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Electroconvulsive Therapy Use in Major Depressive Disorder Hospitalizations in Portugal

Utilização de Eletroconvulsivoterapia em Hospitalizações por Perturbação Depressiva *Major* em Portugal

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ABSTRACT

Introduction: Depression, recognized as a major contributor to global disability, requires diverse therapeutic strategies. While psychological therapy and antidepressant medications are primary interventions, electroconvulsive therapy (ECT) emerges as a valuable option for severe and treatment-resistant cases.

This retrospective observational study explores the scenery of depressive disorder-related hospitalizations in Portuguese public hospitals from 2008 to 2015.

Methods: Utilizing administrative data provided by Administração Central do Sistema de Saúde I.P. (ACSS), hospitalizations with primary depression diagnoses were examined. Therefore, all hospitalizations from patients aged 18 or older with a primary diagnosis of depression, selected by International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) codes 296.2x to 296.3x (Major depressive disorder), 300.4 (Dysthymic disorder) and 311 (Depressive disorder, not elsewhere classified) were included.

Results: Over the study period, 32 648 hospitalizations with primary depression diagnoses were identified. Major depressive disorder recurrent episodes dominated ECT procedures (72.6%), with only 2.8% of depression hospitalizations having received ECT in the last year. A linear increase in ECT cases from 2010 to 2015 was observed, coinciding with a decline in total depressive disorder-related hospitalizations. A higher proportion of men received ECT compared to women. The mean age of ECT recipients was significantly lower.

Discussion: The study's findings demonstrate an underuse of ECT procedures in depression hospitalizations in Portugal. The observed increase in ECT utilization in the study period may indicate evolving perceptions and improved accessibility.

Conclusion: Depressive disorders constitute a significant portion of psychiatric hospitalizations in Portugal. This study contributes to understanding ECT use in Portugal.

Keywords: Depressive Disorder, Major/therapy; Electroconvulsive Therapy; Hospitalization

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RESUMO

Introdução: A depressão é uma das principais causas de incapacidade global, exigindo diversas estratégias terapêuticas. Enquanto intervenções psicoterapêuticas e psicofarmacológicas são intervenções de primeira linha, a electroconvulsivoterapia (ECT) emerge como opção em casos graves e resistentes ao tratamento.

Este estudo observacional retrospectivo explora as hospitalizações relacionadas com perturbações depressivas em hospitais públicos portugueses de 2008 a 2015.

Métodos: Utilizando dados administrativos fornecidos pela Administração Central do Sistema de Saúde I.P. (ACSS) foram examinadas hospitalizações com diagnóstico primário de depressão. Assim, todas as hospitalizações de pacientes com 18 anos ou mais, com diagnóstico primário de depressão, selecionados através dos códigos 296.2x a 296.3x (Perturbação depressiva *major*), 300.4 (Distímia) e 311 (Perturbação depressiva, não classificada) do ICD-9-CM foram incluídas.

Results: Durante o período do estudo, foram identificadas 32 648 hospitalizações com diagnósticos primários de depressão. Os episódios recorrentes de perturbação depressiva *major* dominaram os procedimentos de ECT (72,6%). Observou-se um aumento linear nos casos de ECT de 2010 a 2015, coincidindo com uma diminuição nas hospitalizações relacionadas com perturbações depressivas. Uma maior proporção de homens recebeu ECT em comparação com mulheres. A idade média dos doentes submetidos a ECT foi significativamente mais baixa do que a dos restantes doentes com depressão.

Os resultados do estudo encontram-se alinhados com os dados de outros países, destacando a ECT como uma intervenção valiosa na perturbação depressiva *major*, especialmente em casos graves e resistentes ao tratamento. A maior utilização de ECT pode traduzir melhor compreensão e acessibilidade à técnica.

Conclusão: As perturbações depressivas constituem uma parte significativa das hospitalizações psiquiátricas em Portugal. Este estudo contribui para a compreensão dos padrões de utilização de ECT em Portugal.

Palavras-chave: Electroconvulsivoterapia; Hospitalizações; Perturbação Depressiva *Major*

INTRODUCTION

Depression is a prevalent disease, considered by WHO as one of the largest contributors of disability and a major contributor to the overall global burden of diseases.¹⁻³ Depressive symptoms may vary in severity and lead to different psychiatric disorders, major depressive disorder (MDD) being one of the most severe forms of depression. Hospitalizations are common in patients with MDD. Suicidal ideation and behavior are one of the leading causes of hospitalizations among patients with MDD, and about 12% of patients with MDD are hospitalized throughout their lifetime.^{4,5} Psychological therapy is recommended as a first-line treatment option for both mild and moderate to severe MDD. Moreover, antidepressant therapies (ADTs) are established as first-line therapy for moderate to severe MDD.⁶ Treatment guidelines recommend using ADTs for 4–6 weeks at an optimal dose before adding or switching therapy and treating for at least 6 months (including after symptoms remit).⁷ Combination of individual cognitive behavioral therapy (CBT) and an antidepressant is often considered for moderate to severe MDD. In the case of severe MDD and patients with treatment-resistant depression (TRD) who have failed to respond to standard treatments, neurostimulation is also used. Neurostimulation involves applying electrical or magnetic stimulation to target specific brain regions; treatments use electrical or magnetic stimulation targeting specific brain regions with non-invasive techniques, such as repetitive transcranial magnetic stimulation (rTMS) and electroconvulsive therapy (ECT), as well as invasive surgical techniques, such as vagus nerve stimulation (VNS) and deep brain stimulation (DBS).⁸ Despite being one of the oldest psychiatric treatments, ECT

is used worldwide for patients with severe and treatment-resistant psychiatric disorders.⁹ The recognition of psychopharmacology's limitations and side effects, as well as the safety of ECT's procedure with modern devices, has helped in overcoming the associated stigma of this technique over the last decades. Today, ECT is an effective and well-established treatment method for depressive and other mental disorders.¹⁰ It is delivered in a controlled clinical setting, after induction of general anesthesia and application of a muscle relaxant and there are no absolute contraindications for ECT. ECT is generally recommended as a second-line treatment for MDD because of adverse effects, but ECT can be considered a first-line treatment in some clinical situations, such as psychotic features and/or suicidal ideation, where ECT is associated with fast symptom relief.¹¹ Although ECT's mechanism of action is still under investigation, it is considered the most effective biological treatment for MDD, with response rates reaching 80% to 90% when compared with 60% to 70% of antidepressant drugs.⁵ Although it is advised that ECT should not be used only as a last resort, reports on ECT utilization largely vary and there is no uniform worldwide practice.¹²⁻¹⁴ In what comes to ECT use in an inpatient setting in Portugal, a study reckoned that most patients had a primary diagnosis of episodic mood disorder, in which a recurrent episode of MDD was the most frequent and that the majority were females with a mean age of 50.5 years, all in line with data from other European countries.¹⁵ The primary aim of this study was to describe depressive disorder related hospitalizations in Portuguese public hospitals and to overview the use of ECT in hospitalized psychiatric patients in Portugal. The secondary aim was to analyze

electroconvulsive therapy outcomes in depressive disorder related hospitalizations in Portuguese public hospitals.

METHODS

a. Study Design and Reporting

A retrospective observational study was conducted using an administrative database provided by the Administração Central do Sistema de Saúde I.P. (ACSS), which collected all registered hospitalizations in Portuguese public hospitals from 2008 to 2015. Data analysis, reporting, and manuscript formatting follow the Reporting of Studies Conducted using Observational Routinely-Collected Data (RECORD) statement recommendations.¹⁶ This project was approved by the Faculty of Medicine of the University of Porto Ethics Committee (n° 221/CEFMUP/2023).

b. Data Source, Access, and Cleaning Methods

The database used in the study was conceived to estimate and calculate the reimbursement costs associated with hospitalizations occurring in public hospitals in Portugal and was already used in several epidemiological studies in mental health.^{15,17} Therefore, it contains administrative anonymized data from all hospitalizations registered in Portuguese mainland public hospitals; data from private hospitals and those located in the autonomous regions of the Azores and Madeira are not included. Inpatient episodes from 2008 to 2015 were analyzed.

The authors conducted data cleaning by removing redundant hospitalizations, a common occurrence in the district of Oporto in the northern region of Portugal. In this region, all psychiatric patients undergo pre-hospitalization at a central hospital (Hospital de Magalhães Lemos) before being transferred to their designated regional psychiatric facility. All episodes documented in this central hospital, whose patients did not fall within its geographic coverage area, were excluded from the analysis. This methodology has been previously employed and detailed in earlier studies.^{17,18}

c. Study Population and Setting

All hospitalizations from patients aged 18 or older with a primary diagnosis of depression and a discharge occurring between 2008–2015 were selected. International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) codes were used to select the diagnoses of interest. Therefore, all patients with primary diagnosis codes 296.2x to 296.3x (Major depressive disorder), 300.4 (Dysthymic disorder) and 311 (Depressive disorder, not elsewhere classified) were included. Depressive episodes associated with bipolar disorder were not included.

To ascertain the patient count, we conducted an anonymous identification process through a sequential tally of corresponding cases utilizing three variables: date of birth, residential address, and sex. This approach calculates the patient quantity under the presumption of the most probable scenario, wherein no patients share identical output for all three variables.

d. Variables

Hospitalization episodes were the unit of analysis. Individual characteristics and outcomes were gathered from each hospitalization episode. Individual characteristics included sociodemographic variables such as age at admission, sex and residence address and administrative variables: primary and secondary diagnoses, admission date and type, discharge date, length of stay (LoS), medical/surgical procedures, and discharge status.

The type of admission was dichotomized into elective or emergent admissions as well as the discharge status, dichotomized into deceased and all others (unknown, palliative care, home discharge, to another institution, against medical advice, post-hospital care, specialized aftercare, home service, long-term hospital care).

Psychiatric comorbidities were also encompassed and selected according to their Clinical Classification Software codes (CCS)¹⁹: adjustment disorders, anxiety disorders, attention-deficit, conduct and disruptive behavior disorders, delirium, dementia, and amnesic and other cognitive disorders, developmental disorders, disorders usually diagnosed in infancy, childhood, or adolescence, mood disorders, personality disorders, schizophrenia and other psychotic disorders, alcohol-related disorders, substance-related disorders, suicide and intentional self-inflicted injury. The Charlson Comorbidity Index (CCI) was employed to evaluate and compare the presence of comorbidities across hospitalization episodes. The authors utilized the improved ICD-9-CM coding algorithm for Charlson Comorbidities, as put forth by Quan *et al.*²⁰ A subgroup analysis was performed based on the presence or not of the procedure code 94.27 (Other electroshock therapy) defined by the ICD9-CM (collecting all procedures associated with ECT), using as the index group the MDD related hospitalizations.

Differences in outcomes of the compared groups were analyzed by LoS and in-hospital mortality.

e. Statistical Methods

Descriptive statistical analyses, Independent Sample t-tests, Chi-Square tests, Mann-Whitney tests and linear regression models were performed using IBM SPSS Statistics v.29 for Windows (Armonk, NY: IBM Corp).

RESULTS

During the 8 years of the study there were a total of 32 648 hospitalizations with a primary diagnosis of depression (patients aged 18 or older). Considering all hospitalization episodes, 6625 (20.3%) were due to major depressive disorder single episodes and 9754 (29.9%) to major depressive disorder recurrent episodes, 7236 (22.2%) had dysthymia and 9033 (27.7%) due to depression, unspecified episodes. Only 1.5% (n=493) of depression related hospitalizations had a co-register of an ECT procedure. Of all primary diagnoses, the one with the most ECT procedures registered was major depressive disorder recurrent episodes, accounting for 72.6% of all 493 ECT procedures. The fact that most hospitalizations, in both groups, were

due to major depressive disorder recurrent episodes should also be considered (Table 1).

During the period of the study there was a significant decrease in total hospitalizations due to a depressive disorder, with a maximum of 4241 episodes in 2008 and a minimum in 2015 ($n=3769$), as shown in Fig. 1. However, from 2010 to 2015 it is observed a linear and significant increase in the number of patients who underwent ECT, with a minimum

of 28 episodes in 2010 and a maximum of 104 episodes in 2015 ($r=0.055$; $B=-8,46$; $p<0.001$). The frequency of episodes involving ECT treatments increased 2,8-fold over the study period. However, despite this rise, the overall use of inpatient ECT in depression-related hospitalizations remained low, increasing only from 1.0% in 2008 to 2.8% in 2015 (Table 1).

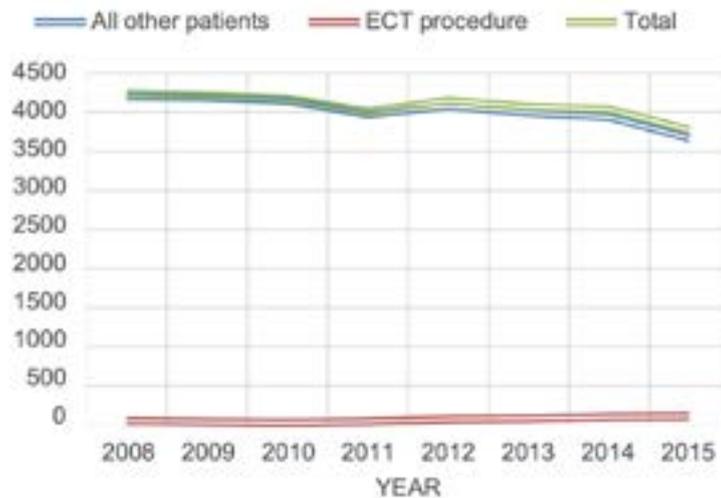


Figure 1. Number of admissions per year.

Most hospitalizations were associated with female patients (70.5%; $n=23\ 018$). This trend was registered as well in depressive patients who were treated with ECT, with females corresponding to 63.9% ($n=315$) of all procedures. Still, between men, there was a higher proportion – 1.8% - who underwent ECT versus 1.4% of women who did. These differences were statistically significant ($p<0.001$). The mean age of patients with a registered procedure of ECT was 50.1 years (SD:14.7), whereas the mean age of the rest of the patients with depression was 59.4 years (SD: 12.7) - these differences were found to be statistically significant ($p<0.001$).

The region with more registered hospitalizations was the north of Portugal with 36.5% ($n=11\ 931$). However, Alentejo is the region where there is a higher record of ECT procedures within depressive episodes hospitalizations, given that in 3.1% of 2236 total hospitalizations, this treatment option was chosen.

The median LoS for patients with a registered procedure of ECT was 14 days, while for other patients with a depressive disorder was 12 days. Nevertheless, these differences weren't statistically significant ($p=0.411$).

The majority of admissions due to depression were emergent (89.5%; $n=29\ 216$). In hospitalizations with registered ECT procedures, elective admissions were slightly more frequent than emergent admissions (51.3%, $n=253$ versus 48.7%, $n=240$), being this difference statistically significant ($p<0.001$).

All cases of deceased patients were observed only in depressive episodes who had not undergone an ECT procedure, corresponding to a 0.25% in-hospital mortality.

About 51.7% ($n=16889$) of the hospitalizations with a primary diagnosis of depression were associated with other psychiatric comorbidities (as defined by CCS categories 650–661). The most frequent comorbidities were suicide and intentional self-inflicted injury (25.6%; $n=4332$), followed closely by personality disorders (21.7%; $n=3663$), alcohol-related disorders (15.6%; $n=2628$) and anxiety disorders (15.1%; $n=2547$). Within patients with a registered procedure of ECT the psychiatric comorbidity more frequent were suicide and intentional self-inflicted injury (27.7%; $n=33$), delirium, dementia, and amnesic and other cognitive disorders (21%; $n=25$) and personality disorders (14.3%; $n=17$) (Table 2). Differences between both groups were found in all three more frequent comorbidities.

Table 1. Sociodemographic and clinical variables in patients hospitalized with a depressive episode in Portuguese public hospitals between 2008 and 2015.

| | Patients with a depressive episode with a registered procedure ICD-9-CM Code of ECT | All other patients with a depressive episode | Total |
|----------------------------------------------|--------------------------------------------------------------------------------------------|-----------------------------------------------------|---------------|
| Primary diagnosis (n; %within group) | | | |
| MDD, single episode | 111 (22.6) | 6514 (20.3) | 6625 (20.3) |
| MDD, recurrent episode | 358 (72.6) | 9396 (29.2) | 9754 (29.9) |
| Dysthymia | 7 (1.4) | 7229 (22.5) | 7236 (22.2) |
| Depression, unspecified | 17 (3.4) | 9016 (28.0) | 9033 (27.7) |
| Total | 493 (100) | 32 155 (100) | 32 648 |
| Sex (n; %) | | | |
| Female | 315 (1.4) | 22 703 (98.6) | 23 018 (100) |
| Male | 178 (1.8) | 9452 (98.2) | 9630 (100) |
| Age (Mean; St.Deviation) | | | |
| | 50.1 (14.7) | 59.4 (12.7) | 50.2 (14.7) |
| Residence address (n; %within region) | | | |
| Norte | 110 (0.9) | 11 821 (99.1) | 11 931 (100) |
| Centro | 125 (1.3) | 9793 (98.7) | 9918 (100) |
| Lisboa | 155 (2.2) | 7010 (97.8) | 7165 (100) |
| Alentejo | 70 (3.1) | 2166 (96.9) | 2236 (100) |
| Algarve | 33 (2.6) | 1248 (97.4) | 1281 (100) |
| Year of admission (n; % within year) | | | |
| 2008 | 44 (1.0) | 4197 (99.0) | 4241 (100) |
| 2010 | 28 (0.7) | 4145 (99.3) | 4173 (100) |
| 2012 | 69 (1.7) | 4073 (98.3) | 4142 (100) |
| 2015 | 104 (2.8) | 3665 (97.2) | 3769 (100) |
| Total | 493 (100) | 32 155 (100) | 32 648 |
| LoS (Median days, Q1-Q3) | 14.0 (1.0 – 49.0) | 12.0 (6.0 – 20.0) | - |
| Type of admission (n; %within group) | | | |
| Emergent | 240 (48.7) | 28 976 (90.1) | 29 216 (89.5) |
| Elective | 253 (51.3) | 3179 (9.9) | 3432 (10.5) |
| Total | 493 (100) | 32 155 (100) | 32648 |
| In-hospital mortality (n; %) | 0 | 79 (0.25) | 79 (0.24) |

Table 2. Psychiatric comorbidities in patients hospitalized with a depressive episode in Portuguese public hospitals between 2008 and 2015. Comorbidities were classified using the Clinical Classification Software (CCS) approach.

| | Patients with a depressive episode with a registered procedure ICD-9-CM Code of ECT (n; %) | All other patients with a depressive episode (n; %) | Total (n; %) |
|-------------------------------------------------------------------|--------------------------------------------------------------------------------------------|-----------------------------------------------------|--------------|
| Adjustment disorders | 3 (2.5) | 214 (1.3) | 217 (1.3) |
| Anxiety disorders | 12 (10.1) | 2535 (15.1) | 2547 (15.1) |
| Attention-deficit, conduct and disruptive behavior disorders | 2 (1.7) | 283 (1.7) | 285 (1.7) |
| Delirium, dementia, and amnesic and other cognitive disorders | 25 (21) | 648 (3.9) | 673 (4.0) |
| Developmental disorders | 3 (2.5) | 865 (5.2) | 868 (5.1) |
| Disorders usually diagnosed in infancy, childhood, or adolescence | 1 (0.8) | 21 (0.1) | 22 (0.1) |
| Impulse control disorders, NEC | 0 | 114 (0.7) | 114 (0.7) |
| Mood disorders | 9 (7.5) | 325 (1.9) | 334 (1.9) |
| Personality disorders | 17 (14.3) | 3646 (21.7) | 3663 (21.7) |
| Schizophrenia and other psychotic disorders | 2 (1.7) | 161 (1.0) | 163 (1.0) |
| Alcohol-related disorders | 9 (7.5) | 2619 (15.6) | 2628 (15.6) |
| Substance-related disorders | 3 (2.5) | 1040 (6.2) | 1043 (6.2) |
| Suicide and intentional self-inflicted injury | 33 (27.7) | 4299 (25.6) | 4332 (25.6) |
| Total | 119 (100) | 16 770 (100) | 16 889 (100) |

DISCUSSION

Of all the primary diagnoses selected the one with more ECT procedures registered was major depressive disorder recurrent episodes (accounting for 72, 6% of them), in agreement with the fact that besides most hospitalizations related to depression are due to recurrent episodes of major depressive disorder, ECT is still especially reserved for patients with severe and treatment-resistant depression after one or more trials of psychotropic medications have failed.²¹ From 2010 to 2015 it is observed a linear and significant increase in the number of patients who underwent ECT, much likely reflecting the acquisition of more data supporting the use of it and the improvement on accessibility to the technique throughout the years. Our data clearly demonstrates a significant underuse of ECT in hospitalizations for depressive patients. The highest recorded usage rate was only 2.8% of all depression-related hospitalizations, a figure considerably lower than those reported in other studies, which range from 9.4% to 14.8% in the U.S. for recurrent major depression, specifically in hospitals where ECT is available.^{22,23} Although major depressive disorders account for the largest proportion of inpatient ECT treatments in Portugal (~27.8%, ICD-9-CM codes 296.2x and 296.3x),¹⁵ ECT remains underutilized in this population. Although results indicate that the majority of patients receiving ECT treatment were female, which is in line with

other Portuguese studies,¹⁵ as well as studies from other Western countries,⁵ there was a higher proportion of men with a depressive disorder undergoing ECT compared to women. This can be explained by the fact that most hospitalizations due to a depressive disorder are more common in women, as they are at greater risk of having depressive disorders.²⁴ Furthermore, effects of treatments and their possible negative outcomes are classically less studied on women. Nevertheless, it is important to note that ECT as a biological treatment for MDD is equally effective in women and men.²⁵ The mean age of patients with a registered procedure of ECT was much lower (50.1 years versus 59.4 years in the rest of the patient population), possibly because it's a treatment option preferably chosen in younger patients, with fewer comorbidities, even though results of several studies show that ECT is effective and may have higher remission rates when applied to elderly patients.^{26,27} The median LoS for patients with a registered procedure of ECT was 14 days, while for other patients with a depressive disorder was 12 days. Even though these differences were not statistically significant it is important to note that electroconvulsive therapy is a procedure that requires its administration for a total of 6 to 12 sessions performed in a serial manner at a rate of about 2 to 3 times a week, to produce a desirable therapeutic effect.¹⁰ Therefore, it is

often initially performed in an inpatient regimen, which can partially justify the longer LoS and why elective admissions were slightly more frequent. We considered that LoS can not be used as a measure of impact on depressive patient outcomes, as the study discards ECT performed in outpatient settings.

Alongside concerns of cognitive sequelae (like short-term memory loss), ECT is underutilized because of the stigma associated with the technique and the fear of medical risks, including the risk of death.¹⁵ The null in-hospital mortality found in this study alongside others²⁸ contributes to demystifying this fear.

About 51.7% of the hospitalizations with a primary diagnosis of depression were associated with other psychiatric comorbidities. Considering patients who did not underwent ECT the most frequent comorbidities were suicide and intentional self-inflicted injury, in conformity with it being one of the leading causes of hospitalizations among patients with MDD.^{4,5} Within patients with a registered procedure of ECT the psychiatric comorbidities found to be statistically significant were suicide and intentional self-inflicted injury and delirium, dementia, and amnesic and other cognitive disorders, in line with the fact that ECT is particularly more effective and commonly more used as a first-line treatment in depression with psychotic features (delirium) and/or suicidal ideation.^{11, 26}

a. Strengths and Limitations

The strengths inherent in this study encompass the extensive, population-based sample utilized. Despite the fact that administrative databases were not originally designed to provide clinical information for scientific purposes, Real-world evidence derived from them contributes with valuable and broadly applicable insights into hospitalizations related to mental disorders. In Portugal, all codifiers are medically trained professionals with specific training, ensuring a high standard of registry quality. However, it is essential to acknowledge the potential for diagnostic and procedural miscoding. The methodological approach employed to estimate the number of patients possesses a very

specific limitation, even if with low impact, as patients may have altered their residence during the study period, potentially leading to an overcount. Additionally, due to the coding specificities of ICD-9-CM, it is not feasible to discern the specific method employed in ECT (unilateral versus bilateral), as well as other treatment-related characteristics. Another limitation is that the data collection extends only up to 2015, which may raise concerns about its representativeness in the current paradigm. However, it is noteworthy that ECT therapeutic options for depressive disorders have seen minimal alterations since the study period, providing some continuity in the treatment landscape.

CONCLUSION

Depressive disorders are one of the leading causes of hospitalization in Portuguese psychiatric departments, being responsible for approximately 1 in 5 hospitalizations with a psychiatric diagnosis in the country.¹⁷ Considering the high prevalence of depressive disorders in Portugal and low rates of ECT use, it is important to evolve toward modern ECT units, with specialized teams. This study delineates the characteristics of the Portuguese inpatient population suffering from depression who underwent ECT, aiming to establish a groundwork for subsequent reviews that may highlight more favorable outcomes linked to this therapeutic approach, conducting continuous improvements in therapeutic approaches for depression.

While this study illustrates a rise in the utilization of (ECT) in Portugal over the years, there remains a necessity for a comprehensive international review concerning the current application of this treatment and enhanced informational methodologies pertaining to ECT.

This study contributes not only to the understanding of ECT utilization in Portugal but also underscores areas warranting future attention, including enhancements in coding methodology and the need to distinguish specific treatment details.

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RESPONSABILIDADES ÉTICAS

Conflitos de Interesse: Os autores declaram a inexistência de conflitos de interesse na realização do presente trabalho.

Fontes de Financiamento: Não existiram fontes externas de financiamento para a realização deste artigo.

Confidencialidade dos Dados: Os autores declaram ter seguido os protocolos da sua instituição acerca da publicação dos dados de doentes.

Proteção de Pessoas e Animais: Os autores declaram que os procedimentos seguidos estavam de acordo com os regulamentos estabelecidos pela Comissão de Ética responsável e de acordo com a Declaração de Helsínquia revista em 2024 e da Associação Médica Mundial.

Proveniência e Revisão por Pares: Não comissionado; revisão externa por pares.

ETHICAL DISCLOSURES

Conflicts of Interest: The authors have no conflicts of interest to declare.

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Confidentiality of Data: The authors declare that they have followed the protocols of their work center on the publication of patient data.

Protection of Human and Animal Subjects: The authors declare that the procedures followed were in accordance with the regulations of the relevant clinical research ethics committee and those of the Code of Ethics of the World Medical Association (Declaration of Helsinki as revised in 2024).

Provenance and Peer Review: Not commissioned; externally peer-reviewed.

DECLARAÇÃO DE CONTRIBUIÇÃO

MA: Designed the study and participated in all phases of the study, undertook the statistical analysis, wrote the first draft of the manuscript.

MNP: Designed the study and participated in all phases of the study.

AF: Undertook the statistical analysis.

All authors contributed to and have approved the final manuscript.

CONTRIBUTORSHIP STATEMENT

MA: Concebeu o estudo e participou em todas as fases do estudo, efectuou a análise estatística, escreveu o primeiro rascunho do manuscrito.

MNP: Concebeu o estudo e participou em todas as fases do mesmo.

AF: Efectuou a análise estatística.

Todos os autores contribuíram e aprovaram o manuscrito final.

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