Title
Retrospective Studies of Opiate Utilization After Implementation of Spinal Cord Stimulators

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I. Background Information and Significance

Pain has been defined as “an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.” (2) Furthermore, neuropathic pain is a particular kind of pain that is specific to the dysfunction of the nervous system. It is often described as shooting, radiating, or burning. It is estimated that about 1.5% of the population in the United States have neuropathic pain, and is often times very difficult to manage. (1) Pain that is present for longer than 6 months or has symptoms that last longer than would be expected for tissue healing is considered chronic pain. Chronic pain often becomes a cause physical and emotional suffering that affects people in multiple aspects of their life. Unfortunately, a large proportion of people with chronic neuropathic pain fail to obtain pain relief with a pharmacological approach. Patients with chronic pain may have a diagnosis of failed back surgery syndrome and complex regional pain syndrome. People who are said to have intractable pain due to these diagnoses are a candidate for spinal cord stimulation. The role of SCS is to achieve pain control where other pharmacological management approaches fail to do so.

Shealy et al, (1967) first described spinal cord stimulation as therapy for chronic intractable pain as early as 1967. (6, 7) Since its initial conception, SCS has evolved in technical and methodological aspects. Some of the dissatisfaction that SCS has faced is its limited role to provide long-term pain relief in patients with chronic pain problems. Improvements in the 1990s have permitted SCS to target specific dermatomes providing paresthesia (that result in pain relief) to certain anatomical regions leading to improved long-term outcomes.

SCS achieves its efficacy in relieving intractable chronic pain by providing a low voltage stimulus to nerve fibers along dorsal column of the spinal cord. Its function is based on the gate control theory based on the work performed by Drs. Melzack and Wall in 1965. In a healthy human, normal sensation is conducted through the large-diameter A beta fibers (transmitting touch sensation) and nociceptive small un-myelinated C fibers (transmitting pain sensation). The theory asserts that stimulation of dorsal column A beta fibers activate inhibitory interneurons in the dorsal horn that interfere with nociceptive C fibers signaling, thus attenuating pain. Other mechanisms are
likely at play including afferently (orthodromic) mediated supraspinal signals that include: 1) activation of noradrenergic (NE) signaling and 2) serotonergic system (5HT) signaling, both through descending dorsolateral funiculus (DLF). This DLF signaling activates gaba-ergic inhibitory interneuron therefore suppressing C fiber nociceptive mediated message. Opiate medications can act through a similar supraspinal noradrenergic system therefore possibly superseding one mechanism SCS mediated pain reduction (4).

II. Specific Aims

- **Aim 1:** To determine if there is a change in pain based on the visual analogue scale, as well as perceived pain reduction reported when comparing pretrial to post trial clinic visits.
- **Aim 2:** To identify changes in opioid use when comparing pre-trial to post trial morphine equivalents recorded at each clinic visit.
- **Aim 3:** To determine if the morphine equivalents before permanent implantation correlate with changes in VAS pain or perceived pain at post trial clinic visits.

III. Research Design and Methods

**Patients**

With the approval of the Institutional Review Board, we reviewed the medical records for 233 subjects that were implanted with spinal cord stimulators through the UCSD Pain Management department from 2011 to 2013. The selection criteria consisted of patients diagnosed with chronic pain due to one or more of the following etiologies: chronic regional pain syndrome, failed back syndrome, refractory peripheral neuropathy, phantom limb. Furthermore, the patients that were selected had a successful SCS implant trial, defined as 50% or greater reduction in perceived pain at about 1 week after trial implantation, and that subsequently underwent permanent implantation with scheduled clinic follow up visits.

**Research Design**

In order to achieve Aim 1, we extracted the data from the medical records which included the VAS pain scores (0-10) at pre-trial, post-trial, and at consecutive follow up visits (3 months, 6 months, 12 months, 24 months and 36 months). The perceived pain reduction, which is the estimated percentage that the patient believes their pain has decreased after undergoing implantation, was taken from the post-trial clinic visit and at 3, 6, 12, 24 and 36 months. Likewise, to achieve Aims 2 and 3, the opioid doses over time (pre-trial, pre-permanent implantation, 3, 6, 12, 24 and 36 months) were taken and converted to morphine equivalents for comparison.

**Statistical Methods**

For Aim 1, we calculated the mean for VAS pain scores at all times points. We then utilized a paired t-test to compare the mean VAS pain score change between each point and the pre-trial measurement. The mean was also
calculated for the perceived pain reduction at the different time points and a t-test was applied to compare the perceived pain reduction over time.

For Aim 2, the mean value was calculated for the morphine equivalents at 7 different time points. A paired t-test was used allowed us to compare the change in morphine equivalents between each point and the pre-trial value.

To achieve Aim 3, we calculated Pearson’s correlation coefficient for the reported VAS pain scores and the morphine equivalents. The Pearson’s correlation coefficient was also calculated for perceived pain scores and morphine equivalents.

IV. Results

The results are still under analysis phase. However, we do have preliminary results that show the following.

1. SCS decreases VAS scores post trial, 3 and 6 months but not at twelve months (Table 1 and Figure 1).
2. SCS decreases pain perception post trial and at all subsequent time points (Table 2 and Figure 2).
3. Morphine use did not decrease post trial and at all subsequent time points (Table 3 and Figure 3).
4. There was no correlation between pre-trial morphine use and post-trial SCS reduction in VAS or pain perception (Table 4).
V. Discussion & Conclusion

SCS is known to improve pain in syndromes such as: 1) failed back surgery syndrome, 2) complex regional pain syndrome and 3) radiculopathy. Based on our current analysis of SCS is able to improve pain up to 6 months when measured with VAS and throughout all time points when measured with a reduction in pain perception. Although analyses are still underway we did not see a direct correlation between pre-trial opiate use and efficacy of SCS. Based on our current analyses we can conclude that SCS reduces pain perception for up to 36 months in patients with: 1) failed back surgery syndrome 2) refractory radiculopathy pain syndrome and 3) complex regional pain syndrome. Further analyses will determine whether or not pre-trial incremental titration off of opiates have any bearing on: 1) the longevity of SCS efficacy and 2) efficacy that may be dependent on a particular diagnosis.
Bibliography


