Sativex® for Spasms and Spasticity in MS: Patient selection and outcomes in Cardiff and Vale and Cwm Taff

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Introduction

Sativex® is a mouth (oromucosal) spray containing two chemical extracts derived from the cannabis plant: delta-9 tetrahydrocannabinol (THC) and cannabidiol (CBD).
It is the first cannabis-based medicine to be licensed in the UK.

In 2014 The AWMSG (All Wales Medicine Strategy Group) announced that

Delta-9-tetrahydrocannabinol/cannabidiol (Sativex®) is recommended as an option for use within NHS Wales as treatment for symptom improvement in adult patients with moderate to severe spasticity due to multiple sclerosis who have not responded adequately to other anti-spasticity medication and who demonstrate clinically significant improvement in spasticity related symptoms during an initial trial of therapy.

In 2016 approval was gained to use Sativex® for Cardiff and Vale and Cwm Taff patients and to set up a specific clinic using the pay per responder scheme.

Patient Selection for trial

Using the AWMSG criteria (measuring spasticity using a NRS and physical assessment) and knowing the aggravating factors of spasticity were well managed.

Contraindications
- Not < 18yrs
- Personal or family history of severe mental health disorder other than depression
- Pregnancy
- Breast feeding
- Hypersensitivity to cannabinoids or any other component of the spray

Cautions

- Significant renal, hepatic or cardiac disease
- Currently using other cannabinoids
- Driver (need to stop driving whilst on the trial)

Information and outcome measures in clinic

We perform a number of outcome measures and provide patients with information on how to get the medication, take the medication, titrate the dose, what to expect, what to do if they are a driver and who to contact with any issues.

At a follow up clinic (approx. 5 weeks later) we review their response and repeat the outcome measures to identify responders.

- Numerical Rating scale: spasticity and sleep
- Penn spasm frequency scale
- Patients Global Impression of Change (PGIC) Scale
- Modified Ashworth scale
- Spasticity Quality of Life (discontinued, as repeated other outcome measures and not sensitive enough)

Demographics

- 74 patients (50 Cardiff and Vale, 42 Cwm Taf)
- 32 M:42 F
- EDSS range 3.5-9.0
- Age range when trialed 28-78
- Trialed between 28/9/16-2911/21
- 17 Drivers
- 14 via VC

Results

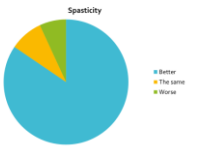
Trial data suggests a 50% response rate with a reduction in symptoms of 20% or more being significant

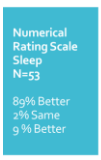
Currently our response rate is 56/74 patients, 75.67%, with a variable percentage of symptom reduction

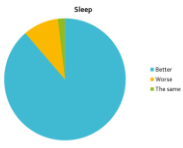
Of the 18 who didn't respond or continue

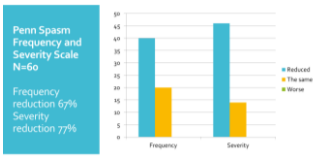
1 unable to manage spray
5 had se's so discontinued after trial
9 had no benefit so discontinued after trial
3 continued after trial then discontinued independently

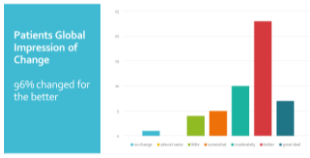
51 remain on it (6 RIP, 5 responders one non-responder)











Stop leg kicking out at night

Reduce pain and stop spasms in the morning

Make the right leg more bendy

Relax leg and improve balance to stand and exercise

Improve sleep and spasms

To reduce continuous feeling of tension in legs

Conclusions

Definitely has a place in spasticity and spasm management
Particularly if lots of **spasm,** and especially if it is **disturbing sleep**

COVID-19 Update

We continued to run the service throughout the pandemic, and have managed online using VC. All patients need to have had a physical assessment recently and are well known to us. We have been unable to use the Ashworth scale but continued with other OM's

Reference
AWMSG, 2014. Sativex Final Appraisal Recommendation. Available from: http://www.awmsg.org/awmsgonline/app/appraisalinfo/644