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COMPARISON OF PTNS AND TENS ON BLADDER CAPACITY IN THE CONSCIOUS SHEEP MODEL

Hypothesis / aims of study

Two methods of tibial nerve neuromodulation are used clinically for the treatment of overactive bladder. Percutaneous tibial nerve stimulation (PTNS) which is a FDA approved therapy that uses an inserted needle to deliver stimulation directly to the nerve[1]. More recently, tibial-directed transcutaneous electrical nerve stimulation (TENS) which utilizes a non-invasive, superficial patch to deliver electrical stimulation has been investigated[2]. Using a newly developed large animal model[3], we quantified the effects of PTNS and TENS on cystometric bladder function as well as motor thresholds and tolerability in the fully conscious sheep.

Study design, materials and methods

Three adult, female polypay sheep were tested once per week using repeated cystometry, with ten trials per testing session. The first five trials of cystometry were performed without stimulation (Baseline) followed by tibial nerve stimulation for the remaining five trials (Stimulation). Stimulation (bilateral, 10 Hz, 0.21 ms pulses, at maximum tolerable amplitude) was terminated until the next week's session. Sheep were randomized to either a percutaneous needle (PTNS Stim) or a pair of transcutaneous patches (TENS Stim) placed at the distal tip of the tibia and fibula bones to mimic clinical usage. To ensure no carry over effect, two weeks of cystometry were performed with no stimulation between PTNS and TENS testing. Sheep then received the other form of tibial stimulation for two weeks. Motor thresholds and maximum tolerable amplitudes were used as previously described[3]. Urological data were analyzed with a Mann-Whitney Rank on Sums test using unpaired data, with a p < 0.05 considered significant (SigmaPlot, San Jose, CA).

Results

Five test sessions from three sheep were collected and analyzed for acute PTNS and TENS stimulation. Motor thresholds were identified as the first visible reflex to electrical stimulation and were 2.9 ± 0.4 V for PTNS and 19.2 ± 3.9 V for TENS. Maximum tolerable amplitudes used for stimulation during cystometry were 3.3 ± 0.4 V for PTNS and 20.7 ± 4.3 V for TENS.

The median bladder capacity for PTNS baseline trials was 44 ml and increased to 96 ml during PTNS stimulation trials (p < 0.05). In contrast, the median bladder capacity for TENS was 55 ml for baseline trials and 62 ml during stimulation trials and was not significantly different (p > 0.3).

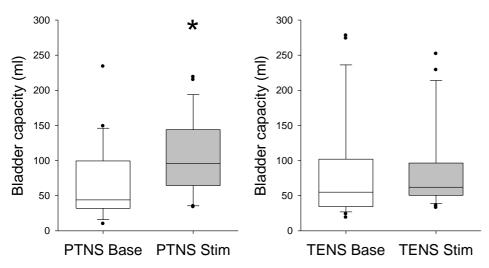


Figure 1: PTNS, but not tibial-directed TENS, significantly increases bladder capacity.

Interpretation of results

These data clearly demonstrate the acute effect of PTNS in increasing functional bladder capacity. The increase in bladder capacity was similar to that seen with sacral neuromodulation³. Interestingly, tibial-directed TENS did not evoke an alteration in functional bladder capacity, even though a motor response could always be evoked. One reason for the urological difference between these two approaches may be the location of the electrical field. In PTNS, the needle is in close apposition to the nerve and the resulting electrical field alters activity in the tibial nerve. For tibial-directed TENS, the patches are on the surface of the skin, where the distance from the nerve and the high resistance of skin may not allow full activation of the tibial nerve.

Concluding message

In the fully conscious sheep, PTNS evokes a motor response and a significant increase in bladder capacity. In contrast, tibialdirected TENS evoked a motor response but did not alter bladder capacity. Future work will more fully investigate stimulation parameters as well therapy delivery optimization.

References

- 1. Moossdorff-Steinhauser HF and Berghmans B. Effects of percutaneous tibial nerve stimulation on adult patients with overactive bladder syndrome: a systematic review. Neurourol Urodynam, 32(3): 206-214, 2013.
- 2. Tellenbach M, Schneider M, Mordasini L, Thalmann GN and Kessler TM. Transcutaneous electrical nerve stimulation: an effective treatment for refractory non-neurogenic overactive bladder syndrome? World J Urol, 31(5): 1205-1210, 2013.
- 3. Brink TS, Zimmerman PL, Mattson MA, Su X and Nelson DE. A chronic, conscious large animal platform for quantifying therapeutic effects of sacral neuromodulation on urinary bladder function. J Urol, doi: 10.1016/j.juro.2015.01.109, 2015.

Disclosures

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