
Transcutaneous Mechanical Nerve Stimulation Using Perineal Vibration: A Novel Method for the Treatment of Female Stress Urinary Incontinence

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Purpose: We defined basic guidelines for transcutaneous mechanical nerve stimulation in modifying pelvic floor responses in women and determined the efficacy of transcutaneous mechanical nerve stimulation in treating stress urinary incontinence.

Materials and Methods: Perineal and clitoral transcutaneous mechanical nerve stimulation was performed in healthy volunteers while measuring changes in peak urethral pressure to determine optimal vibration amplitude and site of stimulation. Perineal transcutaneous mechanical nerve stimulation was then performed weekly for 6 weeks in a cohort of women with stress urinary incontinence (33). Reduction in incontinence episodes and pad use on voiding diary were compared from baseline to 6 weeks. Global efficacy was determined at 6 weeks and 3 months after the completion of the program.

Results: In healthy subjects a vibration amplitude of 2.0 mm resulted in the highest urethral pressure increase. Although the increase with perineal transcutaneous mechanical nerve stimulation was lower than that seen with clitoral stimulation (80 vs 115 cm H₂O), perineal transcutaneous mechanical nerve stimulation was more acceptable to the patient and resulted in a better subjective response. Urethral pressure increases with transcutaneous mechanical nerve stimulation at either site were greater than with voluntary contraction (60 cm H₂O). After 6 weeks of transcutaneous mechanical nerve stimulation in the subjects with stress urinary incontinence, there was a significant reduction in daily incontinence episodes (2.6 ± 1.1 vs 0.5 ± 1.1 , paired t test $p < 0.001$) and pad use (3.5 ± 0.9 vs 0.6 ± 1.3 , paired t test $p < 0.001$). At 6 weeks the cure rate (no incontinence episodes) was 73%, with durability through 3 months with 67% still reporting persistent resolution.

Conclusions: Perineal transcutaneous mechanical nerve stimulation has promise as a noninvasive and well tolerated method of treating stress urinary incontinence.

Key Words: urinary incontinence, stress; vibration; pelvic floor; physical stimulation

Stress urinary incontinence is a prevalent problem.¹ The current first choice therapy of female SUI is pelvic floor muscle training including various types of behavioral interventions. Unfortunately a majority of women either do not comply with or do not respond to the interventions.²⁻⁴

It is well-known that transcutaneous mechanical nerve stimulation through penile vibratory stimulation can induce reflex ejaculation in the majority of upper motor neuron lesion spinal cord injured men.⁵ In these men reflex ejaculation is induced via the dorsal penile nerves which are branches of the pudendal nerve.⁶ Afferent nerve impulses

travel through the pudendal nerve into the sacral spinal cord (S2-S4) and then stimulate 2 types of efferent responses. Sympathetic outflow from the thoracolumbar cord (T11-L2) causes seminal emission, and somatic sacral efferent outflow (S2-4) causes contraction of the periurethral and pelvic floor muscles, effecting projectile ejaculation.

In a previously published study we performed detailed real-time measurements of bladder and urethral sphincter pressures during vibratory ejaculation in spinal cord injured men.⁷ In addition to characterizing the sequence of events associated with ejaculation, other observations were also made. The application of the vibrator to the penis resulted in prompt and forceful contraction of the pelvic floor and periurethral muscles, and suppression of reflex bladder activity. Thus, the applicability of external vibration to induce pelvic floor contraction through the pudendal nerve was theorized. The purpose of this prospective pilot study was to examine the effect of TMNS via vibratory stimulation of the clitoris or perineum on pelvic floor muscle contraction in healthy women, and to evaluate a possible beneficial clinical effect of TMNS in women with stress urinary incontinence.

MATERIALS AND METHODS

Phase 1

Ethical committee approval was obtained before study initiation. Healthy female volunteers without incontinence

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Study received ethical committee approval.

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were recruited. Baseline urethral pressure was measured using a 10Fr urodynamic perfusion catheter (CR Bard, Inc., Tewksberry, Massachusetts) inserted into the urethra with the monitoring pressure port located at the point of peak urethral resistance. The point of peak urethral resistance was chosen as the best location for testing the external urethral sphincter pressure/pelvic floor muscle contraction. All women were asked to make 5 voluntary pelvic floor muscle contractions while measurements were taken.

TMNS was performed with a FERTI CARE@personal vibrator (Multicept A/S, Gørløse, Denmark). The center of the vibrating disc (35 mm diameter) was placed on the clitoris for 10 seconds, followed by a pause of 10 seconds, and then placed on the perineum for 10 seconds. This stimulation pattern was repeated after 2 minute rest periods with progressively increasing vibratory amplitude (1.0 – 1.5 – 2.0 – 2.5 – 3.0 mm) to find the strongest pelvic floor muscle response to TMNS. A constant frequency of 100 Hz was used.

On day 2 of the study urethral pressure measurements were taken in a similar fashion but using a single amplitude of 2.0 mm based on results of day 1. Five voluntary pelvic floor muscle contractions were made by each woman to re-establish baseline conditions. TMNS was performed on the clitoris for 10 seconds followed by a pause of 10 seconds, and the cycle was repeated for 5 stimulations. After 5 minutes of rest the same stimulation pattern was used on the perineum. The women were asked which TMNS anatomical location provided the strongest subjective pelvic floor muscle contraction.

Phase 2

Women with self-reported symptoms of SUI with a minimum of 3 incontinence episodes during 3 days were included in analysis. Overactive bladder and compliance problems were excluded with cystometrogram (first sensation more than 100 ml, cystometric bladder capacity more than 400 ml). All subjects had tried other treatments including pelvic floor muscle training (100%), behavioral intervention (100%) and peripheral electrical stimulation (3 patients), which had failed.

Perineal TMNS was performed weekly at a frequency of 100 Hz and an amplitude of 2.0 mm based on results from phase 1. The vibrator was applied to the center of the perineum for 10 seconds followed by a pause of 10 seconds, with this pattern repeated for a total of 10 cycles per session. In the first 16 subjects the TMNS procedures were performed in the clinic setting by a single therapist once weekly for 6 weeks. The subsequent 17 subjects performed an identical TMNS program at home themselves, following careful instruction.

Incontinence episodes and pad use were recorded for 24 hours in a urinary diary before the first TMNS session and again after the final TMNS stimulation. The number of women cured, defined as no incontinence episodes on voiding diary and subject stating complete resolution of symptoms, was noted immediately after completion of TMNS treatment. Subjects were defined as improved if they had ongoing incontinence episodes but with a reduction in frequency, based on the diary, and subjective improvement in symptoms.

After completion of the TMNS program all subjects were instructed to perform standard pelvic floor muscle contrac-

tion for 3 months with no TMNS during the followup period. Subjects were contacted by telephone to determine the durability of improvement. The number of incontinence episodes and number of pads used (voiding diary) before and after TMNS treatment were compared with a paired t test.

RESULTS

Phase 1

Five healthy and continent women 28 to 34 years old were included in analysis. Voluntary pelvic floor contraction yielded a urethral pressure increase over baseline of 60 cm H₂O (range 45 to 75). Pressure increases over baseline induced by clitoral and perineal TMNS are listed in table 1. The highest pressure increases were registered at an amplitude of 2.0 mm for clitoral and perineal stimulation.

On day 2 an amplitude of 2.0 mm was uniformly used based on the day 1 results. Urethral pressure increases due to voluntary pelvic floor contraction, clitoral TMNS and perineal TMNS were consistent with pressures recorded on day 1, and consistent across each TMNS stimulation cycle (table 2).

All 5 women reported a stronger sensation of muscle contraction with perineal compared to clitoral TMNS. Furthermore, they reported greater comfort with the use of the perineal site for the stimulation procedures. Although the objective measurements showed that clitoral stimulation was resulting in a higher pressure contraction, the subjects were quite clear that the better patient acceptability of the perineal site should be weighed heavily in phase 2 of the study. Based on these results it was decided to perform perineal TMNS with a vibratory amplitude of 2.0 mm at 100 Hz frequency in phase 2.

Phase 2

A total of 33 women 19 to 44 years old were enrolled in phase 2 of the study. There was no difference noted in any of the results between those having TMNS performed by the therapist and those performing the procedure at home. Thus, the results from the entire cohort are presented. There were no adverse events reported by any subject. Furthermore, post-TMNS external examinations revealed no sign of skin changes.

The results are shown in table 3. After 6 weeks of TMNS there was a highly statistically significant reduction in the number of incontinence episodes and the number of pads used as recorded in the voiding diary. Of the 33 subjects 24 (73%) were cured and 29 (88%) were cured or the condition

TABLE 1. Urethral pressure increase over baseline in response to voluntary pelvic floor contraction and clitoral and perineal TMNS

Vibratory Amplitude (mm)	Mean ± SD Urethral Pressure Increase Over Baseline (cm H ₂ O)		
	Clitoris Stimulation	Perineal Stimulation	Voluntary Contraction
1.0	18.0 ± 5.1	15.0 ± 3.2	60.0 ± 11.4
1.5	21.0 ± 4.9	19.0 ± 6.6	
2.0	107.0 ± 16.3	77.0 ± 15.4	
2.5	79.0 ± 17.7	66.0 ± 4.9	
3.0	71.0 ± 18.5	67.0 ± 11.7	

TABLE 2. Consistency of urethral pressure increases between voluntary pelvic floor contractions and stimulation cycles in response to clitoral and perineal TMNS at a vibratory amplitude of 2.0 mm

Stimulation Cycle	Mean Urethral Pressure Increase Over Baseline (cm H ₂ O)		
	Clitoris Stimulation*	Perineal Stimulation†	Voluntary Contractions‡
1	120	75	70
2	100	90	60
3	110	60	55
4	90	70	40
5	120	95	70

* Mean ± SD 108.0 ± 11.7.
 † Mean ± SD 78.0 ± 12.9.
 ‡ Mean ± SD 58.0 ± 10.3.

TABLE 4. Cure rate and durability following TMNS

	After Perineal TMNS	3 Mos Later
% Pts cured (No./total No.)	73 (24/33)	67 (22/33)
% Pts cured or improved (No./total No.)	88 (29/33)	79 (26/33)

improved. The results were durable at 3 months with few cases of relapse (table 4).

DISCUSSION

Urinary incontinence is an important problem in society.¹ In a large recent study Hannestad et al surveyed 27,936 women older than 20 years and found an overall incidence of incontinence of 25%.⁸ In a meta-analysis Minassian et al calculated a rate of 27.6%.⁹ Estimates from epidemiological studies vary widely depending on the definition of incontinence, the age of the patient population studied and the methodology applied to the studies. Hannestad et al determined that 20-year-old women experienced a prevalence of 10% vs 35% of women older than 85 years.⁸ Stenzelius et al found that more than 39% of women older than 74 years were incontinent.¹⁰

The financial burden of incontinence on the patient and the health care insurance system is substantial. After a diagnosis of stress urinary incontinence there was doubling of health care costs for subjects undergoing nonsurgical treatment (\$4,478 vs \$9,147) and a tripling of total health care costs for those undergoing surgical treatment (\$4,475 vs \$14,129).¹¹ The lifetime total cost of treating stress urinary incontinence has been estimated to be \$58,000.¹²

Stress urinary incontinence in women represents 50% to 77% of all cases of urinary incontinence.^{1,9} The condition can be caused by poor pelvic floor support leading to hypermobility of the bladder neck and change in the intra-abdominal influence on urethral closing pressure. Intrinsic sphincter deficiency can also lead to stress incontinence even without hypermobility due to inability of the internal sphincter to generate a sufficient closing pressure to maintain urinary

TABLE 3. Reduction in incontinence episodes and pad use with TMNS

	Baseline	After Perineal TMNS
Incontinence episodes/24 hrs:		
Mean (SD)	2.6 (1.1)	0.5 (1.1)*
% Reduction		81
No. pads/24 hrs:		
Mean (SD)	3.5 (0.9)	0.6 (1.3)*
% Reduction		83

* p < 0.001.

control. Often both of these patterns exist in the same patient.

Treatment of SUI has been varied and ranges from simple containment (diapers, etc) without specific treatment of the condition, to Kegel exercises to retrain the pelvic floor muscles, and surgical procedures such as suspensions and sling operations. Unfortunately, since Kegel exercise efficacy is so low, this type of therapy leaves much to be desired. This cure rate with Kegel exercises has been estimated to be 12% to 18%.^{2,4} Surgical sling procedures are effective with a high degree of satisfaction, but the treatment is invasive and has potential complications such as the need for intermittent catheterization or urethrolitholysis to empty the bladder due to obstructive postoperative urinary retention.¹³ There is a great need for the development of an effective, safe and noninvasive therapy for this condition.

Transcutaneous mechanical nerve stimulation through PVS was developed as a method to induce ejaculation in men with spinal cord injury, allowing procreation. After proper vibration parameters were established by Sønksen et al in 1994, PVS became highly successful (more than 90%) in men with SCI with spastic upper motor neuron lesions.⁵

During the course of studying PVS we made certain observations from early studies of fertility of men with SCI that led to other nonfertility related investigations.^{14,15} One was that spasticity of skeletal muscle was suppressed for a period after either ejaculation induction procedure.¹⁶ Furthermore, uncontrolled reflex bladder activity, a common cause of incontinence in people with SCI, was seemingly suppressed as well, as patients noticed an increase in bladder capacity and a decrease in incontinence episodes.¹⁷

A systematic study of the effects of PVS on internal and external urinary sphincter and bladder activity was reported in 2001.⁷ Nine men with SCI with varying lesion characteristics underwent continuous monitoring of sphincter and bladder pressures during ejaculation induction. This investigation certainly added to our knowledge of the physiology of ejaculation, but another interesting observation was made. The application of the vibrator to the penis resulted in prompt and complete relaxation of the spastic bladder. Furthermore, application of the vibrator to those men with SCI with intact reflex arcs caused prompt and forceful contraction of the pelvic floor. Thus, the applicability of external vibration to control bladder activity was theorized.

A study of the effect of intermittent penile vibratory ejaculation on bladder physiology was performed in men with SCI. Intermittent procedures were effective in inhibiting reflex bladder activity. Cystometric bladder capacity at leak point increased from a median of 193 ml at baseline to 290 ml at the end of the study. The effect appeared to be acute and chronic.¹⁸

The current study suggests that TMNS for the purpose of improving continence can also be applied to nonspinal cord injured individuals. The procedure was noninvasive, well

tolerated and highly effective in curing stress incontinence. The results also appear durable, at least up to 3 months. Perineal TMNS was preferable to clitoral stimulation because of subject comfort and subjective sense of contraction efficiency. The efficacy of clitoral TMNS in reducing SUI was not studied.

The exact mechanism by which TMNS improves SUI is not known. Subjective physical examination findings (acknowledging the limitations) would suggest that perineal TMNS allows for efficient training of voluntary pelvic floor muscle contraction. There may also be neuromodulatory effects on reflex sphincter contraction. Current investigations correlating urodynamic findings with efficacy of this treatment are ongoing and may give more information as to the physiological changes associated with TMNS.

Clearly this study is limited as it is a pilot study with no control group. Placebo rates in drug studies for SUI may be as high as 50% in the reduction of incontinent episodes, so the lack of control group here limits our ability to make a final conclusion. These results need to be verified in future studies with an adequate control group and with comparisons to other noninvasive methods of treating SUI such as standard pelvic floor muscle training.

CONCLUSIONS

Significant external urethral sphincter contractions in response to clitoral or perineal vibratory stimulation have been demonstrated in healthy women. Of 33 women 29 with SUI reported resolution (24) or improvement (5) in incontinence symptoms following 6 perineal vibratory stimulations performed once weekly. The effect was durable for 3 months in combination with a standard pelvic floor muscle training program but without additional vibratory stimulation in 27 of 29 women.

Abbreviations and Acronyms

PVS	=	penile vibratory stimulation
SCI	=	spinal cord injury
SUI	=	stress urinary incontinence
TMNS	=	transcutaneous mechanical nerve stimulation

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