#85: Validity, reliability and feasibility of pelvic floor muscle EMG as a tool to assist during placement and (re)programming of the lead electrodes in sacral neuromodulation patients

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Hypothesis / aims of study

- To assess the validity, reliability and feasibility of EMG as a tool to measure pelvic floor muscle (PFM) contractions during placement and (re)programming of the lead electrodes in sacral neuromodulation (SNM) patients.

Study design, materials and methods

- PFM EMG was recorded using the multiple array probe (MAPLe ®), placed intravaginally – figure 1.
- All stimulations (monophasic pulsed square wave, 210 µsec, 14 Hz) were performed using the standard SNM stimulation equipment. During lead implantation, all 4 lead electrodes were stimulated with fixed increasing current stimulations (1-2-3-5-7-10 V). During lead electrode (re)programming, 5 bipolar lead electrode configurations were stimulated twice up to the PFM EMG motor response (PEMR), sensory response and pain response threshold, with a 10 minutes rest interval.
- Of the PEMRs, additionally amplitude and latency were determined.
- Validity, reliability and feasibility were statistically expressed using the weighted Cohen's kappa, intraclass correlation coefficient and simple linear regression, respectively.

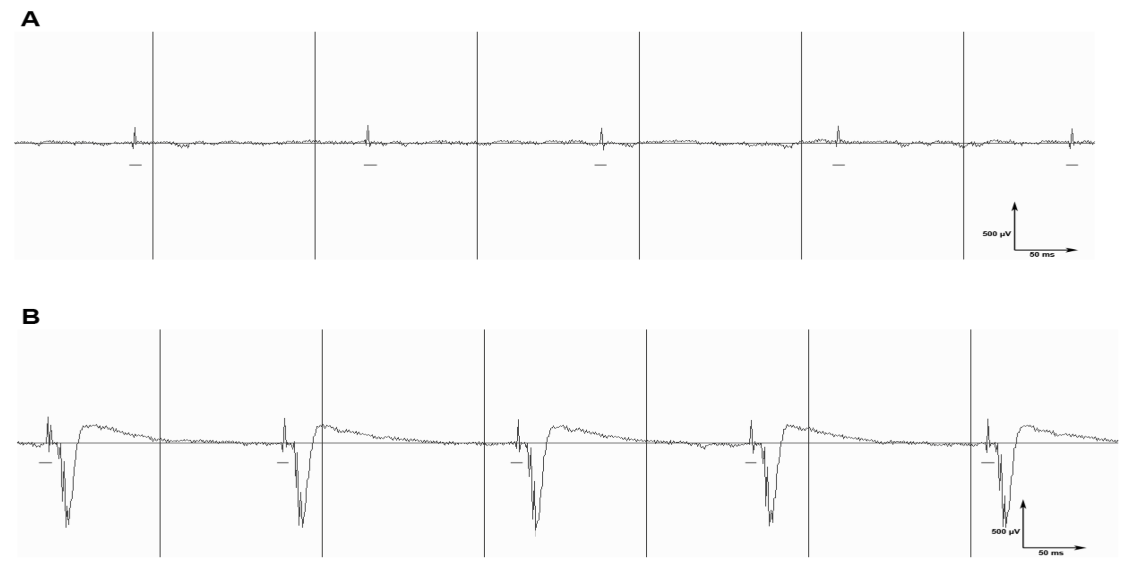

Figure 1

Exemplary EMG traces (sweep length: 500 ms) of the PFM upon stimulation of a lead electrode

A. The first trace shows a stimulation artefact (denoted by small vertical lines below the trace) without being followed by a PEMR.
B. The second trace shows a stimulation artefact followed by a PEMR.

Results

- *Validity*: PEMRs were strongly associated with visually detected PFM motor responses (κ=0.90) – figure 2.
- *Reliability*: PEMR amplitude (ICC=0.99) and latency (ICC=0.93) showed excellent repeatability – figure 3.
- *Feasibility*: simple linear regression (PEMR threshold = 0.18 mA + 0.76 * sensory response threshold) showed an increase in the sensory response threshold is associated with a smaller increase in PEMR threshold, with the PEMR occurring before or on the sensory response threshold in 83.8% of all stimulations – figure 4.

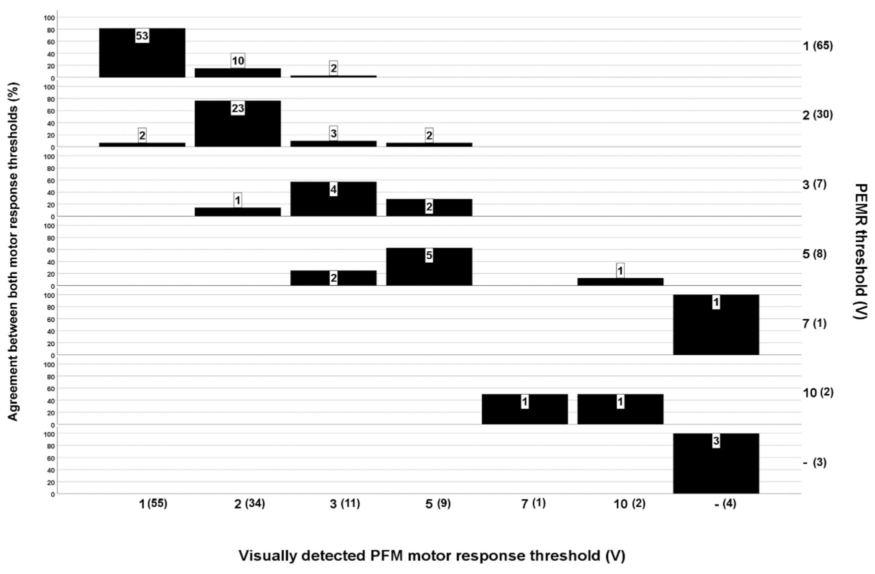

Figure 2

PFM EMG validity: frequency of the PEMR thresholds and visually detected PFM motor response thresholds and the association between them

Six different motor thresholds (1, 2, 3, 5, 7 or 10 V) or the absence of one (-) are displayed for PFM EMG (rows) and visual detection of the PFM (x-axis).
The frequency of each motor response threshold is denoted by the numbers in brackets near each motor response threshold for PFM EMG and visual detection.
The bars show the association between both motor response thresholds by representing the frequency of each PEMR threshold in regard to the frequency of the corresponding visually detected PFM response threshold (expressed as count (number in/above black bars) and % (y-axis)).

For example, of the 65 stimulations which firstly elicited a PEMR at current stimulation 1 V, a first visual detected PFM motor response was noted in 53 (81.5%) of stimulations. Of the remaining 12 stimulations which firstly elicited a PEMR at current stimulation 1 V, a first visual detected PFM motor response was noted at current stimulation 2 V in 10 (15.4%) stimulations and at current stimulation 3 V in 2 (3.1%) of stimulations
In the 89 (76.7%) stimulations the exact same motor thresholds were noted for PFM EMG and visual detection.

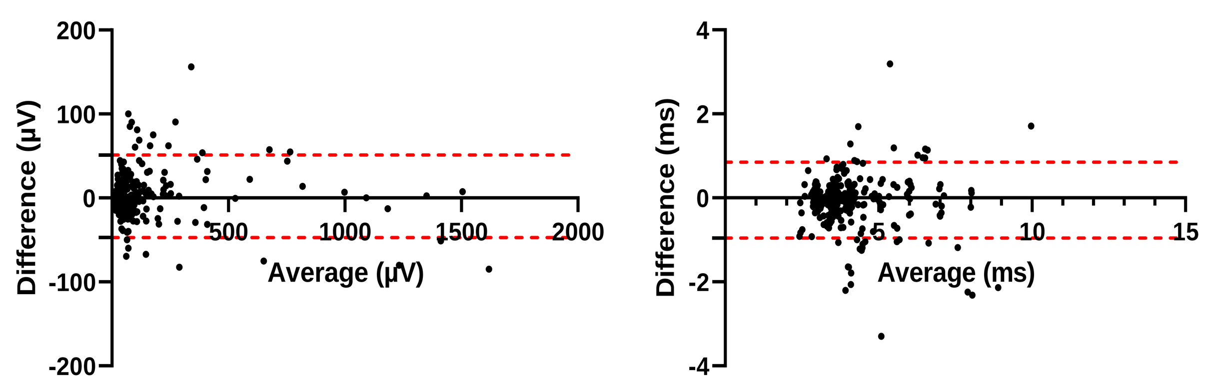

Figure 3

PFM EMG reliability: repeatability of PEMR amplitude and latency upon stimulation of the lead electrodes at the sensory response threshold

Left graph: The Bland-Altman plot indicates a good agreement between the first and second measurement of the PEMR amplitude. Mean and standard deviation obtained by the first measurement is 111.30 ± 220.83 µV. Mean and standard deviation obtained by the second measurement is 113.32 ± 219.11 µV. The average difference between the two measurements is 2.02 ± 25.02 µV. The limits of agreement, defined as the average difference plus or minus two times the standard deviation of the differences, are –47.02 µV and 51.07 µV (red lines).

Right graph: The Bland-Altman plot indicates a good agreement between the first and second measurement of the PEMR latency. Mean and standard deviation obtained by the first measurement is 4.01 ± 1.18 ms. Mean and standard deviation obtained by the second measurement is 3.96 ± 1.17 ms. The average difference between the two measurements is -0.02 ± 0.26 ms. The limits of agreement, defined as the average difference plus or minus two times the standard deviation of the differences, are 0.96 ms and 0.85 ms (red lines).

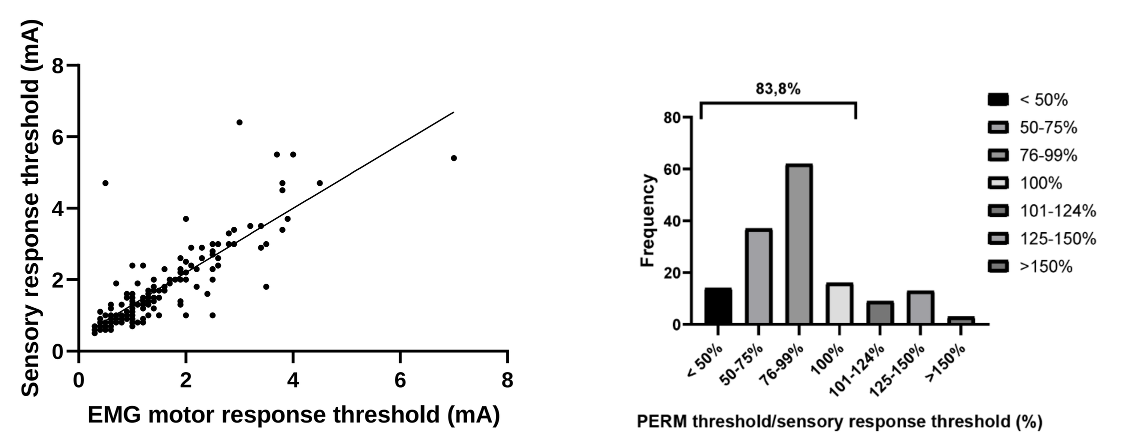

Figure 4

PFM EMG feasibility: (cor)relation between PEMR threshold and sensory response threshold

Left graph: The correlation plot shows a strong positive correlation (r^2 = 0.83, p<0.001) between the PEMR threshold (x-axis) and sensory response threshold (y-axis). Furthermore, one can notice the regression line is tilted to the x-axis, as, on average, an increase in the sensory response threshold is associated with a smaller increase in PEMR threshold (regression line: PEMR threshold = 0.18 mA + 0.76 (95% CI: 0.68; 0.84) * sensory response threshold).

Right graph: The frequency plot illustrates the frequency of the ratio groups, expressing the order in which the thresholds are achieved (PEMR vs sensory response). The latter by dividing the current stimulation needed to evoke a PEMR by the current stimulation needed to evoke a sensory response and multiplying the result by 100%. A ratio of <100%, 100% and >100% means that the current stimulation needed the evoke a PEMR is respectively lower, equal or higher than the current stimulation needed to evoke a sensory response. In the large majority (83.8%) the PEMR threshold was achieved before or on the sensory response threshold.

Interpretation of results

- PEMRs are perfectly associated with visual detection of the motor response by the naked eye. Therefore, PFM EMG can be used as an objective tool to measure and quantify contractions of the PFM. As a results it is possible to differentiate PFM contractions elicited by stimulation of different locations within one subjects.
- Although placement of the lead in sacral neuromodulation patients is mostly done based upon assessment of the motor response, the use of the motor response is abandoned during lead programming and troubleshooting as the current stimulations needed to elicit a visual motor response are often too high leading to an uncomfortable sensation in an awake patient. The use of PFM EMG solves this problem as our results show an EMG motor response can be measured before or on the sensory threshold in all patients for at least one lead electrode configuration and for 83.8% of all lead electrode configurations stimulated.
- PFM EMG allows to examine the effect of the motor response elicited by stimulation of the sacral spinal nerves on the clinical efficacy through objective quantifiable data.

Concluding message

- PFM contractions can be validly, reliably and feasibly measured by EMG during placement and (re)programming of the lead electrodes in SNM patients. Therefore, EMG can be considered a potential tool to assist during the latter procedures.

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