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URETHRAL SPHINCTER EMG CONTROLLED DORSAL PENILE/CLITORAL NERVE STIMULATION TO TREAT NDO.

Hypothesis / aims of study

Electromyography (EMG) of the external urethral sphincter (EUS) is highly correlated with bladder activity. In normal conditions, the EUS EMG activity increases during bladder filling [1]. Then, when the situation is appropriated, the EUS relaxes just before the bladder starts to contract. However, with a neurological condition this coordination is often changed into detrusor sphincter dyssynergia (DSD) which consists of simultaneous contraction of both the detrusor and the EUS. When DSD is combined with neurogenic detrusor overactivity (NDO) can lead to very high transient pressures during filling phase resulting in vesicoureteral reflux and eventually renal failure.

It has been shown that electrical stimulation of pudendal nerve afferents can be used to suppress the involuntary detrusor contractions and increase bladder capacity. [2] Several biosignals have been investigated to control the stimulator. However, no signal has yet shown good performance in a real-time situation.

The goal of this study was to investigate whether EUS EMG controlled dorsal/penile nerve stimulation can suppress indeed undesired detrusor bladder contractions during a filling cystometry.

Study design, materials and methods

7 subjects (4 males and 3 females) were included in the study. Inclusion criteria were a history of NDO and DSD, bladder capacity below 300 ml and age above 18 years. Subjects were not asked to stop medication prior to participating in this study. All seven subjects were spinal cord injured patients with a history of NDO. EUS EMG was recorded in patients using wire electrodes during a filling cystometry. Either 25-gauge or 30-gauge disposable hypodermic needles were used to placed the wire electrodes in the EUS through the pelvic floor in males or paraurethrally in females. The EMG was filtered and processed online to control an electrical stimulator. To detect relevant EMG activity an algorithm was developed in LABVIEW®. Whenever this relevant EUS EMG was detected the stimulator came on. The algorithm uses window-based integration scaled with a kurtosis function. Subjects underwent two filling cystometries at a filling rate of 30 ml/min. The first one was without stimulation and it was intended both to diagnose the NDO and DSD and to set the EMG threshold. The second one was with automatic EMG controlled stimulation. The stimulation was provided with two surface electrodes placed on the dorsum of the penis or on the clitoris. Stimulation lasted at least 20 s and no longer than 45 s.

Results

Of 7 subjects recruited, six showed NDO and DSD. In 5 patients relevant EMG activity was detected and stimulation suppressed at least one contraction. In one subject EMG controlled stimulation failed. The 5 subjects showed an average increase of 72% of bladder capacity during filling 2 (with stimulation) compared to the first one (without stimulation). The number of suppressed contractions was on average 3. In two subjects, filling was stopped before any leakage could be seen because they reached the maximum infused volume of 400 ml. The mean increase in detrusor pressure at the time the stimulator was on average approximately 4 cmH_2O. Figure 1 shows an example of two fillings in one subject.

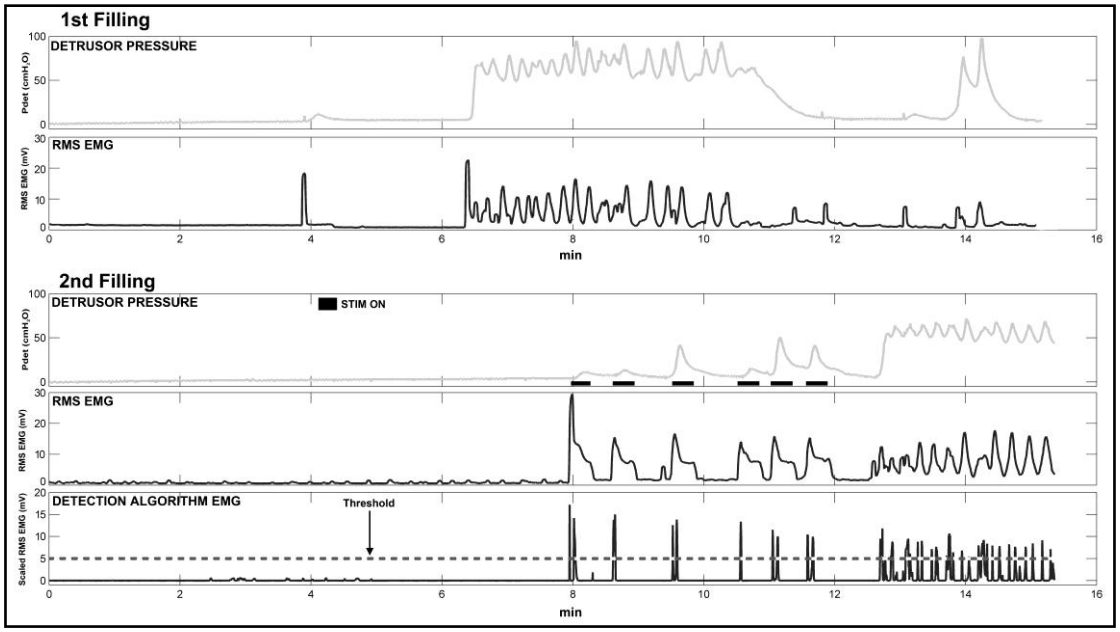

Figure 1. Two filling cystometries are shown. First is without stimulation. Second is with stimulation. Black bars just below the pressure line indicate when the stimulator was on. In the second filling, the detection algorithm is also plotted jointly with the EMG threshold.

Interpretation of results

Although the number of investigated patients is small, EUS EMG proved to be a good online predictor for the onset of bladder contractions and in turn, could trigger a stimulator. EMG triggered stimulation failed in one female subject because there was no clear EUS EMG activity during bladder contractions compared to periods without. The EMG threshold was set too high to suppress

effectively one single contraction. A lower threshold though would have led to many false positives. In two male subjects the increase in bladder capacity was 100% and it could have been even more if the filling would not have been stopped because we reached the maximum infused bladder volume of 400 ml.
Monitoring EUS EMG has advantages compared with other biosignals that have been used to predict bladder contractions such as intravesical pressure or electroneurography which proved to be reliable but not feasible. If compared to conditional stimulation based on intravesical pressure, the stimulation started on average three seconds earlier which is an improvement since the earlier the stimulation can start the most likely undesired detrusor contractions can be suppressed. The mean increase in pressure at the starting point was 4 cmH_2O whereas in pressure based systems the threshold to trigger the stimulation is often set at 10 cmH_2O. In addition, if compared with electroneurography where detection algorithms are complex and not suitable for online settings, a much simpler EMG detector (time domain) showed to be sufficient to discriminate the onset of bladder contractions.

Concluding message

The study shows that EUS EMG can be both reliable and feasible trigger event to control dorsal penile/clitoral nerve stimulation to suppress undesired bladder contractions and in turn to increase bladder capacity in subjects with both NDO and DSD. The inclusion of EUS EMG as an input signal in a future neuroprosthesis implant for bladder control in selected subjects is thus feasible.

References

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What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Institut Guttmann Local Ethics Committee**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**