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Data Article

Pharmacological treatment profiles in the FACE-BD cohort: Treatment description and complete data for bipolar subtypes



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ABSTRACT

In the current study, we provide the list of pharmacological interventions applied during the one-year follow-up period of the Pharmacological treatment profiles in the FACE-BD cohort study. These data show the treatments used in the new clusters formed in this previous study and also in usual bipolarity subtypes. The proportion of each treatment used during the follow-up was calculated. Days on each treatment were also included in this dataset. The complete clinical and paraclinical data analyzed for clusters and bipolar subtypes were included in this dataset. Socio-demographic self-administered and clinician-administered scales, clinical evaluation during the follow-up, psychiatric and somatic comorbidities, and blood tests are shown in this material.

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Specifications Table

Subject	Data Mining and Statistical Analysis
Specific subject area	Results from unsupervised machine learning methods. Clinical and paraclinical results are shown in this dataset, and treatments used for classifying patients in new clusters.
Type of data	Tables
How data were acquired	The FACE-BD cohort recruited patients from a national network of 12 expert centers in France, set up by the French FondaMental Foundation (www.fondation-fondamental.org). General practitioners and psychiatrists referred outpatients with bipolar disorders to these Expert Centres. Recruitment started in June 2008. We extracted the data on 02/04/2019. The FACE-BD cohort includes a follow-up at 12, 24, and 36 months (respectively V12, V24, and V36). Expert Centres filled up the data through a web application, e-bipolar [®] .
Data format	Analyzed
Parameters for data collection	The assessment protocol, including a letter of information for patients, was approved by the institutional review board (CPP-Ile-de France IX, January 18th, 2010), in accordance with French laws for non-interventional studies. Anonymized data are stored in a national database that was approved by the French body overseeing the safety of computerized databases (Commission Nationale de l'Informatique et des Libertés, DR-2011-069).
Description of data collection	This dataset is made by clinical and paraclinical results: The structured clinical interview for DSM-IV Axis I disorders (SCID) was used for the diagnosis of bipolar disorders, as well as bipolar subtypes. We calculated days on treatment during the first year for each active ingredient. Hence, each patient can have up to 365 days on treatment for each active ingredient. Evaluation of patients at inclusion and V12 used clinical evaluation and biological measurements. Clinical evaluation at inclusion and V12 included characterization of mood episodes within last year and questionnaires. Clinical

(continued on next page)

	evaluation at inclusion also included characterization of mood episodes within lifetime. We evaluated the mood using the Montgomery and Asberg Depression Rating Scale (MADRS), the Young Mania Rating Scale (YMRS), the Quick Inventory of Depressive Symptoms 16 items (QIDS-SR16) and the Altman Mania Rating Scale (AMRS). We evaluated the global functioning using the Global Assessment of Functioning (GAF) and the Functioning Assessment Short Test (FAST). We assessed the severity of the disease using the Clinical Global Impression–Severity scale (CGI-S). We assessed the quality of sleep using the Pittsburgh Sleep Quality Index (PSQI). At inclusion, we evaluated childhood trauma using the Childhood Trauma Questionnaire (CTQ) and childhood symptomatology of ADHD using the Wender Utah Rating Scale (WURS). We evaluated adherence to pharmacological treatment using the Medication Adherence Rating Scale (MARS) and side effects of treatments using the Patient Rated Inventory of Side Effects inventory (PRISE-M). Biological measurements at inclusion and V12 were creatinine, HDL, LDL, total cholesterol, triglycerides, ASAT, ALAT, fasting blood sugar, platelets, TSH, T3 and T4.
Data source location	Institution: City/Town/Region: Cr�teil 94,000 Country: France Fondation Fondamental, 40 rue de Mesly H�pital Albert Chenevier, P�le de Psychiatrie
Data accessibility	With the article
Related research article	S. Brodeur, H. Terrisse et al. Pharmacological treatment profiles in the FACE-BD cohort: an unsupervised machine learning study, applied to a nationwide bipolar cohort, <i>Journal of Affective Disorders</i> , in press. https://doi.org/10.1016/j.jad.2021.02.036 https://www.sciencedirect.com/science/article/pii/S016503272100154

Value of the Data

- These data are essential to understand the different treatments analyzed and unpublished in Pharmacological treatment profiles in the FACE-BD cohort: an unsupervised machine learning study [1]. The percentages of treatments used and the days under each treatment are shown. In addition, all the data analyzed are present for the subtypes of bipolarity, whereas the above-mentioned study addresses more the data for the clusters formed.
- Readers of the article Pharmacological treatment profiles in the FACE-BD cohort: an unsupervised machine learning study will be able to benefit from this additional material by comparing cluster results to the usual bipolarity classification.
- Data from paraclinical tests are also available in a more comprehensive manner.

1. Data Description

- Treatment description file shows treatment received and days on treatments if received using new clusters formed and usual bipolar subtypes. In the article published in the journal of affective disorders, only the first 13 most commonly used treatments were illustrated. One hundred and seventeen treatments analyzed are shown in this data set.
- Additional data for subtypes of bipolar disorders and clusters file are included in this data in brief. Regarding bipolar subtypes both self-administered and clinician-administered scales are shown in this data (QIDS-SR16, ALTMAN, PSQI, PRISEM, MARS, WURS, CTQ, MADRS, YMRS, FAST, CGI-Severity, GAF). The clinical assessment of the first episode, the actual mood episode, the lifetime assessment and the assessment of the last year are presented (only baseline data were presented in the first article). Psychiatric and somatic co-morbidities and blood tests are presented in these data. For clusters, blood tests are available in these supplementary data.

2. Experimental Design, Materials and Methods

This data set come from the complete analysis of data from bipolar subtypes but also from cluster formed in Pharmacological treatment profiles in the FACE-BD cohort study. This study was based on the patient database from FondaMental Advanced Centres of Expertise for Bipolar Disorders (FACE-BD) cohort. We searched for clusters of individuals based on their treatments during the first year following inclusion. We then compared the patients baseline characteristics and one-year follow-up according to these clusters. We similarly compared the patients according to the usual bipolar subtypes. The FACE-BD cohort recruited patients from a national network of 12 expert centres in France, set up by the French FondaMental Foundation (www.fondation-fondamental.org). General practitioners and psychiatrists referred outpatients with bipolar disorders to these Expert Centres. Recruitment started in June 2008. We extracted the data on 02/04/2019. The FACE-BD cohort includes a follow-up at 12, 24 and 36 months (respectively V12, V24 and V36). The assessment protocol, including a letter of information for patients, was approved by the institutional review board (CPP-Ile-de France IX, January 18th, 2010), in accordance with French laws for non-interventional studies. Anonymized data are stored in a national database that was approved by the French body overseeing the safety of computerized databases (Commission Nationale de l'Informatique et des Libertés, DR-2011-069). Inclusion criteria for our study included an evaluation in one of the Expert center at baseline and at least one follow-up visit, a diagnosis of bipolar disorder and ambulatory patients between 18 and 65 years old. The criteria for non-inclusion were having a schizophrenia spectrum and other psychotic disorder diagnosis. The structured clinical interview for DSM-IV Axis I disorders (SCID) [2] was used for the diagnosis of bipolar disorders, as well as bipolar subtypes. We calculated days on treatment during the first year for each active ingredient. Hence, each patient can have up to 365 days on treatment for each active ingredient. Evaluation of patients at inclusion and V12 used clinical evaluation and biological measurements. Clinical evaluation at inclusion and V12 included characterization of mood episodes within last year and questionnaires. Clinical evaluation at inclusion also included characterization of mood episodes within lifetime. We evaluated the mood using the Montgomery and Asberg Depression Rating Scale (MADRS) [3], the Young Mania Rating Scale (YMRS) [4], the Quick Inventory of Depressive Symptoms 16 items (QIDS-SR16) [5] and the Altman Mania Rating Scale (AMRS) [6]. We evaluated the global functioning using the Global Assessment of Functioning (GAF) [7] and the Functioning Assessment Short Test (FAST) [8]. We assessed the severity of the disease using the Clinical Global Impression Severity scale (CGI-S) [9]. We assessed the quality of sleep using the Pittsburgh Sleep Quality Index (PSQI) [10]. At inclusion, we evaluated childhood trauma using the Childhood Trauma Questionnaire (CTQ) [11] and childhood symptomatology of ADHD using the Wender Utah Rating Scale (WURS) [12]. We evaluated adherence to pharmacological treatment using the Medication Adherence Rating Scale (MARS) [13] and side effects of treatments using the Patient Rated Inventory of Side Effects inventory (PRISE-M) [14]. Biological measurements at inclusion and V12 were creatinine, HDL, LDL, total cholesterol, triglycerides, ASAT, ALAT, fasting blood sugar, platelets, TSH, T3 and T4. Expert Centres filled up the data through a web application, e-bipolar®. Clinicians reported all treatments received. We then computed the days on treatment for each active ingredient during the first year following inclusion. The QIDS-SR16, AMRS, PSQI, PRISE-M, MARS, WURS and CTQ were self-administered. The clinician administered the MADRS, YMRS, FAST, CGI-S and GAF.

We analyzed the quantitative variables without modification. We performed hierarchical agglomerative clustering to understand patterns of treatments for bipolar patients. The features we used to classify the patients were the days on treatment for each active ingredient present in the dataset during the first year following the inclusion. The distance metric was the squared Euclidean distance. We used Ward's agglomerative methods. We chose the number of clusters using the visual analysis of the dendrogram associated to the hierarchical agglomerative clustering and the interpretability of the groups. We then compared the clinical outcomes between the identified clusters. We used Chi-squared tests for categorical outcomes if all expected

frequencies of the contingency table were higher than 5, else we used Fisher's exact test. We used ANOVA for continuous outcomes. For continuous outcomes at one-year follow-up, if the value at inclusion was available, we used ANCOVA instead of the ANOVA, to account for the inclusion value. We performed the same analysis for bipolar subtypes comparisons. All tests were bilateral, with a first-type error level of 0.05. As the purpose of this paper is to describe patient profiles, we did not correct for multiple testing. However, we provide all calculated p-values for transparency. We did not impute missing data and performed the analysis for complete cases only. We performed all analysis using R software version 3.6.3. As a post-hoc analysis, we compared the ANCOVA for the FAST scale using either the bipolar subtypes or the clusters using Akaike Information criterion (AIC). The lowest the AIC, the better the model explains the data.

Ethics Statement

The assessment protocol, including a letter of information for patients, was approved by the institutional review board (CPP-Ile-de France IX, January 18th, 2010), in accordance with French laws for non-interventional studies. Anonymized data are stored in a national database that was approved by the French body overseeing the safety of computerized databases (Commission Nationale de l'Informatique et des Libertés, DR-2011-069).

CRedit Author Statement

Sébastien Brodeur: worked on literature search, tables, study design, data collection, data analysis, data interpretation, tables and writing; **Hugo Terrisse:** worked on study design, data collection, data analysis, data interpretation, figures, tables and writing; **Sébastien Brodeur** and **Hugo Terrisse:** contributed equally to this manuscript; **Jean-Luc Bosson:** worked on study design; **Mircea Polosan:** worked on literature search, study design, data collection, data analysis, data interpretation and writing; **Arnaud Pouchon:** worked on data interpretation and data analysis; **Bruno Etain:** worked on data collection, data analysis, data interpretation and writing; **Ophelia Godin, Bruno Aouizerate, Valerie Aubin, Frank Bellivier, Raoul Belzeaux, Thierry Bougerol, Philippe Courtet, Caroline Dubertret, Sebastien Gard, Emmanuel Haffen, Chantal Henry, Marion Leboyer, Emilie Olié, Christine Passerieux, Ludovic Samalin, Raymund Schwan:** worked on data collection and reviewed the article.

Declaration of Competing Interest

Dr. Brodeur, H. Terrisse, Dr. Pouchon, O. Godin, Dr. Aubin, Dr. Bellivier, Dr. Belzeaux, Dr. Bougerol, Dr. Courtet, Dr. Dubertret, Dr. Gard, Dr. Henry, Dr. Leboyer, Dr. Roux, Dr. Schwan, Dr. Bosson have nothing to disclose. Dr. Aouizerate reports personal fees from Janssen-Cilag, personal fees from Lilly, personal fees from Sanofi, during the conduct of the study. Dr. Haffen reports personal fees and non-financial support from Janssen, personal fees and non-financial support from Lundbeck, personal fees and non-financial support from Otsuka, outside the submitted work. Dr. Olié reports personal fees from Janssen-Cilag, outside the submitted work. Dr. Samalin reports personal fees and non-financial support from Janssen, personal fees and non-financial support from Lundbeck, personal fees and non-financial support from Otsuka, outside the submitted work. Dr. Etain reports grants from INSERM, grants from Assistance Publique des Hôpitaux de Paris, grants from Agence Nationale pour la Recherche, grants from Fondation de France, grants from Research Council of Norway, personal fees from SANOFI, outside the submitted work. Dr. Polosan reports personal fees from Lundbeck, personal fees from Janssen-Cilag, outside the submitted work.

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Supplementary Materials

Supplementary material associated with this article can be found in the online version at doi:[10.1016/j.dib.2021.107004](https://doi.org/10.1016/j.dib.2021.107004).

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