GAIT INITIATION EVALUATION IN MULTIPLE SCLEROSIS

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Background

Recently, Nabiximol was approved as a treatment in MS spasticity. However, most data leading to its approval and clinical use, although widely recognised, are based on subjective scales.

AIM

To quantitatively assess the functional modifications in spasticity induced by Nabiximol in MS.

Materials & Methods

A group of patients were enrolled. Inclusion criteria were a diagnosis of MS according to the 2010 McDonald criteria, being able to walk for at least 6 m regardless of the use of aids - and the ability to assume Nabiximol according to medical judgment and the Italian drugs agency (AIFA) criteria. All patients were non-responders to previous spasticity treatments. For each patient were evaluated, NRS, three-dimensional gait analysis (spatial-temporal and kinematic) and ultrasound elastography of the rectus femoris at baseline (T0-T1) and after one month of Nabiximol. Kinematic data were expressed means of Gait Profile Score (GPS) and real time elastography was scored with scale from 0 (no stiffness) to 5 (maximum stiffness). Variation of each parameter (from T0 to T1) was evaluated at by means of one-way ANOVA.

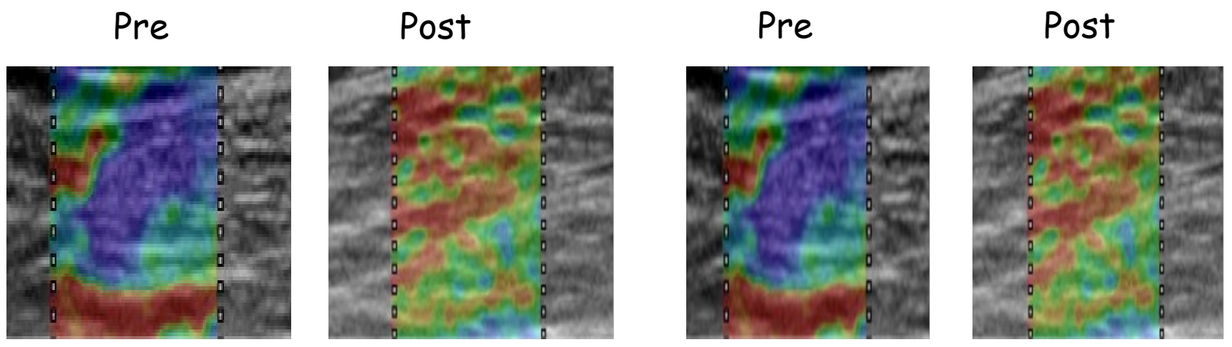
Results

Twenty patients were enrolled – 9 male and 11 female – with mean EDSS of 5.3 (SD ± 0.81) and mean reduction of NRS during Nabiximol of 1.88 (NRS response rate was 65%). The spatial-temporal parameters of gait revealed an increase in speed (+15%, p < 0.001), cadence (+6%, p < 0.001) and stride length (+10%, p < 0.001) after treatment. Regarding the kinematics data, the GPS after treatment was reduced by 10% (p < 0.001): Significant changes involved the pelvic district, hip rotation and knee flexion-extension. All patients showed an improvement at real time elastography examination with a mean reduction of 1.0 point (p<0.001).

Spatial–temporal gait parameters	T0	T1	Time *p* value
Stride length (m)	0.79 ± 0.18	0.87 ± 0.20	**<0.001**
Gait speed (m sec^{-1})	0.43 ± 0.22	0.49 ± 0.26	**<0.001**
Cadence (steps min^{-1})	69.17 ± 24.28	73.27 ± 23.90	**<0.001**
Step width (m)	0.17 ± 0.04	0.16 ± 0.04	0.223
Stance phase (% of the gait cycle)	68.12 ± 11.59	68.90 ± 6.76	0.696
Swing phase (% of the gait cycle)	29.68 ± 6.17	30.81 ± 6.93	0.175
Double support time (% of the gait cycle)	21.59 ± 8.39	20.06 ± 8.12	0.321

Statistically significant *p* values are indicated in bold

Parameters at T0 (before nabiximols assumption) and at T1 (after 1 month of stable treatment) and respective *p* value

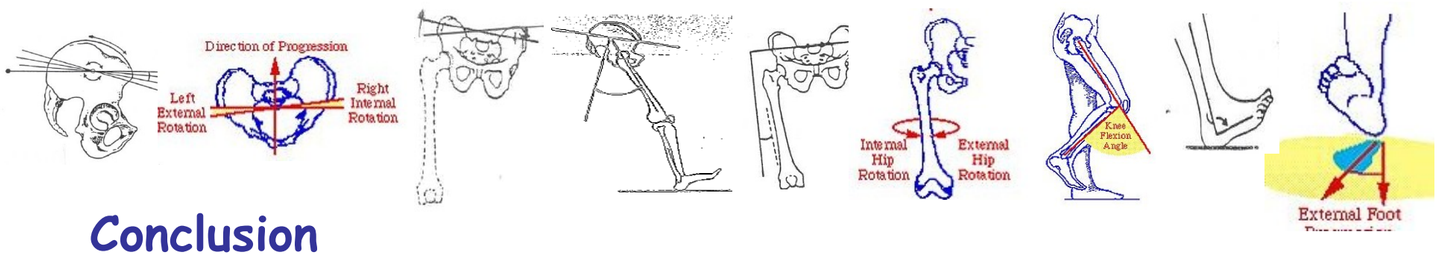


GPS and GVS scores			
	T0	T1	Time *p* value
GPS (deg)	12.25 ± 3.47	10.91 ± 3.24	**<0.001**
GVS (deg)			
Pelvic tilt	12.90 ± 7.05	9.81 ± 6.10	**<0.001**
Pelvic rotation	9.09 ± 5.35	7.75 ± 4.79	**0.005**
Pelvic obliquity	5.11 ± 2.52	4.63 ± 2.26	**0.043**
Hip flexion–extension	18.33 ± 7.90	15.83 ± 7.12	0.055
Hip abduction–adduction	5.09 ± 2.65	5.12 ± 2.50	0.931
Hip rotation	14.30 ± 7.10	10.11 ± 4.03	**0.001**
Knee flexion–extension	17.25 ± 5.19	15.90 ± 5.77	**0.046**
Ankle dorsiflexion	9.54 ± 3.82	9.51 ± 4.44	0.927
Foot progression	9.77 ± 3.95	10.61 ± 5.51	0.244

Statistically significant *p* values are indicated in bold

Higher GVS/GPS scores indicate larger deviations from physiological gait. Parameters at T0 (before nabiximols treatment) and at T1 (after 1 month of stable treatment) and respective *p* value

ashworth	score picture	rthe picture	description
0			elastic muscle fibers evenly distributed
1			elastic muscle fibers in the central part of the muscle
2			inelastic muscle fibers, distributed in the periphery of the muscle
3			predominance of inelastic muscle fibers both in the center as well as in the periphery
4			inelastic muscle fibers, evenly distributed with the existence of a spot of elastic muscle fibers
5			a lack of elastic muscle fibers



Conclusion

We found that treatment with Nabiximol is able to improve speed, cadence and stride length. The kinematic of gait patterns results closer to the physiologic values. Furthermore the real time elastography showed significant morphological changes in muscular stiffness. What is more interesting is that the results concern an heterogeneous group of patients composed by NRS responder and nonresponders suggesting that the effects of the drug are more complex that a "pure" antispastic action.