EMG registration of the pelvic floor and pelvic floor muscle activity patterns during, abdominal, hip adductor, and gluteal muscle contractions in healthy women

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To describe the EMG activity of the pelvic floor muscles (PFM) with a bi-polar EMG probe and the MAPLe and effect on the registered EMG activity with the probes in relation to the contractions of the muscles surrounding the pelvic floor. To describe...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Muscle disorders
Study type	Interventional

Summary

ID

NL-OMON44423

Source ToetsingOnline

Brief title Crosstalks during pelvic floor contraction

Condition

Muscle disorders

Synonym Pelvic floor Function and crosstalk

Research involving

Human

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Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum Source(s) of monetary or material Support: Novuqare

Intervention

Keyword: Crosstalks, EMG, Pelvic Floor, Validation

Outcome measures

Primary outcome

EMG signals of the pelvic floor and EMG signals of the surrounding muscles

Validation of the fixation ring

Secondary outcome

NA

Study description

Background summary

Commercially available bi-polar EMG probes are not valid to use as a comparison between different sessions within patients and comparison between patients. Besides this, the electrodes of these probes cover multiple muscles and giving a summation of EMG signals, making the resulting differential signal invalid and unfitted for any comparison.

The MAPLe is the only commercially available probe which is used in a unipolar configuration. This makes the MAPLe valid for comparison between other muscles and between individuals. Furthermore, the location of the electrodes is validated in MRI and 2D and 3D ultrasound. The results show that the single electrodes are located nearest to the individual muscles of the pelvic floor (5). Also, the MAPLe has small electrode surfaces, making it less sensitive for cross-talk. Besides this, the size of the probe (15mm in circumference) is chosen to be as minimally invasive as possible to prevent a reaction of the PFM to the presence of the probe. Also, the MAPLe has a standard location for orientation and depth, assuring an optimal placement and replacement of the probe. On the contrary, the electrodes of MAPLe are located nearest to the individual muscles of the pelvic floor and capable of differentiating between these muscles. Research shows that it is proven to be reliable and valid. This makes it possible to make a comparison of EMG activity of individual muscles

within and between patients.

Relationships among the PFM and abdominal muscles are thought to exist in order to allow women to maintain for example urinary continence in situations of elevated urethral pressure (6-8). Co-activation of the abdominal muscles appears to contribute to the generation of a strong PFM Sapsford et al. found that the PFM were activated during abdominal muscle contractions and that the converse was also true, that is, the abdominal muscles were activated during PFM contractions (7). Similarly, Neumann and Gill reported that it was not possible for continent women to fully contract their PFM without also contracting their transversus abdominis and the internal obligue muscles (8). Bo et al., in studying three physiotherapists who were well trained in isolating PFM contractions, determined that these individuals were not able to perform a maximal PFM contraction without a rise in EMG activity in the lower portion of rectus abdominus (6). Together, these studies indicate that there is co-activation between the PFM and abdominal muscles. However, literature addressing the crosstalk problem is scarce and oftentimes flawed (9).

Study objective

To describe the EMG activity of the pelvic floor muscles (PFM) with a bi-polar EMG probe and the MAPLe and effect on the registered EMG activity with the probes in relation to the contractions of the muscles surrounding the pelvic floor.

To describe the validity and reliability of the fixation rings on the MAPLE for EMG measurements in sitting and standing position

Study design

Ten healthy pelvic floor physiotherapists without no known history of incontinence, neurological disease, or urinary tract infection and able to perform a correct pelvic floor muscle contraction using the MAPLe in daily practice will be approached by mailthe SOMT if they want voluntarily participate in this research.

The ability to voluntary contract the PFM will be evaluated by vaginal palpation.

A commercially available bi-polar EMG probe (Periform, Neen) and the Multiple Array Probe Leiden (MAPLe, Novuqare Pelvic Health) will be used for EMG registrations. EMG activity will be recorded continuously with the participants lying in a supine position and the knees bend and supported, in sitting and in standing position.

Crosstalk from the EMG activity will be evaluated in supine, sitting and standing position:

1. pelvic floor alone : Rest, Maximum Voluntary Contraction (MVC) and endurance

2. hip adductor contraction with resistance, during rest, MVC and endurance of

the pelvic floor

3. gluteal muscle contraction, , during rest, MVC and endurance of the pelvic floor

 ${\bf 4.}\ contraction$ of the M.Transversus abdominus, , during rest, MVC and endurance of the pelvic floor

5. backward tilting of the pelvis, , during rest, MVC and endurance of the pelvic floor

6. Lifting the head, during rest, MVC and endurance of the pelvic floor

The procedure will be performed with probe placed vaginally and observation of inward movement of the perineum during contraction.

An integrated EMG with estimation of the area covered by the interference EMG curve was chosen as an overall measure for the total increase in muscle activity.

Coughing and Valsalva are omitted because of the displacement of the probe during these manoeuvres. Coughing and Valsalva are expected to be heterogeneous, with low reliability, in clinical test situations. Potential crosstalk from other muscles involved in coughing could limit the interpretation of our results (10).

Intervention

NA

Study burden and risks

NA

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age Adults (18-64 years) Elderly (65 years and older)

Inclusion criteria

Healthy volunteers able to perform a correct pelvic floor muscle contraction will be included

Exclusion criteria

without no known history of incontinence, neurological disease, or urinary tract infection and able to perform

Study design

Design

Study phase:	4
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	31-10-2017

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Enrollment:	10
Туре:	Actual

Medical products/devices used

Generic name:	Intra vaginal Probe
Registration:	Yes - CE intended use

Ethics review

Approved WMO	
Date:	12-09-2017
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register CCMO **ID** NL62043.058.17