

Ghonaime EA, Craig WF, White PF, Ahmed HE, Hamza MA, Henderson BN, Gajraj NM, Huber PJ, Gatchel RJ. Percutaneous Electrical Nerve Stimulation for Low Back Pain. JAMA 1999;281:818-23.

Design: Randomized crossover trial.

Population/sample size:

- 60 patients (29 men, 31 women, mean age 43), with 3 months or more of low back pain due to ‘radiologically confirmed degenerative disk disease,’ maintained at a stable level for at least 3 months with oral non-opioid medication
- Excluded if long-term use of opioid analgesics, change in character/severity of back pain in last 3 months, acute sciatica, past use of non-traditional therapies, pending workers’ compensation claim

Main outcome measures:

- Principal outcomes were the changes in VAS scores for pain, level of physical activity, quality of sleep (all scored on a scale from 0 to 10); also the changes in SF-36 physical (PCS) and mental (MCS) component scores before and after receiving each of four interventions: percutaneous electrical nerve stimulation (PENS), sham PENS, transcutaneous electrical nerve stimulation (TENS), and supervised exercise
- Each patient received each intervention 30 minutes 3 times a week for 3 weeks (9 sessions), with 1 week between interventions; the sequence was determined by a random process by computer
- PENS consisted of placement of ten 32-gauge acupuncture-type needle probes into the soft tissue in the lower back to a depth of 2 to 4 cm in the dermatomal distribution of the pain, with a 4 Hz frequency electrical pulse whose intensity was adjusted to produce the maximum tolerable “tapping” sensation without muscle contraction
- Sham PENS consisted of an identical placement of needles, with no electrical current applied to the needles
- TENS consisted of placement of 4 cutaneous electrical pads in a standard dermatomal pattern, with a stimulation frequency of 4 Hz
- Exercise consisted of spine flexion and extension with the patient seated on a chair with hips abducted; the patient slowly touched the floor with both hands while remaining seated, with at least 30 repetitions per 30 minute session
- PENS associated with greater improvements in SF-36 scores than TENS, sham PENS, or exercise at end of 4 week periods of each intervention
 - o On the SF-36, average improvement with PENS was greater than the average improvement with TENS on the PCS (4.66 points), was greater than sham PENS (4.97 points) and exercise (5.82 points)
- PENS associated with improvements in VAS scores for pain, activity, and sleep from baseline to end of the 3 week treatment period; sham PENS and exercise did not reduce pain measurably, and TENS produced a reduction in pain which was smaller than that for PENS

- Oral analgesic use was reduced by 50% with PENS, beginning on the second day of treatment and continuing for 20 days of treatment; TENS reduced analgesic use to a lesser degree, and for only 6 of the 21 day treatment period; sham PENS and exercise did not reduce analgesic use for any of the 21 days of their administration
- PENS preferred by 91% of patients as ‘most desirable modality,’ and would pay out-of-pocket to receive PENS in the future

Authors’ conclusions:

- PENS more effective than TENS & exercise in short-term relief of low back pain
- Prolonged trial of PENS with longer follow-up needed to measure long-term effects
- Ongoing exercise program needs to be incorporated in PENS therapy

Comments:

- “Radiologically confirmed” disk disease may not be valid classification, since imaging tests not shown to identify discogenic pain
- Carryover effects (1 week between interventions) not measured, and there is no report of period effects, which are therefore not distinguished from treatment effects
- Figures 2 and 3 (pain, activity, sleep, and analgesic use) provide a display of data for only the 21 days during which each treatment was administered; no data is presented for the 7 day washout period, and it cannot be determined whether PENS had a carryover effect of even one day
- TENS usually applied prn under the control of the patient; this trial applied TENS on fixed schedule in the clinic only, and does not constitute a valid comparison of PENS with actual TENS use
- The administration of TENS, sham PENS, and exercise (fixed schedule in clinic) was probably done to create structurally similar placebo comparisons to PENS; this is reasonable for methodological purposes, but the cost is high: a TENS comparison which sheds little light on what would have happened if TENS had been used in its usual manner in the real world
- Although some PENS comparisons with other interventions (namely, the MCS component of the SF-36) are reported as if they were significant, the standard deviation of the difference for each of these comparisons is greater than the mean difference; they appear not to differ any more than could occur by chance

Assessment: Inadequate for evidence about the superiority of PENS over TENS (crossover studies need to report period, crossover, and treatment effects; the administration of TENS does not model its use in clinical practice)
 Adequate for evidence that PENS is superior to placebo or sham PENS