Quality of Life of Participants with Bipolar and Schizoaffective Disorder in an Australian Cohort: Results After 12 Months


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Bipolar I Disorder
- Affects ~1% of the general population
- Mood disorder characterised by:
  - Acute, affective episodes (manic, depressed, mixed)
  - Full or partial inter-episode remission
  - Symptoms of psychosis, if present, occur during mood episodes only
- Debilitating, long-term, recurrent condition with significant personal, social, and societal costs

Schizoaffective Disorder
- Similar prevalence and features as bipolar disorder
- Characterised by both mood episodes and features of psychosis e.g. hallucinations, delusions, disturbed thinking
- Symptoms of psychosis occur during or separate from the mood disturbance

The Bipolar Comprehensive Outcomes Study

- BCOS is examining outcomes associated with treatment in a “real-life” context.
- The primary objective of the study is to compare the proportion of patients with bipolar I or schizoaffective disorder that experience symptomatic relapse following treatment with olanzapine as a mood stabiliser versus conventional mood stabilisers, which will be reported elsewhere.
- Secondary objectives include the further assessment of clinical, functional, quality of life, and economic outcomes.

Here we report on the quality of life outcomes for participants after 12 months observation.

METHODOLOGY

STUDY DESIGN

- Two-year, prospective, observational, open-label study
- Two study centres in Victoria, Australia
- Usual standard-of-care at the discretion of the treating team and no concomitant medication was excluded
- Participants prescribed at least one of the following at baseline:
  - Olanzapine
  - Lithium carbonate
  - Sodium valproate
  - Carbamazepine

- Study assessments at baseline and every 3 months
- Assessment of adverse events (incl. weight change) were conducted as part of participants’ normal clinical management and any consequent changes to medication/dosage were at the discretion of the investigator.
QUALITY OF LIFE MEASURES

- **EuroQol Instrument – Five Dimensions (EQ-5D):** Self-rated scale assessing overall health status.

- **Visual Analogue Scale (VAS):** Self-rated scale assessing overall health status.

- **36-item Short Form Health Survey (SF-36):** Self-rated scale assessing generic QoL including assessment of mental & physical functioning and well-being.

- **Streamlined Longitudinal Interview Clinical Evaluation from the Longitudinal Interval Follow-up Evaluation (SLICE/LIFE):** Disease-specific scale assessing life satisfaction, relationships, and work status.

- **Diagnostic Interview for Psychosis (DIP):** Structured interview assessing work status, attendance, unmet needs and service usage.

DATA ANALYSIS

- Study Entry comparisons were assessed using Fisher's Exact Test for categorical measures and ANOVA or the medians test for continuous measures.

- All longitudinal profiles were assessed using Mixed Model Repeated Measures (MMRM*) adjusted for the following:
  - Study entry factors: Age, gender, diagnosis, length of hospital stay in previous 3 months, hospitalised, overall CGI-BP-S, alcohol dependence past 12 months (from MINI), smoking status, partner status, employment status, visit and site.
  - Medications taken over the 12 months: amount of time on Mood Stabilizers and/or Antidepressants and/or Antipsychotics and/or Benzodiazepines/Hypnotics.

- Interaction effects were assessed at the 0.1 level.

* MMRM with random effect for time & intercept. Model statement includes visit & visit^2. Covariance Structure used was Spatial Power.
### Characteristics at Baseline (N=239)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years (range)</td>
<td>41.8,18 to 79</td>
</tr>
<tr>
<td>Women</td>
<td>58%</td>
</tr>
<tr>
<td>Bipolar I disorder</td>
<td>73%</td>
</tr>
<tr>
<td>Smoked Daily</td>
<td>51%</td>
</tr>
<tr>
<td>Consumed alcohol 3+ days/week (3 months pre-enrolment)</td>
<td>26%</td>
</tr>
<tr>
<td>Unemployed</td>
<td>29%</td>
</tr>
<tr>
<td>Prevented from working by mental illness</td>
<td>18%</td>
</tr>
<tr>
<td>Rating of Life Satisfaction (3 months pre-enrolment):</td>
<td></td>
</tr>
<tr>
<td>Satisfied/Very Satisfied</td>
<td>47%</td>
</tr>
<tr>
<td>Dissatisfied/Very Dissatisfied</td>
<td>30%</td>
</tr>
<tr>
<td>Currently in a romantic relationship</td>
<td>41%</td>
</tr>
<tr>
<td>At least 1 day in hospital (3 months pre-enrolment)</td>
<td>33%</td>
</tr>
</tbody>
</table>

### Reasons for Drop-Out

- After 12 months, 7 participants had decided to discontinue from the study.
- Two participants died due to medical causes.

<table>
<thead>
<tr>
<th>Participant Disposition</th>
<th>Total (N = 239)</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>Completed*</td>
<td>175</td>
</tr>
<tr>
<td>Partially completed</td>
<td>50</td>
</tr>
<tr>
<td>Participant decision</td>
<td>7</td>
</tr>
<tr>
<td>Lost-to-follow-up</td>
<td>4</td>
</tr>
<tr>
<td>Death**</td>
<td>3</td>
</tr>
</tbody>
</table>

*Total number entered into database at 12 month data lock
**2 medical cause, 1 suicide
EQ-5D VAS: Overall Health State

- Self-rated overall health significantly improved over 12 months (p=.005).

![Graph showing VAS scores over visits](image)

Best imaginable health state = 100
General pop. ≈ 82*


Baseline:  N = 239
12 months: N = 220

EQ-5D: Utility scores

- EQ-5D utility scores significantly increased over 12 months (p=.095).
- 67% of patients ‘Low’ on EuroQoL - Normal Indicator (age/sex adjusted).

![Graph showing utility scores over visits](image)

Best imaginable health state = 1
General pop. ≈ 0.88*


Baseline:  N = 239
12 months: N = 220
SF-36: Mental & Physical Health

- Standardised **mental** (p<.001) and **physical** (p=.047) component scores significantly increased over 12 months.

![Graph showing SF-36 component scores over time](image)

Population norm = 50*

BCOS Physical scores

BCOS Mental scores

Best imaginable health state = 100


Baseline: N = 236

12 months: N = 221

QUALITY OF LIFE

- Self-reported quality of life significantly improved over 12 months (p<.001), as measured by **SLICE/LIFE** total scores.

![Graph showing SLICE/LIFE total scores over time](image)

Maximum possible score = 5

Baseline: N = 239

12 months: N = 220
**LIFE SATISFACTION**

**SLICE/LIFE: Rating of life satisfaction**

- More participants were satisfied or very satisfied with their overall health after 12 months: 56% vs. 47% at baseline.

![Bar chart showing the percentage distribution of life satisfaction ratings between baseline and 12 months.](chart1.png)

-Baseline: N = 239
12 months: N = 233

**EMPLOYMENT STATUS**

- 90% of participants with employment at baseline were still employed after 12 months, with unemployment also decreasing during this time.
- Unemployment remained higher than Australia-wide rate: 5.1%.*

![Bar chart showing the percentage distribution of employment status between baseline and 12 months.](chart2.png)

*Australian Bureau of Statistics (2005)
WORK IMPAIRMENT

- After 12 months:
  - Mental illness prevented fewer participants from working.
  - Overall severity of work impairment was reduced.

SOCIAL FUNCTIONING

- After 12 months:
  - Overall improvement in social functioning
  - Self-reported improved enjoyment of recreational activities:
### Self-reported improvement in relationships:

- **With friends**
  - Very good: Baseline 22, 12 Months 27
  - Good: Baseline 32, 12 Months 20
  - Fair: Baseline 41, 12 Months 9
  - Poor: Baseline 23, 12 Months 13
  - Very poor: Baseline 2, 12 Months 7

- **With relatives**
  - Very good: Baseline 23, 12 Months 14
  - Good: Baseline 34, 12 Months 6
  - Fair: Baseline 27, 12 Months 7
  - Poor: Baseline 22, 12 Months 4
  - Very poor: Baseline 2, 12 Months 3
  - Not applicable: Baseline 13, 12 Months 6

### Hospitalisation

- 28% of participants were hospitalised at least once.
- Significantly fewer illness-related hospital admissions after 12 months (p<.001).
- No participants were in hospital for 12 month visit: 0% vs. 7% baseline.

#### 12 month Summary

<table>
<thead>
<tr>
<th></th>
<th>n</th>
<th>Mean (SD)</th>
<th>min</th>
<th>max</th>
</tr>
</thead>
<tbody>
<tr>
<td>Length of stay (days)</td>
<td>238</td>
<td>8.9 (18.4)</td>
<td>0</td>
<td>93</td>
</tr>
<tr>
<td>Length of stay (non zero days)</td>
<td>79</td>
<td>26.8 (23.4)</td>
<td>1</td>
<td>93</td>
</tr>
<tr>
<td>No. of admissions</td>
<td>239</td>
<td>0.5 (1.1)</td>
<td>0</td>
<td>7</td>
</tr>
</tbody>
</table>
## Summary of Results

<table>
<thead>
<tr>
<th>Scale</th>
<th>Baseline&lt;sup&gt;a&lt;/sup&gt;</th>
<th>12 months&lt;sup&gt;a&lt;/sup&gt;</th>
<th>Overall&lt;sup&gt;b&lt;/sup&gt;</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>EQ-5D Health State</td>
<td>66.4 (63.85 – 68.95)</td>
<td>70.3 (67.80 – 72.80)</td>
<td>68.9 (64.84 – 73.04)</td>
<td>.005</td>
</tr>
<tr>
<td>EQ-5D Utility</td>
<td>0.74 (0.71 – 0.78)</td>
<td>0.79 (0.76 – 0.82)</td>
<td>0.78 (0.73 – 0.84)</td>
<td>.095&lt;sup&gt;c&lt;/sup&gt;</td>
</tr>
<tr>
<td>SF-36 Mental</td>
<td>36.8 (35.17 – 38.46)</td>
<td>41.1 (39.43 – 42.75)</td>
<td>37.3 (34.45 – 40.21)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>SF-36 Physical</td>
<td>46.7 (45.39 – 49.85)</td>
<td>47.7 (46.33 – 49.04)</td>
<td>48.23 (45.95 – 50.51)</td>
<td>.047&lt;sup&gt;c&lt;/sup&gt;</td>
</tr>
<tr>
<td>SLICE/LIFE Total</td>
<td>2.42 (2.33 – 2.50)</td>
<td>2.13 (2.05 – 2.21)</td>
<td>2.30 (2.15 – 2.45)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>SLICE/LIFE Work</td>
<td>2.55 (2.40 – 2.69)</td>
<td>2.07 (1.93 – 2.20)</td>
<td>2.34 (2.10 – 2.59)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>SLICE/LIFE Interpersonal</td>
<td>2.59 (2.44 – 2.74)</td>
<td>2.37 (2.18 – 2.64)</td>
<td>2.41 (2.18 – 2.64)</td>
<td>.008&lt;sup&gt;c&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

<sup>a</sup> Values are observed means (95% CI),
<sup>b</sup> Values are means (95% CI), adjusted for age, gender, diagnosis, no. of alcoholic drinks per day and smoking.
<sup>c</sup> Visit*Visit analysis. Significance level set at p<.10.

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## CONCLUSIONS

- People with bipolar and schizoaffective disorders experience diminished quality of life.
- After 12 months observation, BCOS study participants have improved on many QoL measures.
- Emerging patterns can be further explored with QoL assessments at the 24 month study endpoint.
- The results of BCOS will enhance understanding of real-life clinical practice outcomes of patients receiving pharmacological treatment for bipolar and schizoaffective disorders in Australia.
References


Acknowledgements

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