

Validity and reproducibility of the Italian version of the Patient Determined Disease Steps scale in people with Multiple Sclerosis

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Purpose: The Patient Determined Disease Steps (PDDS) scale is a self-assessment disability scale providing a patient-reported outcome (PRO) of the impact of Multiple Sclerosis (MS) on walking. The aims of the study were to translate and adapt the PDDS in Italian (PDDS/IT) and to test it in people with MS (pwMS).

Methods: three professional translators with experience in health terminology produced three independent translations. The three translators discussed these versions and a consensus version was produced. Subsequently, the Italian version was back-translated into English and compared to the original one. The consensus translation was evaluated at a meeting of the translators, neurologists with experience in MS and health outcomes research, and three bilingual (English-Italian) pwMS who completed both scales for comparability.

PwMS were examined to obtain EDSS and performed 3"and 2" Paced Auditory Serial Addition Test (PASAT), Symbol Digit Modalities Test (SDMT), Timed 25-Foot Walk (T25FW), 6-Minute Walk (6MW), Time Up to Go test (TUG), 9-Hole Peg Test (9HPT) and completed the PDDS/IT and the 12-Item Multiple Sclerosis Walking Scale (MSWS-12). Spearman rho correlation coefficients (ρ) were used to evaluate association between variables. Restesting PDDS/IT after 15 days, we calculated the Intraclass Correlation Coefficient (ICC).

Inclusion criteria: confirmed MS diagnosis (by revised McDonald criteria), age > 18 years, independent ambulation or ambulation with an assistive device, willingness to voluntarily complete testing.

Exclusion criteria: an exacerbation in the past 90 days, an additional neurological disease or with one or more concomitant comorbidities.

Demographic and clinical features	
Age (yr)	40 (31-48)
Sex (n, % female)	67(69.8%)
Education (yr)	13 (13-14)
MS Type (n, % RRMS)	85 (88.5%)
Time since diagnosis (yr)	6 (3-15)

Table 1: demographic and clinical features

	Median	Q1-Q3
EDSS	2	1.5-4
PDDS/IT	2	0-3
TUG	8.7	7.4-10.8
6MW	500	370.3-540
MSWS12	20.8	4.2-37.5
9HPTDH	25.2	21.0-30.0
9HPTNDH	25.3	21.9-30.1
T25FW I	6.6	5.1-8.2
T25FW II	6.2	5.1-7.6
SDMT	39	30-50
PASAT 3	37	27-48
PASAT 2	28	19-36

Table 2: EDSS, PDDS/IT, ambulatory, upper limbs and cognitive scores

Results: 96 pwMS were enrolled (Table 1). We found a strong correlation ($p < .0001$) between EDSS and PDDS/IT (Fig. 1). ρ values between both scales and considered variables showed a small correlation with disease duration, education and PASAT, a strong correlation with 6 MW, MSWS-12 and T25FW, a moderate correlations with TUG and SDMT and no correlations with 9HPT (Table 3). Retest was calculated on 28 pwMS. Median value was 2 (1-3) for the first and second time ($p = 0.593$). Limits of agreement were -0.943 to 0.943 (Fig. 2). Retest showed a high reliability (ICC 0.95).

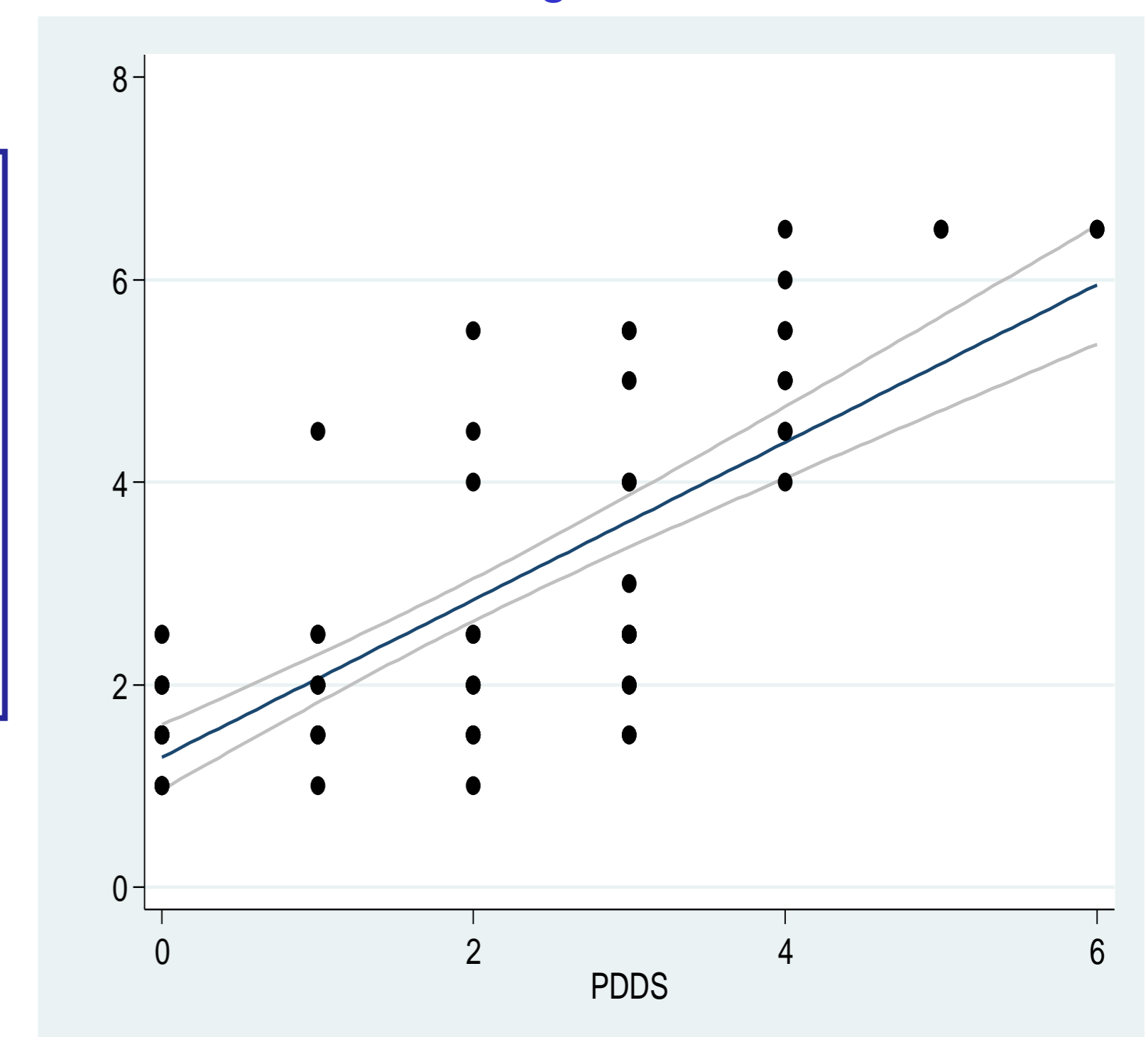


Figure 1. Scatterplot along with line of best fit and 95% confidence intervals of EDSS and PDDS

	PDDS/IT		EDSS		p
	rho	CI95%	rho	CI95%	
Disease duration	0.264	0.07;0.44	0.205	0.00-0.39	0.997
Age	0.333	0.14;0.50	0.337	0.15-0.50	0.9998
Education	-0.14	-0.33;0.06	-0.095	-0.29;0.11	0.997
TUG	0.479	0.31;0.62	0.43	0.25;0.58	0.999
6MW	-0.633	-0.74;-0.50	-0.737	-0.82;-0.63	0.998
MSWS12	0.853	0.79;0.9	0.632	0.49;0.74	0.996
9HPTDH	0.394	0.21;0.55	0.536	0.38;0.67	0.996
9HPTNDH	0.495	0.33;0.63	0.591	0.44;0.71	0.998
T25FW I	0.556	0.4;0.68	0.562	0.41;0.69	0.9998
T25FW II	0.587	0.44;0.71	0.565	0.41;0.69	0.9995
SDMT	-0.402	-0.56;-0.22	-0.391	-0.55;-0.21	0.9996
PASAT 3"	-0.24	-0.42;-0.04	-0.187	-0.37;0.01	0.997
PASAT 2"	-0.247	-0.43;-0.05	-0.246	-0.43;-0.05	0.9999

Table 3: EDSS and PDDS/IT scores correlations with demographic, ambulatory, upper limbs and cognitive scores

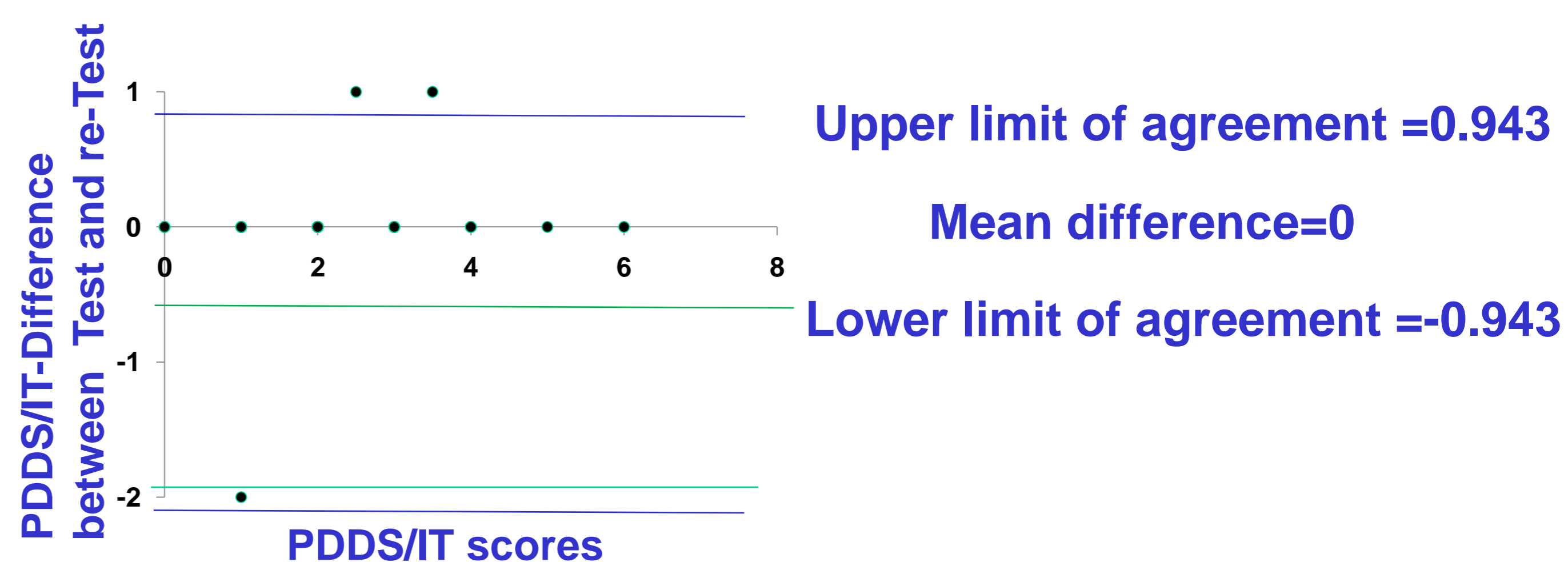


Figure 2: Bland Altman plot analyzing the agreement between Test and Retest of PDDS/IT.

Conclusions: We adapted the PDDS for Italian pwMS and then validated its scores for measuring disability level in Italian pwMS. The PDDS/IT was reliable and valid as PRO of the impact of MS on walking and as an alternative test for assessing disability in MS.