

Neuropathy and Veterans

(The Hidden Epidemic Behind the Veteran Opioid Crisis)

BACKGROUND:

The Foundation was started in 2006 with four objectives and purposes: 1. To provide education and training to qualified microsurgeons, which will increase the number of surgeons trained to operate and correct neuropathy. 2. To conduct research relating to improving nerve technology and research relating to understanding the process of nerve pain and nerve death. 3. To provide charitable financial assistance to those patients with neuropathy who are unable to afford surgery. 4. To engage in any related activity and to provide charitable assistance related to the activities described above.

NEUROPATHY COSTS AND DEMOGRAPHICS:

It is estimated that greater than 20 million Americans are afflicted with painful neuropathy. Given the stigmata associated with peripheral neuropathy such as, chronic pain (exposing them to much higher risk of opioid addiction), neurological and motor disability resulting in the inability to work, ulcerations, wound infections, and amputations requiring long term hospital stays. Neuropathy has an enormous economic cost to our society. Over 90% of neuropathic patients are prescribed one or more pain medications with the most frequently prescribed medication being opioids (53.0%), followed by antiepileptic drugs (49%), and then anti-depressants (<20%) with the total mean annualized costs after adjusting for relevant demographic and clinical covariates totaling \$27,259 per patient (95% CI 25,199-29,319).¹ Therefore, we can then estimate the annual economic burden on the US Economy for symptomatic neuropathy to be in the range of \$500 billion annually, not including the cost of opioid addiction on society. If we include the cost of opioid addiction (including transition to heroin) based on the National Institutes of Health's National Institute of Drug Abuse (revised March 2018) numbers², where 21% to 29% of chronic pain opioid patients misuse them and 4% to 6% of people who misuse opioids transition to heroin and the White House Council of Economic Advisers³ (report November 2017) report where the average per person cost of chronic opioid misuse is approximately \$208,000, then we expect to add another approximately \$500 billion to the estimated cost.

To put this in perspective, we would expect the annual economic burden of just 500 patients (our study size) to be around \$13.5 million annually with an additional \$13.7 million opioid misuse costs. Furthermore, painful neuropathy is particularly more prevalent in Veterans who have certain service-related exposures (e.g. Agent Orange, Herbicides, Persian Gulf Syndrome, High Velocity, Acoustic and/or Cavitation Weapons Exposures, Conventional Traumatic Injuries, and other military service exposures).

Finally, neuropathy is present in up to 60% of diabetics while Pacific Islanders, South Asians, and Filipinos have the highest diabetes prevalence among all racial/ethnic groups including minorities traditionally considered high risk. Therefore, we would anticipate that Veterans from these racial groups would have the highest rates of symptomatic neuropathy among all racial/ethnic and occupational categories in the United States representing a key research target group for researching for a potential cure for neuropathy.

METHODS:

The goal of this long-term study⁴ (10 to 20 years in duration) is to demonstrate that High Motor Evoked Potential at Release (“high EMG”) Intra-operative Nerve Monitored (IONM) surgical patients (52% of patients) have enduring reversal (i.e. cure) of lower extremity neuropathy (which is currently considered incurable) and the quality of life (QOL) of these “high EMG” IONM surgical patients is greater or equal to similarly rated non-surgically treated neuropathic patients (Case-Control Study). “high EMG” IONM Neuropathy Microsurgery has been independently validated⁵ in 2017 by a surgeon trained by Dr. Edwards’ Medtronic (New Therapy Development) training video (included).

Finally, we wish to demonstrate that “high EMG” IONM patients would require less pain medications for their neuropathy compared to non-surgically treated patients. The internal control for the initial IONM study was the paired unoperated leg of the study subject and for the external controls we have recruited control subjects treated non-surgically at outside clinics. The final experimental and control data set, which will be completed in 2019 and 2020, may also be used to look at further future interventions (Cohort Studies) on subjects which claim to provide relief of neuropathic conditions and other elements of neuropathic pain in the context of military exposure and other unknown parameters.

RESULTS:

IONM microsurgical neuropathy data was previously compiled from 111 surgery subjects from 2006-2008 (pre-surgery data, post-operative data and 1-year post surgery data) which was compiled at the time of discovery of acute motor evoked potential changes during neuropathy microsurgery. For non-surgically treated contemporaries (N= 500 control arm goal) data was analyzed from 620 veteran family research subjects recruited from a Neurology pain. 99.2% of subject response data was entered into research database in 2015 (Positive Neuropathic Sensory Symptoms and Neuropathy Instrument Screening Questionnaires included here). Positive symptomatic lower extremity neuropathy was found in 80% of subjects from Veteran families (high risk racial category) which yielded a final non-surgical control arm of N=497. Furthermore, greater than 93% of Veteran respondents in the pain clinic control survey had symptomatic lower extremity neuropathy representing a major health risk in Veterans and current active military personnel. In order, to validate the long-term effectiveness of the surgical intervention to cure neuropathy, in 2019, we will home survey (door to door interviews to ensure highest completion rate) the 111 original IONM surgical patients (2006-2008 surgical group) and compare this outcome data to a follow-up of our 497 non-surgically (VA) treated chronic neuropathy subjects via mail or in clinic.

CONCLUSION:

We believe this long-term study will have the potential to dramatically improve the lives of veterans and substantially reduce the costs of care on our society for neuropathic Veteran patients by providing a curative option for at least one-half of lower extremity neuropathy sufferers while avoiding the use of addictive pain medications. In summary, we believe that neuropathy is the heretofore hidden “gateway” leading to the opioid addiction crisis in Veterans. The diagnosis of peripheral neuropathy in Veterans results in a service disability rating assignment and we will need to assess if this “designation” or diagnosis is substantially different in the VA Healthcare setting versus private healthcare environments treating Veterans who are detached from disability rating cost economics.

REFERENCES:

¹ *Pain severity and the economic burden of neuropathic pain in the United States: BEAT Neuropathic Pain Observational Study, Schaefer, C. et al. ClinicoEconomics and Outcomes Research 2014;6 483-496.*

² <https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis> (National Institutes of Health National Institute of Drug Abuse “The Opioid Crisis” March 2018)

³ *The Underestimated Cost of the Opioid Crisis. Executive Office of the President of the United States. The Council of Economic Advisers, November 2017.*

⁴ *Long term reversal of distal symmetric polyneuropathy by guided real-time motor evoked potential microsurgical decompression of localized nerve entrapments: A 10+ year retrospective review of disease progression in surgical patients compared to non-surgically treated controls. Edwards M.C. Protocol Number: 690344, IRB Approval Number: IRCM-2018-200. 2018*

⁵ *Acute improvement in intraoperative EMG following common fibular nerve decompression in patients with symptomatic diabetic sensorimotor peripheral neuropathy: 1. EMG Results. Anderson JC et al. J. Neurol Surg A 2017; 78: 419-430.*