Evaluation of Effectiveness of Fampridine in Walking Capacity of Multiple Sclerosis Patients in a University Hospital

Campelo IC¹; Ribeiro Rama AC^{1,2}; Sousa L³.

1. Pharmacist, Department of Pharmacy, Centro Hospitalar e Universitário de Coimbra, Prc. Mota Pinto. 3000-075 Coimbra, Portugal. e-mail: <u>isabel.campelo@gmail.com</u>

2. Pharmacist, Center for Pharmaceutical Studies, Faculty of Pharmacy, Universidade de Coimbra

3. Neurologist, Demyelinating Diseases - Department of Neurology, Centro Hospitalar e Universitário de Coimbra, Prc. Mota Pinto. 3000-075 Coimbra, Portugal.

INTRODUCTION

Multiple Sclerosis (MS) is a chronic, inflammatory, autoimmune disorder, characterized by demyelination and neurodegeneration of the central nervous system (CNS). It usually affects people beginning in their 20s or 30s and is one of the most common causes of nontraumatic disability in young adults.

The destruction of myelin and axons occurs in various degrees producing significant physical disability (Fig 1). According to the Portuguese Society of MS, nearly 60% of patients suffering from this pathology, 20 years after being diagnosed, need help for their daily activities. Walking related disability is one of the main complaints, conditioning not only their basic activities but also professional performance, with impact on socioeconomic status. Fampridine SR, a voltage-dependent potassium channel blocker (Fig 2), is the first treatment approved for walking improvement in adult MS patients with Expanded Disability Status Scale (EDSS) 4-7.

▼ This medicine is subject to additional monitoring, allowing quick identification of new safety information.

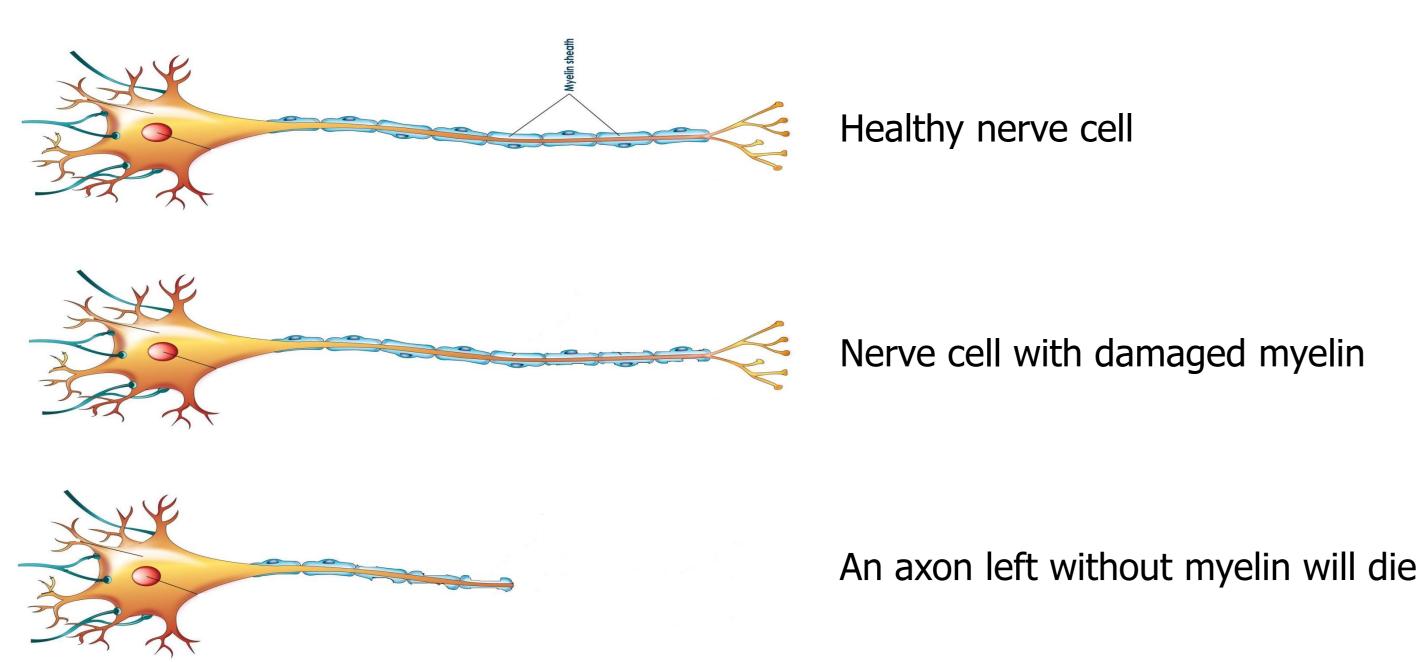


Figure 1 — Destruction of myelin and axons

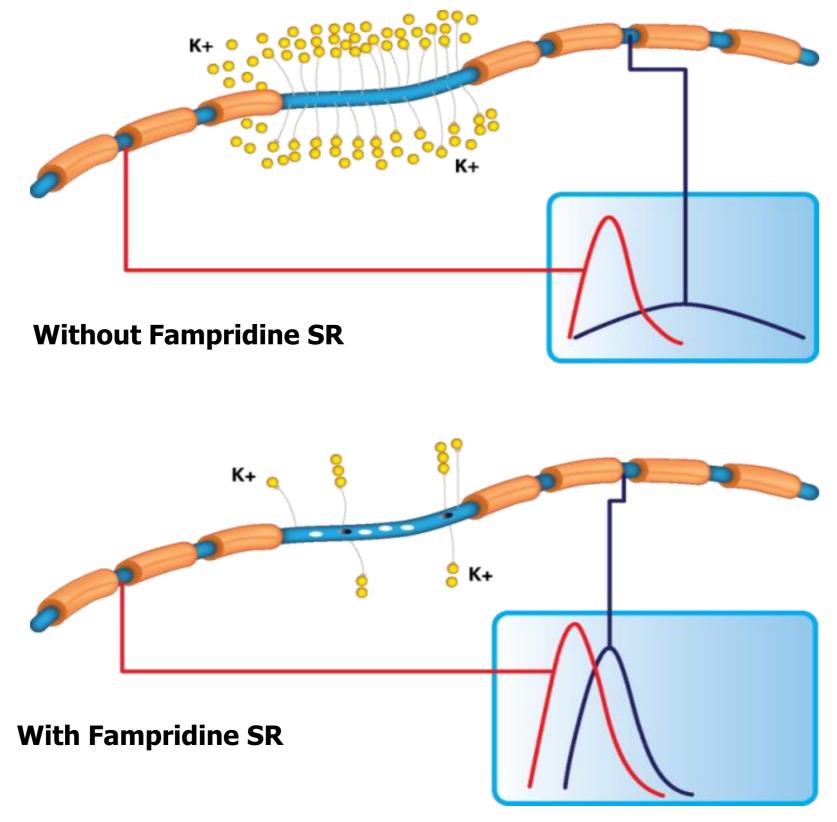


Figure 2 – Fampridine's mechanism of action

OBJECTIVE

The aim of the present study was to evaluate the effectiveness of Fampridine SR in walking ability (WA) of adult MS patients. Since this a medicine included in EMA's Additional Monitoring List, we also focused on the adverse events profile.

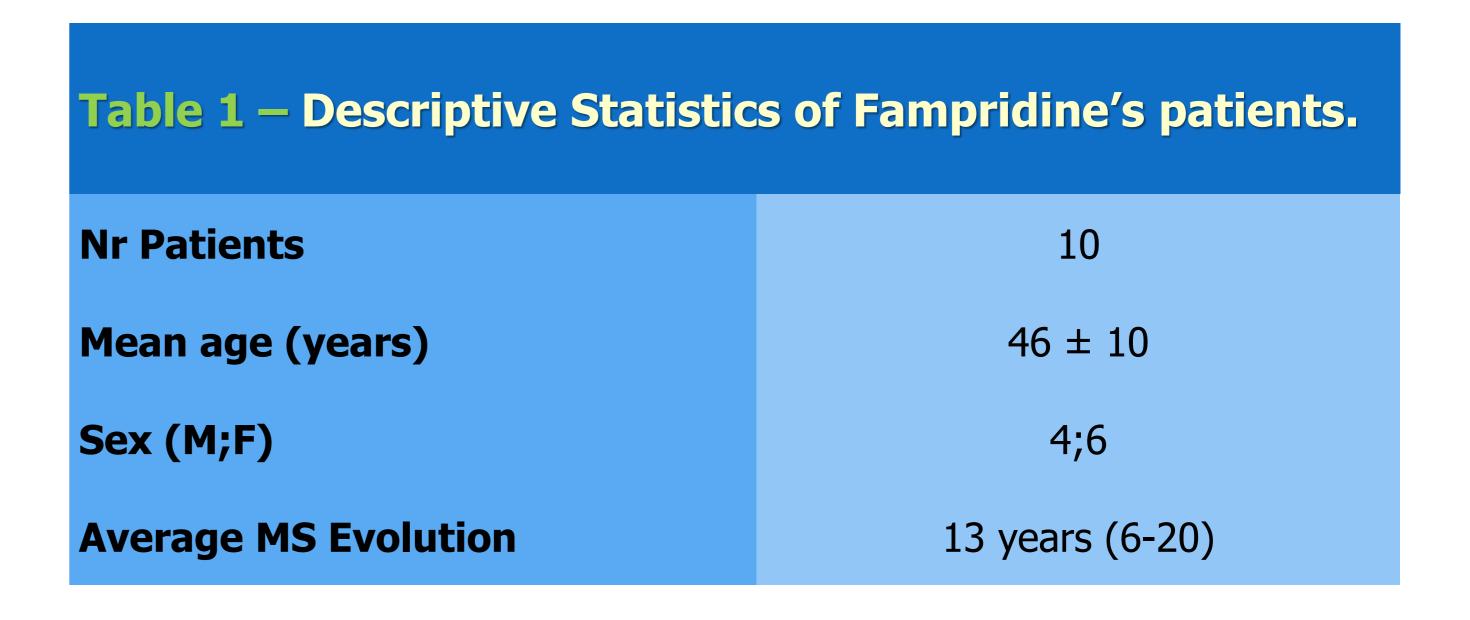
METHODS

A one year (2012-2013) retrospective study of patients with Fampridine SR prescription, 10mg twice daily. Data were collected by reviewing patient's clinical records from the Neurology department and pharmacist's reports to The National Medicines Agency. Parameters measures: timed 25-foot walk test (T25FW), 12-item MS walking scale (MSWS-12) questionnaire, at baseline and 15 days after first dose. A responder is defined as a patient who consistently has a faster walking speed for at least three visits.

The safety of the therapeutic was established according to the adverse events reported.

RESULTS

- ▶ The study included 10 patients, with an average of 46±10 years (4 male). The MS evolution ranged from 6-20 years. (Table 1). All the patients were treated with disease modifying drugs.
- ▶ 2 patients were excluded because they were prior exposed to amifampridine.
- ▶ 3 out of the 8 patients were non-responders (T25FW showed no improvement at baseline and 15 days after Fampridine SR) and treatment was suspended.
- ▶ The drug was administered orally 10mg twice daily and was well tolerated.
- ▶ The average WC improvement rate was approximately 40% (Figure 3) and patients changed their average perception of movement's limitations from "pretty" to "moderatly" in MSWS-12 (Table 2).



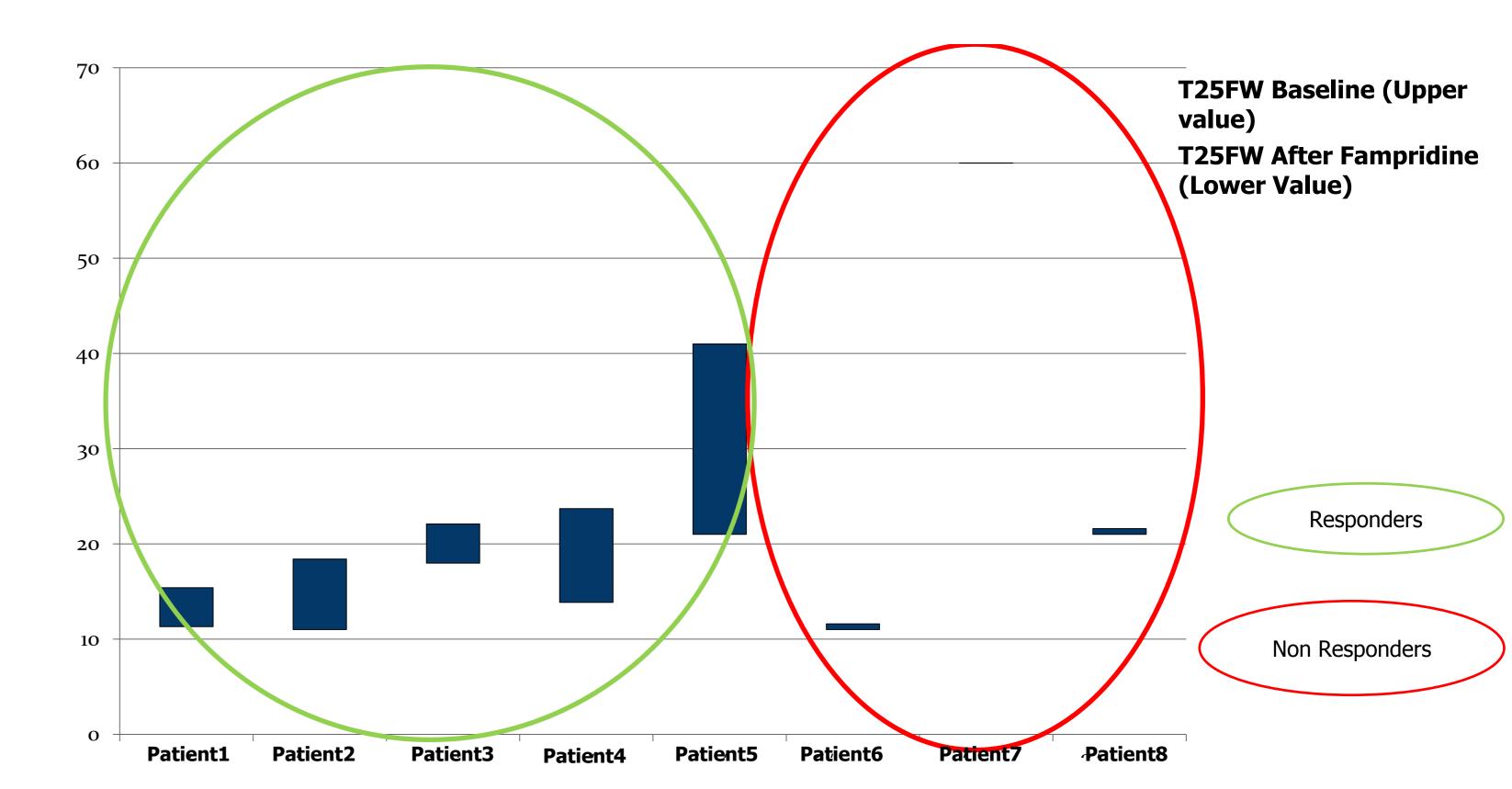


Figure 3 – Average WC improvement rate (F25FW).

Table 2 — The multiple sclerosis walking scale (MSWS-12)					
	1=Not at all	2=A little	3=Moderatly	4=Pretty	5=Extremely
Baseline	0.00%	0.00%	12.5%	50%	37.5%
After fampridine	0.00%	0.00%	62.5%	25%	12.5%

CONCLUSIONS

- ✓ MS is a chronic, usually progressive, disease that primarily affects young adults. Walking impairment is one of the most commonly reported symptoms and has been reported as one of the most impactful symptoms on the quality of life.
- √ Fampridine SR is the only licensed medication for walking disability in MS and may be useful in certain patients.
- √ It has an acceptable adverse event profile.
- √ In our hospital, we've seen an improvement of nearly 40% in WC in 65% of patients taking Fampridine. We're also interested in finding out if it has some effect on cognitive improvement as well.
- \checkmark We lack long-term studies of the efficacy of this medicine and therefore it is not clear the effect of treatment over long-term in responders.
- √ Given the burden of walking disability in MS, this treatment represents some hope for MS patients.

REFERENCES

Treatment 2011; 7: 229-239.

1. Compston A, Coles A. Multiple Sclerosis. Lancet 2002; 359:1221-31.

3. Hayes KC. Impact of extended-release dalfampridine on walking ability in patients with multiple sclerosis. Neuropsychiatric Disease and