

Study of prescription-indication of methylphenidate in adults in a Healthcare Management Area

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SUMMARY

Introduction: Even though in Spain methylphenidate is approved for attention deficit hyperactivity disorder (ADHD) in children older than 6 years, there are prescriptions in adult patients both for the treatment of ADHD and in other indications. The objective of this study is to analyse the adequacy of the prescription of methylphenidate in adult patients in the South of Seville Healthcare Management Area (SSHMA).

Methodology: Retrospective observational prescription-indication study of the use of methylphenidate of all adult patients (>18 years) who had active methylphenidate prescriptions in September 2018.

Results: We included 91 adult patients on treatment with

methylphenidate with a mean age of 21 years (range 18-90 years). 67.03% were men. The diagnosis that most frequently motivated the prescription of methylphenidate was ADHD, which is the indication for which it is authorized. 36.26% of the patients presented indications not included in the technical data sheet. The mean daily dose prescribed was 36 mg (range 5-108 mg). 7 patients had prescribed doses higher than the maximum recommended.

Conclusions: This study demonstrates different prescription patterns of methylphenidate in adults. Draws attention, the duration of treatment and non-suspension during adulthood. In addition, it is observed that the use of methylphenidate outside indications of technical data sheet is a common practice in adults.

Key Words: Methylphenidate, adults, prescription, indication.

Estudio de prescripción-indicación de metilfenidato en adultos en un Área de Gestión Sanitaria

RESUMEN

Introducción: A pesar de que en España el metilfenidato está aprobado para el trastorno por déficit de atención-hiperactividad (TDAH) en niños mayores de 6 años, existen prescripciones en pacientes adultos tanto para el tratamiento del TDAH como en otras indicaciones. El objetivo de este estudio es analizar la adecuación de la prescripción de metilfenidato en pacientes adultos en el Área de Gestión Sanitaria Sur de Sevilla.

Métodos: Se realizó un estudio observacional retrospectivo y de corte transversal de utilización de medicamentos de tipo prescripción-indicación de todos los pacientes adultos (>18 años) que tenían activas prescripciones de metilfenidato en septiembre de 2018.

Resultados: Se incluyeron 91 pacientes adultos en tratamiento con metilfenidato con una mediana de edad de 21 años (rango 18-90 años). Un 67,03% eran hombres. El diagnóstico que más frecuentemente motivó la prescripción

del metilfenidato fue el TDAH, que es la indicación para la cual está autorizada. Un 36,26% de los pacientes presentaron indicaciones no incluidas en ficha técnica. La mediana de dosis diaria prescrita fue de 36 mg (rango 5-108 mg). 7 pacientes tenían prescritas dosis superiores a la máxima recomendada.

Conclusiones: Este estudio demuestra diferentes patrones de prescripción de metilfenidato en adultos. Destacan la duración del tratamiento y la no suspensión durante la edad adulta. Además, se observa que el uso del metilfenidato fuera de indicaciones de ficha técnica es una práctica habitual en adultos.

Palabras clave: Metilfenidato, adultos, prescripción, indicación.

INTRODUCTION

Methylphenidate is a psychostimulant that inhibits the reuptake of dopamine (DA) and norepinephrine (NE), increasing the amount of these monoamines in the synaptic cleft. Methylphenidate inhibits the reuptake of these monoamines by blocking their transporters: dopamine transporter (DAT) and noradrenaline transporter (NET), presenting greater affinity for DAT than for NET¹.

Methylphenidate has structural and pharmacological similarity with drugs such as cocaine and D-amphetamine, so there is reason to suspect that it may have a potential for significant abuse².

Currently in Spain, methylphenidate is only approved for attention deficit hyperactivity disorder (ADHD) in children from 6 years of age when other measures by themselves have proven to be insufficient³.

Treatment with methylphenidate is not indicated for all children with this syndrome and the decision to use the drug should be based on a very complete assessment of the severity and chronicity of the child's symptoms in relation to their age³.

There are different commercial presentations currently available on the market. The technical data sheet of some presentations (Equasym[®], Medikinet[®] and Rubifen[®]) specifies that they are not indicated for adults. The rest of the presentations do not rule out this possibility for teenagers patients whose symptoms persist until adulthood and who have demonstrated a clear benefit. However, it is not appropriate to start treatment in adulthood³.

Regarding long-term use of methylphenidate (more than 12 months), the safety and efficacy of methylphenidate treatment have not been systematically evaluated in controlled studies. Treatment with methylphenidate should not be and is not required to be indefinite, it is usually suspended during or after puberty³.

In the last decades, the diagnosis of ADHD and the use of stimulants has increased significantly, reaching up to triple the prescription rate of methylphenidate⁴.

Other clinical uses, outside the technical specifications described in the bibliography, are:

- Narcolepsy⁵ (indication approved by the FDA).
- Depressive anxious disorder (obsessive compulsive disorder⁶, bipolar disorder⁶, major unipolar depressive disorder⁷, schizoid personality disorder⁸).
- Disorder of the use of stimulants⁹ (detoxification).
- Sleep disorders (obstructive sleep apnea¹⁰, idiopathic hypersomnia¹¹).
- Autism spectrum disorders¹².
- Cognitive enhancement¹³.

The use of medical stimulants such as methylphenidate to enhance intellectual capacity is increasing in some countries not only in patients with brain disorders but also in healthy individuals. Patients who consume cognition-enhancing drugs are at risk of developing dependence and suffer adverse effects due to the abuse of these substances¹³⁻¹⁵.

The aim of our study was to analyse the suitability of the prescription of methylphenidate in adult patients in the South of Seville Healthcare Management Area (SSHMA).

METHODS

Retrospective observational prescription-indication study of the use of methylphenidate in the South of Seville Healthcare Management Area. All adult patients (>18 years old)

who had active methylphenidate prescriptions in September 2018 were included.

The following variables were collected: demographic (age and sex) and clinical (indication of treatment, total daily dose, posology, duration of treatment).

As outcome variables were collected: percentage of patients with off-label indications, percentage of patients with inadequate doses and percentage of patients with treatment duration of more than one year.

Patients with active prescription of methylphenidate from the SSHMA were obtained from the application LIS-TADOS[®]. The rest of the variables were collected from the digital clinical history (Diraya[®]) and from the prescription module (Prescripciones 5[®]).

RESULTS

Patients

91 adult patients on treatment with methylphenidate were included. The median age was 21 years old (range 18-90 years) 67.03% were men.

The greatest number of patients who consumed methylphenidate were between 18 and 25 years old (61.54%). A 12% of the cases were older than 60 years.

Indication study

The prescription indications for methylphenidate were collected in table 1. 36.26% of the patients presented indications not included in the technical data sheet.

Dosage

The mean daily dose was 36 mg (range 5-108 mg) given in one or two daily doses. 7.7% of patients (7) had prescribed doses higher than the maximum recommended (60 mg day), 6 of them with a diagnosis of ADHD and one diagnosed with narcolepsy. Of these 7 patients, two had prescribed a total daily dose of 108 mg, another two 80 mg daily and the three remaining 72 mg daily.

Treatment duration

The duration of the treatment was measured approximately, since there are no electronic prescription records beyond the year 2003, the year in which the Recipe XXI was incorporated into the Andalusian Health System¹⁶.

The mean duration of treatment was 7.8 years (range 13.2-0.53 years). 96.7% of patients had been prescribed methylphenidate for more than a year.

DISCUSSION

The diagnosis that most frequently motivated the prescription of methylphenidate was ADHD, which is the indication for which it is intended. This states that CNS stimulants continue to be the first pharmacological line for this pathology. However, methylphenidate has not been approved in adults or the elderly, as there are no safety studies in these populations.

The increase in prescriptions and the prolongation of their duration is likely to cause an increase in adverse effects, despite the fact that most individuals with ADHD adequately use their medications¹⁷.

In the study population, the largest number of patients who consumed methylphenidate were included in the age group (18-25 years) who maintained the treatment initiated during childhood, which has not been suspended.

Table 1. Indications of methylphenidate prescription

Treatment indication	N.º patients (91)
ADHD	58 (63,74%)
Depressive anxious disorder	9 (9,9%)
Waking sleep disorder (narcolepsy, daytime hypersomnia...)	6 (6,6%)
Mental retardation and autism spectrum disease	4 (4,4%)
(OSAHS)	3 (3,3%)
Detoxification due to drug use	2 (2,2%)
Non-relatable indication	4 (4,4%)
No data	5 (5,5%)

ADHD: attention deficit hyperactivity disorder; OSAHS: obstructive sleep apnea-hypopnea syndrome.

It was found that not all the prescribed doses were within the ranges recommended by the data sheet. Doses higher than these are associated with signs of generalized central CNS stimulation that can culminate in convulsions². In our case, 7 patients had prescribed doses higher than those recommended.

CONCLUSIONS

This study demonstrates the different patterns in the prescription of methylphenidate in adults. Draws attention, the long duration of treatment with methylphenidate and the non-suspension of it during adulthood. In addition, it is observed that the use of methylphenidate outside indications of technical data sheet is a common practice in adults. These prescription patterns imply the need to incorporate strategies to minimize the risk of adverse reactions and the risk of misuse or abuse, particularly in the elderly.

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