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RELIABILITY OF PELVIC FLOOR MUSCLE EMG VALUES MEASURED IN HEALTHY VOLUNTEERS USING A NEW DEVICE: THE MULTIPLE ARRAY PROBE (MAPLE).

Hypothesis / aims of study

Many electrodes have been developed for intravaginal and intra-anal biofeedback registration in the treatment of pelvic floor dysfunction (PFD). However, these probes have all been developed empirically and are not specifically designed with the pelvic floor anatomy in mind. As a result, they are not optimised for biofeedback registration of the pelvic floor musculature. In addition, there is no scientifically validated standard for normal pelvic floor function measured with these devices. To address these issues, we developed a new multiple electrode probe, the Multiple Array Probe (MAPLe), which is designed to optimally register EMG signals from the various sides and layers of pelvic floor musculature (PFM). The aim of this study was to measure EMG values for the different PFM layers using the MAPLe in healthy volunteers.

Study design, materials and methods

The MAPLe is a probe with a matrix of 24 electrodes for measuring EMG signals from the different PFM layers. On each side of the 15 mm-wide probe (front, left, back and right), there are 6 electrodes placed at a distance of 10 mm apart. On each side, the electrodes are numbered from 1 to 6, from top to bottom respectively, where the bottom is located at the level of the sphincter/introitus. Additionally, surface electrodes register the activity of abdominal, gluteal and adductor muscles.

Healthy volunteers not seeking treatment and not using medication for symptoms of prolapse, lower urinary tract symptoms, bowel symptoms, pain and/or sexual function related to PFD were qualified to participate. Feasibility analysis predicted that a sample size of 30 participants per group would be adequate to detect differences in EMG values between the groups. The volunteers, aged ≥ 18-75 years, were divided into 5 groups. Group I: males; Group II: females nulliparous, premenopausal; Group III: females parous, premenopausal; Group IV: females nulliparous, postmenopausal; Group V: females parous, postmenopausal.

After insertion of the probe, subjects were asked to perform five consecutive tasks, with a 1-minute rest between each task: 1 minute rest, 10 maximum voluntary contractions (MVCs) held for < 3 sec, 3 maximal endurance contractions of 30 sec, 3 maximal effort coughs, and 3 Valsalva manoeuvres. Women were first measured vaginally and then anally, and men were measured anally. Placement of the probe was checked by MRI in a random group of volunteers and correct pelvic floor muscle contraction was checked using ultrasound.

Unipolar raw EMG signals were acquired for each electrode at a sample rate of 2048 Hz using a TMSi® Porti32. For each task and electrode, the root mean square (RMS) values of the raw EMG signals were computed using a window of 0.1s. Mean EMG values were computed to detect differences. Test-retest reliability was performed using Pearson’s correlation coefficient. Data processing was performed using Matlab® R2009b. Data analyses were performed using SPSS vs18.

Results

In total, 228 healthy volunteers were assessed: Group I: N=61, mean age 41 (19-70); Group II: N= 86, mean age 24 (18-49); Group III: N= 37, mean age 44 (32-56); Group IV: N=5, mean age 54 (50-65); and Group V: N=40, mean age 58 (51-72).

Vaginal measurement in women showed significant differences in mean EMG values (Table) between nulliparous premenopausal (Group II) and parous premenopausal (Group III) in tone at rest (p = 0.008), MVCs (p= 0.001) and endurance (p = 0.01). For nulliparous premenopausal (Group II) and parous postmenopausal (Group V) there was a significant difference in tone at rest (p = 0.001), MVCs (p = 0.001) and endurance (p = 0.05).

There were no significant differences in tone at rest, MVCs and endurance between nulliparous premenopausal (Group II) and nulliparous postmenopausal (Group IV).

Also significant differences were seen between the left and right sides of the pelvic floor for tone at rest, MVCs and endurance, in Group II to V (p = 0.0001). EMG values for the right side of the pelvic floor were significantly higher.

Tone at rest after a MVC showed no significant differences in any of the groups, although tone at rest after MVC of the pelvic floor was slightly lower (except for Group II).

The mean EMG values during coughing were significantly higher than during an active MVC.

During Valsalva there was an increase in EMG values compared to tone at rest and to MVCs in more than 60% of all participants.

In regression analysis, EMG values were dependent on age and parity for all nulliparous and parous women, both premenopausal and postmenopausal.

Anal measurement showed significant differences between men and women of all groups in tone at rest, MVCs and endurance at sphincter level and at levator ani level (p< 0.001).

For the test-retest reliability, the agreement rate between the two tests exceeded 95% and the intraclass correlation ranged from moderated to high. The device was experienced as comfortable.

Interpretation of results

This study confirms that, as a device for assessing PFM, the MAPLe is effective in measuring EMG values at different levels and different sides of the pelvic floor.

The results show significant differences in pelvic floor function between men and women, and between nulliparous and parous women. This suggests that, in the future, diagnosis and treatment of pelvic floor dysfunction (PFD) should be different for men and women and for nulliparous and parous women. The MAPLe will also assist pelvic floor physiotherapists in evaluating the pelvic floor function at different sides and at different levels. Finally, the EMG values measured using the MAPLe in healthy volunteers in this study can be used as a reference in the diagnosis and treatment of patients.

Concluding message

The MAPLe is a new and reliable EMG instrument, and its inclusion in PFM assessment in daily practice is recommended.

Measurement	Females nulliparous, premenopausal	Females parous, premenopausal	Females nulliparous, postmenopausal	Females parous, postmenopausal
Tone at rest (µV)	14.8 (SD ± 9.2)	7.2 (SD ± 7.7)	11.8 (SD ± 4.0)	6.8 (SD ± 4.5)
Tone at rest after action (µV)	15.3 (SD ± 10.3)	7.1 (SD ± 5.7)	9.5 (SD ± 2.6)	6.6 (SD ± 5.4)
MVC (µV)	37.8 (SD ± 19.3)	23.0 (SD ± 14.7)	36.8 (SD ± 21.6)	23.0 (SD ± 15.0)
Endurance (µV)	36.1 (SD ± 22.3)	20.6 (SD ± 13.6)	27.2 (SD ± 13.5)	22.6 (SD ± 20.4)

Table: Mean EMG values measured vaginally at the right side at levator ani muscle level

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Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**Yes**
Specify Name of Public Registry, Registration Number	**Centrale Commissie Mensgebonden Onderzoek, Registration number: 17997**
Is this a Randomised Controlled Trial (RCT)?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Medical Ethical Committee of the Leiden University Medical Center**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**