Critique author	Edward Whitney
Bibliographic Data	
Authors	Blum K, Chen AL, et al
Title	The H-Wave® Device Is an Effective and Safe Non-Pharmacological Analgesic for Chronic Pain: a Meta-Analysis
PMID	18636234
Citation	Adv Ther 2008;25(7):644-657
Other information if relevant	

Methods	
Aim of study	To review and summarize the data on the efficacy and safety of the H-wave device as a nonpharmacologic intervention for chronic soft tissue inflammation and chronic pain
Design	Meta-analysis of published studies of the H-wave device

	Reasons not to cite as evidence
Objectives of the systematic review or meta-analysis	- PICOS criteria require that the research question be stated in terms of an intervention and a comparison or control intervention - The control interventions are not specified for the H-wave studies, making it necessary to examine the individual studies - The Blum & DiNubile 2006 study is essentially a case series with no control group - The Blum & Chen 2006 study is also a case series with no control group - Kumar & Alvaro 1998 used sham H-wave as a control group, as did Kumar & Marshall 1997 - Julka & Alvaro 1998 did not have a control group - None of the studies compares H-wave with other commonly available electrical stimulation devices such as TENS - Consequently, it is not possible to assess whether H-wave is equal to, more effective than, or less effective than other e-stim interventions for any outcome

Study selection	- The authors cited Jadad 1996 as a quality scale, but the Jadad scores are not reported for the individual studies in their Table 2 - Because Jadad scores only apply to randomized trials, the three studies without a control group would have a score of 0 for that scale - Kumar 1997 and Kumar 1998 are reported as single-blind randomized trials, but the method of randomization is not reported, and this is one of Jadad's criteria - In addition, the Division uses other criteria for ensuring that there has been adequate control of the risk of bias, including allocation concealment, which protects against selection bias in randomized trials; neither Kumar paper met this criterion - Neither Kumar study reports a functional outcome for H-wave; both studies report only pain score outcomes - The Division also uses selective outcome reporting as a criterion for control of bias; this entails a criterion that the authors of a randomized trial specify a primary outcome in the methods section, along with any secondary outcomes which may be measured; neither randomized trial designated a primary outcome measure
Meta-analysis presentation	- Table 2 does not display a forest plot for the included studies, which is acceptable for systematic reviews in which the authors decide not to pool the study data in a single summary estimate, but is necessary for the interpretation of a meta-analysis - Table 2 combines effect sizes from studies with and without control groups, which is problematic, since an effect size from a study with a control group will be expressed as a difference between the two groups in the study, and a case series study does not measure the effect in a control group; this probably explains why a forest plot was not done in Table 2 - Therefore, the summary measure for reduction in pain is unacceptable as evidence for the effectiveness of the H-wave
Additional comments	- Because there are no studies comparing H-wave with other active treatments, the meta-analysis fails to present evidence that H-wave should be preferred to TENS and other e-stim devices - It does not appear that any studies since 2008 have compared H-wave with other interventions - The five studies included in the meta-analysis have been done by only two investigator groups, one led by Kumar and the other by Blum - This meta-analysis has been cited only three times in the past nine years, twice by Blum in 2008 and 2009 and once by a 2013 Cochrane review on interventions for complex regional pain syndrome, suggesting further that work on this device has not progressed since 2006, when the two Blum studies were published - Although it is likely from the two Kumar studies that H-wave is superior to placebo, the same claim can be made by other devices, and there is no reason to prefer H-wave over any of these devices

Additional references

- Kumar D, Alvaro MS, Julka IS, Marshall HJ Diabetic peripheral neuropathy. Effectiveness of electrotherapy and amitriptyline for symptomatic relief. Diabetes Care. 1998 Aug;21(8):1322-5
- Kumar D, Marshall HJ. Diabetic peripheral neuropathy: amelioration of pain with transcutaneous electrostimulation. Diabetes Care. 1997 Nov;20(11):1702-5.
- Blum K, DiNubile NA, et al. H-Wave, a nonpharmacologic alternative for the treatment of patients with chronic soft tissue inflammation and neuropathic pain: a preliminary statistical outcome study. Adv Ther. 2006 May-Jun;23(3):446-55.
- Blum K, Chen TJ, et al. The H-Wave small muscle fiber stimulator, a nonpharmacologic alternative for the treatment of chronic soft-tissue injury and neuropathic pain: an extended population observational study. Adv Ther. 2006 Sep-Oct;23(5):739-49.
- Julka IS, Alvaro M, Kumar D. Beneficial effects of electrical stimulation on neuropathic symptoms in diabetes patients. Journal of foot and ankle surgery 1998;37(3):191-4
- Jadad AR, Moore RA, et al. Assessing the Quality of Reports of Randomized Clinical Trials: Is Blinding Necessary? Controlled Clinical Trials 1996; 17:1-12