:

Anxiety is a natural psychologically protective response to a dangerous or undesirable circumstance.¹ Work, social, and health functioning are the areas where anxiety has a big negative impact.² The most common psychiatric problems are anxiety disorders, which carry a heavy burden of sickness.³ The majority of generalized anxiety disorder (GAD) patients arrive between the ages of 35 and 45 years.⁴ In India, 44.9 million of the population suffered with anxiety disorders in 2017.⁵

Quality of life (QoL) is defined by the WHO as “individuals' perceptions of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns”. QoL is a broad concept that takes into consideration of a person's physical and mental state, independence level, socialization, and personal confidence, as well as their relationship with environment.⁶ Both health related and non-health related aspects of life (economical, political and cultural) are included in QoL for assessing people's perceptions of their lives in general. The component of a person's QoL, known as health related quality of life (HRQoL) illustrates the functional effect of a disease along with its resulting treatment as experienced by a person suffering from illness.⁷ HRQoL focuses solely on a patient's nonclinical data such as functional status, well-being, perception of health, return to work following an illness, and other health outcomes that are directly impacted by health status, while QoL considers all facets of life.⁸ Throughout the lifetime, anxiety disorders significant and noxious affect QoL especially in untreated case.^{2,9}

The aim of this study is to assess HRQoL in GAD for adult using two different sets of questionnaires for QoL. These questionnaires are used for better understanding of the impact of GAD on humanistic outcome in pharmacoeconomics.

MATERIALS AND METHODS:

Study Design

This was a prospective observational study and the site of the study was Psychiatry Department, Teerthanker Mahaveer Hospital and Research Centre, Moradabad, India. HRQoL is assessed for the adults with GAD in Indian population who sought health care for their mental health disorder from December 2022 to November 2023.

Study Population

The inclusion criteria were patients with GAD, both male and female patients, patients within 18-60 years age group, and willingness to participate. Patients in pregnancy and lactation, not willingness to participate, and patients on psychotherapy for GAD were exclusion criteria.

Signing an informed consent form is prerequisite to participate in the study for each and every patient. Questionnaires were asked to the enrolled patients at the first visit in the hospital.

Sample size calculation

Sample size was calculated 377 supported by Epi-Info software of Centre for Disease Control and Prevention.

Assessment of Quality of Life

HRQoL data were collected for patients with GAD using the Short Form-12 Health Survey-version 2 (SF-12v2) and EuroQoL-5 Dimension (EQ-5D-5L) questionnaires. The validated and reliable Hindi version of SF-12v2 and EQ-5D-5L questionnaires for India was provided by QualityMetric and EuroQol group respectively. SF-12v2 questionnaire consists of 12 questions incorporating Physical Component Summary (PCS-12) and Mental Component Summary (MCS-12). All the questions have 5 response options except two physical health questions with only 3 options as shown in Table 1. The standardization of both PCS and MCS is carried out with a mean and standard deviation (SD) scores of 50 and 10 respectively.¹⁰ Better health status has the higher score and vice versa.¹¹

Mobility, self-care, usual activities, pain/discomfort, and anxiety/depression are five dimensions each with five severity levels (no problems, slight problems, moderate problems, severe problems, and extreme problems/unable) make up the descriptive self-administered EQ-5D-5L questionnaire system hence it defines $5^5=3125$ possible health states.¹² A 5-digit code representing the patient's health status in EQ-5D-5L can be formulated by combining the response for the five dimensions ranging from 11111, which indicates no problem at all to 55555, which indicates extreme problems/unable.¹³ Participants indicate their health state on EQ visual analog scale (VAS), which range from 0 (the worst possible health) to 100 (the best possible health).¹² The range of index scores is -0.59 to 1 .¹⁴ Negative value, zero and one represent worse than death, zero and perfect health respectively.¹²

Statistical analysis

The data was statistically analyzed using SPSS Statistics version 23. Continuous data were presented as mean $\pm$ SD, whereas categorical data were expressed as percentage. Student's t test as statistical method was used to compare the means of two groups. Statistical significant was considered at $p < 0.05$ for all the tests. Patient-Reported Outcome (PRO) CoRE software was used for scoring of SF-12v2 Questionnaire whereas the EQ-5D-5L index was calculated utilizing the method established by the EuroQol Group.

Ethical consideration

The protocol was approved by Teerthanker Mahaveer University Institutional Ethics Committee (TMU-IEC), Moradabad (Registration Number TMU/IEC/2021-22/66). Researcher invited enrolled patients for the baseline interview after sharing them about all study relevant information.

Table 1 SF-12 structure component and number of response options

Component	Subscale	Item Code	Number of response options
Physical component score (SF-12)	General health	Item 1	5
	Physical health	Item 2 and 3	3
	Role-physical	Item 4 and 5	5
	Bodily pain	Item 8	5
Mental component score (SF-12)	Role-emotional	Item 6 and 7	5
	Mental health	Item 9 and 11	5
	Vitality	Item 10	5
	Social function	Item 12	5

RESULTS:

All 352 patients responded to SF-12v2 and EQ-5D-5L at baseline in hospital. Table 2 summarizes the sociodemographic characteristics of the 352 patients. The majority of patients were females (56.5%) under 60 years of age. PCS-12 is higher in patients with age less than 40 years compared to age greater than or equal to 40 years (48.86 ± 7.83 versus 42.97 ± 5.52). There was not fixed trend in PCS-12 and MCS-12 for patients having primary, secondary, intermediate, and university education level. Data shows that mean value of MCS-12 is lesser than PCS-12 (36.32 ± 4.78 versus 47.68 ± 5.99) as shown in Table 3. PCS-12 has the minimum score of 39.07 and the maximum score of 58.37 whereas MCS-12 has the minimum score of 25.65 and the maximum score of 42.76.

Table 2 PCS-12 and MCS-12 scores of SF-12v2 in different levels of sociodemographic characteristics

Characteristics	Total Sample (N=352) n (%)	PCS-12 mean $\pm$ SD	MCS-12 mean $\pm$ SD
Age (years)			
<40	231 (65.6)	48.86 ± 7.83	36.28 ± 5.32
≥ 40	121 (34.4)	42.97 ± 5.52	36.49 ± 3.72
Sex			
Male	153 (43.5)	47.29 ± 6.35	37.19 ± 5.09
Female	199 (56.5)	47.85 ± 7.21	35.95 ± 5.01
Education level			
Primary	79 (22.4)	43.15 ± 4.13	36.64 ± 3.64
Secondary	57 (16.2)	55.54 ± 6.35	31.65 ± 4.43
Intermediate	102 (29.0)	46.34 ± 5.63	38.61 ± 4.62
University	114 (32.4)	51.47 ± 6.28	36.67 ± 2.79
Marital status			
Married	159 (45.2)	47.66 ± 4.65	36.06 ± 3.49
Unmarried	151 (42.9)	49.86 ± 8.55	36.13 ± 7.67
Widowed	31 (8.8)	39.07 ± 4.21	38.42 ± 3.86
Divorced	11 (3.1)	46.38 ± 2.43	34.43 ± 4.17
Employment status			
Employed	71 (20.2)	45.97 ± 5.87	37.76 ± 7.06
Unemployed	281 (79.8)	48.11 ± 6.71	35.96 ± 4.64

Data shows that mean value of MCS-12 is lesser than PCS-12 (36.32 ± 4.78 versus 47.68 ± 5.99) as shown in Table 3. PCS-12 has the minimum score of 39.07 and the maximum score of 58.37 whereas MCS-12 has the minimum score of 25.65 and the maximum score of 42.76.

Table 3 SF-12v2 Physical and Mental Component Summary Scores

Component summary of SF-12v2	No. of patients	Mean	Standard deviation	Minimum score	Maximum score
PCS-12	352	47.68	5.99	39.07	58.37
MCS-12	352	36.32	4.78	25.65	42.76

Scoring of SF-12v2 was performed using PRO CoRE software developed by QualityMetric as shown in Figure 1.

	A	B	C	D	E	F	G
1	RECORDID	USUBJID	VISIT	QSTESTCD	QSSTRESN	QSTEST	QSDRVFL
2	TMUH001	RKPH001	Baseline	SF12301		4 SF123-In General You Say Your Health Is	
3	TMUH001	RKPH001	Baseline	SF12302A		3 SF123-Limit Moderate Activities	
4	TMUH001	RKPH001	Baseline	SF12302B		3 SF123-Limit Climbing Several Flights	
5	TMUH001	RKPH001	Baseline	SF12303A		5 SF123-Physical: Accomplished Less	
6	TMUH001	RKPH001	Baseline	SF12303B		5 SF123-Physical: Limited Kind of Work	
7	TMUH001	RKPH001	Baseline	SF12304A		4 SF123-Emotional: Accomplished Less	
8	TMUH001	RKPH001	Baseline	SF12304B		3 SF123-Emotional: Did Work Less Carefully	
9	TMUH001	RKPH001	Baseline	SF12305		4 SF123-Pain Interfere With Normal Work	
10	TMUH001	RKPH001	Baseline	SF12306A		4 SF123-Have You Felt Calm and Peaceful	
11	TMUH001	RKPH001	Baseline	SF12306B		4 SF123-Did You Have a Lot of Energy	
12	TMUH001	RKPH001	Baseline	SF12306C		4 SF123-You Felt Downhearted and Depressed	
13	TMUH001	RKPH001	Baseline	SF12307		4 SF123-Time Phys/Emotional Interfered	
14	TMUH001	RKPH001	Baseline	SF12308		100 SF123-Physical Functioning 0-100 Score	Y
15	TMUH001	RKPH001	Baseline	SF12309		100 SF123-Role Physical 0-100 Score	Y
16	TMUH001	RKPH001	Baseline	SF12310		25 SF123-Bodily Pain 0-100 Score	Y
17	TMUH001	RKPH001	Baseline	SF12311		25 SF123-General Health 0-100 Score	Y
18	TMUH001	RKPH001	Baseline	SF12312		25 SF123-Vitality 0-100 Score	Y
19	TMUH001	RKPH001	Baseline	SF12313		75 SF123-Social Functioning 0-100 Score	Y
20	TMUH001	RKPH001	Baseline	SF12314		62.5 SF123-Role Emotional 0-100 Score	Y
21	TMUH001	RKPH001	Baseline	SF12315		50 SF123-Mental Health 0-100 Score	Y
22	TMUH001	RKPH001	Baseline	SF12316		57.06 SF123-Phys Functioning Norm-Based Score	Y
23	TMUH001	RKPH001	Baseline	SF12317		57.46 SF123-Role Physical Norm-Based Score	Y
24	TMUH001	RKPH001	Baseline	SF12318		30.67 SF123-Bodily Pain Norm-Based Score	Y

Figure 1 Scoring of SF-12v2 Questionnaire using PROCoRE software by QualityMetric

Response of all GAD patients for SF-12v2 in term of number and percentage of patients is shown in Table 4.

Table 4 Response of GAD patients for SF-12v2

Question No.	Questions	Total Sample (N=352) n (%)				
		1	2	3	4	5
1	General rating of health	28 (8.0)	14 (4.0)	104 (29.5)	195 (55.4)	11 (3.1)
2	Limitations in moderate activities due to health	91 (25.8)	188 (53.4)	73 (20.7)	—	—
3	Limited in climbing stairs due to health	89 (25.3)	235 (66.8)	28 (7.9)	—	—
4	Accomplished less due to physical health	35 (9.9)	32 (9.1)	94 (26.7)	149 (42.3)	42 (11.9)
5	Limited in daily activities due to physical health	32 (9.1)	39 (11.1)	107 (30.4)	58 (16.5)	116 (32.9)
6	Accomplished less due to emotional problems	42 (11.9)	31 (8.8)	203 (57.7)	76 (21.6)	0
7	Less careful due to emotional problems	16 (4.5)	72 (20.4)	187 (53.1)	77 (21.9)	0
8	Pain affected normal work	0	65 (18.5)	218 (61.9)	44 (12.5)	25 (7.1)
9	Felt calm and peaceful	0	4 (1.1)	187 (53.1)	97 (27.5)	64 (18.2)
10	Had a lot of energy	5 (1.4)	43 (12.2)	93 (26.4)	151 (42.9)	60 (17.0)
11	Felt down and depressed	8 (2.3)	45 (12.8)	201 (57.1)	63 (17.9)	35 (9.9)
12	Physical health or emotional problems affected social activities	7 (2.0)	49 (13.9)	127 (36.1)	144 (40.9)	25 (7.1)

All the 352 patients responded to EQ-5D-5L at baseline in hospital. Figure 2 summarizes the response of GAD patients for five different dimensions with five severity levels.

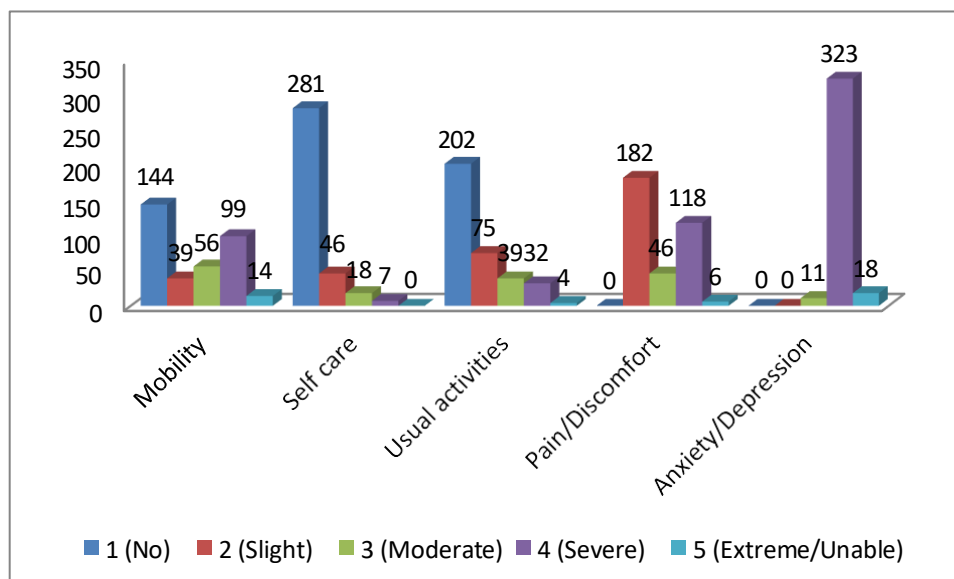


Figure 2 Response of GAD patients for EQ-5D-5L

EQ-VAS score, EQ-5D-5L index, and different dimensions were calculated for EQ-5D-5L as shown in Table 5. EQ-VAS score for total patients was found to be 54.44 ± 18.1 whereas EQ-5D-5L index for total patients was found to be 0.276 ± 0.112 . EQ-VAS score for female is lesser compared to male patients (52.0 ± 20.49 versus 57.5 ± 17.08). Similarly, EQ-5D-5L index for female is lesser compared to male patients (0.268 ± 0.105 versus 0.281 ± 0.119). Pain/discomfort (2.9 ± 0.99) and anxiety/depression (2.5 ± 1.18) are the two dimensions with higher mean score among five dimensions.

Table 5 EQ-VAS score, EQ-5D-5L index and different dimensions of EQ-5D-5L

Variables	Total	Male	Female	p value
Number of patients	352	153	199	
Age (years)	32.62 ± 12.86	30.50 ± 10.17	34.03 ± 14.37	0.043
EQ-VAS score	54.44 ± 18.1	57.5 ± 17.08	52.0 ± 20.49	0.231
EQ-5D-5L index	0.276 ± 0.112	0.281 ± 0.119	0.268 ± 0.105	0.213
Mobility	2.4 ± 1.35	1.67 ± 1.15	2.71 ± 1.38	0.275
Self care	1.1 ± 0.32	1.0 ± 0.0	1.14 ± 0.38	0.545
Usual activities	1.7 ± 1.06	1.67 ± 1.15	1.71 ± 1.11	0.455
Pain/Discomfort	2.9 ± 0.99	3.0 ± 1.0	2.86 ± 1.07	0.349
Anxiety/Depression	2.5 ± 1.18	2.33 ± 1.15	2.57 ± 1.27	0.586

DISCUSSION:

This is the first study to assess HRQoL for GAD patients using both SF-12v2 and EQ-5D-5L till date. In this study, SF-12v2 questionnaire was used to assess both physical and mental health in GAD patients while EQ-5D-5L to assess mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The advantage of the SF-12v2 and EQ-5D-5L is that both allow the comparison of HRQoL among different diseases compared to specific disease questionnaire. They are simple and

small instrument with accuracy and the minimal loss of information. Participants showed low baseline QoL indicated by below par scores.

The mean and standard deviation were calculated for each of the physical component summary (PCS) of SF-12v2 (PCS-12) and mental component summary (MCS) of SF-12v2 (MCS-12) for the analysis using listed variables. It was observed that variables are generally associated with lower scores on MCS-12 than on PCS-12 in the analysis of the variables. The mean scores for PCS-12 and MCS-12 in study were 47.68 ± 5.99 and 36.32 ± 4.78 respectively. MCS-12 was lower in female patients compared to male patients (35.95 ± 5.01 versus 37.19 ± 5.09). Education does not seem to be affecting PCS-12 and MCS-12 in particular trend.

The health state and utility score of female patients was lower than that of male patients in EQ-5D-5L. Self care and usual activities are the two most affected dimensions for GAD patients. It was also found that GAD has significant burden on HRQoL and functioning of the patient. This agrees with the findings of Dennis A Revickiet al.¹⁵

CONCLUSION:

This study provides the evidence that SF-12v2 and EQ-5D-5L are reliable and valid measure of HRQoL in Indian population. GAD has potential to decrease HRQoL significantly by affecting both physical and mental health status of the patients in SF-12v2 in addition to mobility, self-care, usual activities, pain/discomfort, and anxiety/depression in EQ-5D-5L. The use of two HRQoL instruments is a better option to assess health status compared to single HRQoL instrument due to wider range of consideration.

Conflicts of Interest:

The authors declare no conflicts of interest.

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