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QUALITY OF LIFE IN BIPOLAR AND SCHIZOAFFECTIVE DISORDER - A NATURALISTIC APPROACH

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Abstract

Purpose: The aim of this study was to evaluate the health-related quality of life (HRQoL) in bipolar type I (BD I) and schizoaffective (SQA) patients during a two-year period in a naturalistic study.

Methods: This study was based on the data generated by the Bipolar Comprehensive Outcome Study, a prospective, non-interventional, observational study of participants with BD I and SQA disorder. Mixed-Model Repeated Measures Analysis was used to analyse changes in the SF-36 and EQ-5D.

Results: Participants exhibited low health status at baseline with SF-36 mean scores of 46.7 ± 10.5 and 36.9 ± 12.9 (best imaginable health = 100, normal population ≈ 50) for physical and mental components, respectively. No significant differences were found between the ratings of the BD I and SQA patients on HRQoL. The SF-36 SMC improved significantly over 24 months although SPC scores remained consistent across the study. On the whole, the lowest SMC score was observed among the depressed patients (38.20), followed by the patients with a mixed state (39.01) and the manic patients (39.83).

Limitations: The observational design may have limited the causal relationships and the generalizability within the current findings.

Conclusions: HRQoL was significantly impaired in all stages of BD and SQA when compared to the general population. The impairment of HRQoL was most pronounced in the depressed state, followed by the mixed state and then the manic state. The euthymic patients showed the least impairment. In addition, patients showed a global improvement in their mental health satisfaction over the 2 years follow up period.

Key words: Bipolar Disorder; Schizoaffective Disorder; Health-related quality of life; SF-36; EQ-5D; Naturalistic design

Introduction

Bipolar disorder (BD) is a severe mental disease with a chronic and disabling course. Therefore, it is important not only to assess recovery in terms of symptom reduction, rates of relapse or hospitalisation, but also to recognise the patient's perspective and subjective experience of their illness to provide valuable information about outcome. Supporting this, there is an emerging consumer led movement which emphasizes that for people with severe mental disorders, wellness is not always related to symptom-reduction interventions, but is core to the subjective experience of recovery. Accordingly, mental health systems in several countries, such as the United States, the United Kingdom, Australia, New Zealand and Italy, have adopted a new consumer and family oriented care with recovery as its primary aim [1].

More specifically, there has been a recent attempt to capture the impact that changes in functioning and general well-being may have in mental disorders. In mood disorders, studies have focused on the evaluation of quality of life (QoL) [2]. The World Health Organization describes QoL as “ ‘individuals’ perception of their position in life in the context of the culture and the value system in which they live and in relation to their goals, expectations, standards and concerns”[3]. The health-related quality of life (HRQoL) is a more specific concept that refers to aspects of an individual's life that impact directly upon their health [4].

There has been growing interest in characterizing QoL and HRQoL in BD. It has been observed that patients with BD consistently have lower scores on QoL and functionality compared to the general population [5, 6]. Furthermore, some studies have found that BD is accompanied by a reduction in QoL similar to that in other psychotic disorders [7-9]. Within the BD spectrum, the lowest HRQoL scores were found during the depressed state, followed by manic/hypomanic states. While the euthymic state was associated with the least impairment of HRQoL [10-12].

The majority of these studies were retrospective and conducted with post-hospitalized euthymic bipolar patients. One recent longitudinal study in Iran examined QoL in non-euthymic bipolar patients and found that persistent depressive symptoms might be the primary determinant of impaired QoL in patients with bipolar I disorder (BD I) [9].

On a broad level, literature on quality of life and psychotic disorders suggest that there is a global impairment in the majority of these disorders, specially in schizophrenia and particularly during relapses [13]. However, there are critical gaps in the literature concerning the SQA patients and their HRQoL perception. To our knowledge, there are no previous studies focusing on the topic.

There are a wide range of instruments to assess HRQoL, the most commonly used being the 36-item Short-Form Health Survey (SF-36), the WHO Quality of Life (WHO-QoL), the Quality of Life Enjoyment and Satisfaction Questionnaire (Q-LES-Q) and the European Quality of Life Index (EQ-5D). All these are non-disease-specific instruments and predominantly were designed for monitoring health levels in whole communities [14].

The purpose of this study was therefore (a) to prospectively evaluate the HRQoL in BD I and schizoaffective (SQA) patients in a naturalistic non-interventional follow up study during a two-year period and (b) to assess the differences in QoL between the different diagnostic groups (euthymic, depressed, manic or mixed patients).

Methods

Subjects

This study was based on the data generated by the Bipolar Comprehensive Outcome Study (BCOS) [15]. This was a 2-year, prospective, non-interventional, observational study of adults with BD I or schizoaffective disorder examining clinical, functional, and economic outcomes associated with naturalistic treatment. All patients provided informed consent to participate in the study, which was conducted according to Australian ethics and privacy laws. This study included consenting males and females at least 18 years of age, with a primary diagnosis of BD I (manic, mixed, or depressed episode) or SQA disorder as defined by the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition Text Revision (DSM-IV-TR). In addition, participants had to be prescribed at least one of the following conventional mood stabilizers (CMS) (lithium carbonate, sodium valproate, or carbamazepine) or olanzapine as a mood stabilizer, or a combination of CMS plus olanzapine, actively participated in the interview process, and were willing and able to complete the self-administered instruments. Trained evaluators assessed participants on 9 separate occasions – at study entry, and every 3 months up to 24 months. Participants were assessed using formal assessment measures including Mini-International Neuropsychiatric Review (MINI) Version 5 to confirm diagnosis, the 21-item Hamilton Depression Rating scale (HAM-D21), the Young Mania Rating Scale (YMRS) and the Clinical Global Impressions-Bipolar Version Severity of Illness scale (CGI-BP) for severity of the illness. The social and occupational functioning was evaluated using the Streamlined Longitudinal Interview Clinical Evaluation from the Longitudinal Interval Follow-up Evaluation (SLICE/LIFE) and the Diagnostic Interview for Psychosis (DIP) was also used to rate impairment in work, housework and study. Each patient reported on his/her health status at each visit using a suite of assessment measures including the EQ-5D and the SF-36. Exclusion criteria were having diagnosis of schizophrenia, organic psychosis or dementia; having been involved in a clinical trial 30 days before study entry or during the study. Of a total of 499 participants screened, 48% (n = 240) were enrolled, 26% (n = 129) were eligible, but unable to participate or refused

consent, and 26%; ($n = 130$) did not meet the inclusion criteria. Of the 239 participants who had post-study entry visits 222 (93%) completed the study.

Methods

Data were obtained from participant interviews, patient medical records, and electronic administrative health care records, and were incorporated into a running record. Information collected included quality of life (both subjective and objective measures), use of concomitant medications, stability of treatment, medication adherence (patient self-reported), employment status, and any lost productivity due to illness.

Since this was an observational study, participants were not randomized to treatment, but instead, were maintained on their prior medication regimen with changes allowed. Comprehensive information about the study design, patient populations and methodology has been previously published [15].

The SF-36 is a widely used instrument. It consists of eight health dimensions: physical functioning, bodily pain, general health perception, vitality index, social functioning, overall wellbeing index, physical index, and mental health index [16]. Each of the eight dimensions is separately scored, using item weighting and additive scaling. Summed data are transformed onto a 0-100 point scale. These eight dimensions can be combined into two key health status measures, the Standardized Physical Component (SPC) and the Standardized Mental Component (SMC). For computation of the SPC and SMC, each dimension score is weighted in a three-step process to produce a standardized T-score (where the population mean score is 50, $SD = 10$). This instrument was validated in 1995 for the Australian general population and profiles were presented for individuals experiencing some illness conditions [17].

The EQ-5D is a non-disease-specific instrument for describing and valuing health states. It includes five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension has 3 levels: no problems, some problems and extreme problems. An EQ-5D health state may be converted to a single summary index by applying a formula that essentially attaches weights to each of the levels in each dimension. This enables its use in cost-effectiveness studies. This instrument has been validated in 15 countries [18].

The CGI-BP [19] is a non-symptom-based instrument that provides global measures of disease severity and improvement and it may be a better candidate than symptom-based scales to capture clinical remission since it gives a more succinct estimation of a symptom-free state. It allows for separate assessments of each phase of the illness (i.e. mania, depression, and overall illness).

Statistics

The Mixed-Model Repeated Measures Analysis (MMRM) was used to analyse change in the SF-36 standardized physical and mental health scores and the

estimated marginal means along with the mean difference and 95% confidence intervals are presented by mood disorder status (i.e. either depressed, maniac or mixed state). Depression and mania were derived from the total HAMD21 score and the total YMRS score with appropriate cut-offs respectively (≥ 15 for both instruments). The MMRM model adjusts for the fixed effects of gender, age and treatment and the random effects of YMRS and HAMD21 scores and includes all available data at each time point (9 visits). All tests were 2-tailed and a p-value of 0.05 was used for statistical significance. All analyses were performed using SPSS (Version 21).

Results

Participant characteristics

Of a total of 499 participants screened, 48% ($n = 240$) were enrolled. The sample size and its demographic characteristics as well as the clinical status of patients at baseline are summarised in Table 1. Of the 239 participants who had post-study entry visits 222 (93%) completed the study. Participants were of similar age (mean $\pm$ SD = 42 ± 13 years) and ethnic background (97.1% Caucasian). The majority of them had a diagnosis of BD I according to DSM-IV-TR criteria (73.3%). Overall, more females participated in the study (58.3%). Clinically, participants were moderately ill, based on a CGI-BP Overall mean mean ($\pm$ SD) of $3.8 (\pm 1.3)$. The HAMD21 Total mean score was $13.4 (\pm 8.6)$ and the YMRS Total mean score was $8.2 (\pm 8.5)$. On the whole, 32.9% of participants had been hospitalized in the three months prior to study entry, spending an average of 24.0 days in hospital. Interestingly, the group of SQA patients had been more often hospitalized than the BD I patients and had also had a longer average stay (30.0).

Health-related quality of life assessment

Overall, participants exhibited low health status and functioning at baseline with SF-36 mean ($\pm$ SD) scores of $46.7 \pm (10.5)$ and $36.9 (\pm 12.9)$ (best imaginable health = 100, normal population ≈ 50) for physical and mental components, respectively. No significant differences were found between the ratings of the BD I and SQA patients on both components of the SF-36 at the baseline and the following 8 visits. Whereas participants with BD I rated their overall health significantly higher than the schizoaffective participants, as measured by the EQ-5D utility scores (0.77 vs 0.67, $p=0.008$) and visual analogue scores (68.2 vs 61.6, $p=0.023$) at baseline, these differences were not significant when all 9 visits were taken into account (Figure 1). Overall, participants experienced some improvements in QoL during the course of the study. The SF-36 SMC improved significantly over 24 months (from 36.8 to 41.2; $p = 0.029$; Figure1), although SPC scores remained consistently low across the study (from 46.7 to 46.9; $p = 0.384$). These results were irrespective of age, gender, treatment or any other socio-demographical characteristics.

Health-related quality of life and diagnostic groups

The means of the SMC were significantly different depending on whether the participants were in a depressed, manic or mixed state. Tables 2, 3 and 4 show the association between the mood episode and the SPC and SMC scores on the SF-36. On the whole, the lowest SMC score was observed among the depressed patients (38.20), followed by the patients with a mixed state (39.01) and the manic patients (39.83). The euthymic patients showed the best scores on both SMC (48.02) and SPC (49.73), these approaching those of the general population. Regarding the SPC score, no significant differences were found between the manic or mixed patients and the general population. The depressed patients, however, showed a lower mean score of SPC than the other groups and general population (Table 2). These findings suggest that the depressed state is the strongest predictor of psychological and physical QoL with a mean difference of 6.62 for the SMC and of 1.16 for the SPC mean scores with respect to the non-depressed patients. It is worth pointing out that the mixed and the manic states respectively can also be good predictors of psychological QoL impairment.

Discussion

In this first prospective non-interventional observational study evaluating naturalistic outcomes of BD I and SQA patients to be conducted in Australia, we observed that on average, all participants experienced a diminished QoL when compared to general population. This finding was in line with some previous studies that reported impaired quality of life in patients with bipolar disorder [6, 10, 12]. We then compared the bipolar and schizoaffective groups, and could not find substantive differences in terms of the SF-36 and EQ-5D mean scores. There are very few studies that assess QoL in BD versus schizoaffective disorder. Saarni and colleagues found that schizoaffective disorder was associated with more severe HRQoL impairment than schizophrenia while BD was associated with similar levels of QoL as schizophrenia [20].

The main finding of this study is that the QoL is significantly lowered in all mood states. In particular, the depressed state was associated with the lowest mean score on the SMC, followed by the mixed stage and the manic stage. These results were maintained when adjusted for age, gender and treatment. Interestingly, euthymic patients showed the lowest impairment in QoL with scores approaching those in the general population. There are several studies that suggest that depressed symptoms are strong predictors of lower physical and psychological QoL [10, 21, 22]. In addition, Hayhurst and colleagues found that the depressed stage of BD was dramatically associated with low HRQoL, followed by manic/hypomanic stages, with euthymic patients reporting the least HRQoL impairment [11]. This has clear clinical implications since depression represents the predominant abnormal mood state for treated outpatients with BD I and BDII, being BD I patients depressed over 30% of the time [23]. More effort

is consequently needed to better manage depressive symptoms so that these patients can experience a better level of wellbeing.

Regarding subjective physical health perception, no significant differences were observed between the participants in a manic, mixed or euthymic state on the SPC of the SF-36. The depressed subgroup, however, showed a significantly lower score on the SPC and this could be related to the presence of somatic symptoms, which are common in this mood state with rates as high as 60% [24].

In the present study, HRQoL was not associated with age or gender or any other putative socio-demographical predictors of QoL, e.g. ethnic group, work status or relationship status. A general improvement on mental health scores was observed during the 48 months and this was irrespective of the treatment. This is a consistent finding across follow up studies, and could be interpreted as the patients felt better cared than before entering the study, since they had interviews every 3 months, added to their usual follow-up, or could reflect effects of treatment or regression to the mean.

Several limitations have to be considered when interpreting this data. First of all, observational studies are not designed to establish causal relationships but rather to examine associations. Secondly, more severe patients were excluded at study entry since they were required to provide consent to participate. In addition, it is also important to consider that we used self-reported HRQoL rating instruments and the validity of self-reports of people with severe mental disorders is sometimes questioned [20]. However, the strengths of the study are the high external validity, the high retention rate, the patient centric approach and the real world setting.

Conclusion

Overall, HRQoL was significantly impaired in all stages of BD and SQA when compared to the general population. A lowered HRQoL was most pronounced in the depressed state, followed by the mixed state and then the manic state, while the euthymic patients showed the least impairment. These findings show that persistent depressive symptoms are strong predictors of psychological and physical QoL impairment and that mixed and manic symptoms, respectively, can also be considered as predictors of loss in mental QoL. In addition, patients showed a global improvement in their mental health satisfaction over the 2 years period. These results were irrespective of age, gender, treatment or any other socio-demographical characteristics.

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Figure 1. Mental and Physical Health Assessment at Each Visit During the 24-Month Study. Mental and Physical health were assessed using the Short-Form Health Survey (SF-36).

Table 1
Demographic characteristics, clinical status and quality of life

Characteristics Total	Gender		Diagnosis		
	Women	Men	Schizoaffective disorder	Bipolar I disorder	
Total number of participants: n (%)	140	100	64	176	
240	(58.3)	(41.7)	(26.6)	(73.3)	
Ethnic group: n (%)					
Caucasian	136	97	63	170	
233	(97.1)	(97.0)	(98.4)	(96.6)	
Aboriginal and/or Torres Strait Islander	–	1 (1.0)	–	1 (0.6)	1
(0.4)					
East Asian		2 (1.4)	1 (1.0)	1 (1.6)	2 (1.1)
3 (1.3)					
West Asian	1 (0.7)	–	–	1 (0.6)	1
(0.4)					
Others	1 (0.7)	1 (1.0)	–	2 (1.1)	2
(0.8)					
Age, years: mean (SD)	42.2	41.3	39.6	42.6	
41.8	(12.5)	(12.9)	(10.3)	(13.4)	
CGI-BP-S: mean (SD)					
Mania	2.9 (1.5)	3.0 (1.8)	3.1 (1.5)	2.9 (1.7)	3.0
(1.6)					
Depression	3.5 (1.3)	2.8 (1.3)	3.1 (1.1)	3.2 (1.4)	3.2
(1.3)					
Overall bipolar illness	3.8 (1.2)	3.8 (1.4)	3.7 (1.2)	3.9 (1.4)	3.8
(1.3)					
YMRS total: mean (SD)	7.7 (8.1)	9.0 (9.1)	9.4 (10.1)	7.8 (7.9)	8.2
(8.5)					
HAMD21 total: mean (SD)	14.3 (8.7)	12.1 (8.3)	15.5 (8.4)	12.6 (8.5)	13.4
(8.6)					
Hospital admissions (in the past 3 months)					
No. of participants with an admission (%)	40 (28.6)	39 (39.0)	23 (35.9)	56 (31.8)	79
(32.9)					
Number of hospital stays					
1	33 (82.5)	35 (89.7)	15 (65.2)	53 (94.6)	68
(86.1)					
2–3	7 (17.5)	4 (10.3)	8 (34.8)	3 (5.4)	11
(13.9)					
Total number of days, mean (SD)	25.6 (18)	22.3 (13.5)	30.0 (19.6)	21.5 (13.6)	24.0
(15.9)					
SF-36 standardized					
Physical component scale, mean (SD)	45.6 (10.8)	48.1 (9.9)	45.7 (9.8)	47.0 (10.7)	46.7
(10.5)					
Mental component scale, mean (SD)	35.9 (12.9)	38.3 (12.9)	36.3 (12.6)	37.1 (13.1)	36.9
(12.9)					
EQ-5D					
VAS b, mean (SD)	65.5 (20.0)	67.8 (20.3)	61.6 (22.7)	68.2 (18.8)	
66.5 (20.1)					
Utility score c, mean (SD)	0.74 (0.3)	0.75 (0.3)	0.67 (0.3)	0.77 (0.2)	0.75
(0.3)					

Abbreviations: CGI-BP = Clinical Global Impressions-Bipolar Version Severity of Illness scale; YMRS = Young Mania Rating Scale; HAMD21 = 21-item Hamilton Depression Rating scale; SF-36=36-item Short-Form Health Survey; EQ-5D=EuroQol instrument.

Table 2. Modelling for changes in SF36 - Physical and Mental health scores by depressed patients using Mixed Model Repeated Measures Analysis

Characteristics	Estimated Marginal Means		Mean difference ¹	p-value	95% CI	
	Non-depressed	Depressed			Lower	Upper
SF-36 Standardized Mental Component Scale ¹	44.82	38.20	6.62*	<0.001	5.21	8.02
SF-36 Standardized Physical Component Scale ¹	49.33	48.18	1.16*	0.040	0.05	2.26

¹The model adjusts for Gender, Age and Treatment.

*The mean difference is significant at the 0.05 level.

Table 3. Modelling for changes in SF36 - Physical and Mental health scores by manic patients using Mixed Model Repeated Measures Analysis

Characteristics	Estimated Marginal Means		Mean difference ¹	p-value	95% CI	
	Non-manic	Manic			Lower	Upper
SF-36 Standardized Mental Component Scale ¹	43.19	39.83	3.36*	0.002	1.25	5.48
SF-36 Standardized Physical Component Scale ¹	48.87	48.64	0.24	0.812	-1.71	2.18

¹The model adjusts for Gender, Age and Treatment.

*The mean difference is significant at the 0.05 level.

Table 4. Modelling for changes in SF36 - Physical and Mental health scores by mixed patients using Mixed Model Repeated Measures Analysis

Characteristics	Estimated Marginal Means		Mean difference ¹	p-value	95% CI	
	Non-mixed	Mixed			Lower	Upper
SF-36 Standardized Mental Component Scale ¹	44.00	39.01	4.99*	0.000	2.85	7.13
SF-36 Standardized Physical Component Scale ¹	49.05	48.46	0.59	0.529	-1.26	2.44

¹The model adjusts for Gender, Age and Treatment.

*The mean difference is significant at the 0.05 level.

Highlights

- *A prospective observational study evaluating naturalistic outcomes of bipolar disorder and schizoaffective patients.
- *No differences were found between the bipolar patients and the schizoaffective patients on the HRQoL.
- *The lowest SMC score was observed among the depressed patients.
- *The euthymic patients showed the best scores on both SMC and SPC.

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