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Introduction

Pelvic floor muscle (PFM) function could play a role in male lower urinary tract symptoms (LUTS) but has not been studied extensively. This was, amongst others, due to a lack of sound technical methods. Multiple Array Probe Leiden (MAPLe) is a multiple electrode probe that has been designed to acquire and discriminate electromyography (EMG) signals from the different sides and layers of the PFM; this device could support future assessment of the male PFM and study its association with pelvic floor symptoms. Information on the reproducibility of MAPLe is essential and, as a matter of fact, the test-retest reproducibility is one of the important aspects of a measuring device. Outcomes of an observational study (presented at ICS meeting 2019) suggested a poor test-retest reproducibility (1). These poor outcomes could have been the result of the methods applied, including a follow-up period that was too long. As such, the validity of the outcomes of that study were debated and it was decided to repeat the study. In the current study, outcomes are reported of the test-retest reproducibility of MAPLe's results in men with LUTS.

Methods and Materials

Men who had participated in the observational cohort study that was conducted in 2018 at the urology outpatient department of a large non-academic teaching hospital in The Netherlands were invited (1). In short, adult male patients with LUTS (International Prostate Symptom Score 8 or higher), without complications (eg. urinary tract infection, history of prostate surgery) were enrolled. Exclusion criteria were: previous urologic cancer and/or urologic surgery or insufficient knowledge of Dutch language. Men were informed about the background of this second study and were asked for their consent. For the current study, 54 out of 57 patients from the initial study were invited (2 men had died, while 1 patient was not invited due to side effects in the first study). The MAPLe assessment was performed by a trained investigator, according to a strict protocol that was recommended by the manufacturer. There was no other involvement of the manufacturer in this study. After a baseline assessment, a second assessment was conducted after 3 hours, and after one week. A total of 13 measurements were provided for every patient, in detail: the average (micro)voltage amplitude during the rest measurement and the average (micro)voltage amplitude, peak amplitude, onset time and offset time during the maximum voluntary contraction (MVC) measurement, endurance measurement and press (Valsalva) measurement. To avoid a possible learning effect, practice contractions were performed before the start of the measurement. For normally distributed variables, the test–retest reproducibility was assessed using an intra-class correlation coefficient (ICC); for the not normally distributed outcomes, the test-retest reproducibility was determined using Spearman's correlation coefficient (SCC).

	Median (IQR)	Number (%)
Age	70 (63-75)	
BMI		
Normal weight (BMI 18,5-24,9)		8 (34,8%)
Overweight (BMI 25-29,9)		13 (56,5%)
Obese (BMI 30-39,9)		2 (8,7%)
MLUTS score	16 (14-20)	
Voiding subscore	9 (5-10)	
Incontinence subscore	4 (2-6)	
Influence of urinary complaints on daily life (0-10)	5 (2-8)	
Medication		
Alpha-Blockers		8 (34,8%)
5-alpha-reductase		2 (8,7%)
Tolterodin		1 (4,3%)
Mirabegron and alpha-blockers		1 (4,3%)
Previous surgery		
TURP		3 (13%)
TURP and laser treatment		1 (4,3%)
Previous pelvic physiotherapy		6 (26,1%)
Perform the pelvic floor exercise		6 (26,1%)
Normal stool frequency		15 (65,2%)
Normal stool consistence		15 (65,2%)
Difficulty defecating		6 (26,1%)
Involuntary stool lost		4 (17,4%)
Feeling that mucous membrane/tissue is coming out of the anus		3 (13%)
Sexual activity with the partner		13 (56,5%)
IIEF-5 (N=13)		
No erectile dysfunction		1 (7,7%)
Mild Erectile Dysfunction		7 (53,8%)
Mild to Moderate Erectile Dysfunction		3 (23,1%)
Moderate erectile dysfunction		1 (7,7%)
Severe Erectile Dysfunction		1 (7,7%)
Pain in the pelvic area		
Pain in 1 location		6 (26,1%)
Pain in 2-3 locations		2 (8,7%)
Pain in 5 locations		1 (4,3%)
Pain score (0-10)	0 (0-4.5)	

IQR = interquartile range, BMI = Body Mass Index, MLUTS = Male lower urinary tract symptoms, TURP = Transurethral resection of the prostate, IIEF-5 = International index of erectile function, N = number

Table 1 Characteristic study population

Results

Of the invitees, 12 agreed to participate in two measurements on one day and 23 to participate in three measurements on two days; 18 men refused participation and one man did not respond. Twelve men were excluded: 9 men did not meet the inclusion criteria, whilst 3 men could not be scheduled because the study had been terminated earlier, due to the COVID measures. The characteristics of the 23 participants are shown in Table 1. The ICC ranged from 0.61 (0.12-0.86) to 0.91 (0.81-0.96) (Table 2). The agreement was generally higher for the intraday determinations than for the interday determinations. An excellent intraday agreement had been seen in the mean (micro)voltage amplitude of both the MVC measurement (ICC 0.91 (0.81-0.96)) and the endurance measurement (ICC 0.90 (0.79-0.96)). Moderate intraday agreement had been seen at the peak (micro)voltage amplitude of both the MVC measurement (ICC 0.67 (0.38-0.85)) and the endurance measurement (ICC 0.64 (0.32-0.83)). The SCC varied widely, from -0.17 to 0.84 (Table 2). Not all SCC values were statistically significant. The lowest correlation had been seen at the intraday endurance offset time (SCC -0.17). The endurance onset time (SCC intraday 0.70; interday 0.84) and the press measurement offset time (SCC intraday 0.76; interday 0.70) had the strongest correlations. Also, in the press (Valsalva) measurement, a stronger correlation had been seen among the intraday measurements compared to the interday measurements.

	Intraday (M1-M2)		Interday (M1-M3)	
	ICC (CI)	SCC	ICC (CI)	SCC
Rest avr. µV	0,81 (0,44-0,93)		0,73 (0,37-0,91)	
MCV avr. µV	0,91 (0,81-0,96)		0,77 (0,44-0,92)	
MCV peak µV	0,67 (0,38-0,85)		0,78 (0,43-0,92)	
MCV onset time		0,62**		0.41
MVC offset time		0,62**		0,70**
Endurance avr. µV	0,90 (0,79-0,96)		0,87 (0,61-0,96)	
Endurance peak µV	0,64 (0,32-0,83)		0,61 (0,12-0,86)	
Endurance onset time		0,70**		0,84**
Endurance offset time		-0,17		0,45
Pressure avr. µV		0,78**		0,66**
Pressure peak µV		0,62**		0,51
Pressure onset time		0,58**		0,53
Pressure offset time		0,76**		0,70**

M1 = first measurement, M2 = second measurement, M3 = third measurement, MCV = maximum voluntary contraction, ICC = Intraclass correlation coefficient, SCC = Spearman's correlation coefficient, CI = 95% confidence interval, MVC = maximum voluntary contraction, avr. = average, µV = microvoltage, * = significance level p<0.05, **= significance level p<0.01

Table 2. ICC and SCC of the MAPLe variables

Discussion

This observational study in men with LUTS suggests that the test-retest of MAPLe measurements is sufficiently reliable. The ICC between measurements ranged from 0.61 (0.12-0.86) to 0.91 (0.81-0.96) and the SCC from -0.17 to 0.84; in literature there are several interpretation models for the ICC (2), As a result, the choice of a model makes little difference to some of the results. ICC of 0.91 is interpreted as very strong according to all models. Lower values, in particular, showed a very variable interpretation. An ICC of 0.61 can be interpreted as unacceptable or questionable, but also as strong (i.e.more than 0,50). These problems are also seen in the interpretation of the SCC. In addition, in the study for the validation of the MAPLe based on healthy male volunteers, an ICC of 0.53 to 0.70 for the mean (micro)voltages amplitudes of the resting, MVC and endurance measurements was found (3); so the current study finds ICC values are similar or even slightly higher.

Conclusions

Under the correct test conditions in the present study, the test-retest reproducibility of the MAPLe in men with LUTS was good. However, the reproducibility decreases with a longer interval between measurements; as a consequence, it is important to follow a strict measurement protocol in daily practice. Furthermore, this study was conducted with a small study population, so results should be interpreted with some caution. A next step in the evaluation of the clinical value of the MAPLe assessment is to study which changes are clinically relevant.

References

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