Journal of Anesthesiology and Pain Research

Markowitz et al., J Anesthesiol Pain Res 2019, 2:1

Research Article Open Access

The Effect of Surface Acoustic Wave (SAW) Device on the Symptomatology of Trigeminal Neuralgia

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Received date: January 8, 2019; **Accepted date:** January 14, 2019; **Published date:** January 22, 2019

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Abstract

The Authors evaluate the effect of a Surface Acoustic Wave device (NanoVibronix Inc. Elmsford, NY, USA) on the symptomatology of Trigeminal Neuralgia. 59 subjects completed the trial. This was a double-blinded randomized control trial that measured subjective pain relief as measured by VAS and subjective results measured by the reduction of use of breakthrough narcotic medications. There was a significant reduction in subjective pain reported as well as in the number of uses of breakthrough opioid medications. There was trending towards an increase in quality of life scores. The investigational device had no adverse events or complications and was deemed both safe and efficacious.

Keywords: Trigeminal neuralgia; Surface acoustic waves; Ultrasound; Opioid

Introduction

Trigeminal neuralgia was defined by the International Association for the Study of Pain as a sudden, usually unilateral, severe, brief, stabbing recurrent pain in the distribution of one or more branches of the fifth cranial nerve [1]. The International Headache Society (Anonymous 2004) set the following criteria for trigeminal neuralgia.

A. Paroxysmal attacks of pain lasting from a fraction of a second to two minutes, affecting one or more divisions of the trigeminal nerve and fulfilling criteria B and C.

B. Pain that has at least one of the following characteristics:

1. Intense, sharp, superficial or stabbing.
2. Precipitated from trigger areas or by trigger factors:

- Attacks are stereotyped in the individual patient
- There is no clinically evident neurological deficit
- Not attributed to another disorder [2]

Koopman reports that the annual incidence of TN in the United States is 12.7 per 100,000 adults [3]. Devor reports that Compression of the trigeminal nerve root, at or near the dorsal root entry zone, by a blood vessel is a major causative or contributing factor [4]. Cheng reports that other rare causes include infiltration of the nerve root, trigeminal ganglion or nerve by a tumor or amyloid, and small infarcts or angiomas in the pons or medulla [5]. The pain of idiopathic trigeminal neuralgia is indistinguishable from that caused by a demonstrable structural lesion other than vascular compression. Zakrzewska reports that as the attacks become more frequent, the patient may develop persistent pain between episodes. Attacks may come in clusters and can completely disrupt activities of daily living if left untreated [6].

Antiepileptic drugs have been used in pain management since the 1960s. The clinical impression is that they are useful for neuropathic pain, especially when the pain is lancinating or burning [6-9]. Non-antiepileptic drugs have been used to treat trigeminal neuralgia since the 1970s, but studies have shown mixed efficacy [10-12]. Surgical treatments divide into two main categories: ablative (destructive to the nerve) or non-ablative (preserving nerve function and decompressing the nerve). The only non-ablative technique is microvascular decompression, in which no damage to the trigeminal nerve is intended but it is the most invasive of all the procedures and necessitates on average a five-day hospital stay. Ablative procedures can be done at three anatomical levels: peripheral, Geassrian Ganglion or Posterior Fossa. All surgeries have limited evidence of efficacy with few RCT's performed and the results vary from study to study [13-15].

Ultrasound is a directed acoustic wave that has varying physiological effects depending on the intensity, frequency, and amplitude of the wave. Acoustic waves range from Surface Acoustic Waves (SAW) at the low end of frequency to Shockwaves at the high end. SAW has been shown to decrease inflammation, cause neo-



Figure 1: PainShield device.

angiogenesis, increase blood flow and tissue oxygenation, and to repair and regenerate soft tissue. It has also been found to have a bactericidal effect, as well as being a significant pain modulator [16-19]. The authors evaluate the PainShield device (NanoVibronix Inc. Elmsford, NY, USA). The device (Figure 1) is a self-contained SAW actuator at a fixed frequency and intensity. The authors evaluate the device for the mitigation of symptoms in TN and the reduction of breakthrough medication use.

Methods

Before initiating enrollment in the study, IRB approval was received (Salus IRB, Austin, TX).

Subject selection

Subjects were identified from a number of sources. Patients coming to the Neurology clinic and suffering from TN were offered enrollment. Also, an email advertisement was sent to all members of the Facial Pain Association, a patient support group, offering to screen for potential enrollment in the study. All applicants were screened by a member of the study staff and determination of eligibility was decided. In total 59 subjects were enrolled and were able to complete the study.

The device

The PainShield is a self-contained SAW device, comprising a driver and an actuator patch. The patch generates acoustic waves at approximately 96 kHz. The patch is attached on the lateral face (Figure 2), and if necessary can be further held in place with a self-adhesive bandage. The device produces active acoustic waves for 30 minutes and then idles with no acoustic wave generation for thirty minutes. The device cycles for six and a half hours before automatically shutting off.

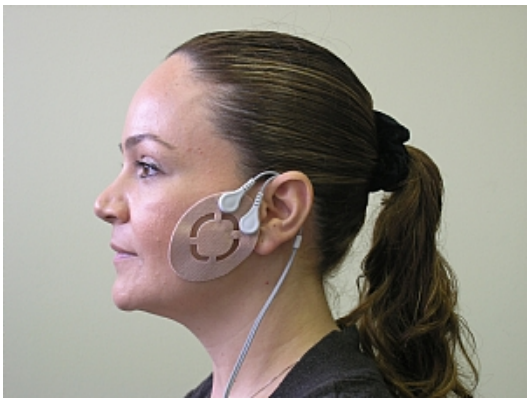


Figure 2: PainShield placement for TN.

Study methodology

This was a double-blinded Randomized Controlled Trial. Subjects were randomized to either the control group or the treatment group. Prior to enrollment, all subjects listed their pain management regimen including their breakthrough medications. They were also asked to fill in a daily Visual Analog Scale (VAS) for their average daily pain, as well as a detailed medication log, for one week leading up to initiation of the study. Average weekly VAS was calculated and established as the baseline for each subject. The number of uses of breakthrough medication was also averaged out for the week and established as the subject's baseline. Also, subjects were asked to fill out a number of Quality of Life Questionnaires, and the responses were established as a baseline.

Subjects were then given a PainShield Device. Outwardly there was no difference between the active and the sham devices. The sham devices were even programmed to emit an electric hum identical to that of the active device to further blind the subjects and investigators. Subjects were told to use the device for the entire night while they slept. They were shown how and where to place the actuator patch, as well as how to properly use and care for the device. Subjects were asked to fill out daily VAS scales, as well as daily medication logs.

After thirty days of using the device, subjects returned for a follow-up evaluation and their VAS and Pain Medication logs were collected. Also, they were asked to fill out a series of QOL questionnaires that were used as comparators to the baseline. The results of the last week of VAS scores were averaged as was the last week's number of uses of breakthrough medications, and these were used as comparators to the baseline.

Results

59 subjects were recruited and completed the study. Thirty of the subjects were male and 29 were female. The ages of the subjects ranged from 36-68. All of the subjects had been diagnosed with TN for a minimum of 9 months. All were on a pain medication regiment that was unchanged for 90 days prior to beginning the study. Breakthrough medications included: Percocet, Oxycodone, Hydrocodone, Codeine, and Morphine patches.

The figure shows that subjective pain scales measured by VAS (0-10) showed that at baseline the active and control groups were statistically comparable; 8.12 (active) to 8.00 (control) (Figure 3). At the end of four weeks, the active group averaged 3.65 while the control group reported 7.82. This was statistically significant ($p<0.01$). The active group reported a 55.05% difference in their reported pain as compared to 2.25% in the control group.

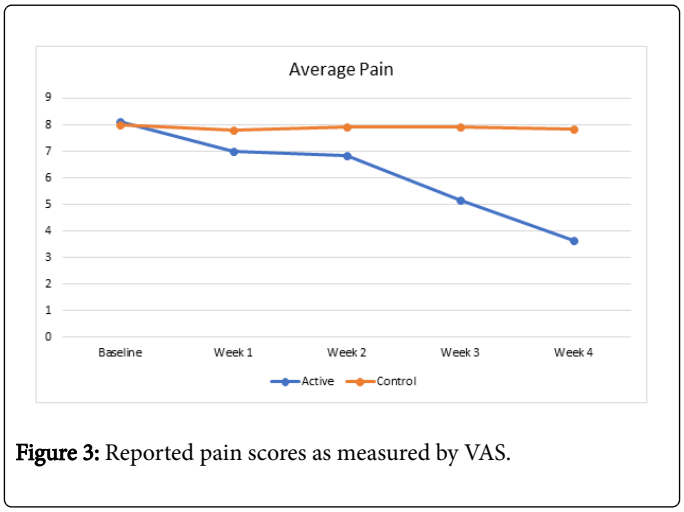


Figure 3: Reported pain scores as measured by VAS.

The weekly average use of breakthrough medications showed that at baseline both groups were statistically comparable, with the active group reporting an average of 16.06 weekly uses of medication compared to 14.39 uses in the control group as shown in the figure below (Figure 4). At four weeks the active group reported 8.61 uses as compared to 14.17 uses in the control group. This was statistically significant ($p<0.01$). The active group reported a 46.4% decrease in breakthrough drug use as compared to 1.52% in the control group.

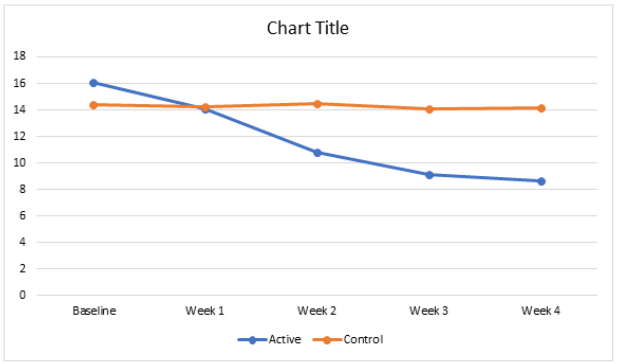


Figure 4: Average number of uses of breakthrough medications.

Quality of Life measurements showed a non-significant difference between the groups at four weeks, although there was a statistical trending in the active group as compared to the control group. The active group showed a 25% change in their subjective QOL scales as compared to 1.5% in the control group.

Discussion

Trigeminal Neuralgia is a serious condition that severely affects those who suffer from it. Typical pain medications are for the most part ineffective in controlling the pain, and patients often have to utilize significant amounts of narcotics in order to attain a modicum of analgesia. Surgical procedures abound, but patients relate varying degrees of success as well as an overwhelming amount of recurrence. This study evaluated the PainShield SAW device for the reduction of symptoms in patients suffering from TN. The study was a well-designed, double-blinded, randomized controlled study. The device was utilized for thirty days and subjective and objective data was obtained daily. The results at the end of the thirty-day period were compared to the results obtained at baseline. While these results were significant for the immediate effect, the evaluation of the long-term effect of the device could not be evaluated. Further evaluation of the chronicity of the effect of the device is required. Alternatively, a study utilizing the device for longer than thirty days would be required in order to evaluate if the device could provide a sustained effect.

The significant reduction in symptomatology can be attributed to a number of known physiologic effects of US. First, by reducing inflammation caused by the compression of the artery on the nerve. Second, the increase in blood flow through the area could have had a positive effect on the damaged artery compressing the nerve. Also, the regenerative effect of US would have been affecting the damaged nerve itself and causing healing of the injury. The results showed a significant reduction in pain as well as the use of breakthrough medications. Because of the short duration of the trial, patients were wary to approach their physicians to alter their base medication regiment. Breakthrough medication, however, was left up to the subjective determination of the subjects and was, therefore, able to be significantly reduced, even in the short term.

The significant reduction of breakthrough pain medication use is of particular note with the opioid abuse crisis. The reduction of narcotic use by almost 50% in a one-month period is significant. The reduction of pain was consistent among subjects, both in time to onset of relief as well as the level of relief. This is probably due to the sameness of the therapy being provided to all subjects, and the use of bone as a conducting medium to further spread the effect of the acoustic wave. The trending in the QOL's is indicative that with sustained reduction of pain and the consequent reduction of narcotic use, this trend would become significant. The reason behind the trending opposed to statistical significance is multifaceted. First, with the delay in onset of the reduction of symptoms, subjects were not given a full month of relief to report on. Second, the reduction in pain medication use would have an immediate effect on scores regarding wakefulness, alertness and ability to work. Scores regarding happiness and emotions will have a much later effect. It is the author's belief that with extended continued use of the device, these scores will also be positively affected.

No adverse events were reported. The main fear with continued US use is a thermal injury. Because of the low intensity of the investigated device, this was not a concern. A few subjects reported some difficulty in keeping the SAW patch attached and in place, but this problem was resolved almost immediately and without complication. Subjects reported an ease of usability of the device, which helped to increase compliance to the trial, thus also contributing to the greater effect.

Conclusion

The PainShield SAW device is very effective at controlling the symptomatology of TN. In addition, use of the device can mitigate the need for the use of breakthrough narcotic medications.

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