Pudendal Nerve Modulation

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15.1 Electrical Modulation of the Pudendal Nerve

As the pudendal nerve is one of the major nerves which stimulates the pelvic floor muscles, the external urethral and anal sphincters and the pelvic organs, this nerve is being increasingly investigated as a treatment option, particularly patients with neurogenic OAB.

The pudendal nerve is composed of nerve fibers originating from S2 to S4 nerve roots which innervate the pelvic floor muscles, the external urethral and anal sphincters, and the pelvic organs. It is a mixed nerve that contains somatic and autonomic nerve fibers.

The pudendal nerve leaves the pelvis via the intra-piriform foramen and passes dorsally in an arc around the ischial spine through the lesser sciatic foramen into the ischiorectal fossa and before leaving Alcock's canal (pudendal canal) divides into two terminal branches: the perineal nerves and the inferior rectal nerves.

These nerves supply motor and sensory innervations to the striated muscles (bulbocavernosus muscle and external anal sphincter) and partly to the urethra and the dorsal nerve of the penis or clitoris. The caudal portion of the pudendal nerve runs through the pudendal canal, which lies against the sidewall of the pelvis and duplicates the fascia of the obturator internus muscle.

Anatomy, physiology, and neurophysiology of the pudendal nerve have been studied extensively, particularly when its role in continence mechanisms has been more elucidated [1, 2]. One of the first works investigating the clinical significance of pudendal nerve anatomy was performed by Juenemann et al. [3]. The authors

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demonstrated that in patients with neurogenic lower urinary tract dysfunction, electrostimulation of the sacral root and pudendal nerve markedly increased intraurethral closure pressures.

Today, there is much knowledge obtained on the pudendal nerve anatomy and innervations' role. New studies continue to be performed to further assist physicians operating in close proximity to this nerve or when using this nerve for various therapeutic applications. These studies should also help to get a better understanding of the underlying neuronal mechanism and the involved pathways in humans when the pudendal nerve is stimulated.

Due to the anatomy of Alcock's canal, surgical exposure of the nerve has been difficult in the past due to the increased risk of damage to the nerve itself, but with recent developments in the implant procedure and equipment, chronic pudendal nerve stimulation (PNS) can now be easily achieved. Anatomy of the pudendal nerve and its terminal branches from a cadaver was published by Schraffordt SE et al. in 2004 [4]. This study documented the anatomy of the pudendal nerve by looking into 28 cadavers, in order to examine the course of the pudendal nerve and its branches in the perineum. The study concluded that a sound knowledge of the anatomical variations of the pudendal nerve and its branches is essential for all surgeons operating in the perineal region.

Today, chronic pudendal nerve stimulation can easily be performed using the existing InterStim device. The treatment is minimally invasive by using a percutaneous approach to reach Alcock's canal [5]. A permanent tined lead can be implanted in the first implant stage to evaluate the clinical efficacy; this avoids any risk of efficacy changes when the permanent INS is implanted. The tined lead, which was originally developed for sacral nerve stimulation, to create a more secure lead position has also contributed to making pudendal nerve stimulation a safe option for surgeons and patients [6]. Additionally, neurophysiological monitoring helps to implant the lead in the correct position and helps to verify effective stimulation.

This monitoring is done by assessing electromyographic activity (EMG) of the external anal sphincter (EAS). A cadaver study, published by Reitz in 2007 [7], provides data which indicates safe needle placement via the posterior approach, which is the approach used by author.

15.2 Surgical Technique

15.2.1 Lead Implant

The patient is placed in prone position. Bony topography is drawn with the use of a fluoroscopy x-ray device in order to spot the greater trochanter and the ischial tuberosity (Fig. 15.1) These two reference marks are used to find the two points as schematic images shown below (Fig. 15.2).

This technique is recommended to stay clear of veins and arteries and to avoid possible needle punctures or injections of anesthesia directly into the vascular

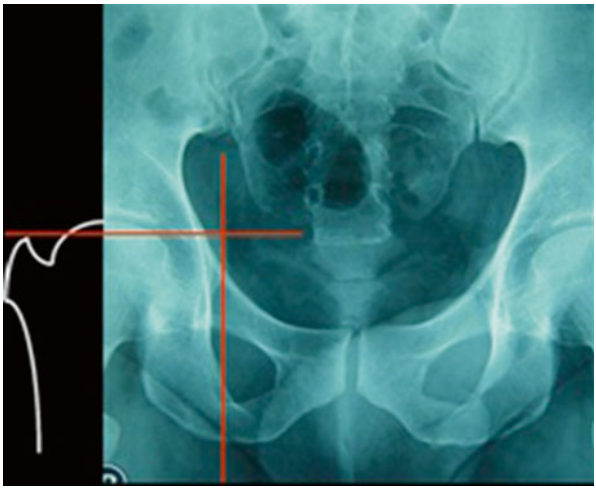

Fig. 15.1 X-ray showing lead insertion position

Fig. 15.2 Diagrammatic view of lead puncture insertion position

system. The x-ray C-arm should be ready to perform anterior-posterior image of the pelvis. Locate the ischial tuberosity tip (*ITT*) and the greater trochanter (GT) with a pair of 90° angle crossed stylets placed on the patient's skin, mark with a dot where the stylets cross.

Puncture the intersection of the lines drawn vertically from the ITT and horizontally from the GT, as demonstrated in Fig. 15.4:

15.2.2 Preparation for Lead Insertion

Anesthesia should be administered to the patient only if proceeding with lead implant after skin drawing. Muscle relaxants should not be used. Avoid general anesthesia. Anesthetic choices include lidocaine solution for injections, maximum dose is 500 mg for healthy patients and bupivacaine with maximum recommended dose of 200 mg. Dosage should be minimized to preserve nerve response. Minimize the risk of vascular absorption by injecting slowly and in small boluses local anesthetic or chemotoxic substances, aspirate before injecting.

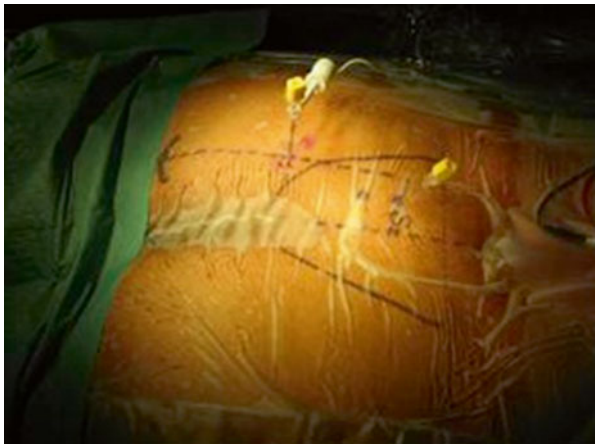

Fig. 15.3 Acute test with test needle

15.2.3 Acute Test with Test Needle to Locate Optimal Position

Place patient in a prone position, prepare the patient's lower quadrant and connection site, and prepare perineum, gluteus, and sacrum for sterile surgery. Drape to allow observation of the pelvic floor for muscle response to test stimulation. Clean dry skin area, and affix the ground pad to it. Electromyography recording needle is gently inserted in the anal sphincter stimulation. Patient stimulation cable is connected to electromyography output. Vertically insert the insulated foramen test needle. Connect the mini-hook from the patient cable to the non-insulated part of the foramen needle and stimulate; see Fig. 15.3.

A 1 mA step increasing pulse current from 0 is used to locate the tip of the needle adjacent to the pudendal nerve by comparing the generated CMAP with the reference trace. An acceptable CMAP should be within a variability of 2 ms compared with the reference trace.

When satisfied with the needle position, replace needle stylet with the directional guide. Holding the directional guide, remove the foramen needle. Make a small incision on either side of the directional guide. Fit the dilator and introducer sheath over the directional guide and advance to the third most proximal depth marker on the directional guide with the top of the dilator; see Fig. 15.4.

15.2.4 Tined Lead Insertion

While holding the lead in place, retract the introducer sheath until the second visual marker lines up with the top of the introducer sheath handle (Fig. 15.5). A 1 mA step increasing pulse current from 0 is used to locate the tip of the needle adjacent to the pudendal nerve by comparing the generated CMAP with the reference trace. Stimulate the various electrodes and observe the generated CMAP; see Fig. 15.6.

Hold sheath and lead together when adjusting lead position.

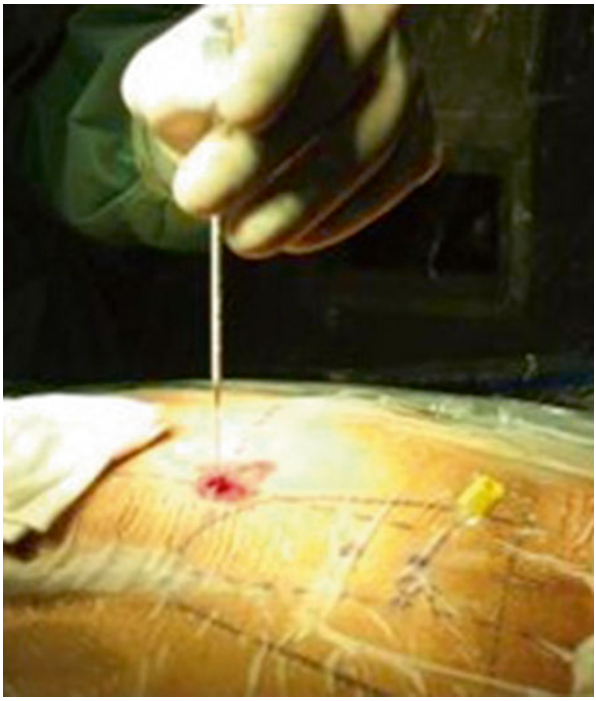

Fig. 15.4 Preparation for tined lead insertion

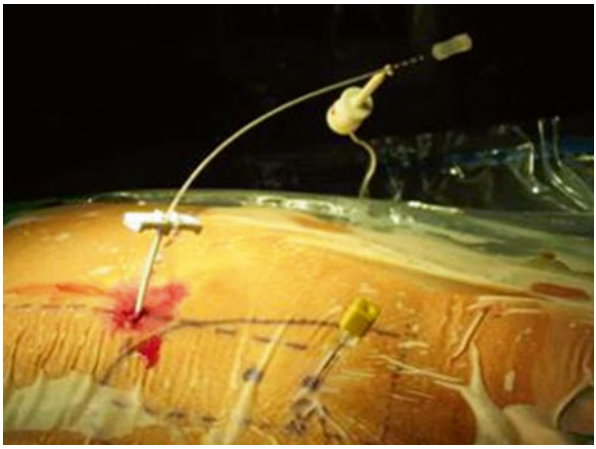

Fig. 15.5 Tined lead insertion

When satisfied with the lead position, hold the lead in place and carefully withdraw the introducer sheath and the lead stylet. Ensure the lead is in the correct position before deploying the tines. Do not dislodge the lead as tines are deployed. Stimulate the four electrodes to confirm the CMAP previously observed. If you need to advance lead after tines are deployed, do so after lead stylet is inserted. If you need to retract, do so completely using gentle traction and place it again.

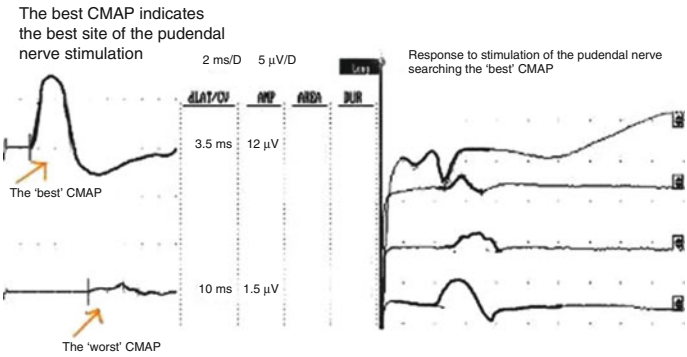

Fig. 15.6 Review of CMAP to locate the best tined lead position

15.2.5 Tunnelization from Pocket Site to Incision Site and Lead Connection to the Test Stimulator

Identify the site for the neurostimulator subcutaneous pocket. Make a small opening large enough for the percutaneous extension lead connector at the future neurostimulator pocket site. Either the abdomen or buttocks are suitable sites. Make a tunnel from the pocket site to the incision site. Lead tunneling should not be too deep. Gently feed the lead through the tube, remove the tube and keep the lead in place, close the lead implant incision, and dress the wound appropriately. Make a small incision contralateral to the neurostimulator pocket site where the percutaneous extension will exit the skin, and tunnel at the subcutaneous level from the pocket to the stab wound. Connect the lead and the percutaneous extension, and position the lead and extension in order to avoid sharp bends or kinks. Insert lead into percutaneous extension screw set connector. The connection to the test stimulator is now available for test stimulation. Tunnel the lead to the future neurostimulator pocket site. Close the initial incision and staple the wound leaving only the fine percutaneous extension wires and pin connector protruding from the skin.

15.2.6 Parameter Settings

Suggested parameter settings in the test stimulator are bipolar stimulation between the best stimulating electrodes, frequency of 5 Hz, pulse width 210 ms, continuous mode, and amplitude as low as possible (1–5 V below patient's sensitivity). It is not suggested to seek for patient sensory responses.

The patient should be carefully instructed about hygienic and general conduct during the test phase. In addition to providing the patient manual, explain the procedure for managing the test stimulator.

If any adverse events occur during the first-stage implant, these will be recorded and documented.

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