Does Fixed-Site High-Frequency Transcutaneous Electrical Nerve Stimulation Provide Analgesia Beyond Application Site? Shai N. Gozani, MD, PhD and Xuan Kong, PhD; NeuroMetrix Inc., Waltham, MA, USA

INTRODUCTION

Transcutaneous electrical nerve stimulation (TENS) is a non-invasive treatment for chronic pain that has no major side effects. Conventional TENS is delivered through surface electrodes at a frequency and intensity that produces a strong, nonpainful sensation. The resulting stimulation of large diameter, deep tissue afferents produces pain relief by decreasing central excitability and increasing central inhibition.

In traditional practice, TENS electrodes are applied to the painful area. Alternative sites are recommended if localized placement is undesirable due to skin irritation or allodynia, or impractical as in the case of phantom limb pain. Stimulation proximal to the pain, distal to the pain, contralateral to the pain, within the same dermatomes as the pain and extra-segmentally have all been shown to be effective.

The widespread analgesic effects of TENS form the mechanistic basis for fixed-site high-frequency TENS (FS-TENS). In this approach, the stimulator is designed for a predetermined location rather than for colocalization with the patient's pain. A single target site enables discreet devices that are suitable for frequent use and are compatible with activity and sleep. FS-TENS has been shown to be effective in chronic lower extremity and low back pain.

In this study, we evaluated whether FS-TENS has widespread effects by comparing outcomes in subjects with and without pain in the area of electrical stimulation.

METHODS

Data previously collected from 130 subjects with chronic pain using an FS-TENS placed on the upper calf was analyzed (Gozani 2016). Inclusion criteria were age≥40 years and low back pain (LBP) or lower extremity pain (LEP) involving the feet or legs for \geq 3 months.

Subjects completed a baseline demographic, medical history and pain (Brief Pain Inventory, BPI-SF) questionnaire. At 60 days, self-rated change in chronic pain (5-point PGIC), self-reported change in analgesic consumption (5-point scale) and endpoint BPI-SF were All subjects signed electronic informed consent at assessed. enrollment.

Table 1 Comparison of baseline demographics and pain characteristics between subjects with and without lower extremity pain

Characteristic

Female: N (%)

Age: N (%) <50 years 50-65 years >65 years

Duration of pain >4

- Number of pain site
- Distribution of pair Low back Upper extremity

Number of painful mean (SD)

Brief Pain Inventor Average pain Worst pain Sleep interference Walking ability in General activity in Mood interferenc Pain relief

Notes: ^aMore than one category per participant may apply. ^btwo sample z-test. ^cPearson chisquared test. ^dMann-Whitney U test. Abbreviations: SD. standard deviation.

Table 2 Change i

Characteristic

Brief Pain Invento Average pain Worst pain Sleep interference Walking ability General activity Mood interferen Pain relief

Abbreviations: SD, standard deviation.

	No Lower Extremity Pain (N=25)	Lower Extremity Pain (N=63)	p-value
	(11-23)	(11-03)	
	9 (36.0)	31 (49.2)	0.26 ^b
	6 (24.0)	17 (27.0)	0.91 ^c
	14 (56.0)	32 (50.8)	
	5 (20.0)	14 (22.2)	
4 years: N (%)	17 (68.0)	39 (61.9)	0.59 ^b
es: mean (SD)	1.9 (1.0)	4.0 (2.1)	<0.01 ^b
n: N (%) ^a			
	25 (100)	50 (79.4)	0.01 ^d
	11 (44.0)	44 (69.8)	0.02 ^d
health conditions:	1.6 (0.82)	2.3 (1.3)	0.02 ^d
ry: mean (SD)			
	5.7 (1.5)	6.0 (1.5)	0.23 ^d
	6.9 (1.7)	7.2 (1.4)	0.55 ^d
e	5.6 (2.5)	7.1 (2.4)	0.01 ^d
nterference	5.2 (2.9)	6.6 (2.5)	0.04 ^d
nterference	5.8 (2.3)	6.7 (2.7)	0.06 ^d
e	5.6 (2.6)	6.3 (2.5)	0.25 ^d
	41 (21)	45 (23)	0.44 ^d

F	From baseline to 60-da No Lower Extremity Pain (N=25)	Lower Extremity Pain (N=63)	p-value
tory: mean (SD)			
-	-0.76 (1.6)	-0.19 (1.6)	0.27
	-0.76 (2.2)	-0.81 (1.7)	0.87
nce	-0.44 (2.4)	-1.4 (2.7)	0.16
v interference	-0.76 (3.9)	-1.4 (2.3)	0.34
y interference	-0.48 (2.7)	-1.3 (2.3)	0.23
nce	-1.0 (3.3)	-0.56 (2.7)	0.45
	16 (25)	16 (27)	0.86

Notes: Brief pain inventory p-values determined by Mann-Whitney U test.

RESULTS

Follow-up data was available for 88 subjects; 25 -LEP and 63 +LEP.

At baseline (Table 1), the groups differed in pain sites (-LEP 1.9 ± 1.0 vs. +LEP 4.0 \pm 2.1, p<0.01), painful conditions (1.6 \pm 0.82 vs. 2.3±1.3,p=0.02), LBP (100% vs. 79.4%, p=0.01), upper extremity pain (44.0% vs. 69.8%, p=0.02), and interference with walking $(5.2\pm2.9 \text{ vs.} 6.6\pm2.5, \text{ p}=0.04)$ and sleep $(5.6\pm2.5 \text{ vs.} 7.1\pm2.4, \text{ s}=0.04)$ p=0.01).

At 60-days, there were no statistically significant differences in PGIC ("improved/much improved", 84.0% vs. 79.4%, p=0.62), reduction in analgesic use ("decreased a-lot/decreased a-little", 60.0% vs. 69.8%, p=0.38), and baseline to endpoint changes in pain intensity or interference (Table 2).

CONCLUSIONS

FS-TENS does not require pain at the site of stimulation to be effective. This result suggests that the analgesic effects of FS-TENS are related to segmental and extra-segmental circuits, likely involving descending pain inhibition.

References

Gozani SN. Fixed-site high-frequency transcutaneous electrical nerve stimulation for treatment of chronic low back and lower extremity pain. Journal of Pain Research. 2016;9:469-479.