

AUTOMATED CONDITIONAL NEUROMODULATION OF NEUROGENIC DETRUSOR OVERACTIVITY USING A COMBINED SACRAL ANTERIOR AND POSTERIOR NERVE ROOT STIMULATOR IN SPINAL CORD INJURY.

Hypothesis / aims of study

Suprasacral spinal cord injury frequently results in neurogenic detrusor overactivity (NDO). This can result in high intravesical pressures, vesico-ureteric reflux, incontinence and ultimately renal impairment. Neuromodulation (NM) via dorsal penile nerve stimulation is well established as a method of experimentally suppressing NDO and improving bladder capacity (1). We have previously described the SPARSI (Sacral Anterior & Posterior Nerve Root Stimulator), that potentially allows for combined NM (via *posterior* root stimulation) and emptying on demand (via *anterior* nerve root stimulation) (2). In addition, SPARSI obviates the need for posterior rhizotomy (hence no neural damage occurs) and subsequent loss of erections and ejaculation. We aimed to test a system of closed-loop automated conditional neuromodulation via implanted SPARSI in five patients.

Study design, materials and methods

Five male patients with existing SPARSI implants were selected. All drugs modulating the lower urinary tract were stopped 5 days prior to testing. Standard filling cystometry (at 30 ml/min) was performed, under both control and test conditions. Patients were placed in a sitting position, in order to replicate normal wheelchair positions. Software was devised whereby an arbitrary waveform generator (AWG) was triggered for 1 minute when P_{det} reached 10 cmH₂O. Rectangular pulses of 200 μ sec were used; frequency of stimulation was 15Hz. Amplitude was set at three times that required to produce a pudendo-anal reflex (at levels much lower than that required to produce a detrusor contraction). Combined S_{3,4} nerve roots were stimulated to effect neuromodulation. The fill was terminated when a sustained $P_{det} > 35$ cmH₂O was reached, or voiding occurred.

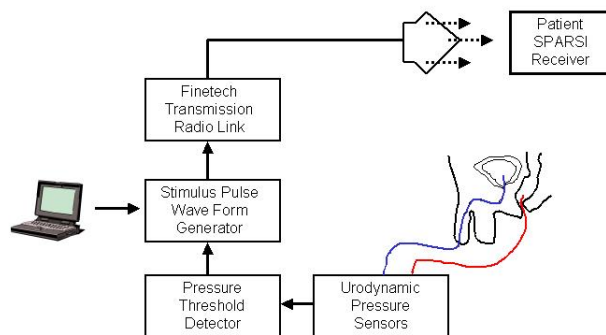


FIGURE 1: Equipment configuration.

Rises in P_{det} above the threshold of 10 cmH₂O result in triggering, and neuromodulation pulses are applied to the implant via the standard external transmitter, thus suppressing NDO.

Results

All patients demonstrated integrity of posterior nerve roots, via preservation of reflex erections, bulbocavernosal reflexes, ankle jerks and NDO. Automated implant-driven conditional neuromodulation was able to suppress NDO in all patients, resulting in an increased bladder capacity.

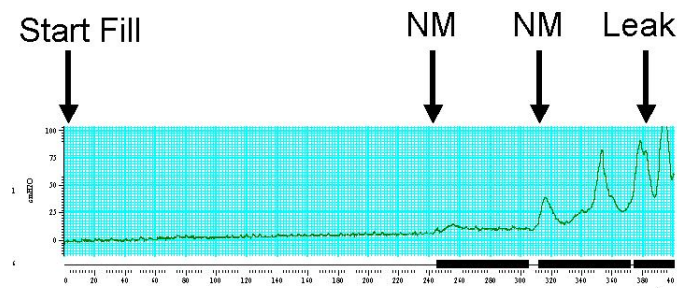


FIGURE 2: Automated conditional neuromodulation

The neuromodulation commences as the detrusor pressure passes the threshold for stimulation. This continues for 1 minute. Detrusor suppression is seen to occur (NM arrows). Eventually leakage occurs due to neuromodulation 'breakthrough'.

Interpretation of results

These tests are the first to describe the potential for automated control of NDO via a chronically-placed permanent device. In addition, there has been no evidence of permanent neural injury. Whilst the equipment arrangement would not be suitable for the testing in the patients' own home environment, we are currently devising a compact system to replicate the function of the experimental arrangement in more 'ambulatory' circumstances.

The ideal permanent device would be capable of detecting the onset of NDO, ideally by recording signals from the sacral posterior nerve roots emanating from the bladder; this would be the trigger for conditional stimulation (3). The same device would also be required to empty the bladder via anterior root stimulation.

Our tests obviously require the patient to be catheterised in order to detect the onset of contractions. They do however serve to clearly demonstrate that automated closed loop neuromodulation is possible with chronically-implanted electrodes.

Concluding message

This is the first demonstration of automated closed loop neuromodulation via a permanently implanted device in humans with spinal cord injury. Whilst not necessarily demonstrating a currently feasible modality of management, it provides a great deal of information regarding the specification and capabilities of future devices.

References

- (1) The acute effects of continuous and conditional neuromodulation on the bladder in spinal cord injury. *Spinal Cord* 2001; 39(8):420-428.
- (2) Neuromodulation through sacral nerve roots 2 to 4 with a Finetech-Brindley sacral posterior and anterior root stimulator. *Spinal Cord* 2002; 40(6):272-281.
- (3) Detection and inhibition of hyperreflexia-like bladder contractions in the cat by sacral nerve root recording and electrical stimulation. *NeuroUrol Urodyn* 2001; 20(2):215-230.

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