

## TRANSGLUTEAL PLACEMENT OF A PUDENDAL NERVE STIMULATOR FOR THE TREATMENT OF REFRACTORY URGE URINARY INCONTINENCE: DESCRIPTION AND TECHNIQUE.

### Hypothesis / aims of study

To describe the technique of the transgluteal placement of a pudendal nerve stimulator in 5 patients with idiopathic refractory urge urinary incontinence (UUI).

### Study design, materials and methods

A Cyberonics® (Houston, Texas) 102R Pulse Generator with HMRI (Huntington Medical Research Institutes, Pasadena, CA) Bipolar Electrode array currently marketed for the treatment of refractory epilepsy has been modified and successfully surgically implanted in 5 patients with idiopathic refractory UUI.

### Results

All patients underwent successful surgical placement of a Cyberonics VNS (vagal nerve stimulator) model 102R pulse generator with HMRI bipolar electrode array. Preoperative work-up included history and physical examination, urodynamics of the bladder and sphincter, I-PSS and collection of voiding diaries. For device implantation patients were placed under general anesthesia in the prone position and after identification of the surgical landmarks (greater trochanter, ischial tuberosity, sacrotuberous and sacrospinous ligaments, sacrum, and coccyx) a 6 centimeter incision was made above the gluteal muscle. Dissection was carried down along the medial border of the ischial tuberosity to the ischial fossa at the level of the ischial spine where the pudendal nerve was encountered and electrode placed encircling the nerve (Figure 1). The pulse generator was then placed in a superficial fat pocket through a separate incision with the leads tunneled and connected.

### Interpretation of results

Through a posterior gluteal approach, a bipolar electrode can safely and accurately be applied to the pudendal nerve to give chronic pulsatile stimulation for the treatment of refractory urgency incontinence.

### Concluding message

A currently marketed VNS system can be successful modified and implanted through a transgluteal incision to directly stimulate the pudendal nerve in patients with idiopathic refractory UUI. Additional studies are ongoing to evaluate the efficacy and safety of pudendal nerve stimulation in terms of symptom control.

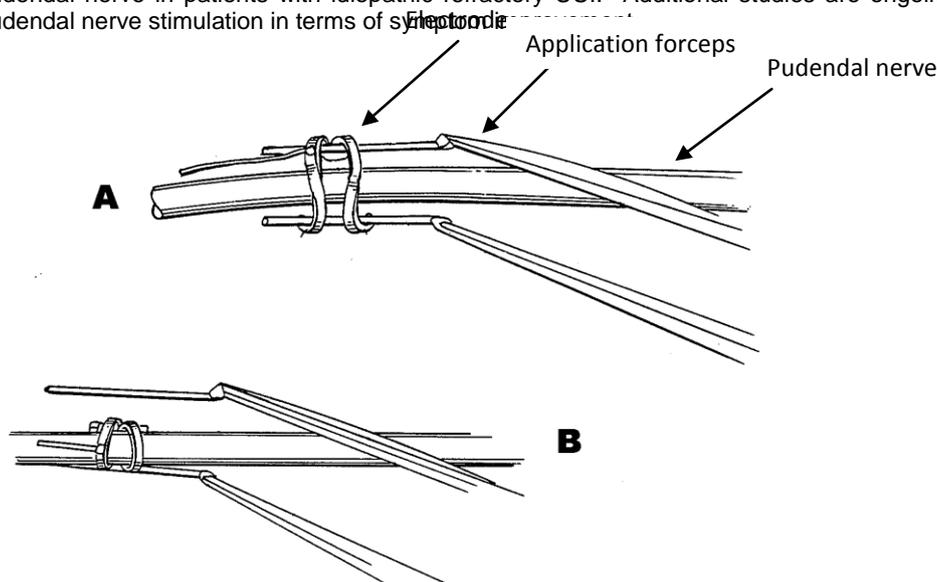


Figure 1: Application of electrode to the pudendal nerve

<b>Specify source of funding or grant</b>	None.
<b>Is this a clinical trial?</b>	Yes
<b>Is this study registered in a public clinical trials registry?</b>	Yes
<b>Specify Name of Public Registry, Registration Number</b>	FDA
<b>What were the subjects in the study?</b>	HUMAN
<b>Was this study approved by an ethics committee?</b>	Yes
<b>Specify Name of Ethics Committee</b>	Institutional Review Board of Washington University
<b>Was the Declaration of Helsinki followed?</b>	Yes
<b>Was informed consent obtained from the patients?</b>	Yes