ANESTHESIA & ANALGESIA

Journal of the International Anesthesia Research Society, the Society of Cardiovascular Anesthesiologists, the Society for Pediatric Anesthesia, the Society for Ambulatory Anesthesia, the International Society for Anaesthetic Pharmacology, and the Society for Tecnology in Anesthesia

Abstracts of Posters Presented at the International Anesthesia Research Society
77th Clinical and Scientific Congress
New Orleans, LA • March 21-25, 2003

S-213

SYMPTOMATIC TREATMENT OF CHRONIC LOW BACK PAIN: DETERMINATION OF OPTIMAL SIGNAL FREQUENCY AND PRELIMINARY EFFICACY OF A TARGETED NON-INVASIVE ELECTRONIC PAIN CONTROL DEVICE

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INTRODUCTION: The Biowave System (Biowave Corporation, Norwalk, CT) introduces two premixed high frequency wave forms (feed signals) through an electrode placed on the skin opposite the pain site (feed electrode). The electric field contains a low frequency component (beat frequency) equal to the difference between the feed signals. The feed signals pass through the body to a second electrode at the treatment site (pain site electrode). The feed signals mix, yielding an electric field equivalent to the beat frequency component, which is believed to interrupt transmission of pain impulses by preventing action potential propagation along pain fibers. This technology is being explored as a novel therapy for treating chronic, acute or post-surgical pain.

METHODS: Volunteers consented to undergo 3 treatment sessions in either of 2 phases with varying beat and feed frequencies separated by at least 24 hours. Criteria for inclusion: age 18-60, low back pain (below T12) for >3 months without radiation, and Visual Analog Scale (VAS) pain score of ≥4 out of 10 at screening. Exclusion criteria were pregnancy, presence of a pacemaker or other implantable devices, cardiac arrhythmias, epilepsy, low back surgery, alcohol or drug abuse, or significant medical or psychological conditions. Subjects were connected to the Biowave device by application of a large hydrogel feed electrode (12.7 cm x 20.3 cm) to the abdomen and a smaller pain site electrode (5.1 cm diameter) to the lower back over the source of the pain. Subjects increased the power output of the device until strong tingling/pressure was felt; treatment continued for 20 min. Patients completed VAS pain assessments at baseline, after 20 min of treatment, and at 10 and 30 min after the device was turned off.

RESULTS: 29 patients were enrolled; at least 3 subjects completed each group. The only adverse reaction observed was skin irritation and minor blistering on one patient at the pain site electrode (n=1).

Feed Freq. (kHz)	Beat Freq. (Hz)	n	VAS Rating Baseline	VAS Rating @20 min	VAS Rating @30 min	VAS Rating @50 min
Phase 1						
8	122	3	4.9±0.8	2.5±1.6	2.6±2.2	1.7±0.8
13.33	122	8	6.7±1.5	4.3±3.0	2.8±1.7**	2.6±2.2**
26.8	122	5	5.7±0.6	2.6±0.8**	1.6±1.3**	2.0±2.2**
Phase 2						
8	90	7	5.3±1.0	2.3±2.1*	1.9±1.1**	3.3±2.5
8	122	3	5.0±1.3	1.6±0.7*	2.6±1.6	0.9±0.4*
8	150	3	5.9±1.8	3.6±2.7	1.8±2.5	0.9±1.1

*p<0.05, **p<0.01 vs. baseline by ANOVA with Dunnett's post-hoc test.

DISCUSSION: At a beat frequency of 122 Hz, all 3 feed frequencies tested produced comparable analgesia as evidenced by >50% reductions in VAS at 30 minutes post-treatment (VAS Rating at 50 min). Variations in beat frequency at a feed frequency of 8 kHz showed significant pain reductions for 122 and 150 Hz, particularly at 30 minutes post-treatment (VAS Rating at 50 min). Analgesia persisted for at least 30 min after the treatments. Further studies are warranted to confirm the efficacy and safety of the system, as well as the duration of analgesia. The data suggest that the Biowave System is effective in the symptomatic treatment of chronic low back pain.

Supported by a grant from Biowave Corporation.