

## Case Report

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# Treatment of Spasticity Due to Multiple Sclerosis with Sativex®: Who Benefits Most? Three Case Reports

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### Abstract

The evidence available suggests that cannabinoid-based products improve spasticity, chronic pain, and bladder dysfunction, which are common symptoms in more than 50% of multiple sclerosis (MS) patients. In this paper we present three cases of patients with progressive or relapsing forms of MS, with different severity, duration, and with various degrees of hypertonia and or bladder dysfunction, treated with nabiximols (Sativex®). Nabiximols was administered as an oral spray to reduce MS-associated hypertonia. The results show the efficacy of the therapy in MS patients with moderate to severe spasticity and resistant or intolerant to common myorelaxants drugs. In conclusion, nabiximols proves to be an effective treatment, easy to administer, even in patients with motor disabilities affecting the hands, and without important side effects.

**Keywords:** Multiple sclerosis; Sativex®; Spasticity; Case report; Nabiximols

### 1. Introduction

Multiple sclerosis (MS) is the most common cause of chronic disability in young adults [1]. The evidence currently available suggests that cannabinoid-based products improve spasticity, chronic pain, and bladder dysfunction, which are common symptoms in more than 50% of MS patients [2-4]. *Cannabis sativa* contains more than 60 different phytocannabinoids [5]; the best-known phyto-derivatives are 9- $\delta$ -tetrahydrocannabinol (THC) and cannabidiol (CBD). Nabiximols (Sativex<sup>®</sup>) is a natural extract of *C. sativa* with a ratio of THC:CBD of 1:1. It is administered as an oral spray and is currently approved for the treatment of spasticity associated with MS.

In this article, we present three MS cases with moderate to severe spasticity, who are treated effectively with nabiximols.

## 2. Case Description

### 2.1 Case 1

Case 1 is a 55-year-old patient with primary progressive MS with onset in 1999 with walking disorders. Since 2008, there have been worsening difficulties in walking with frequent falls and the development of progressive, severe, pyramidal hypertonia in the four limbs. Conventional myorelaxant treatments with baclofen and tizanidine were ineffective, while local administration of botulinum toxin type A gave partial results on contractures affecting the fingers or forearm muscles. Nabiximols was prescribed in July 2014. During this time, the patient had the following scores: Expanded Disability Status Scale (EDSS) 6.5, Numerical Rating Scale (NRS) for spasticity 8, and Ambulation index 8. After 4 weeks, the patient, who took 10 puffs a day, reported subjective improvement of spasticity with greater autonomy in mobilization. The neurological evaluation showed a 2-point reduction on the NRS scale for spasticity. After 3 months, the patient reported a reduction in muscle cramps. No side effects were reported.

### 2.2 Case 2

Case 2 is a 72-year-old patient with secondary progressive MS with onset in 1981 with optic neuritis. Since the mid-1990s, there has been a progressive worsening of walking, pyramidal hypertonia in the four limbs, and sphincter disorders with bladder dyssynergia and the need for daily self-catheterization. Myorelaxant treatment with baclofen was only partially effective, but its use caused significant side-effects, such as excessive generalized asthenia and weakness in the lower limbs. The marked distal spastic hypertonia to the four limbs was treated with botulinum toxin type A, with only a partial benefit. In April 2014, the patient started treatment with nabiximols with the following scores: EDSS 6.5, NRS for spasticity 8, and Ambulation index 8. After 4 weeks, the patient, who took 7 puffs a day, reported subjective improvement of spasticity with increased autonomy in movements and urinary functions and a significant reduction of myalgias. The neurological evaluation showed a 2-point reduction on the NRS scale for spasticity. After 3 months, the patient still referred benefits on spasticity and urinary disorders, with an improvement in the quality of life. No side-effects have been reported.

### **2.3 Case 3**

Case 3 concerns a 38-year-old patient with relapsing MS with onset in 1999 with left optic neuritis. The patient maintained a low level of disability with slight difficulty in walking due to right monoparesis and minimal distal sensory symptoms. Over the last few years, the patient complained of moderate spastic hypertonia affecting the paretic limb. Treatment with baclofen at low doses resulted in excessive generalized asthenia and weakness in the paretic limb, with a significant risk of falls. Four puffs a day of nabiximols were prescribed in June 2014 when the patient presented the following scores: EDSS 3, NRS for spasticity 6, and Ambulation index 1. After 4 weeks, the patient reported subjective improvement of hypertonia with a reduction of cramp-like pains. The neurological evaluation showed a 2-point reduction on the NRS scale for spasticity. After 3 months, the patient reported a satisfactory clinical response to therapy with nabiximols. No side-effects were reported.

### **3. Discussion**

The clinical cases reported here describe a typical population of MS patients with different forms of MS, with varying severity and duration and with different degrees of spasticity. The clinical response to nabiximols *via* oromucosal spray shows the efficacy of the therapy in MS patients with moderate to severe spasticity and resistant or intolerant to common myorelaxants drugs. In Case 1, the significant reduction in spasticity allowed the recovery of personal autonomy with an improvement in the quality of life. In Case 2, where the patient poorly tolerated common muscle relaxants at effective dosages, the introduction of nabiximols reduced the dosage of baclofen and its side effects and improved the urinary disorders. For this reason, nabiximols should also be considered in patients with bladder dysfunction not responsive to anticholinergic or alpha-lytic therapies.

In case 3, despite the patient having a moderate degree of spasticity, the patient could not be effectively treated with common muscle relaxants, which also determined the worsening of generalized asthenia.

In conclusion, nabiximols proves to be an effective treatment, easy to administer, even in patients with motor disabilities affecting the hands, and without important side effects. Its use has been shown to significantly reduce spasticity, even of a severe degree, and to improve urinary disorders and patient's quality of life. Combining nabiximols with oral muscle relaxants allows reducing the dosage of the latter, minimizing adverse events. Finally, the cases presented to demonstrate that the dose of nabiximols varies from patient to patient regardless of the severity of the spasticity.

### **Learning Points**

- Nabiximols proves to be an effective treatment, easy to administer, even in patients with motor disabilities affecting the hands, and without important side effects.

- Nabiximols use can reduce spasticity, even of a severe degree, and improve urinary dysfunction and patient's quality of life.
- Combining nabiximols with oral muscle relaxants allows the dosage of the latter to be reduced, minimizing adverse events.

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