Percutaneous Stimulation of the Skeletal Urethral Sphincter in Patients with Stress Urinary Incontinence Following Radical Prostatectomy: Limitations of the Approach

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Citation

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Abstract

The Aims of the study were to evaluate in patients with stress urinary incontinence methods of direct urethral skeletal sphincter stimulation (electrode placement and parameters) to produce increased urethral pressure without patient discomfort. Methods and materials: Patients were catheterized to record bladder and urethral pressures. A barb electrode was placed with a small needle through the perineum into the skeletal sphincter. Initial testing included 1 to 6 mA, 40 Hz, 200 us pulses for 1 s and was followed by testing with different stimulation parameters. Results: Five male patients with stress urinary incontinence more than 6 months following a radical prostatectomy were enrolled. They had both stress and urge incontinence symptoms. Two subjects were excluded because of a urethral stricture. The remaining 3 patients were catheterized and demonstrated high urethral sphincter pressures to cough and anal contraction. However, 2 of these 3 patients had no urethral electromyography response after placement of the barb electrode and no sphincter pressure response to stimulation. These patients did, however, report discomfort with stimulation. The third subject's electromyography and pressure responses to stimulation were recorded. Two, 4 and 6 mA induced peak urethral pressures of 32, 62, and 100 cm H_20 respectively. Pain was rated as 4 (10 point scale) at 4 mA. Sphincter muscle fatigue was observed during a 10 s stimulation period. The urethral pressure profile during intermittent stimulation showed contractions along an extended length of the urethra. Discussion: This is the first report of direct urethral sphincter stimulation to increase urethral resistance. Three patients had placement of a barbed electrode into or adjacent to the skeletal urethral sphincter and all reported discomfort that depended on the current strength. Only one patient definitely had placement of the electrode in the skeletal urethral sphincter and he had high pressures responses to stimulation. However, wincing and tightening of lower extremities during stimulations was observed. Conclusion: Future studies of direct urethral sphincter stimulation to increase urethral pressure as a possible method to manage stress urinary incontinence should evaluate protocols to reduce discomfort and to produce more sustained sphincter pressures.

INTRODUCTION

Behavioral interventions such as Kegel exercises and bladder training to manage stress urinary incontinence (SUI) are moderately effective[1-3] as well as electrical stimulation of the pelvic floor with vaginal and anal plug electrodes.[5-8] More invasive treatments are offered to patients that seek further treatment such as sphincter or sling surgery.[4] Alternatively, direct electrical stimulation of the urethral skeletal sphincter stimulation with an electrode implanted in the sphincter could be effective for increasing urethral resistance for management of SUI. An initial test of this hypothesis was investigated here with patients enrolled that were suffering from SUI following radical prostatectomy.

MATERIAL AND METHODS

This is a case series study that was approved by the Human Studies Committee at Hines VA Hospital. Male and female patients with SUI were recruited over a 2-year period with a study flier. Subject's medical history and SUI concerns were obtained by interview as well as with the MESA (Medical Epidemiologic and Social Aspects of Aging) Urinary Incontinence Questionnaire and AUA Prostate Symptom scores.[9] Male subjects were excluded if they had a radical prostatectomy within 6 months.

A protocol was conducted in a single urodynamic recording session (Urolab Janis, Life Tech Inc, Stafford, Texas). The catheter (Model SUPC-760S, 6F Millar, Life Tech Inc) included bladder and urethral pressure-tip transducers and a bladder filling tube. To record the skeletal urethral sphincter pressure, the urethral pressure transducer was pulled from the bladder neck at 1 cm increments along the urethra where resting pressures and responses to cough and anal contraction maneuvers were conducted. The urethral sphincter was determined as the highest pressure.

The wire barb electrode (EMG barb electrode, Life-Tech Inc) was in a 27 Gauge needle and was insulated except for the last 5 mm. The perineum site for insertion was ventral to the anal sphincter and just lateral to the midline. The location of the skeletal urethral sphincter was determined by palpation of the urethral catheter. The perineum was anesthetized with an ice cube for one minute and prepped with Betadine prior to insertion of the needle to its full length, 3.5 cm. Correct placement was indicated by an EMG response of 50 µV or greater to anal contraction. To rate discomfort to this and other procedures, a 10 point visual pain scale was used.

A stimulation screening test was used to determine if there was any urethral pressure response to stimulation. The stimulator (Grass S55 & SIU7 constant current; Astromed Inc, West Warwick, RI) used capacitor coupled charged balanced pulses.[10,11] A 2 by 3.5 inch surface electrode (Source 1 Medical Inc. Ocala, FL) was placed on the thigh as the positive return electrode. Stimulation parameters included: 1 to 6 mA, 40 Hz, 200 µs pulses applied for 1 s. Any increase in urethral pressure was considered a passed test. For failed tests, the electrode was withdrawn and a second electrode was inserted.

If the screening test was passed, three additional stimulation tests were conducted: First, 10 s stimulation period at 10, 20 and 40 Hz; second, a urethral pressure profile using ‘ON and OFF’ stimulation trains; third, a stress test with abdominal straining and cough at different bladder filling volumes.

RESULTS

Five male veterans with SUI symptoms enrolled in this study. These subjects had received a radical prostatectomy 2 to 10 years prior at this or other institutions. The average age was 67+2, and co-morbidity included diabetes and high blood pressures in two patients. Self reports from three patients stated moderately bothersome symptoms while two stated that it was very bothersome. Their pad use ranged from multiple changes of underwear during the day to 3 pads per day.

The MESA urge urinary incontinence symptom score for these 5 subjects was 9+2 out of a possible 18, and the stress incontinence score was 15+3 out of a possible 27. The International Prostate Symptom scores was 13+5 out of a possible 35 with nocturia averaging 2 per night. At the time of testing, two patients could not be catheterized due to bladder neck contracture and they were withdrawn from the study.

The remaining three patients were catheterized and the skeletal sphincter was located as high pressure just distal to the bladder neck. This was 18+2 cm H_20 from the urethral meatus. Resting skeletal sphincter pressures were moderate but high pressures were recorded to both cough and anal sphincter contraction (Table 1). The voluntary anal contractions (as to prevent the release of gas) occurred without changes in bladder and abdominal pressure so this was the best maneuver to demonstrate urethral skeletal sphincter contractile activity.

Figure 1

Table 1. Urethral skeletal sphincter pressure measured to cough and anal contractions for the three catheterized male patients.

	Urethral Skeletal Sphincter Pressure (cm H_20)[a]		
Procedure	Resting	Peak	Change
Cough	33±3	118±10	85±8
Anal contract	32±7	110±24	78±17

[a]the urethral skeletal sphincter was located just distal to the bladder neck (see text).

The barb electrode was then implanted into the skeletal urethral sphincter in the 3 catheterized patients and without discomfort (icing). EMG responses from the implanted electrode during cough or anal contraction could not be recorded in the first two subjects. They also had no pressure response during stimulation of the electrode in their sphincter. Thus, these patients probably did not have the electrode accurately placed in the skeletal sphincter. Obesity in these patients made placement difficult, and insertion of a second needle did not improve responses. However, an important observation in these two patients was that the stimulation (40 Hz, 200 us pulses for 1 s) with a rating of 4 (on the 10 point pain scale) at 4 mA with lower ratings for lower currents and higher ratings for higher currents.

The third catheterized patient showed sphincter EMG responses with the implanted electrode to cough and anal contraction (Fig. 1). Stimulation at 40 Hz and 200 µs pulses for 1 s, induced peak urethral pressures of 32, 62, and 100 cm H_20 at 2, 4 and 6 mA respectively (Fig. 2). The vesical and abdominal pressures were unchanged during this stimulation. Like the other two patients that rated the pain during stimulation, this subject also rated 4 for 4 mA and 6 for 6 mA on the 10 point pain scale, showing considerable discomfort. After the 1 s stimulation the sphincter stayed contracted for 1 to 2 s. This extended contraction of the sphincter muscle may have been due to the patient's discomfort indicated by facial wincing and tightening of lower extremities with stimulation.

Figure 2

Figure 1. Urodynamic records to cough and anal contraction for the one patient that had and increased EMG response (third catheterized patient, see text). The record shows that the barb electrode was in the sphincter. The high baseline EMG values probably represent a recording artifact.

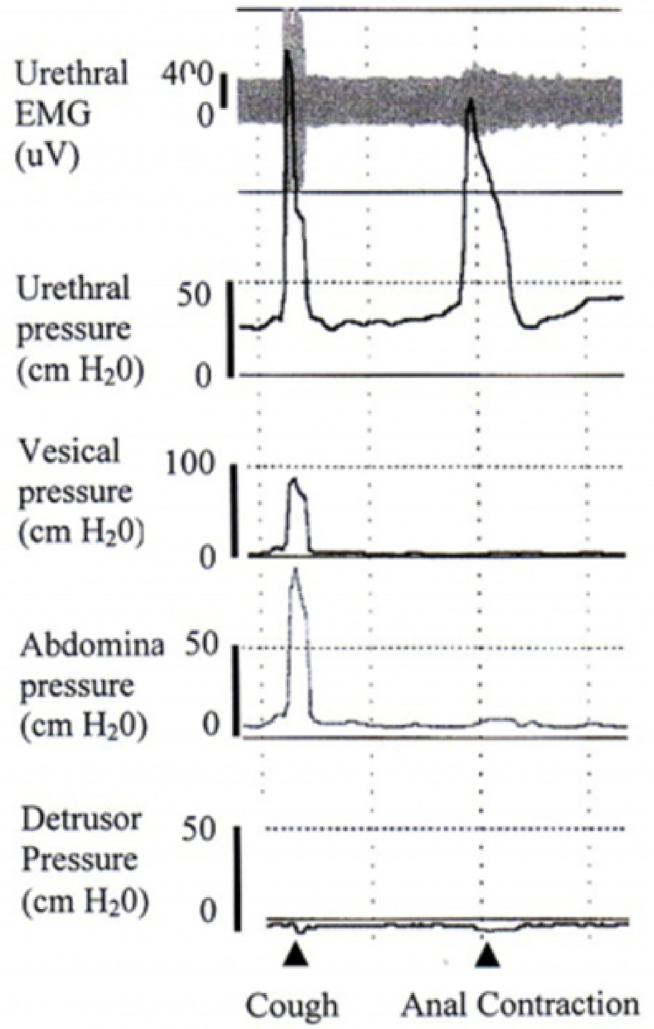


Figure 3

Figure 2. Skeletal urethral sphincter pressure responses to stimulation at 2, 4, and 6 mA. Stimulation applied at 40 Hz, 200 Âµs for 1 s. There is a slow, 1 to 3 sec, decline in urethral pressure following stimulation they may be associated with the patient wincing (see text). Recording from the one patient demonstrating increased pressures with stimulation (third catheterized patient, see text).

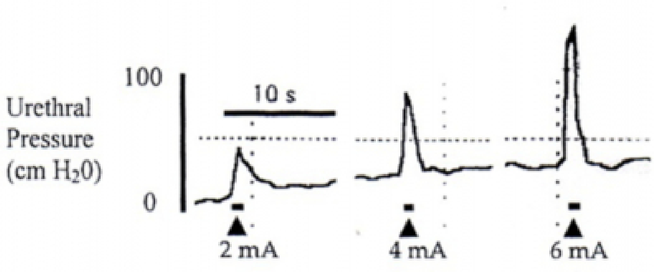


Figure 4

Figure 3. Skeletal urethral sphincter pressure responses to 10 s stimulation periods applied at 10, 20 and 40 Hz, 200 Âµs pulses. Five mA stimulation was used with the 10 Hz and 4 mA was used with the 20 and 40 Hz. Recording from the one patient demonstrating increased pressures with stimulation (third catheterized patient, see text).

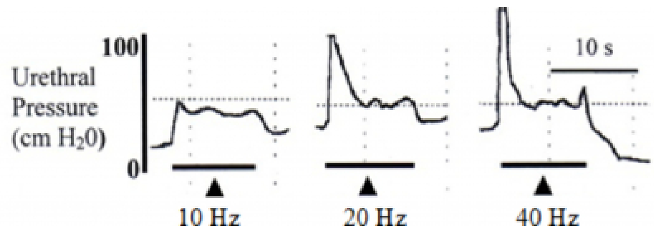
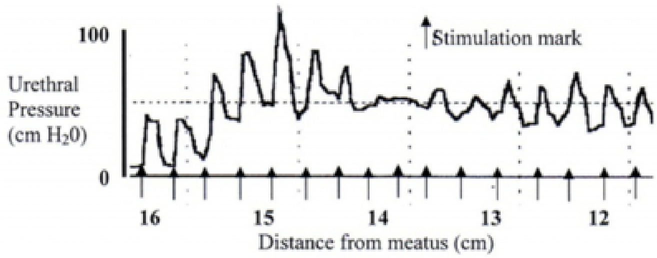


Figure 4 shows a urethral pressure profile from the same patient with intermittent stimulation, 1 s ON and 2 s OFF, at 40 Hz and 4 mA. The highest urethral pressures occurred at the skeletal sphincter, 115 cm H_20; however, increases in pressure were also seen distal and proximal to the sphincter.

Figure 5

Figure 4. Urethral pressure responses during a urethral pressure profile with stimulation of the skeletal urethral sphincter at 4 mA, 40 Hz, 200 us pulses and 1 s ON and 2 s OFF. Recording from the one patient demonstrating increased pressures with stimulation (third catheterized patient, see text).



The final test for this patient, the effects of urethral skeletal sphincter stimulation during an incontinence stress test, was not completed because the subject demonstrated no incontinence during coughing and abdominal straining at bladder filling volumes up to 300 ml.

DISCUSSION

This is the first report that we are aware of using direct stimulation of the skeletal sphincter muscle with an implanted barb electrode to increase urethral sphincter pressures. Two of three patients implanted with the barb electrode did not respond to stimulation indicating placement outside of the sphincter. Extra sphincter placement was also indicated by a lack of EMG response to cough or anal contraction. The 3.5 cm length needle may not have been long enough to reach the sphincter in these 2 patients. Following radical prostatectomy the skeletal sphincter may be farther from the perineum, scar tissue may have interfered with placement, and obesity in these patients may have also made placement difficult.

In the third catheterized patient, the EMG and pressure responses showed that the electrode was in the urethral sphincter. Stimulation at 40 Hz, 1 s and 4 to 6 mA induced urethral pressures over 50 cm H_20 (Figures 2 - 4). However, discomfort with stimulation was a primary limitation. A current of 4 mA was uncomfortable in all 3 patients. Others investigators have reported discomfort for patients with stimulation in this area. The prior studies were conducted for bladder inhibition and stimulation was limited by discomfort.[12-14] A clinical study using bladder neck stimulation for evoked potential with catheter electrodes reported a threshold for sensory perception at 20 to 30 V.[17] Evoked potentials occurred at 40 to 90 V, and at these high voltages a continuous burning sensation into the deep layers of the perineum were reported. In addition, 30% of the patients reported urgency with stimulation. In contrast, no urgency during stimulation was reported by patients in this study.

As peripheral nerves are primarily composed of sensory nerves, it is not surprising that we observed sensory activation during stimulation. Sphincter contractions as a response to pain cannot be ruled out especially with the high ratings of discomfort by the patients on the visual analog scale. The one responding (stimulation) patient showed discomfort by facial wincing and tightening of lower extremities. The recording of prolonged contraction of the sphincter for 1 to 2 s after the end of stimulation also suggests a pain response. Another research group[15] also reported sensory activation including prolonged contractions of the urethral skeletal sphincter with single magnetic pulses applied to the back (activation of sacral nerves) and during the recording of high urethral pressures. In contrast, in our studies in the anesthetized dog (blocked pain reflexes), different sphincter contraction were recorded to direct stimulation of the skeletal urethral sphincter. Using similar stimulation protocols (2 s, 10 to 15 mA, 40 Hz, 200 μs pulses) and electrodes, larger more sustained skeletal urethral sphincter contractions (56 cm H_20) were induced with no contraction following stimulation.[16]

Sphincter fatigue during continuous stimulation could be another limitation of direct urethral sphincter stimulation. Fatigue of the sphincter was seen here during the 10 s of stimulation at 20 and 40 Hz (Fig. 3). However, the 10 Hz showed more sustained responses and should be investigated further. The urethral pressure profile during intermittent stimulation (Fig. 4) showed increased pressures along an extended length of the urethra. This is an important result as increases in pressure over an extended length is considered an important goal in SUI management.[18,19]

No further testing with the current protocol is warranted because of patient discomfort and the difficulty of electrode placement in the skeletal urethral sphincter. Future studies should include a longer needle for better electrode placement in the skeletal sphincter. In addition, a monopolar neurological needle should be considered for initial testing. It is a standard neurological method to use these types of needles first to test different locations and stimulation parameters to locate effective stimulation sites. Stimulation with shorter pulse durations, less than 50 μs, are selective for large motor fibers important for skeletal muscle contraction with less activation of smaller pain fibers. Thus, shorter pulse durations should be included in any future test protocol in this area.[8,15] Bipolar stimulation electrodes should also be considered as they produce less current spread than the monopolar electrodes used here and may result in less discomfort.[17]

The five male patients recruited for this study had both stress and urge symptoms as shown by the high values of their standardized questionnaire scores. Patients have a hard time describing their urinary symptoms and the standardized questionnaires contributed to the evaluation. The three catheterized patients produced strong urethral skeletal sphincter pressures to anal sphincter contraction which was surprising in the light of the severity of their SUI symptoms (Table 1). To manage SUI, behavioral training and Kegel exercises are most often offered.[1,3,5] More invasive treatments are offered to patients that seek further treatment such as sphincter or sling surgery.[4]

CONCLUSIONS

Three patients that had placement of a barbed electrode into or adjacent to the skeletal urethral sphincter and received electrical stimulation reported discomfort with stimulation that increased in severity with increasing stimulating currents. Only one patient definitely had placement of the electrode in the skeletal urethral sphincter and he had high pressures responses to stimulation. However, the pressures may have been, in part, due to reflex sphincter contractions as some wincing during stimulations was observed. Future studies should investigate stimulation protocols to reduce discomfort and to produce more sustained sphincter pressures.

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