

hyperprolactinaemia) instead of placing a prolactin plasma value above this. Considering the current scientific evidence, we should be prudent when generating conclusions about some risks such as the association between antipsychotic drug-related hyperprolactinaemia and the risk of cancer, because the studies on this matter show inconsistent results.

Conflicts of interest

Dr. Javier Labad has been a consultant for or has received fees or research funding from Otsuka, Lundbeck and Janssen-Cilag.

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Shared decision making in mental health: Myths, barriers, and benefits[☆]



Las decisiones compartidas en salud mental: mitos, barreras y beneficios

Sirs,

Shared decision making consists of an interactive clinical relationship process in which the professional helps their patients to choose the best treatment considering their values, preferences and clinical circumstances. Many myths have been considered about this type of healthcare relationship (the patient finally decides himself or herself, or they even let the professional make the decision, they do not want to get involved, etc.).¹ In addition, barriers have been found in the professionals that make applying it difficult, such as the concern that psychiatric patients might not be competent to decide for themselves.² However, perhaps the most significant problem is that of insight.³ Such difficulties can also be seen in the patients: passive patients, ones not interested in the decision or those who think that their negative response constitutes in itself an *active attitude*.⁴ At any rate, all of this can represent a paternalistic stance.⁵

In spite of this, reality shows that applying shared decision making in the sphere of mental health leads to an increase in the patients' quality of life, better communication with the professionals and, consequently, better therapeutic alliance and even greater drug adherence.⁶

But it is important not to think that the process stops with merely giving information about the various treatments and their adverse reactions. Deep down, patients want to be heard and to have their desires incorporated in the decision. That means that the professionals need to have communication skills to improve this shared decision: motivational interviews, negotiation processes, etc.⁶ Although this is not an easy task, a tool to make it possible to ascertain and evaluate how the decision was taken has been created and validated in Spanish.⁷ It consists of a 9-question test given to the patient about the experience he or she has had in the consultation with the professional.

It is understandable that there are clear situations in which a paternalistic model is justified, such as "life or death" decisions or those in which the "best interest" may be applicable.⁶ However, the objective has to be promoting decision making shared with the patients. A valuable way to encourage them to decide is by anticipation of the decisions, such as (for example) an advanced directives document, which has also been shown to have positive effects (both clinical and ethical).⁸

Consequently, we have to urge the professionals to carry out *aware psychiatry*⁹ that goes beyond the biomedical, biological reductionist paradigm and centres on the individual, their needs and their wishes. Shared decisions, whether advance or not, will aid this type of psychiatry, which must be based on both *technical values* and *moral values*.¹⁰ This

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focus will make a change of direction possible in the basis of the healthcare relationship, given that we will go from examining solely the aim of doing good and doing no harm, even without patient consent, to a perspective whose main focus is autonomy and dignity. In this way, the patients' autonomy is increased without leaving them alone in the face of the decision. But this has to be a task performed jointly between the professionals and the patients.

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Tianeptine: Why has it not been classified as a narcotic in Spain?☆



Tianeptina: ¿por qué en España no ha sido catalogada como estupefaciente?

Sirs,

Tianeptine is a tricyclic antidepressant marketed in France since 1988 that has recently entered the Spanish market as a generic medicine.¹ It is a drug that is chemically similar to another amphetamine-type stimulant and antidepressant—amineptine, which was withdrawn from commercialisation in Spain (1999) and in other countries due to its addictive properties and adverse hepatic and cutaneous effects. The structural similarity of tianeptine to amineptine and the cases of abuse and addiction reported for it have given rise to many doubts about its safety profile.^{2,3}

In 2012, France's National Agency for Medicines and Health Products Safety (ANSM is the acronym in French), at the request of the Narcotic Drugs and Psychotropic Substances Committee, decided to re-evaluate the benefit–risk ratio of Stablon® (the brand name of tianeptine in France). When that committee analysed the cases detected, the results permitted them to conclude that, in effect, there was a risk of abuse and addiction associated with its use.⁴ The overall assessment of efficacy and safety led the French agency to decide that the benefit–risk ratio of tianeptine

was favourable, but limited. With respect to its benefits for health, the agency's conclusions were: "Given the available information, bearing in mind the therapeutic alternatives existing and the drug dependence problems identified, Stablon® does not present any benefit for the public health system".⁴

As a consequence, tianeptine has been classified as a narcotic drug in France. Since 3 September 2012,⁵ this antidepressant has been subject to the same prescription and supply restrictions as any other narcotic substance in List I, with a maximum length of prescription of 28 days. Before that, it had been withdrawn from marketing in Georgia and included in the list of psychotropic substances in Russia, Ukraine and Armenia. Tianeptine is not authorised in several Anglo-Saxon countries.

At present, the safety of tianeptine is still a concern. The well-known journal *Prescrire* has repeatedly denounced that its benefit–risk ratio is unfavourable.⁶ Previously, the conclusion reached by the re-evaluation the ANSM performed had been noted and the reason that the French authorities had allowed this drug to continue to be funded had been questioned.⁷ Tianeptine is included in the list of drugs to avoid that this journal publishes every year.⁸ Up till now, the European Pharmacovigilance Risk Assessment Committee has not carried out an assessment of tianeptine, but the data recorded in EudraVigilance (a European database of reports on presumed adverse reactions) confirm that there is a risk of abuse and addiction associated with its use. Up to October 2015, of the 563 cases reported, 125 included abuse and 27, addiction.⁹

In spite of these antecedents, to date no restrictions in the prescription or supply of tianeptine (Zinosal®) have been established in Spain. Given that it is a generic medicinal product, the applicable regulation for obtaining its authorisation is much simpler and only requires bioequivalence studies against the reference compound. It

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