



# MP20: BILATERAL PUDENDAL NERVE BLOCK REDUCES URETHRAL PRESSURE IN SCI PATIENTS WITH DESD

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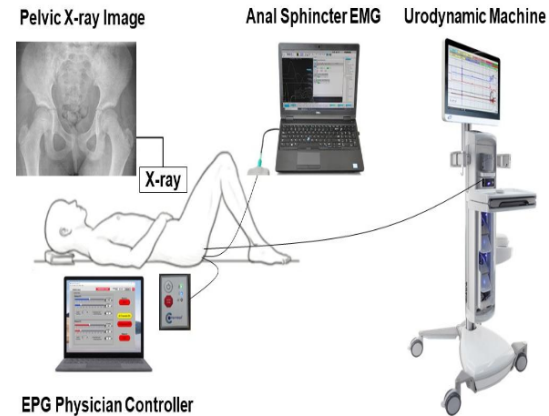
## INTRODUCTION & OBJECTIVE

- We have previously shown in ASIA-A T9 SCI cats that detrusor external sphincter dyssynergia (DESD) could be blocked with high frequency, biphasic, bilateral pudendal stimulation.<sup>1</sup>
- Our objective is to study in the office SCI patients with DESD that are treated with our FDA-approved Nerve Block and Stimulation External Pulse Generator.

## METHODS

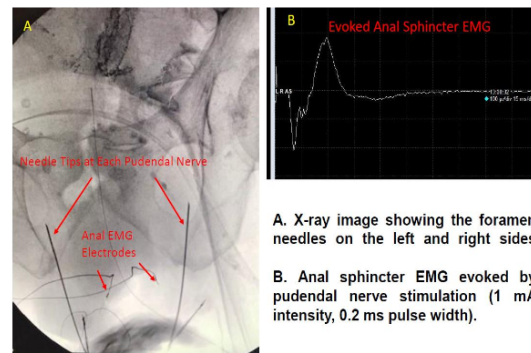
- Study was approved by the WCG and Univ of Pittsburgh IRBs.
- Patients were recruited with ASIA-A SCI between T7 and L5 of at least 1-year duration. No subject had autonomic dysreflexia.
- Prior baseline urodynamics for each patient demonstrated DESD with or without NDO
- A triple lumen urethral urodynamic catheter was placed to record detrusor and urethral pressures, and EMG needle electrodes were placed into the anal sphincter to measure compound muscle action potential (C-MAP) – see Figure 1
- Urodynamics commenced until bladder capacity was reached.
- Crede maneuver was performed, and maximum urethral and bladder pressures were recorded.
- With the patient positioned in the Sonesta chair tilted at 45 degrees and with the use of fluoroscopy, bilateral foramen needles were inserted medial to the ischial tuberosity toward the ischial spine.
- During insertion, each needle was stimulated at 5 Hz and 0.2 ms until optimal pudendal nerve stimulation was confirmed with C-MAP and anal twitch.
- Figure 2A shows fluoroscopic placement of both foramen needles, and Figure 2B shows the C-MAP with anal sphincter EMG during stimulation of the pudendal nerve
- Bilateral pudendal nerve block began with stimulation at 1 kHz and 1mA for 30 seconds.
- If urethral pressure (Pure) during Crede was not reduced to < 50 cm H2O, the stimulation was repeated at 1 kHz and 3.8mA for 30 seconds, for 1 minute, for 2 minutes, and for 4 minutes.
- The primary endpoint was reduction in Pure to < 50 cmH2O.
- All adverse events (AEs) during the test and up to 1 week after were recorded.

## Figure 1: EPG Study Setup



## Figure 2: Needle Placement and EMG

### Foramen Needles Targeting Bilateral Pudendal Nerves



A. X-ray image showing the foramen needles on the left and right sides

B. Anal sphincter EMG evoked by pudendal nerve stimulation (1 mA intensity, 0.2 ms pulse width).

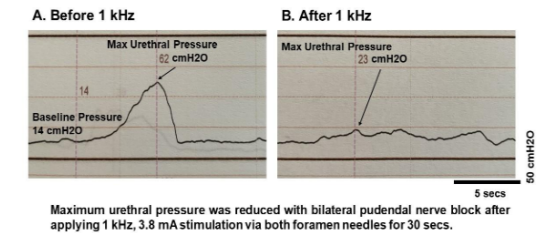
## RESULTS

- A total of 4 patients completed the study – 3 men and 1 woman – see Table.
- The first subject was a 56-year-old male with T9 ASIA-A SCI, and UDS showed DESD but no NDO, and the maximum Pure in this first subject was reduced from 65 to 35 cm H2O with a stimulation of 1 kHz and 3.8mA for 4 minutes.
- The second subject was a 46-year-old female with T8 ASIA-A SCI, and her UDS showed both DESD and NDO. Because urethral pressure was difficult to measure from NDO, detrusor leak point pressure was used, and DLPP was reduced from 70 to 51 cm H2O with a stimulation of 1 kHz and 3.8mA for 4 minutes.
- The third subject was a 55-year-old male with T10 ASIA-A SCI, and UDS showed both DESD and NDO, and the maximum Pure was reduced from 62 cm H2O to 23 cm H2O with a stimulation of 1 kHz and 3.8mA for 30 seconds.
- The fourth subject was a 41-year-old male with T9 SCI and DESD but no NDO, and the maximum Pure was reduced from 94 to 47 cm H2O with a stimulation of 1 kHz and 3.8mA for 3 minutes.
- Figure 3A shows the third subject's baseline and peak Pure before the 1 kHz pudendal nerve block and Figure 3B shows baseline and peak Pure after the 1 kHz pudendal nerve block
- Two mild AEs were noted in the 3<sup>rd</sup> patient. He had mild nausea during Crede that resolved immediately after the procedure, and the dysuria noted 3 days after the procedure did resolve by 7 days after the procedure – UTI was ruled out.

## Table: Results in 4 SCI Patients

| Subject | Age and Sex | ASIA A SCI Level | UDS Findings  | Change Peak Pressure During Crede in cm H <sub>2</sub> O |
|---------|-------------|------------------|---------------|--|
| #1      | 56 yo M     | T-9              | DESD – no NDO | Pure from 65 to 35                                       |
| #2      | 46 yo F     | T-8              | DESD & NDO    | DLPP from 70 to 51                                       |
| #3      | 55 yo M     | T-10             | DESD & NDO    | Pure from 62 to 23                                       |
| #4      | 41 yo M     | T-9              | DESD – no NDO | Pure from 94 to 47                                       |

## Figure 3: P<sub>ure</sub> Reduction Subject #3



Maximum urethral pressure was reduced with bilateral pudendal nerve block after applying 1 kHz, 3.8 mA stimulation via both foramen needles for 30 secs.

## CONCLUSIONS

- Successful reductions in urethral or detrusor leak point pressures were seen in 4 SCI patients with DESD using bilateral pudendal nerve stimulation at 1 kHz.
- The only adverse events were mild transient nausea (from Crede) and dysuria in one subject
- This study supports the development of an implantable device to treat DESD by bilateral pudendal nerve block using 1 kHz stimulation.

## REFERENCE

1. Guo W, Shapiro K, Wang Z, Armann K, Shen B, Wang J, Roppolo JR, de Groat WC, Tai C. Restoring both continence and micturition after chronic spinal cord injury by pudendal neuromodulation. *Exp Neurol*. 2021 Jun;340:113658. doi: 10.1016/j.expneurol.2021.113658. Epub 2021 Feb 24. PMID: 33639209

## ACKNOWLEDGEMENT

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