

UNILATERAL CONDITIONAL DORSAL GENITAL NERVE STIMULATION TO SUPPRESS NEUROGENIC DETRUSOR OVERACTIVITY USING A NEEDLE ELECTRODE.

Hypothesis / aims of study

Electrical stimulation of the dorsal genital nerves (DGN) using surface electrodes has been applied in neurogenic patients with detrusor overactivity (NDO) to suppress involuntary detrusor contractions. The genitor-anal reflex (GAR) could be used to verify whether the electrode is positioned near the genital nerve. The GAR can be evoked by DGN burst stimulation. The primary objective of our study was to determine whether unilateral conditional DGN stimulation can suppress involuntary detrusor contractions in NDO. The secondary objective was to determine whether burst stimulation can be used to guide needle electrode positioning.

Study design, materials and methods

Patients with complete or incomplete spinal cord injury and NDO were included.

First, cystometry was performed at a filling rate of 20 ml/min with water at room temperature. Detrusor pressure was calculated from the vesical and abdominal pressures (pressure catheters BEL MBP5261 and MBP4391). A balloon catheter (Life-tech RPC9) was positioned anally to monitor anal contractions in response to burst stimulation.

After emptying the bladder a needle electrode (Medtronic foramen needle 041828) was inserted at the level of the pubic bone and directed to the DGN at the base of the penis guided by burst stimulation (Oxford instruments; burst stimulation, 1 Hz; 5 pulses per burst, inter-pulse interval 4 ms, biphasic, rectangular, pulse width 200 μ s, 0-10 mA).

Subsequently, cystometry (20 ml/min) was repeated and stimulation was started when an involuntary detrusor contraction of at least 10 cmH₂O occurred (Oxford instruments; single pulse stimulation, biphasic, rectangular, 20 Hz, pulse width 200 μ s, 0-25 mA). Stimulation was switched off after an involuntary detrusor contraction was suppressed. Bladder filling and conditional stimulation was stopped when involuntary detrusor contractions could no longer be suppressed by stimulation. This cystometry was repeated several times at different stimulation amplitudes.

Results

Four SCI male SCI patients were included. NDO was diagnosed in all four patients at first cystometry.

GAR was positive in two patients at needle insertion and negative in two other patients when using needle and surface electrodes. The anal pressure rise at GAR depended on the stimulation amplitude; higher stimulation amplitudes resulted in higher anal pressure rises. The needle electrode was repositioned until the GAR was evoked at low amplitude. Two patients could locate the sensation of burst stimulation, which was sensed in the penile glans when the needle electrode was positioned near the DGN.

The needle electrode was positioned near the DGN in three out of four patients using the GAR or sensations of stimulation. The experiment was ended prematurely in one patient in whom needle positioning could not be guided by GAR or sensations of stimulation.

In the three patients in whom the needle electrode was positioned near the DGN, detrusor contractions at repeated cystometry could be suppressed. Cystometry and stimulation were stopped in patient 1 at the third suppressed detrusor contraction (9.0 mA, Figure 1), in patient 2 after four complete suppressions (16.0 mA) and in patient 3 after the contraction could no longer be suppressed at the fourth detrusor contraction (8.0 mA). Only one detrusor contraction was suppressed in these three patients at 5.0 mA, 8.0 mA and 7.0 mA, respectively.

Interpretation of results

Involuntary detrusor contractions in SCI patients with NDO were suppressed by unilateral conditional DGN stimulation using a needle electrode near the DGN. Burst stimulation to evoke a GAR in combination with sensations of stimulation in the penile glans was used to guide needle electrode insertion and to check positioning of the needle electrode near the DGN in patients with an intact GAR or sensations in the stimulation area.

It was not possible to determine clinical effectiveness of unilateral conditional dorsal genital nerve stimulation with an implanted electrode with this study. Further research is needed to determine the clinical effectiveness, including increase in capacity, decrease of bladder pressures and postponement of incontinence.

Furthermore, chronic application of conditional dorsal genital nerve stimulation in spinal cord injury patients and other (non)-neurogenic patients with DO need to be determined. To our knowledge, no suitable electrode for dorsal genital nerve stimulation is available up to now for a fully implanted system and it is not known what kind of electrode would be most suitable. With the results of this study it seems possible to insert an implantable lead electrode.

Concluding message

Involuntary detrusor contractions in spinal cord injury patients with detrusor overactivity can be suppressed by unilateral conditional dorsal genital nerve stimulation with a needle electrode. Burst stimulation to evoke a genito-anal reflex and sensations of stimulation can be used as a guide for electrode insertion.

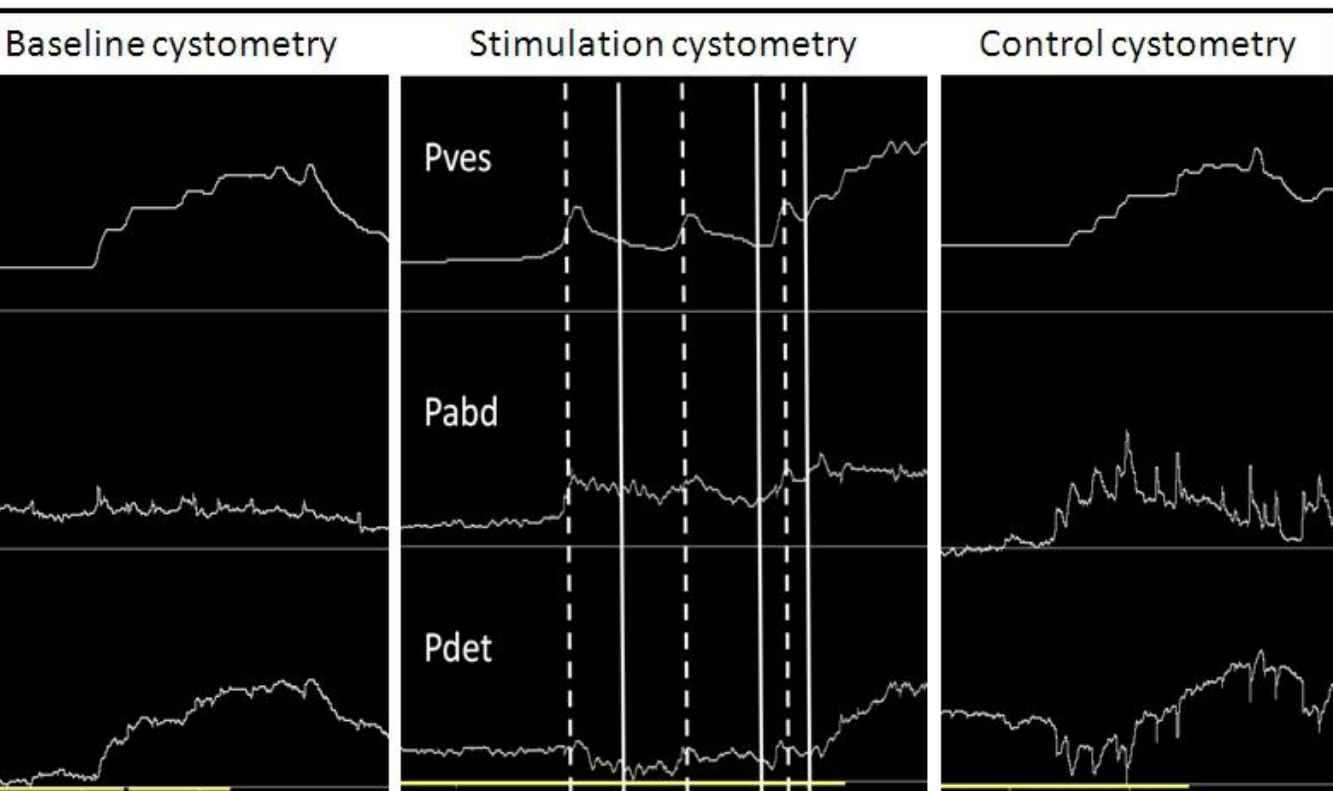


Figure 1: Example of cystometry traces in patient 1

- Baseline cystometry without stimulation
- Stimulation cystometry with markers of conditional stimulation
 - Stimulation switched on
 - _____ Stimulation switched off
- Control cystometry without stimulation

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<i>Is this a clinical trial?</i>	No
<i>What were the subjects in the study?</i>	HUMAN
<i>Was this study approved by an ethics committee?</i>	Yes
<i>Specify Name of Ethics Committee</i>	Commissie Mensgebonden Onderzoek (Committee Human Research) Arnhem-Nijmegen.
<i>Was the Declaration of Helsinki followed?</i>	Yes
<i>Was informed consent obtained from the patients?</i>	Yes