A study of developing standard data of cognitive function using Processing Speed Test in Japanese healthy volunteers

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Conclusions

- The mean PST score (± SD) in Japanese healthy volunteers (HVs) was reported and stratified with their age, educational background, and sex in order to utilize it for cognitive function tests in Japanese patients with MS.
- The PST score in Japanese HVs decreased significantly with age and was significantly higher in participants with higher educational background.
- There was no significant difference between males and females.
- Current results of PST suggests that z scores for Japanese tend to be generally higher.
- The results of the study may contribute to the progress of medical care, such as early screening and the care of cognitive dysfunction in Japanese MS patients in the future.

Introduction

- The Processing Speed Test (PST) is a self-administered, iPad®-based screening tool for cognitive dysfunction in multiple sclerosis (MS) patients.
- Cognitive dysfunction can be observed early in the disease course and independently of physical disability.
- The PST was designed to detect cognitive impairment via brief office visits without the need for a formal neuropsychological assessment.
- In a US study[1], the PST was shown to have excellent test-retest reliability and was highly correlated to the common cognitive test, Symbol Digit Modalities Test.

Objective

- The purpose of this study was to collect and assess the standard data of PST obtained from Japanese healthy volunteers (HVs) in order to utilize it for cognitive function tests in Japanese patients with MS in the future.

Methods

Study design

- Single arm, cross-sectional study
- Study classification: clinical study based on research contract

Inclusion criteria

- Mentally healthy males and females without any neurological, psychiatric, or developmental disorders
- Age ≥ 20 and ≤ 65 years
- Able to provide written consent to participate after full explanation of the study
- Able to communicate in Japanese
- Not undergone iPad-based PST test previously

Exclusion criteria

- Psychiatric disorder diagnosed by DSM-V criteria
- History of drug abuse or alcohol dependence syndrome
- Receiving psychotropic drugs for psychotic disorder, or epilepsy, or chronic sedative drug/hypnotic or narcotic analgesic [selective serotonin reuptake inhibitors (SSRIs) and serotonin norepinephrine reuptake inhibitors (SNRIs) are permitted]
- History of receiving amphetamine/dextroamphetamine combination, methylphenidate, topiramate, rivastigmine tartrate, donepezil hydrochloride, or specific analgesic drug such as oxycodone

Methods - Study endpoint

Primary endpoint

- Distribution of PST score

Secondary endpoint

- Distribution of PST scores stratified by educational status (0-12: under high school graduate, over 13 years: vocational school, college graduate or above), age (categorized by 10-year intervals) and sex: Comparison of PST scores was made by t-test.

Additional endpoint

- Regression analysis: Correlation between PST scores or z score, and ages were analyzed by regression analysis.
- Analysis was made within the groups according to educational status and sex, which were compared to that of the total group. Analysis was also made within the groups according to educational status in each sex group, which were compared to that of total group of each sex.

Results

Japanese HVs

- Of 254 Japanese participants, 242 participants with an Mini-Mental State Examination (MMSE) score ≥ 27 were analyzed.
- Of these participants, the mean age was 44.1 years, 51.2% were male and 60.7% were educated over 13 years (vocational school, university, or higher education) (Table 1).

Primary endpoint

- The PST score was almost normally distributed (Figure 1).
- The mean ± SD was 61.8 ± 10.0, median, maximum, minimum, and values were 62.0, 37 and 88.

Secondary endpoint

- Mean PST scores were significantly different between participants with 0–12 years and over 13 years of education (Figure 2A).
- Mean PST scores were not significantly different between males and females (Figure 2B).
- PST scores tended to decrease with age (Figure 2C).

Regression analysis

- Regression analysis showed that PST scores tended to decrease with age (Figure 3).
- Regression analysis showed a similar decreasing trend of PST scores with age in both males and females (Figure 4A).
- PST scores decreased with age regardless of education status, but in participants with 0-12 years of education, the slope of the regression line was -0.48 (with over 13 years of education, the slope was -0.34) (Figure 4B).
- The slope of the regression line tended to be smaller in both males and females with over 13 years of education (Figure 5).

Z score analysis

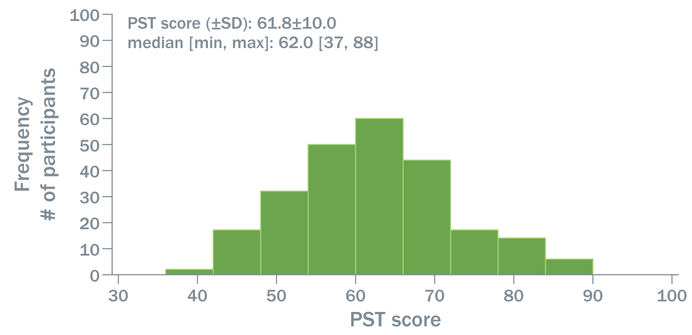
- The z scores presented in CogEval tended to be higher than 0, regardless of age (Figure 6).

Table 1. Japanese HV Demographics

		Total (n= 242)	Male (n= 124)	Female (n= 118)
Age, years	Mean ± SD	44.1 ± 14.3	43.5 ± 14.5	44.6 ± 14.1
	Median [Min, Max]	44.5 [20, 65]	44.0 [20, 65]	45.0 [20, 64]
Age, years, n (%)	20-29	52 (21.5)	28 (22.6)	24 (20.3)
	30-39	45 (18.6)	24 (19.4)	21 (17.8)
	40-49	46 (19.0)	24 (19.4)	22 (18.6)
	50-59	44 (18.2)	22 (17.7)	22 (18.6)
	60-65	55 (22.7)	26 (21.0)	29 (24.6)
Education, years	Mean ± SD	13.9 ± 1.8	14.0 ± 1.9	13.8 ± 1.7
	Median [Min, Max]	14.0 [9, 18]	14.0 [9, 8]	14.0 [10, 16]
Education, years, n (%)	0-12	95 (39.3)	48 (38.7)	47 (39.8)
	≥ 13	147 (60.7)	76 (61.3)	71 (60.2)

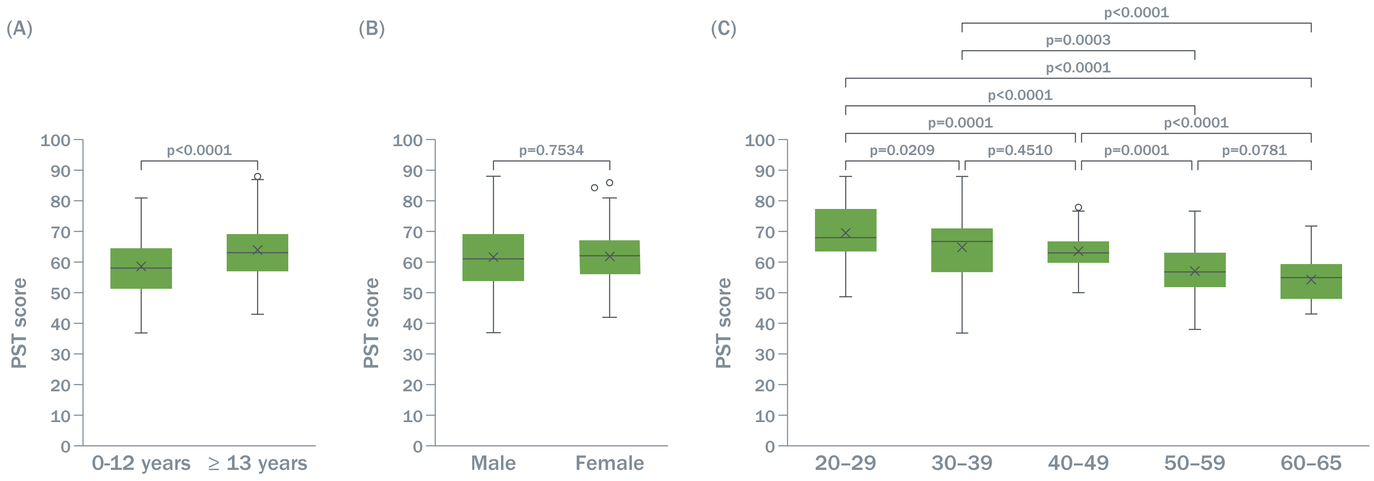
HV, healthy volunteer; max, maximum; min, minimum; SD, standard deviation

Figure 1. Japanese PST Score Distribution



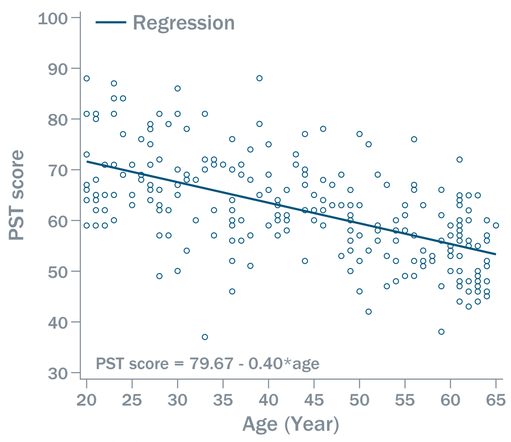
min, minimum: max, maximum; PST, processing speed Ttest; SD, standard deviation

Figure 2. Distribution of Japanese PST scores stratified by (A) education status, (B) sex, and (C) age



PST, processing speed test; SD, standard deviation

Figure 3. Regression analysis between PST score and age

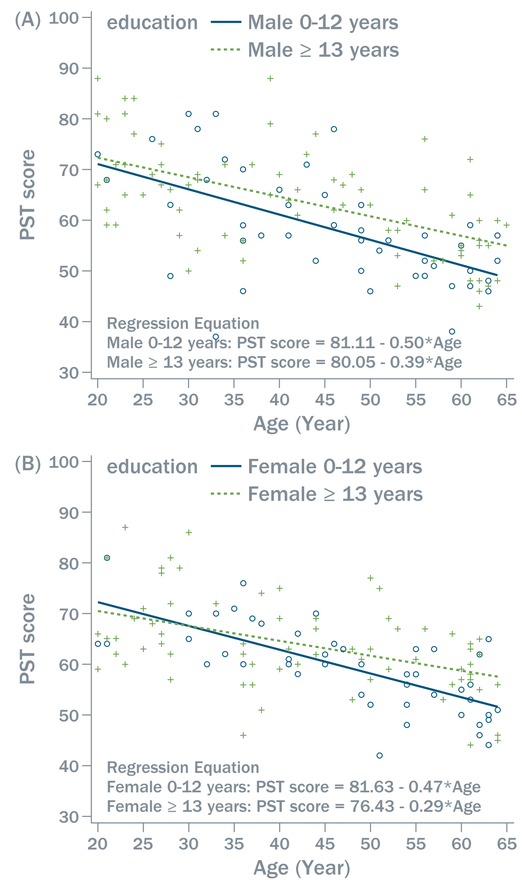


PST, processing speed test

Figure 4. Regression analysis between PST score and age by (A) sex or (B) education

PST, processing speed test

Figure 5. Regression analysis between PST score and age by (A) education in males or (B) education in females



PST, processing speed test; SD, standard deviation

Figure 6. Z score regression line presented by CogEval

References 1. Rao S.M. et al., Mult Scler. 23 (14) : 1929 (2017) **Disclosures** MN and YM: Nothing to declare; MK: Employee of and hold stock/stock options in Biogen. YO is a previous employee of and hold stock/stock options in Biogen. This study was sponsored by Biogen Japan (Tokyo, Japan). Writing and editorial support for the preparation of this poster was provided by Yutaka Suzuki, Ph.D., of inScience Communications, Springer Healthcare (Tokyo, Japan): funding was provided by Biogen.

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