Comparison of Bipolar Lead Electrodes for High-Frequency Blocking of the Pudendal Nerve

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Citation

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Abstract

Aims: High-frequency (HF) pudendal-nerve blocking that includes lead electrodes on the nerve are needed for spinal cord injury (SCI) patients to manage detrusor sphincter dyssynergia (DSD) that causes high urethral resistance. Several bipolar lead electrodes were compared using HF blocking stimulation parameters. Methods: Seven swine were anesthetized and urethral and anal sphincter pressures recorded. The left pudendal nerve adjacent to the sacral spine was exposed and proximal electrode used to induce intermittent contractions of urethral and anal sphincters. Blocking of sphincter contractions with electrodes at a distal location on the pudendal nerve with HF was evaluated. Initial HF tests used bipolar TECA[R] electrodes at 1.2, 10 and 40 kHz; then, different electrodes and stimulating parameters were evaluated.Results: Initial results with HF demonstrated blocking of intermittent sphincter contractions induced by the proximal nerve electrode. Sphincter contraction blocking was greatest at 1.2 and 10 kHz at currents above 0.25 mA and was reduced at 40 kHz. Sphincter pressures, however, were elevated at the end of the 15 seconds of HF stimulation. These unwanted stimulatory effects on sphincter contraction were greatest at 1.2 kHz, reduced at 10 kHz, and least at 40 kHz. Further tests showed reduced nerve blocking effects using electrodes separated from the nerve or small helical Permaloc electrodes. Cutting the pudendal nerve centrally had no effect indicating that afferent fibers were not involved in the HF blocking effects. Conclusions: Bipolar TECA[R] lead electrodes on the pudendal nerve stimulated at 10 kHz with1 to 5 mA of current were most effective in their nerve blocking effects with least unwanted stimulator effects. Nerve blocking without unwanted nerve stimulation was not observed with the variables tested. Therefore, unwanted stimulatory side effects should be anticipated in SCI patients when HF nerve blocking of the pudendal nerve with lead electrodes is implemented for urethral resistance. Thus, further testing is needed.

INTRODUCTION

Detrusor-sphincter-dyssynergia (DSD), or high urethral resistance, during bladder contractions is a serious problem affecting most individuals with spinal cord injury (SCI).[1] Detrusor-sphincter-dyssynergia and other lower urinary tract pathology following SCI is most often managed by a combination of intermittent catheterization and anticholinergic medication for bladder inhibition.[2] Alternatively, implantable bladder control systems are used; the Finetech-Brindley System (Branded as VOCARE in the US) manages DSD by a sacral afferent neurectomy that paralyses the skeletal urethral sphincter.[3-5] Because of the invasive methods needed for the Finetech-Brindley System, new implantable stimulation systems are under investigation. One approach for management of DSD in these new systems is high-frequency (HF) pudendal-nerve blocking that has been shown to be effective with cuff electrodes in animal models[6,7] and lead electrodes sutured to the nerve in one SCI patient.[8] Voiding for this patient, induced with sacral nerve stimulation, was improved by 1.2 kHz HF blocking of the pudendal nerve.

In this study, we evaluate HF pudendal-nerve blocking methods in swine with lead electrodes, Neurological TECA[R] and Permaloc™ placed on the pudendal nerve in swine. Both of these electrodes could be implanted with minimally invasive techniques using a needle; thus, understanding their characteristics is and important prelude to applications in SCI patients.

MATERIALS AND METHODS

ANESTHESIA

The Institutional Animal Studies Committee of the Hines VA Hospital approved these studies. Seven female York-Landrace swine (30±3 Kg) underwent terminal surgeries. Anesthesia was initiated with a pre-anesthetic intramuscular injection of ketamine (25 mg/kg) and xylazine (1-2 mg/kg).

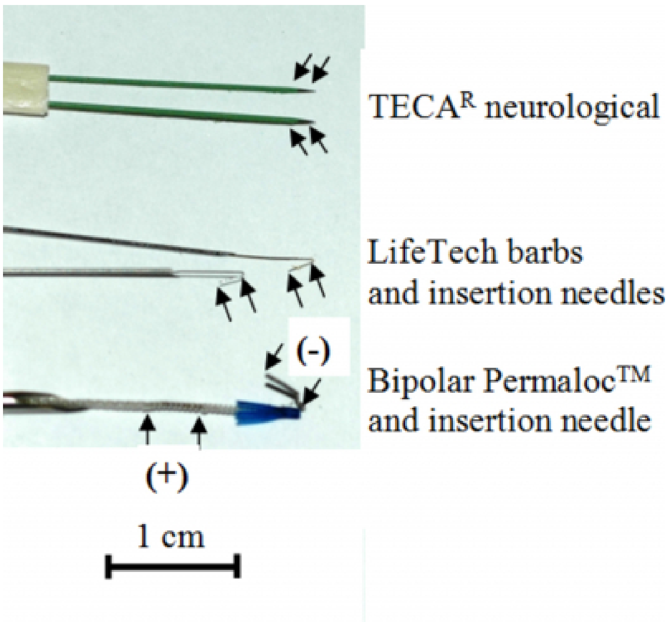
After placement of an intravenous catheter, Propofol (3-6 mg/kg) was initiated. After endo-tracheal intubation the swine were maintained at a surgical plane of anesthesia using inhaled isoflurane (0.5-2.0%) and intravenous fentanyl (5-10 µg/kg/hr).[12] Body temperature was maintained at 38°C with an air-blanket heater. Isotonic fluids were administered intravenously at a rate of 10 mg/kg/hr.

ELECTRODES

Bipolar TECA^R lead electrodes (Fig. 1; 0.36 mm diameter, Carefusion Inc., Middleton WI) were used in initial tests to locate the pudendal nerve and at a distal location in HF blocking protocols. Commercial TECA^R electrodes were modified by removing insulation from the electrode tip to increase the length of the exposed electrode from 0.5 mm to 1.5 mm. Two monopolar TECA^R needle type electrodes were secured together with a separation of 3 mm at the tips to create a bipolar electrode.

Figure 1

Figure 1. Bipolar lead electrodes used in this study: TECA neurological needle; LifeTech barb with 26 gauge insertion needle; Bipolar Permaloc including a polypropylene barb and 16 gauge insertion needle. The needles were not used because the electrode was placed on the exposed pudendal nerve. Arrows highlight the length of stimulating surface of the electrode.



At a proximal location on the pudendal nerve, two LifeTech barb electrodes (EMG type, LifeTech Inc, Houston TX) were inserted adjacent to the nerve. The lead for these electrodes is a single strand of steel wire insulated with Mylar. The electrode tip is 5 mm of exposed wire bent back as a barb. Bipolar stimulation consisted of two electrodes inserted approximately 3 mm apart on the nerve.

At a distal pudendal nerve location, bipolar TECA^R needle electrodes were used in four different HF protocols; the negative electrode was placed distal to the positive electrode. A second electrode used at this location was a bipolar Permaloc™ electrode (Modified Peterson,[9] Synapse Biomedical Inc., Oberlin OH). The modified lead electrode had two, helical-wound, multi-stranded, stainless-steel wires insulated with Teflon.® The electrodes were formed by stripping the insulation from the ends of the lead and using each helix for the two poles of the electrode; the Permaloc™ electrode was placed on the nerve.

STIMULATORS

Pulse stimulators (Grass Model S48, Astromed, Houston, TX) isolated from ground were used for stimulation of the proximal pudendal nerve. Stimulation was charge balanced with a 1.2 µF capacitor (www.Digikey.com) in series with the animal and a 4.2 KΩ resistor across the output of the stimulator. A function generator with amplification and electrical isolation was used in the HF nerve blocking protocols. Isolation was with a transformer that had its ground lead disconnected during testing. The function generator produced a balanced square wave, a form shown to be most effective in producing nerve block.[10,12] We modified a biphasic analog amplifier circuit (5 pin, 20 Watt, Pentawatt specification circuit, www.Digikey.com) to provide adequate amplification for the function generator, electrical isolation, and to reduce electrical noise. Stimulating currents were observed on an oscilloscope and were 0.1 to 10 mA. The stimulating current was calculated from the voltage drop across a 100 ohm resistor in series with the stimulating electrodes and by applying Ohm's law (E = IR).

URODYNAMIC INSTRUMENTATION

Following anesthesia and prior to stimulation tests, the urethra was catheterized with a triple-lumen, 7.4Fr balloon-tipped catheter (Model G15540 Urodynamic catheter, Cook Urological Co. Spencer, IN). One of the lumens was used for bladder filling and a second was capped. The third lumen included a balloon and was used for urethral, skeletal-sphincter pressure recording. Techiques for filling the balloon with water and connecting it to a pressure transducer have been detailed else-where.[13] The urethral meatus in the female swine is recessed 3 to 4 cm within the vaginal opening and catheterization was facilitated by antegrade maneuvers through a 18 gauge needle inserted into the bladder wall. A stylet was advanced through the needle and urethral meatus; the catheter was attached to the stylet and pulled into the bladder. Subsequently, the stylet and needle were removed and the bladder wall closed with a single stitch; the balloon was positioned inside the urethal meatus to record urethral skeletal-sphincter pressures.

An anal balloon for pressure recording was fashioned from silastic tubing (15 mm outside diameter). The ends of the tube were sealed with silicone (Med-1037, NuSil Inc, Carpinteria, CA) and were further enlarged to maintain its position in the sphincter. Pressure transducers (World Precision Instruments Inc, Sarasota, FL) were used for urodynamic measures and recorded with a digital system (PowerLab, AD Instruments Inc, Colorado Springs, CO).

SURGERY AND INTERMITTENT STIMULATION OF THE PROXIMAL PUDENDAL NERVE

An 8 cm incision was made lateral to the sacral spine; hemostasis was maintained with electro-cautery. Blunt dissection and separtion of paraspinal muscles from their fascial plane was carried down approximately 3 cm to the spinal level and the pudendal nerve identified; the nerve is medial to the sciatic nerve.[14] Identification of the nerve was confirmed with low current stimulation using single pulses and observing urethral and anal sphincter pressure spikes without leg movement. Two LifeTech barb electrodes (Fig. 2) were implanted at the proximal end of the nerve. Intermittent urethral and anal sphincter contraction were induced with stimulus trains applied every 2.5 s. Trains consisted of 3 pulses applied at 40 Hz with 50 μs pulse durations. Stimulation currents were increased from 0.25 to 7 mA to induce maximal sphincter contractions without leg muscle contractions.

HIGH-FREQUENCY STIMULATION OF THE DISTAL PUDENDAL NERVE

At the distal pudendal nerve location (Fig. 2), bipolar TECA[R] needle electrodes were placed on the nerve. Sphincter pressure responses were recorded to simultaneous 10 kHz stimulation at 0.25 to 10 mA for 15 s and intermittent stimulation at the proximal nerve location. To limit the total number of stimulations at this frequency, the number of animals tested at the lowest stimulation currents was limited to only those animals that demonstrated nerve blocking at higher currents; thus, three animals were not tested at 0.25 mA and one animal was not tested at 0.5 mA. Also, the number of animals tested at the highest stimulating currents was limited to animals that did not demonstrate leg muscle contractions have baseline pressures over 30 cm H_20 at the end of 15 s during lower stimulating currents; thus, two animals were not tested at both 5 and 10 mA (See Table 1 legend).

Three different HFs were compared; 1.2 kHz was tested because this was the frequency used by Passover et. al. in their clinical study of pudendal nerve blocking[8] and 10 kHz was tested because it has been reported to be the most effective nerve blocking frequency in animal studies.[6,10] We also tested 40 kHz because during initial studies unwanted stimulatory effects were encountered.

Three additional tests were conducted at 10 kHz: one, the TECA[R] electrodes was tested 2.5 mm away from the nerve; two, the bipolar Permaloc[R] electrode was placed next to the pudendal nerve; and three, effects of cutting the pudendal nerve proximal to the proximal electrode was evaluated. Only effects on intermittent peak sphincter pressures were assessed.

One final test was conducted to assess a problem observed during initial testing which was gas evolution seen as bubbles from the TECA [R] needle electrode.. For further assessment, the electrodes were placed against muscle so that the electrodes and bubbles could be seen and the current was increased until bubbles were observed.

ANIMAL CARE, AUTOPSY AND STATISTICS

Animals were sacrificed by administering intravenously 50 ml of saturated KCl while under surgical anesthesia. During autopsy the implanted electrodes were photographed. Summary results are presented as mean±SEM. Student's t-tests with paired data was used for statistical analyses and a statistical significance was set at $p < 0.05$.

RESULTS

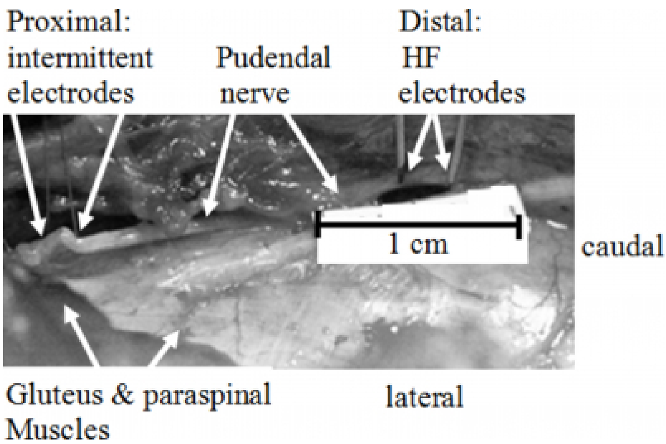
PUDENDAL NERVE BLOCK AT 10 KHZ

Once the pudendal nerve was identified, proximal LifeTech barb electrodes on the pudendal nerve were stimulated with trains of pulses every 2.5 s. These induced intermittent urethral and anal sphincter contractions with high pressures and without leg movements; these trains were used during HF blocking protocols.

High-frequency, 10 kHz, stimulation at 0.25 to 10 mA was tested at a location distal to the proximal electrodes (Fig. 2). As shown for one animal in Figure 3, increasing the stimulating current from 0.25 to 5 mA induced greater increases in the baseline urethral and anal pressures at the beginning of stimulation. At the end of 15 s of stimulation the baseline pressures continued to be elevated and were higher at higher stimulating currents. Elevated baseline pressures at the end of the 15 s are unwanted as they show nerve stimulatory effects.

Figure 2

Figure 2. Pudendal nerve with proximal electrodes for intermittent stimulation and distal electrodes for HF nerve-blocking protocols. Proximal electrodes were bipolar LifeTech barb and distal electrodes were bipolar TECA. Gluteus and paraspinal muscles were pulled lateral.



Similar results were observed in all seven animals (Table 1). Initial baseline urethral sphincter pressures increased with increasing currents whereas at the end of 15 s of stimulation baseline pressures tended to vary. These end pressures tended to increase from 11±6 cm H_20 at 0.25 mA to 17±3 cm H_20 at 1 mA (P = 0.26; n = 4, see Table 1 legend). Stimulation at 10 mA, however, tended to have lower end baseline pressures of 11±3 compared to the response at 1 mA (P = 0.57; n = 5). This trend toward lower pressures occurred even though initial baseline pressures at these higher currents were greater. A maximal initial baseline pressure of 45±4 cm H_20 was observed at 10 mA showing strong sphincter stimulation. Similar baseline sphincter pressure results were observed for the anal sphincter although all of the pressures were lower than urethral pressures.

Figure 3

Table 1. HF (10 kHz) pudendal nerve blocking with bipolar TECA electrodes during intermittent proximal pudendal nerve stimulation

Current	10 kHz urethral baseline Pr		Intermittent urethral peak Pr		
	Initial (cm H_20)	end of 15 s (cm H_20)[s]	Before 10 kHz (cm H_20)	End of 10 kHz[a] (cm H_20)[t]	Complete block (#)[b]
0.25 mA (N=4)[c]	16±9	11±6	23±5	13±7	1 (out of 7)[c]
0.5 mA (N=6)	27±8	17±4	23±4	5±3	3 (out of 7)
1.0 mA (N=7)	38±3	17±3[s]	26±5	7±7[t]	6 (out of 7)
2.0 mA (N=6)[d]	42±5	13±2	25±5	3±3	6 (out of 7)[d]
5.0 mA (N=5)	42±4	9±2	25±6	2±2	5 (out of 6)
10 mA (N=5)	45±4	11±3	22±6	0±0	5 (out of 6)

[a] intermittent peak urethral pressure near the end of the 15 s of 10 kHz stimulation was measured above baseline urethral pressures induced by the HF.

[b]determination of complete block of intermittent urethral sphincter contractions shown by no changes in urethral pressure or no observable movement of the perineum to proximal nerve stimulation and near the end of the 15 s of HF stimulation. Note, evaluation of blocking confounded by high baseline pressures at the end of the 15 s of HF stimulation.

[c] as detailed in methods, not all animals were tested with HF stimulation and low currents because higher currents did not show any blocking effects; for 0.25 mA: n = 4 for statistical comparisons of recorded pressures; n = 7 for assessment of complete block; for 0.5 mA: n = 6 for recorded pressures; n = 7 for complete block.

[d] not all animals tested at HF and high currents because lower currents showed blocking with baseline pressures of 30 cm H_20 at the end of 15 s or strong leg contractions: for 2 mA: n = 6 for recorded pressures; n = 7 for complete block; for 5 mA: n = 5 for recorded pressures; n = 6 for complete block; for 10 mA: n = 5 for recorded pressures; n = 6 for complete block.

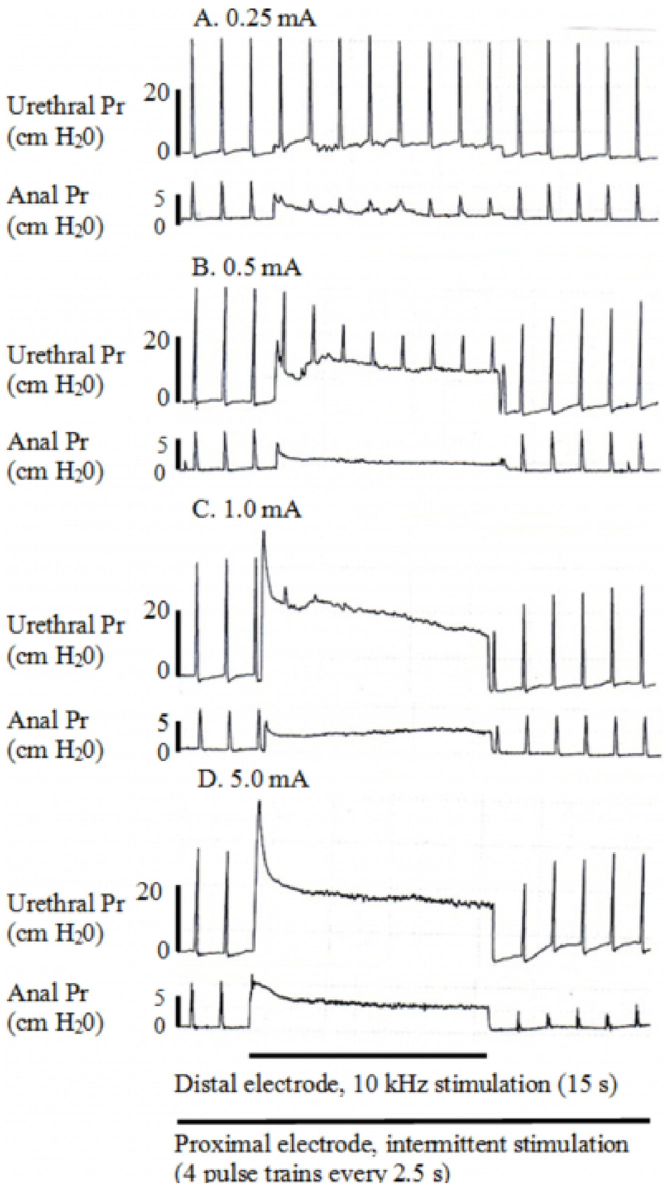
[s] comparison of urethral baseline pressure at the end of the 15 s of HF: 1 mA vs 0.25 mA (p = 0.26, not significant); 1 mA vs 10 mA (p = 0.57, not significant).

[t] comparison of peak intermittent urethral pressure above baseline at the end of the 15 s of HF: 1 mA vs 0.25 mA (p = 0.14, not significant); 1 mA vs 10 mA (p = 0.37, not significant).

In contrast to these unwanted stimulatory effects on the baseline sphincter pressures, the HF stimulation at 10 kHz also produced blocking of intermittent urethral and anal sphincter contractions induced from the proximal electrode. At 0.25 mA (Fig 30-A) there was no blocking of the urethral intermittent contractions whereas the anal contractions were slightly reduced. At 0.5 mA (Fig 3-B) the urethral sphincter contractions were partially reduced whereas the anal contractions were blocked. At 1 and 5 mA (C, D) the intermittent contractions were completely blocked in both sphincters. These blocking effects to the HF stimulation, in contrast to the stimulatory effects seen as increased sphincter baseline pressures, were further confirmed by observation and palpation of the anal sphincter and perineal region. When intermittent sphincter pressures were absent or greatly reduced, there was an abatement of contractions as determined by visual observation and palpation.

Figure 4

Figure 3. Urethral and anal sphincter pressures recorded during intermittent stimulation of the proximal electrodes and 10 kHz stimulation of the distal electrode. Paradoxical effects of the HF stimulation include blocking of intermittent sphincter contractions and unwanted stimulatory affects with increased baseline sphincter pressures. Bipolar Life-Tech barb electrodes were used at the proximal location and bipolar TECA needle electrodes were used for HF blocking at the distal location. Phasic contractions to intermittent stimulation induced with trains of pulses every 2.5 s (3 pulses at 40 Hz, 50 Âµs,



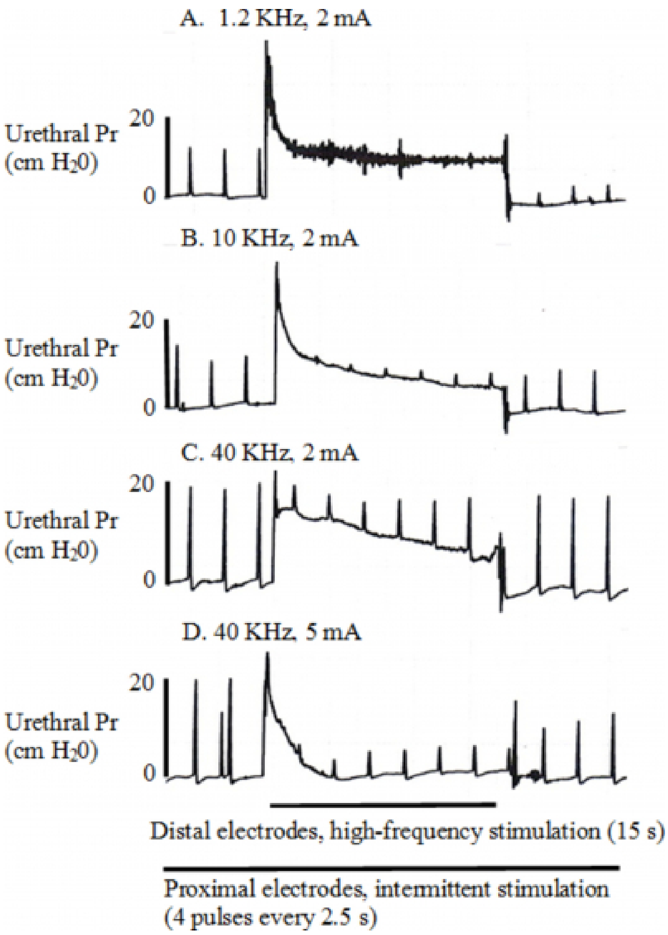
Similar blocking effects of intermittent sphincter contractions with 10 kHz stimulation were observed in all seven animals (Table 1). Increasing the HF blocking current from 0.25 mA to 1 mA caused complete block of intermittent contractions in six animals whereas 0.25 mA only produced complete block in one animal. At even higher stimulating currents from 2 to 10 mA results were similar showing complete block of the intermittent contractions. Importantly, in none of the seven animals were we able to show blocking of the intermittent urethral contractions without some unwanted stimulatory effect as evidenced by lack of increase in baseline urethral pressures. Similar intermittent sphincter pressure responses to the HF stimulation were also observed for the anal sphincter. Peak pressures recorded in the anal sphincter, however, were lower than for the urethral sphincter.

COMPARISON OF 1.2, 10 AND 40 KHZ STIMULATING FREQUENCIES

Effects of 10 kHz stimulation on baseline pressures near the end of the 15 s stimulation was compared for 1.2 kHz. As shown in Figure 4, 1.2 kHz and 2 mA (A) induced higher urethral baseline pressures than did 10 kHz and 2 mA (B). Lower baseline pressures at 10 kHz compared to 1.2 kHz were observed in four out of the five animals tested at these two frequencies. Slight to moderate leg movements occurred during 1.2 kHz and 10 kHz in two of the five animals tested. The unwanted leg muscle contractions are shown in Figure 4-A by the thick line in the urethral pressure recording. In contrast, baseline pressures were often reduced with 40 kHz stimulation compared to 10 or 1.2 kHz. The second of the two recordings at 40 kHz and 5mA (Fig-D) show this with a pressure that changes little when the HF is turned off. The lowest baseline pressures were all recorded at the end of 15 s with 40 kHz compared to 10 kHz or 1.2 kHz for the five animals tested; also, leg muscle contractions were not observed in any of the animals at this higher stimulating frequency.

Figure 5

Figure 4. Urethral sphincter pressures recorded during intermittent stimulation of the proximal pudendal nerve electrodes and 1.2, 10 and 40 kHz HF stimulation at distal electrodes. Both nerve blocking and stimulation are shown to the HF stimulation. Stimulation at 40 kHz and 5 mA demonstrated the most reduction in unwanted increases in baseline urethral sphincter pressures while still partially blocking intermittent sphincter contractions. Electrodes and methods used are described in Figure 3.



Effects of 10 kHz stimulation on intermittent urethral contractions were also compared to 1.2 kHz and 40 kHz stimulation. As shown in Figure 4, at 10 kHz and 1.2 kHz (2 mA, A and B) intermittent contractions were blocked. For four of the five animals tested with these two stimulation frequencies, similar blocking of intermittent contractions occurred; whereas in the fifth animal 10 mA was required to demonstrate a complete block of intermittent contractions at 10 kHz compared to only 1 mA at 1.2 kHz. As shown in Figure 4, at 40 kHz with 2 and 5 mA (Fig 4-C, D) only partial blocking of the intermittent contractions occurred; however, 5 mA (D) was more effective than 2 mA (C). In four of the five animals tested with 40 kHz, no complete blocking of the intermittent contractions were observed whereas in the fifth animal a complete block was observed only at high currents of 10 mA.

EFFECTS OF DISTANCE FROM THE NERVE AND PERMALOC ELECTRODES

TECA[R] bipolar lead electrodes were tested 2.5 mm away from the pudendal nerve at 10 kHz. In two of the three animals, there was no effect of stimulation as evidenced by the lack of change in baseline pressures or intermittent urethral contractions at 5, 8, or 10 mA. In the third animal, there were small baseline changes (initial pressure of 10 cm H_20) in the urethral sphincter pressures at 10 mA but not 5 mA. At both 5 and 10 mA, however, there were no changes in the intermittent urethral contractions for any of the three animals. With stimulations 2.5 mm from the nerve, anal sphincter pressures also showed little or no change.

Bipolar Permaloc™ lead electrodes were tested on the nerve at 10 kHz. Using 5 mA, of current changes in baseline sphincter pressures were much less than those observed with the TECA[R] bipolar needle electrodes on the nerve. In addition, Permaloc™ electrodes produced no blocking of the intermittent urethral sphincter contractions at 5 mA in any of the five animals tested. Higher currents of 10 mA (four animals) and 14 mA (one animal) induced higher baseline pressures and complete blocking of the intermittent urethral sphincter contractions in two animals. Another concern was greater spread of electrical fields with the Permaloc electrodes. In four of the five animals tested, current spread was indicated by slight or moderate leg muscle contractions at 10 or 14 mA; at 5 mA current spread occurred in only one animal.

EFFECTS OF PUDENDAL NERVE TRANSECTION AND ELECTRODE ELECTROLYSIS

The pudendal nerve was transected proximal to the stimulation electrodes to assess spinal reflex effects on pudendal nerve stimulation. Nerve transection had no effect on peak intermittent contractions, 26±6 cm H_20 (n = 4), both before and after cutting. In one of the remaining three animals, effects of pudendal nerve transection could not be assessed because of intermittent sphincter peak pressure changes that may have been associated with slight changes in position of the proximal electrodes on the pudendal nerve; in the other two the tests were not conducted due to limited surgical time. Similar to the urethral sphincter, Intermittent contractions for the anal sphincter were 4±1 (n = 4) before and after transection of the nerve. Thus, spinal reflexes do not play a role in stimulation induced intermittent sphincter contractions.

Gas released from the TECA [R] electrodes due to electrolysis was observed at higher stimulating currents and particularly at 1.2 kHz. Gas production started at 10 mA of current at 1.2 kHz and 20 mA of current at 40 kHz; higher currents led to more gas production. Permaloc™ electrodes, which have a larger surface area, did not produce gas at the same stimulating currents and frequencies. Gas production was not due to heating of the tissue based on two observations: one, there was no visible signs of tissue damage such as tissue reddening; and, two, when electrodes were held between the investigators fingers with isotonic saline to produce the same electrode resistance as in animals, there was no perceptible increase in temperature with prolonged stimulation.

DISCUSSION

Pudendal nerve stimulation at 1.2, 10 and 40 kHz with 0.25 to 10 mA using the TECA [R] bipolar lead electrodes demonstrated stimulatory as well as nerve blocking effects. The unwanted stimulatory effects were seen as elevated baseline sphincter pressures during the 15 s of stimulation. Stimulatory effects on baseline pressure were greater at 1.2 kHz than 10 KHz and were lowest at 40 kHz. The nerve blocking effects of HF stimulation were seen as abolition of the intermittent sphincter contractions occurred in an opposite order than effects on the baseline where 40 kHz demonstrated less blocking than 1.2 and 10 kHz. Blocking effects were observed more often at currents above 0.25 mA; that blocking effects are greater at higher stimulating currents has been reported by others[8-10].

Moving the bipolar TECA[R] lead electrodes away from the nerve did not resolve the side effects and only reduced the stimulator and blocking effects on the nerve. Bipolar Permaloc™ electrodes placed on the pudendal nerve also did not work well as all effects of stimulation were reduced. The bipolar Permaloc™ electrode required higher currents before any effect on the nerve occurred compared to TECA[R] lead electrodes. This is probably due to the fact that the Permaloc™ electrode's helical wire stimulating surface area is much larger and the helix which results in part of the stimulating surface is one mm away from the nerve. Thus, side effects of HF stimulation with lead electrodes may be unavoidable.

Electrolysis at the electrodes during stimulation is unwanted and is characterized by O_2 formation at the anode and H_2 formation at the cathode. Gas production is usually prevented by using balanced biphasic stimulating wave forms. The gas production demonstrated by the TECA[R] but not the Permaloc[TM] lead electrodes shows that small stimulating surface areas are associated with irreversible electrolysis reactions; likewise, the lower current for gas production using TECA[R] lead electrodes at 10 mA for 1.2 kHz and 0.44 ms duration of each stimulation phase compared to 20 mA for 40 kHz and 0.13 ms duration shows that a longer duration of the stimulation phase is also associated with the irreversible reactions.

Our results of HF stimulation are different from those reported by others primarily in the area of the continuing stimulatory effects on the baseline pressures at the end of the 15 s of stimulation.[6,7,10,11] They describe an initial stimulatory effect of HF stimulation seen as increased baseline pressures followed by no continuing effect on the baseline pressure before the end of 15 s stimulation but with complete nerve block. Similar observations have been reported using nerve-cuff electrodes on the pudendal nerve[6,7] and have been observed for skeletal muscle with both intraneural and cuff electrodes.[10,11] The proposed mechanism for the complete nerve block is that HF stimulation at moderate to high currents induces a strong electrical field around each nerve fiber which is initially stimulatory but during sustained HF stimulation the nerve fibers remains depolarized preventing further regenerating action potentials.[10,11]

Considering the difficulties encountered here with lead electrodes in obtaining blocking of intermittent sphincter contractions without residual baseline stimulatory effects, alternative methods need to be tested or there could be inherent problems with lead electrodes for HF stimulation. One alternative lead electrode method would be using a tripolar electrode configuration rather than the bipolar electrodes tested in this study. Tripolar electrodes have been used by others with a central negative electrode and two outer positive electrodes. The tripolar configuration limits the spread of the electrical field on the most distal electrode that may be causing the residual stimulatory effects; also, these are described as ‘virtual’ electrodes.[7,10,11] If the proposed tripolar lead electrode arrangements should fail, intraneural or cuff electrodes could be used. These electrodes, however, are limited due to the invasive methods required to implant them on the pudendal nerve which is deep in the pelvic region.

Possover et al.[8] reported HF nerve blocking with bilateral electrodes adjacent to the pudendal nerve in one SCI patient. Bladder emptying in this subject during sacral nerve stimulation was accomplished only in conjunction with HF pudendal nerve stimulation. The differences between our study and that of Passover et al may be explained by the variation in the stimulation parameters. The stimulating wave form used by Possover et al, was balanced but was short duration square waves of 0.2 ms interspersed with periods of no stimulation of 0.24 ms. In contrast, our balanced square waves at 1.2 kHz were 0.42 ms in duration for both positive and negative phases of the stimulating wave form. Other differences between the two studies include species, spinal cord status, and, obviously, lack of anesthesia in patients post implantation. In both studies, however, lead electrodes were used that could be implanted with minimally invasive procedures; this is highly desirable for implantation of bladder-control systems in patients with SCI. Finally, another explanation of the benefit of HF pudendal nerve blocking for voiding observed by Possover et al[8] is sphincter fatigue.[10] Recordings were not conducted by Possover et al that could have distinguished between the two HF mechanisms: nerve block or sphincter fatigue. Further, prior studies suggest that a minimal nerve blocking frequency of 4-5 kHz and 1.2 kHz used by Possover et al. may be too low to produce nerve blocking effects.[6,10]

In addition to management of DSD in SCI patients, two other lower urinary tract problems in these patients also need to be managed. First, patients with SCI have an overactive bladder and urinary incontinence that needs to be prevented. Possover et al.[8] have shown that this can be accomplished with 20 Hz stimulation of the pudendal nerve with a complete block of all bladder contractions. Second, patients with SCI require induction of bladder contractions for urination. Possover et al.[8] also showed that effective bladder evacuation can be induced with Finetech-Brindley electrodes implanted with minimally invasive procedures on the sacral nerves outside of the sacrum. Our laboratory has been developing bladder stimulation methods by testing electrodes on post pelvic-plexus nerves innervating the bladder.[15-18] In the current animals, and reported elsewhere,[19] direct bladder wall stimulation using the bipolar Permaloc[TM] electrodes was also used and may be useful in SCI patients.

CONCLUSION

Small TECA[R] bipolar needle electrodes placed on the pudendal nerve and stimulated at 10 KHz, 1 to 5 mA, were more effective than bipolar Permaloc[TM] electrodes for blocking of intermittent urethral sphincter contractions induced by proximal electrodes while reducing nerve stimulatory side-effects. Nerve blocking with unwanted nerve stimulation, as evidenced by the increase in baseline pressures, occurred with our stimulation parameters and electrodes. Therefore, further testing is needed to avoidable any side effects. If effective HF blocking of the pudendal nerve with lead electrodes could be shown, this method could become a relatively noninvasive approach to treat the DSD problem of high urethral resistance in SCI patients.

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