



## ORIGINAL ARTICLE

# Assessment of individual clinical outcomes: Regarding an electroconvulsive therapy<sup>☆</sup>



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Received 1 July 2014; accepted 9 July 2014

Available online 29 April 2015

### KEYWORDS

Clinical assessment;  
Reliable change  
index;  
Effectiveness;  
Case study

**Abstract** Evaluation of therapeutic results and of the efficacy and effectiveness of treatments is an area of interest both for clinicians and researchers. In general, randomized controlled trial designs have been used as the methodology of choice in which intergroup comparisons are made having a minimum of participants in each arm of treatment. However, these procedures are seldom used in daily clinical practice. Despite this fact, the evaluation of treatment results for a specific patient is important for the clinician in order to address if therapeutic goals have been accomplished both in terms of statistical significance and clinical meaningfulness. The methodology based on Reliable Change Index (RCI – Jacobson and Truax)<sup>1</sup> provides an estimate these two criteria. The goal of this article is to propose a procedure to apply the methodology with a single case study of a woman diagnosed with major depression and treated with Electroconvulsive Therapy (ECT).

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### PALABRAS CLAVE

Evaluación clínica;  
Efectividad;  
Estudio de caso

**Evaluación de resultados clínicos individuales: a propósito de un caso tratado con terapia electroconvulsiva**

**Resumen** La valoración de resultados terapéuticos y la evaluación de la eficacia y efectividad de los tratamientos es un área interés para clínicos e investigadores. Usualmente se ha utilizado la metodología basada en diseños controlados aleatorios y la comparación intergrupos con un mínimo de participantes incluidos en cada brazo de tratamiento. No obstante, estos procedimientos raramente pueden ser aplicados en la práctica clínica habitual, pero sí es importante

<sup>☆</sup> Please cite this article as: Iraurgi I, Gorbeña S, Martínez-Cubillos M-I, Escribano M, Gómez-de-Maintenant P. Evaluación de resultados clínicos individuales: a propósito de un caso tratado con terapia electroconvulsiva. Rev Psiquiatr Salud Ment (Barc.). 2015;8:11–16.

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para el clínico evaluar si los resultados del tratamiento propuesto para una persona específica cumplen con los objetivos terapéuticos, tanto en su significación estadística como por su relevancia clínica. La metodología basada en el índice de cambio fiable (Jacobson y Truax)<sup>1</sup> permite estimar esta doble consideración y el objetivo del artículo es proponer el procedimiento de aplicación a través del estudio de un caso único diagnosticado de depresión mayor tratado con Terapia Electro Convulsiva (TEC).

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## Introduction

Evaluation is at the heart of the clinical process. It is a key element for diagnosis, treatment planning and evaluation of treatment effects. Obtaining the expected results implies both success of the intervention, and therapeutic discharge, while failure derives in a decision making process regarding change or removal of prescribed treatment or the assumption of new therapeutic recommendations. In any case, information regarding clinical outcomes of an intervention is of utmost importance for health providers.<sup>2</sup>

Specifically, evaluation of therapeutic efficacy based on scientific evidence relies on a methodology that uses comparisons of groups that are exposed to different interventions; one of which is the object of evaluation, the other with a proven therapeutic value. The basic design is known as random clinical trial, a procedure that defines a step-by-step protocol in order to avoid the effect of bias and preserves casualty of intervention on the therapeutic effect. Group variability control and statistic use allows for decision making regarding the cause (chance or intervention) of the observed changes.<sup>3</sup>

However, in day-to-day clinical practice, health providers rarely count on big groups to make comparisons and thus, more often than not, their decisions are based on specific cases. The habitual procedure is to consider change shown by the individual, analyzing variation of the state or trait of interest, normally assessed through biological, symptomatic or orectic indexes. For instance, in mental health, therapy has as a goal to change states (i.e. depressive signs and symptoms) or traits, a personality disposition (i.e. neuroticism). In order to do so, states or traits are assessed with standardized instruments that allow for the scoring of the case in relation to a normative group. Therefore, if a person is evaluated with the same instrument before and after treatment, the difference in scores can offer a quantitative index of change than can be incremental, decremental or equal. Besides, scores can be analyzed with reference to a normative sample, allowing for the ranking of the scores of the person in a functional or dysfunctional range. Scales usually provide information about cutoff points to facilitate clinical decisions.

However, compared with the methodology used for scientific decision making regarding efficacy of treatment modalities, decision making in individual cases lacks tools that could inform if the observed change is both clinically meaningful and statistically significant. We need to know if the change has a sufficient magnitude so as to be considered an important clinical outcome and rule out chance.

The goal of this paper, based on a clinical case treated with Electro Convulsive Therapy (ECT), is to offer an answer using the Reliable Change Index,<sup>1,4</sup> a formula that can help in clinical and statistically significant decision making in individual cases.

## Clinical case

The patient is a 45-year-old married woman, mother of two children and teacher on a sick leave of work. She was admitted in the Psychiatric Unit of a general hospital, being the fifth hospitalization. She was referred by a psychiatrist due to severe depressive symptoms for the past several weeks in the context of a Bipolar Disorder.

The patient showed depressive symptoms, especially inability to enjoy daily activities, more exacerbated in the morning, severe asthenia, psychomotor slow-down, tensional headaches, attention and concentration impairments, and nondelirious thoughts of inadequacy, abandonment, disability and guilt.

Her daily functioning is characterized by being self-demanding, presenting herself as a very respectful, polite and well-mannered person, even rigid in response to a firm sense of duty. Her values showed a strong commitment to her responsibilities around her role as a good mother, daughter, wife and worker. She shows obsessive traits (order and control) and a notable denial of hostility. She refers a very organized daily routine that holds her together.

Her medical record indicates hypothyroidism treated with hormones. With reference to psychiatric antecedents, she relates several affective problems since youth, initially of a depressive sing that would remit with Benzodiazepine, even spontaneously. Three years ago she presented a manic episode with psychotic symptoms, congruent and incongruent (paranoid) with her mood. She refers no psychiatric family history.

The patient states that her first depressive episode goes back 6 years when her father died. It was treated with antidepressants, a medication she continues to use today. Initially she responds to IRSA antidepressants showing a quick and effective response with complete recovery. Since then, at least 5 depressive episodes have occurred with a poorer response to treatment, slower recovery without reaching a true euthymic state and maintaining subclinical depressive symptoms that interfere with functioning and quality of life. Medication was changed several times prescribing dual drugs (Venlafaxina) and later a combination of antidepressants with maximal dose (Venlafaxina and

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