The impact of Clinical Pharmacist Lead Collaborative Care on Quality Of Life of the Patients with Bipolar Disorder: A Unicenter Prospective, Randomization Study

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ABSTRACT

Background: Bipolar disorder is a chronic mental illness, characterized by the presence of manic, depressive and cyclic episodes, usually separated by asymptomatic intervals. Illness significantly affects the patients' quality of life. Hence, clinical pharmacists can contribute to managing the disease condition of the patients, mainly with the use of effective and safe drugs, and improve the patient's quality of life through pharmaceutical care. Methods/design: A Randomized, interventional, prospective study was performed on 304 patients, to compare and assess the impact of pharmaceutical care with the usual care. Patients with bipolar disorder, aged 18 to 65 years, who have been discharged from the outpatient department were randomized and enrolled in the study. The intervention group patients' were served with pharmaceutical care, which was provided by clinical pharmacists, Psychiatrists and Nurses, on other hand control group patients were treated with the usual care. Quality of life of the patients was assessed at the baseline level to 3rd, 6th and 9th months of the follow-up. Result: Total 266 patients were completed the study. No statistically significant difference was observed at the demographic level and baseline level quality of life (p = 0.547) in both the group. After the intervention in the interventional group, significant (p < 0.001) improvement in the quality of life were observed during the study period. Conclusion: conducted study shows that, clinical pharmacist lead collaborative care can enhance the patients' quality of life in compared to usual care, which is showing that, the participation of clinical pharmacist in psychiatry settings may lead to integration in health care delivery systems.

Keywords: Quality Of Life, Bipolar Disorder, Pharmaceutical Care, Mania, Depression, Psycho-Education, Clinical Pharmacist.

INTRODUCTION

A good quality of life (QOL) is not just only better health status even though it is a sum of good physical health; psychological health; environmental health; socio-economic and spiritual well-being. Globally, a good quality of life is an important and broad measure in compared to the health status of the persons' life aspect. As per World Health Organization (WHO) quality of life is an individual perception of their position in life in the context of the culture and value sys-

tem in which they live and relation to their goal, expectation, standards and concerns,⁴ Bipolar disorder impairs quality of life of the patients through mood swings; personal suffering; disturbed familial support and uneven socio-economic functioning.⁵ in India, out of 100,000 lack population 200 people are suffering from bipolar disorder in India.⁶ Indeed, bipolar disorder is a severe, recurrent and chronic mental suffering, which may represent by the mood swing like dys-

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thymia, depression, euphoria, cyclothymia and mania at different time of interval in the same patient with significant functional and cognitive impairment.⁷ Due to cyclic nature of bipolar disorder symptom remission and symptomatic exacerbation can affect the patients' physical; psychological, emotional, economic and social well-being which is directly impaired their overall quality of life.⁸

The usual treatment of bipolar disorder in here pharmacotherapy and psycho-education, many patient responses adequately for such kind of approach but some of do not. They may frequently suffer from the cyclic episode, cognitive impairment, and poor social well-being.⁹ Hence multidisciplinary collaboration of health care professionals like a clinical pharmacist, psychiatrist and nurse are needed to optimize the patients' health and good quality of life.^{10,11,12}

By the help of this type of study, we planned to assess the impact of clinical pharmacist lead collaborative approach. Our study aim was to measure the effect of pharmaceutical care on various domain of the quality of life of the patients with Bipolar disorder through WHO-BREF QOL. Pharmaceutical care is the care provided by the pharmacist which aim towards patient-centered health and to achieve the desired therapeutic outcome, though patient counseling; interdisciplinary cooperation; improve the medication adherence and ultimately improve the patients' quality of life. ^{13,14}

METHOD

Ethical Issue: Approval of the study was obtained by the Institutional ethics committee (IEC: KLEU/Ethic/2015-16/D-93). The study protocol was explained to the patients by the investigator orally and the patient information sheet, Informed consent form, patient information leaflets and booklet were issued to the patient. Written consent was obtained from the participants prior to the initiation of the study.

Study Design and Patient Recruitment: Study was initiated at tertiary care hospital. The study was a Prospective, Randomized, open level, comparative study. Total 266 patients completed their follow-up. Patient age between 18 to 65 years of either gender and diagnosed with the bipolar disorder were enrolled in the study. Patients with the history of epilepsy, schizophrenia, obsessive-compulsive disorder, Alcohol-induced psychosis, mental retardation, pregnant and lactating women were excluded from the study.

Study Protocol: Patients, who satisfied the above-cited study criteria were enrolled in the study and randomized through computer-assisted randomization list. The

randomization list was prepared by the biostatistician, who was not involved in the study. The allocation was concealed using serial Number.

Selected patients were divided into two groups; control group (n=143) and Interventional group (n=143). Clinical information relevant to the study were collected from the patient and their relatives. Control group patients were on care as usual; whereas, Interventional group patients on pharmaceutical care as well as usual care. Interventional group patient population served with medication-related education, psycho-education, lifestyle modification education along with patient information leaflets and booklets. At each visit patient and their family members knowledge about medicine and disease condition was reinforced and study related data were collected.

Patients' Quality of life (QOL) was measured at the baseline level and at the each visit of follow-up (i.e.3rd, 6th and 9th month). At each visit patients interview were taken place, in which we discuss their medication-related problem and quarries related to the disease condition and medications. After the counseling and interview session, self-reported WHO-BREF QOL questionnaire in Kannada and Marathi was provided to them to mark the option of the question, for same 10 min. time provided to the each patient.

The quality of Life (QOL) Assessment: patients' quality of life was assessed by WHOQOL-BREF; which is a self-reported questionnaire, filled by the patients with bipolar disorder. 15,16 WHOQOL-BREF contain 26 item from which, 2 item represent overall quality of life and health status of the patients and rest of 24 item contain four domain, including physical health domain with 7 item (Domain 1), Psychological health domain with 6 item (Domain 2), Social relationship with 3 item (Domain 3) and Environmental health domain with 8 item (Domain 4).¹⁷ Each of the domain is being rated by 5 points Likert scale and scored from 1 to 5 in response scale. According to WHOQOL guideline, a raw score of each domain was transformed 4 to 20 score. All Domains' score were scaled in ascending direction. The mean score in each domain was obtained by computing the mean of transformed scores converted to a 0-100 scale for each domain. A mean score of <40 in each domain denotes poor, 41-60 indicates moderate and >60 indicates good quality of life. 4,18,19

Statistical Analysis: The sample size of the study was calculated by the inverse random sampling formula in the order to reject the null hypothesis. An attrition rate of 15% was considered. Probability values of less than 0.05 were considered for statistical significance. Study data were entered and analysed on IBM SPSS, Version

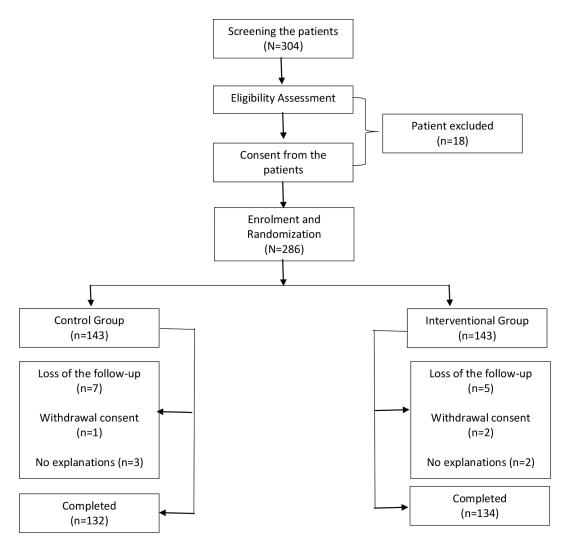


Figure 1: Flowchart showing patients' distribution, a control group receiving usual care and the interventional group receiving pharmaceutical care for a period of 9 months.

20. Socio-demographic data and clinical characteristic of the groups compared with the chi-square test with the frequency, mean, percentage, and degree of freedom. The quality of life both the group was compared and assessed through unpaired student 't' test with mean, standard deviation, 't' value and degree of freedom at 95% confidence interval.

RESULT

Total 304 bipolar disorder patients were screened for the study. Patients who got enrolled after their willingness to informed consent were likewise randomized into two groups, to know the effect of pharmaceutical care in the quality of life (QOL) of the patients. A flowchart representing the patients' distribution, which cited in figure 1. In the control group out of 143 patients, 134 were completed, their follow-up, of which 81 were male and 51 were female; their mean age was 36.6 ± 11.36 years;

mean age of onset of the first episode of Bipolar disorder was 26.84 \pm 8.47 and mean Body Mass Index (BMI) was 24.11 \pm 4.07. Whereas in Interventional group, 84 patients were male and 50 were females; having a mean age of 38.34 \pm 12.91 years; mean age of onset of the first BPAD of 27.46 \pm 10.09 and mean BMI of 24.36 \pm 3.94. No statistically significant differences were observed in mean age, the age of onset of first BPAD and BMI. (Table 1)

In both groups, the majority of the patient population was not shown psychiatry family history. In control group, 86.4% (n=114) had no psychiatry family history; 9.1% (n=12) were shown paternal and 4.5% (n=6) were shown maternal psychiatric family history. On the other hand, in the intervention group, 88.1% (n=118) patients had no psychiatric history; 10.45 (n=14) had paternal and 1.5% (n=2) patients had a maternal psychiatric family history. Childhood adversity is also mentioned

Table 1: Demographic data of the patients.									
SI. No.	o.		Interventional group	t	df	95% confidence Interval		p	
		(n=132)	(n=134)			Lower	Upper		
1	Age	36.6±11.36	38.34±12.91	-1.46	264	-5.123	0.754	0.145	
2	Age of onset of first BPAD	24.11±4.07	24.36±3.97	-0.51	264	-1.226	0.715	0.605	
3	BMI	26.84±8.47	27.46±10.09	-0.53	264	-2.929	1.685	0.596	

Data are represented as mean ± SD BMI= body mass Index

Table 2: Demographic data of the patients.								
SI. No.	Demographic variable	Control group (n=132)	Interventional group (n=134)	Total	Chi square test			
		(11-132)	(11-134)		df	р		
1	Gender Male Female	81 (61.4%) 51 (38.6%)	84 (62.7%) 50 (37.3%)	165 (62.0%) 101 (38.0%)	1	0.824		
2	Religion Hindu Muslim Christian	126 (95.5%) 6 (4.5%) 0 (0.0%)	121 (90.3%) 12 (9.0%) 1 (0.7%)	247 (92.9%) 18 (6.8%) 1 (0.4%)	2	0.214		
3	Marital Status Unmarried Married Widow	35 (26.5%) 96 (72.1%) 1 (0.8%)	29 (21.6%) 105 (78.4%) 0 (0.0%)	62 (24.1%) 201 (75.6%) 1 (0.4%)	2	0.337		
4	Socioeconomic Status Government Job Private Job Daily Basis Homemaker Farmer Student Retired Unemployed	1 (0.8%) 29 (22.0%) 2 (1.5%) 36 (27.3%) 34 (25.8%) 21 (15.9%) 4 (3.0%) 5 (3.8%)	6 (4.5%) 27 (20.1%) 2 (1.5%) 42 (31.3%) 28 (20.9%) 22 (16.4%) 2 (1.5%) 5 (3.7%)	7 (2.6%) 56 (21.1%) 4 (1.5%) 78 (29.3%) 62 (23.3%) 43 (16.2%) 6 (2.3%) 10 (3.8%)	7	0.616		
5	Family History Nothing Significant Paternal Maternal	114 (86.4%) 12 (9.1%) 6 (4.5%)	118 (88.1%) 14 (10.4%) 2 (1.5%)	232 (87.2%) 26 (9.8%) 8 (3.0%)	2	0.332		
6	Childhood Adversity Neglect Physical Health Loss of Parents Absent	9 (6.8%) 0 (0.0%) 2 (1.5%) 121 (91.7%)	14 (10.4%) 2 (1.5%) 0 (0.0%) 118 (88.1%)	23 (8.6%) 2 (0.8%) 2 (0.8%) 239 (89.8%)	3	0.164		
7	Smoker Yes No	37 (28.0%) 95 (72.0%)	38 (28.4%) 96 (71.6%)	75 (28.2%) 191 (71.8%)	1	0.953		
8	Alcoholic Yes No	26 (19.7%) 106 (80.3%)	23 (17.2%) 111 (82.8%)	49 (18.4%) 217 (81.6%)	1	0.594		

Data are presented as % (n)

in Table 2. On the assessment of childhood adversity, in control group, 6.8% (n=9) patients were expressed childhood negligence; 1.5% (n=2) with lost of parents and 91.7% were not expressed any childhood adversity. Whereas in the intervention group, 10.4% (n=14) patients were with childhood negligence; 1.5% (n=2) were with abnormal physical health and 88.1% (n=118)

patients were not shown any childhood adversity. In control group 28.0% (n=37) and interventional group 28.4% (n=38) patients were with smoking habit, while 19.7% (n=26) and 17.2% (n=23) patients, in control and interventional group respectively, were with drinking habit. Patient's marital status, socioeconomic status and religion is mentioned in Table 2.

Table 3: Mean total Quality of Life (QOL) of the patients.									
SI. No.	Baseline and follow-up visit for	Control group	Interventional group	t	df	95% confidence Interval		p	
	QOL	(n=132)	(n=134)			Lower	Upper		
1	Baseline visit	49.47±4.19	49.79±4.38	-0.60	263.7	-1.353	0.718	0.547	
2	Follow-up visit 1	49.54±3.97	54.34±3.79	-10.1	263.0	-5.746	-3.871	0.001	
3	Follow-up visit 2	48.93±3.93	55.25±3.90	-13.1	263.8	-7.260	-5.368	0.001	
4	Follow-up visit 3	49.11±3.84	56.27±3.56	-15.7	261.8	-8.056	-6.268	0.001	

Data are represented as mean \pm SD; Baseline versus visit 1, visit 2 and visit 3 in both of groups. p < 0.05 in increasing the quality of life; unpaired student t test.

df = degree of freedom; QOL=quality of life

Table 4: Quality of life of patients in different Domains of WHOQOL-BREF.								
SI. No.	Domains	Control group	Interventio-nal group	t df Interval			р	
		(n=132)	(n=134)			Lower	Upper	
1	Physical Health							
	Baseline visit Follow-up	51.16±7.9	50.21±8.24	0.95	263.85	-1.004	2.9047	0.339
	visit 1 Follow-up visit 2	52.84±5.9	58.16±5.56	-7.51	262.01	-6.709	-3.921	0.001
	Follow-up visit 3	51.31±4.8	59.39±5.07	-13.29	263.71	-9.282	-6.887	0.001
		51.59±5.2	60.85±5.00	-14.74	263.02	-10.48	-8.016	0.001
2	Psychological Health							
_	Baseline visit Follow-up	50.04±7.2	49.47±6.86	0.664	262.70	-1.129	2.280	0.507
	visit 1 Follow-up visit 2	47.37±5.1	52.92±5.03	-8.323	263.68	-6.418	-3.962	0.001
	Follow-up visit 3	47.18±5.1	53.43±4.92	-10.05	263.46	-7.474	-5.027	0.001
		47.04±4.8	54.70±3.99	-14.00	252.66	-8.732	-6.579	0.001
3	Social Relationship							
	Baseline visit Follow-up	48.66±8.1	49.17±7.44	-0.526	260.87	-2.392	1.384	0.599
	visit 1 Follow-up visit 2	49.34±5.6	53.47±5.07	-6.302	260.60	-5.419	-2.838	0.001
	Follow-up visit 3	49.08±5.4	54.94±5.45	-8.744	263.89	-7.185	-4.543	0.001
		48.93±5.0	55.17±4.88	-10.24	263.39	-7.438	-5.040	0.001
4	Environmental Health							
	Baseline visit Follow-up	48.02±7.5	50.31±7.54	-2.471	263.91	-4.116	-0.465	0.014
	visit 1 Follow-up visit 2	48.25±6.1	52.81±6.27	-6.009	263.95	-6.058	-3.068	0.001
	Follow-up visit 3	48.17±6.0	53.14±6.08	-6.672	263.95	-6.443	-3.506	0.001
		48.86±5.8	54.28±6.23	-7.327	263.27	-6.876	-3.963	0.001

Data are represented as mean ± SD; Baseline versus visit 1, visit 2 and visit 3 in both of groups.p < 0.05 in increasing the quality of life; unpaired student t test. df = degree of freedom; QOL=quality of life.

The quality of life has been being assessed by WHO-QOL-BREF. Change in the quality of life (QOL) from baseline to the end of the study in both groups are shown in Table 3. It is evidence from the result that, the quality of life in the interventional group, were increased gradually at every follow-up. Whereas in the control group, QOL of patients were on stationary stage. The mean score of QOL at baseline, in control and the interventional group, was 49.475 ± 4.191 and 49.792 ± 4.384 . There was no statistical difference (p=0.547) observed at baseline level with 95% confidence interval (CI). After the pharmaceutical care based intervention in the interventional group, it is to be observed

that, during the follow-up visit there were statistically significant improvement were observed (p=0.001).

On the assessment of WHOQOL-BREF, in Domain 1 (Physical health) no significant difference (p=0.339) were observed at baseline in both of the groups. But during the follow-up visits, there was a significant improvement (p=0.001) seen Same as in Domain 2 (Psychological health) and Domain 4 (Environmental health) respectively, no significant differences were observed at baseline, but in Domain 3 (Social relationship) significant difference (p=0.014) was observed. On the other hand, in the interventional group, statistically significant improvement (p=0.001) were observed in all Domains. (Table 4)

DISCUSSION

Ours is the first study to evaluate the impact of pharmaceutical care based on collaborative care for the patients with bipolar disorder in India. As per the result of the study, we assessed the positive effect of pharmaceutical care on intervening patient population in compare to patients with care as usual. Lizer M H et al²⁰ assessed the effect of pharmacist assist psychiatry clinic, in the observation statistically significance difference were observed in physical health and psychological health domain (p<0.001). Ghazavi Z et al²¹ conducted a pilot study to compare the effect of psycho-education on quality of life of the patients, there statistically significant difference were observed in the (mean) quality of life of both study group (p=0.04) and control group (p=0.09). As per the observation of the our study the (mean) quality of life in the interventional group was found p < 0.001 (Table 3). So, we can concluded that pharmaceutical care-based collaborative approach can enhance the patients' quality of life.

We had taken different measures to improve the quality of our study. Firstly, we included the qualified and trained clinical pharmacist during the study, so that we could provide better education and care to the patients. Secondly, we prepared the selective exclusion criteria for the targeted patient population to get the good accuracy of the study result. Thirdly, we prepared a proper plan for the interventional group patients' population, in which, medication-related education, psycho-education and lifestyle related education were provided along with the structured patient information leaflet and booklets in a local vernacular language like Kannada, Marathi, Hindi and English. Fourthly, we used randomization process so that we could assessed better result for the effect of provided care.8 Finally, during the follow-up of the study, we were in telephonic contact with the patient so that we could control the attrition rate of the study. Besides these positive points, our study had some limitations. The first limitation of the study was patient biased, which as passed by the patients. Many patients during the manic phase self-report the high quality of life whereas during the depressive phase poor and during euphoric phase shows the normal quality of life.22 certainly, this kind of bias may change during the cyclic phase of bipolar disorder and mood swing of the patients. The second limitation of the study was to control the attrition rate of the patients due to the patients' psychological condition. Most of the patients left the study without showing any cause. The voluntary withdrawal of the patients may affect the result of study and the third limitation of the study was to control the exposure of patient with other participants during the follow-up, which might alter the result too. Fourthly, we did not assess the symptom improvements of the patients.

Such type of limitation is possible during the study, but most of the patient done follow-up and participate properly in the study. This type of study required for the multicentre level with a high number of patient sample, to show the better effect of care which has provided by the clinical pharmacist as a part of collaborative care team.

CONCLUSION

conducted study shows that, clinical pharmacist lead collaborative care can enhance the patients' quality of life in compared to usual care, which is showing that, the participation of clinical pharmacist in psychiatry settings may lead to integration in health care delivery systems.

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CONFLICT OF INTEREST

There are no conflict of interest.

ABBREVIATION USED

QOL: Quality of life; **BMI:** Body mass index; **BPAD:** Bipolar affective disorder; **WHO:** World health organization.

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SUMMARY

 The authors in this study assessed the effect of pharmaceutical care in the quality of life of the patients with Bipolar disorder between the control group and interventional group, the result of the study indicated that, effective pharmaceutical care can improve the patients quality of life.



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