

## Prospective Evaluation of Peristeen® Transanal Irrigation System in Multiple Sclerosis patients: results from an Italian single centre study

R.Balsamo 1-2, D.Arcaniolo 2, E.Illiano 3, F.Natale 4, E.Costantini 3, M.De Sio 2

1. Magna Graecia University of Catanzaro, 2. Università degli Studi di Napoli Luigi Vanvitelli, 3. Department of Urology and Andrology Clinic, Department of Surgical and Biomedical Sciences, University of Perugia, Perugia, Italy, 4. Urogynecology San Carlo -IDI-Hospital Rome, Italy

### Hypothesis and aims of the study

Patients with multiple sclerosis (MS) often experience severe debilitating lower urinary and bowel dysfunction in addition to the physical disabilities.

The **aim of this study** was to determine the ability of Peristeen® transanal irrigation system to reduce symptoms of neurogenic bowel dysfunction (NBD) and the effects on patient quality of life (QoL), lower urinary tract and sexual function.

### Materials and methods

From January 2016 to January 2017, consecutive patients with diagnosis of neurogenic bowel dysfunction secondary to MS who were unsuccessful with their current bowel regimen were recruited from our neurological department. This was a prospective clinical trial of 6-month period: the **first phase** of 3 months was a roll-in time to determine whether patients respected inclusion criteria, to appreciate their bowel habits and to verify how many urinary tract infections (UTIs) were present during this period.



The **second phase** of 3 months was the operative trial with the use of transanal irrigation. Luts were evaluated with the International Prostate Symptoms Score (**I-PSS**), neurological impairment was assessed using the Expanded Disability Status Scale (**EDSS**), bowel dysfunction was investigated with the Neurogenic Bowel Dysfunction score (**NBDs**) and sexual dysfunction was recorded with the International Index of Erectile Function (**IIEF-15**) and Female Sexual Function Index (**FSFI**).

### Results

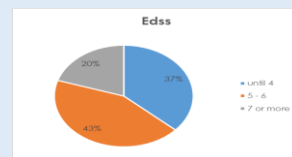
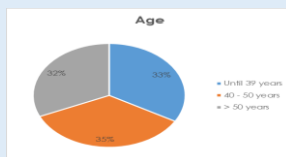
60 patients completed the study and were included in the analysis (20 (20%) **men** and 40 (80%) **women**).

**Mean age** was 41.2±11.6 years and **mean duration of the disease** was 11.5±7.5 years.

**Mean EDSS score** was 3.77±2.01 with no significant difference between the types of clinical course of the disease. Comparing questionnaire scores before and at the end of the study, the mean±s.d. scores were as follows: **NBD total score** was 17.0±2.3 versus 9.46±4.40 (P<0.001); **IIEF total score** was 41±8.2 versus 65±7.2 (P<0.001); **FSFI total score** was 21.2±4 versus 25.8±3.7 (P<0.001); **IPSS** was 26±4 versus 18±4 (P<0.0001).

Regarding **UTI**, data collected evidenced a general decrease during the study, particularly, of Escherichia coli infections: 24 UTI in 3 months before treatment (9 E. coli) versus 6 (3 E. coli) during trial (P<0.01). There was an increase in patients' opinion of their **intestinal functionality** (P<0.001), their **QoL score** (P<0.001) and their answers regarding the degree of **satisfaction** (P<0.001).

	Mean		Average		Standard Dev.		Coeff. Variation		N	
	10	16	10	16	10	16	10	16	10	16
Edss	5,5	5,5	4,8	4,8	1,8	1,8	37,8%	0,4	60	60,0
Duration disease	13	13,0	13,8	13,8	4,7	4,7	34,0%	0,3	60	60,0
Bristol scale	100%	-	87%	0,3	34%	0,5	39,6%	1,4	60	60,0
NBD score	17	9,4	17,5	8,3	2,3	4,4	40,1%	0,3	60	60,0
UTI episodes, n (%)	3	-	3,0	0,6	0,8	0,8	27,2%	1,3	60	60,0
Ipps	26	18,0	24,4	15,1	4,3	4,0	17,6%	0,3	60	60,0
IIEF-tot	41	65,0	37,0	62,0	8,2	7,7	22,1%	0,1	25	25,0
FSFI-TOT	21,2	25,8	23,3	26,8	4,0	3,7	17,3%	0,1	35	35,0



About modality for evacuation, we observed a significant reduction in manual extraction (25 patients before versus 4 after the trial; P<0.01), in suppositories or enema (18 patients before versus 5 after the trial; P<0.01) and in the use of oral laxatives (17 patients before versus 5 after the trial; P<0.01). Patients with an EDSS score< 4 showed an higher improvement of bowel habit.

### Conclusion

Our results suggest that **transanal irrigation is a valid treatment**, it improves bowel disturbances, quality of life and seems to reduce the risk of urinary tract infections.

