Study Protocol and Statistical Analysis Plan

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Descriptive Study of Catatonic Syndrome in Adult Patients at Basurto University Hospital:Incidence, Comorbidity, and Short-Term Outcomes

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1. Background and Rationale

Catatonic syndrome is a severe neuropsychiatric condition characterized by a distinctive constellation of motor, behavioral, and speech abnormalities, frequently accompanied by autonomic and affective disturbances. Typical manifestations include stupor, mutism, negativism, posturing, rigidity, waxy flexibility, echolalia, echopraxia, agitation, and stereotyped movements, among others. These symptoms may fluctuate over time and can coexist with marked alterations in consciousness, emotional expression, and autonomic regulation.

Catatonia was first described in detail by Karl Ludwig Kahlbaum in the nineteenth century as a cyclic psychomotor disorder with characteristic motor and affective features. Kahlbaum conceptualized catatonia as a distinct disease entity with a potentially favorable prognosis. Subsequently, Emil Kraepelin incorporated catatonia into the nosological framework of dementia praecox, a decision that profoundly influenced psychiatric classification throughout the twentieth century. As a consequence, catatonia became closely associated with schizophrenia, and for decades it was largely regarded as a subtype or manifestation of psychotic illness.

This narrow conceptualization had important clinical consequences. Catatonia was often underrecognized outside psychiatric settings and insufficiently considered in patients with medical or neurological conditions. Moreover, the strong association with schizophrenia contributed to diagnostic overshadowing and delayed recognition of catatonia in non-psychiatric contexts.

Over the past several decades, accumulating clinical and research evidence has led to a substantial reconceptualization of catatonia. Contemporary diagnostic systems, including the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5), and the International Classification of Diseases, Eleventh Revision (ICD-11), now recognize catatonia as a transdiagnostic syndrome that may occur in association with a wide range of psychiatric disorders—particularly affective disorders and psychotic disorders—as well as neurological, medical, metabolic, toxic, and autoimmune conditions. DSM-5 includes catatonia as a specifier applicable to several mental disorders and also allows for a diagnosis of catatonia due to another medical condition or unspecified catatonia.

This shift in classification reflects the recognition that catatonia represents a final common pathway of diverse pathophysiological processes rather than a disorder specific to schizophrenia. From a clinical perspective, this transdiagnostic framework underscores the need for heightened awareness of catatonia across all medical specialties, particularly in general hospitals.

Catatonia is clinically relevant not only because of its striking phenomenology but also because of its associated morbidity and potential mortality. Untreated or unrecognized catatonia can lead to severe medical complications, including dehydration, malnutrition, aspiration pneumonia, pressure ulcers,

venous thromboembolism, rhabdomyolysis, renal failure, infections, and autonomic instability. In its malignant form, catatonia may be life-threatening and requires urgent recognition and treatment.

Importantly, catatonia is also a potentially reversible condition when promptly identified and appropriately managed. Benzodiazepines, particularly lorazepam, constitute first-line treatment and are associated with rapid clinical improvement in a substantial proportion of patients. In cases of inadequate response, electroconvulsive therapy (ECT) is highly effective and may be lifesaving. The reversibility of catatonia contrasts sharply with the severity of its complications when diagnosis and treatment are delayed, highlighting the importance of early recognition in routine clinical practice.

From an epidemiological standpoint, reported incidence and prevalence rates of catatonia vary widely depending on the population studied, diagnostic criteria applied, and clinical setting. Population-based studies conducted in high-income countries have estimated incidence rates of approximately 4–5 cases per 100,000 person-years. These figures likely underestimate the true burden of catatonia, given historical underrecognition and variability in diagnostic practices.

In contrast, studies conducted in acute psychiatric inpatient settings have consistently reported much higher prevalence rates, often ranging from approximately 20% to over 40% of admitted patients. Such variability reflects differences in case mix, diagnostic vigilance, and the use of standardized assessment tools. Hypokinetic forms of catatonia appear to be more frequent than hyperkinetic or mixed presentations in most hospital-based samples, particularly among older adults.

In general hospital settings, catatonia often presents outside psychiatric wards, including emergency departments and medical units. Studies from general hospitals have shown that a substantial proportion of patients with catatonia are ultimately diagnosed with underlying medical or neurological conditions rather than primary psychiatric disorders. In particular, catatonia has been increasingly recognized in association with autoimmune and neuroinflammatory conditions, such as anti–NMDA receptor encephalitis and other autoimmune encephalitides, as well as metabolic disturbances, infections, and toxic states.

In Spain, available data on catatonia are limited and largely restricted to selected hospital-based subpopulations. Studies conducted by liaison psychiatry services in general hospitals have reported catatonia in approximately 8–9% of older adults assessed during hospital admission. Other studies focusing on specific psychiatric populations have described markedly higher prevalence rates, including nearly 40% among geriatric psychiatry inpatients and approximately 20–25% among patients hospitalized for first-episode psychosis.

While these studies provide valuable insights, they are inherently limited by their focus on specific age groups, diagnostic categories, or clinical services. To date, no studies in Spain have systematically examined the incidence or prevalence of catatonic syndrome across an unselected

adult hospital population, irrespective of underlying diagnoses or specific clinical subgroups. As a result, the true burden, clinical characteristics, and short-term outcomes of catatonia in a general hospital context remain insufficiently characterized.

Given the transdiagnostic nature of catatonia and its potential presentation across multiple hospital services, general hospitals represent a critical setting for improving detection and management of this syndrome. A comprehensive description of catatonia in an adult general hospital population may contribute to increased clinical awareness, improved diagnostic accuracy, and more timely initiation of effective treatment.

2. Justification of the Study

The present study is justified by several converging clinical and epidemiological considerations. First, catatonia is a severe but potentially reversible condition whose prognosis depends largely on early recognition and appropriate treatment. Despite this, catatonia remains underdiagnosed in routine clinical practice, particularly outside psychiatric settings.

Second, existing epidemiological data are heterogeneous and largely derived from highly selected populations. There is a clear lack of data describing catatonia in unselected adult hospital populations, particularly in Spain. This gap limits the generalizability of existing findings and hampers the development of effective detection strategies across medical and psychiatric services.

Third, the increasing recognition of catatonia in association with neurological, autoimmune, and medical conditions underscores the need for systematic assessment in general hospitals. Understanding the distribution of underlying etiologies, clinical presentations, and short-term outcomes in this setting is essential for improving multidisciplinary care.

Finally, the absence of recent Spanish studies examining catatonia across all hospital services represents a significant gap in the literature. By prospectively describing the incidence, clinical characteristics, comorbidity profile, treatment response, and short-term outcomes of catatonic syndrome in an adult general hospital population, this study aims to provide clinically relevant data that may inform future research, clinical guidelines, and training initiatives.

3. Objectives

3.1 Primary Objective

The primary objective of this study is to determine the incidence of catatonic syndrome in adult patients attended at Basurto University Hospital during the defined study period.

Incidence will be estimated by identifying all new cases of catatonic syndrome diagnosed in adults aged 18 years or older during routine hospital care and relating this number to the reference population of the hospital catchment area. Incidence rates will be expressed as cases per 100,000 inhabitants per year. This approach is intended to provide an epidemiologically meaningful estimate of the burden of catatonia in a general hospital setting, capturing cases presenting across medical and psychiatric services.

Determining incidence in this context is particularly relevant given the transdiagnostic nature of catatonia and the absence of previous Spanish studies assessing its occurrence in an unselected adult hospital population. By adopting a hospital-wide approach, the study aims to overcome the limitations of prior research restricted to specific diagnostic categories, age groups, or clinical services.

3.2 Secondary Objectives

The secondary objectives of the study are designed to provide a comprehensive clinical and epidemiological characterization of catatonic syndrome in the general hospital setting.

Specifically, the study aims to:

- Describe the sociodemographic characteristics of adult patients diagnosed with catatonic syndrome, including age and sex distribution, and to explore potential age-related patterns in clinical presentation.
- Characterize the clinical manifestations of catatonia at presentation, including the distribution of clinical subtypes (hypokinetic, hyperkinetic, and mixed or dyskinetic forms) and the severity of catatonic symptoms as assessed by standardized clinical instruments.
- Describe the psychiatric and medical comorbidity associated with catatonic syndrome, with particular emphasis on neurological and autoimmune conditions, in order to reflect the transdiagnostic framework of catatonia.
- Describe the therapeutic approaches used in routine clinical practice for the management of catatonia, including pharmacological treatments such as benzodiazepines and the use of other interventions when indicated.

- Assess short-term clinical outcomes during hospitalization, including response to treatment, occurrence of medical complications, length of hospital stay, discharge destination, and in-hospital mortality.

Together, these secondary objectives aim to provide a detailed description of the short-term clinical course of catatonia in an adult general hospital population.

4. Hypotheses

Given the observational and descriptive design of the study, the hypotheses are formulated as expected patterns rather than as confirmatory causal hypotheses.

Based on existing literature and clinical experience, the following hypotheses are proposed:

- The incidence of catatonic syndrome observed in this study will fall within the range reported in population-based studies conducted in high-income countries.
- Catatonic syndrome will occur across a wide age range, with increased frequency in early adulthood and in older age groups, reflecting a bimodal distribution.
- Hypokinetic forms of catatonia will be more frequently observed than hyperkinetic or mixed presentations in the general hospital setting.
- Catatonia will be associated with a heterogeneous range of underlying psychiatric and medical conditions, including affective disorders, psychotic disorders, neurological diseases, metabolic disturbances, and autoimmune conditions.
- Treatment with benzodiazepines will be associated with a high rate of short-term clinical improvement during hospitalization.
- Catatonic syndrome will be associated with an increased risk of medical complications related to immobility and autonomic dysfunction, but without a marked increase in short-term in-hospital mortality.

These hypotheses serve to guide data description and interpretation rather than to support formal hypothesis testing.

5. Study Design

The study is designed as a prospective, observational, descriptive cohort study with a single cohort and short-term longitudinal follow-up.

All eligible patients diagnosed with catatonic syndrome during the study period will be consecutively included. The prospective design allows for systematic data collection and standardized assessment of catatonic symptoms and clinical outcomes during hospitalization.

The study does not involve any experimental interventions. All diagnostic procedures, therapeutic decisions, and clinical management will be determined by the treating clinical teams according to routine clinical practice. The study therefore reflects real-world clinical care and does not interfere with standard treatment pathways.

Follow-up will be limited to the duration of hospital admission, from the time of diagnosis of catatonia until medical discharge or in-hospital death. No long-term follow-up after discharge is planned.

6. Study Setting

The study will be conducted at Basurto University Hospital, a general university hospital providing secondary-level care to the adult population of the Bilbao area (Spain). The hospital provides emergency care and inpatient services across a broad range of medical and psychiatric specialties.

Patients will be recruited from all clinical settings within the hospital, including the Emergency Department, medical wards, and psychiatric units. This inclusive approach reflects the transdiagnostic nature of catatonia and acknowledges that catatonic syndrome may present in diverse clinical contexts beyond psychiatric services.

By including patients from all hospital services, the study aims to provide a comprehensive picture of catatonia as it occurs in routine clinical practice in a general hospital.

7. Study Population

The study population consists of adult patients aged 18 years or older who are diagnosed with catatonic syndrome during routine hospital care at Basurto University Hospital.

No restrictions are applied based on underlying psychiatric diagnoses, medical conditions, or clinical services. The deliberate inclusion of an unselected adult hospital population is intended to capture the full clinical spectrum of catatonia, including cases associated with psychiatric, neurological, medical, metabolic, toxic, and autoimmune etiologies.

This approach is consistent with contemporary conceptualizations of catatonia as a transdiagnostic syndrome and aims to enhance the external validity and generalizability of the study findings.

8. Inclusion and Exclusion Criteria

8.1 Inclusion Criteria

Patients will be eligible for inclusion in the study if they meet all of the following criteria:

- Age 18 years or older at the time of hospital care.
- Diagnosis of catatonic syndrome established according to DSM-5 criteria, requiring the presence of at least three characteristic catatonic signs identified through systematic clinical assessment.
- Diagnosis of catatonia made during routine hospital care at Basurto University Hospital, irrespective of the clinical service in which the patient is attended.
- Catatonia of any etiology, including psychiatric, neurological, medical, metabolic, toxic, or autoimmune causes.
- Provision of informed consent by the patient or, when applicable, by a legally authorized representative. In cases of acute catatonia with impaired decision-making capacity, deferred consent will be accepted and obtained once the patient's clinical condition allows adequate understanding.

The inclusion criteria are deliberately broad in order to capture an unselected adult hospital population diagnosed with catatonic syndrome according to DSM-5 criteria, reflecting the transdiagnostic nature of catatonia and its presentation across different clinical settings.

8.2 Exclusion Criteria

Patients meeting any of the following criteria will be excluded from the study:

- Refusal to participate expressed by the patient or their legally authorized representative.
- Withdrawal of informed consent at any point during the study period.

No exclusions will be applied based on underlying psychiatric diagnosis, medical comorbidity, severity of catatonia, or hospital service, to minimize selection bias and enhance the representativeness of the study population.

9. Diagnostic Procedures

The diagnosis of catatonic syndrome will be established according to DSM-5 criteria in all included patients. DSM-5 defines catatonia by the presence of three or more characteristic psychomotor signs, including but not limited to stupor, catalepsy, waxy flexibility, mutism, negativism, posturing,

mannerisms, stereotypy, agitation not influenced by external stimuli, grimacing, echolalia, and echopraxia.

Diagnostic assessment will be performed through systematic clinical evaluation by trained clinicians as part of routine hospital care. Given the fluctuating nature of catatonic symptoms, repeated clinical assessments may be conducted during hospitalization when clinically indicated.

In addition to DSM-5 diagnostic criteria, the Bush–Francis Catatonia Rating Scale (BFCRS) will be administered in all included patients. The BFCRS will be used to:

- Support standardized diagnostic assessment of catatonia.
- Quantify the severity of catatonic symptoms at presentation.
- Monitor clinical evolution and response to treatment during hospitalization.

The BFCRS will be administered at the time of diagnosis and may be repeated during follow-up according to clinical judgment. The use of this scale aims to enhance diagnostic reliability and comparability with existing literature.

10. Study Variables

10.1 Primary Variable

The primary study variable is the annual incidence of catatonic syndrome diagnosed according to DSM-5 criteria.

Incidence will be calculated as the number of new cases of catatonic syndrome diagnosed in adult patients (≥18 years) at Basurto University Hospital during each calendar year of the study period, divided by the reference population of the hospital catchment area, and expressed as cases per 100,000 inhabitants per year.

10.2 Secondary Variables

Secondary variables will be collected to provide a comprehensive clinical and epidemiological characterization of patients diagnosed with catatonic syndrome according to DSM-5 criteria.

10.2.1 Sociodemographic Variables

- Age at the time of diagnosis.
- Sex.

10.2.2 Catatonia-Related Variables

- Clinical subtype of catatonia (hypokinetic, hyperkinetic, or mixed/dyskinetic).

- Severity of catatonic symptoms as measured by the BFCRS total score at diagnosis.
- Clinical severity and global functioning assessed using the Global Clinical Impression (GCI) scale at admission and discharge.

10.2.3 Comorbidity Variables

- Underlying psychiatric diagnoses, including affective disorders, psychotic disorders, and other mental health conditions.
- Medical comorbidities, with particular attention to:
- neurological disorders,
- autoimmune and neuroinflammatory conditions,
- metabolic disturbances,
- infectious diseases,
- toxic or substance-related conditions.

Comorbid diagnoses will be established based on clinical evaluation and available diagnostic investigations documented in the medical record.

10.2.4 Treatment-Related Variables

- Type of treatment administered for catatonia, including:
- benzodiazepines,
- electroconvulsive therapy,
- other pharmacological interventions.
- Response to benzodiazepine treatment, categorized as present or absent based on clinical judgment and symptom evolution.

10.2.5 Outcome Variables

- Short-term clinical outcome during hospitalization, categorized as:
- complete recovery,
- partial or incomplete recovery,
- lack of response,
- death during hospitalization.
- Occurrence of medical complications related to catatonia or its management.
- Length of hospital stay, expressed in days.
- Discharge destination (home, psychiatric facility, medical facility, or other).

11. Data Collection Procedures

Clinical and demographic data will be collected prospectively from electronic medical records and routine clinical assessments during hospitalization.

Data collection will be performed by authorized study personnel using standardized data collection forms. Only variables specified in the study protocol will be recorded. Identifiable personal data will be separated from the study database and replaced with pseudonymized codes prior to analysis.

12. Statistical Analysis Plan

The statistical analysis plan has been designed in accordance with the observational and descriptive nature of the study and aims to provide a comprehensive characterization of catatonic syndrome diagnosed according to DSM-5 criteria in an unselected adult hospital population.

All statistical analyses will be conducted using standard statistical software routinely employed in clinical research. The analysis will be primarily descriptive, and no formal hypothesis testing or inferential modeling is planned, given the exploratory objectives of the study.

12.1 Descriptive Analysis

Categorical variables will be summarized using absolute frequencies and percentages. Quantitative variables will be described using measures of central tendency and dispersion, including mean and standard deviation or median and interquartile range, as appropriate, depending on data distribution.

Sociodemographic variables, clinical characteristics, comorbidities, treatment strategies, and short-term outcomes will be described for the overall cohort of adult patients diagnosed with catatonic syndrome according to DSM-5 criteria.

12.2 Incidence Estimation

Annual incidence rates of catatonic syndrome will be calculated as the number of new cases diagnosed according to DSM-5 criteria during each calendar year of the study period, divided by the reference population of the hospital catchment area. Incidence will be expressed as cases per 100,000 inhabitants per year.

This approach is intended to provide an epidemiologically meaningful estimate of the occurrence of catatonia in a general hospital setting, encompassing patients attended across all medical and psychiatric services.

12.3 Handling of Missing Data

Missing data will be documented and reported. Given the descriptive nature of the study, no imputation techniques are planned. The extent and potential impact of missing data will be considered in the interpretation of results.

13. Bias and Limitations

Several potential sources of bias and limitations are acknowledged.

First, catatonia remains an underrecognized condition in routine clinical practice, particularly outside psychiatric services. Despite systematic assessment and the use of DSM-5 criteria supported by the Bush–Francis Catatonia Rating Scale, some cases may remain undetected, potentially leading to underestimation of incidence.

Second, the study is conducted in a single general hospital, which may limit the generalizability of findings to other healthcare settings. However, the inclusion of an unselected adult hospital population across all services enhances external validity within similar general hospital contexts.

Third, the relatively low incidence of catatonia may result in a limited sample size, restricting the ability to explore subgroup analyses. The study is therefore focused on descriptive characterization rather than comparative analysis.

Finally, follow-up is limited to the duration of hospital admission, and long-term outcomes after discharge are not assessed. As a result, conclusions are restricted to short-term clinical evolution.

14. Ethical and Legal Considerations

This study will be conducted in accordance with the ethical principles outlined in the Declaration of Helsinki and with applicable national and European legislation governing biomedical research and personal data protection.

The study protocol has been reviewed and approved by the corresponding Research Ethics Committee. Participation in the study is voluntary, and refusal to participate or withdrawal of consent will not affect the medical care provided.

14.1 Informed Consent

Written informed consent will be obtained from all participants diagnosed with catatonic syndrome according to DSM-5 criteria or from their legally authorized representatives whenever clinically feasible.

Given the nature of catatonia, some patients may lack decision-making capacity at the time of diagnosis. In such cases, a deferred consent procedure will be applied, and informed consent will be sought once the patient's clinical condition allows adequate understanding. This approach aims to balance respect for patient autonomy with the need to avoid systematic exclusion of the most severely affected patients.

In the event of in-hospital death before consent can be obtained, clinical data may be included in the study in accordance with ethical committee guidance and applicable legal provisions, in order to minimize selection bias and preserve the representativeness of the cohort.

14.2 Confidentiality and Data Protection

Clinical data will be collected from electronic medical records by authorized study personnel. All data will be pseudonymized prior to analysis. Identifiable personal information will be stored separately from the study database under restricted access and appropriate technical and organizational security measures.

Data processing will comply with Regulation (EU) 2016/679 (General Data Protection Regulation), Spanish Organic Law 3/2018 on Personal Data Protection and Guarantee of Digital Rights, and Law 14/2007 on Biomedical Research.

15. Dissemination of Results

Study results will be disseminated through scientific publications and presentations at national and international conferences. All dissemination activities will ensure full confidentiality of participant data, and no information allowing individual identification will be disclosed.

The findings of this study are expected to contribute to improved recognition and management of catatonic syndrome diagnosed according to DSM-5 criteria in general hospital settings and to inform future clinical and research initiatives.

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