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Neurostimulation should be used as a method of reducing or eliminating opioids in the treatment of chronic pain: the digital drug revolution

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“Evidence suggests that this technique can reduce the need for opioids, reduce pain, improve quality of life and reduce healthcare utilization and costs.”

More than a decade ago, I had the opportunity to work with a panel of experts in the arena of intrathecal drug delivery systems (IDDS) and the proper uses of these devices [1]. In the course of that consensus conference, I had the pleasure of meeting Russell Portenoy, a leader in the field, and became familiar with the theory of prescribing opioids that discussed a subgroup of patients that could be treated with opioids and not develop tolerance or addiction. This later evolved into what was called ‘treat to effect or side effect’ theory of opioid prescribing for non-cancer pain [2]. This view of opioid prescribing suggested that there was no ceiling to opioid intake in chronic pain and that the treating physician should consider increasing the dose until the patient received proper analgesia or developed side effects that were unacceptable. Since that time, there has been much debate as to the true intent of this thought process, but issues have arisen that have troubled physicians, patients and society and made many including the original advocates of these thought processes question the wisdom of liberal opioid prescribing [3]. The problem of hyperalgesia has been identified, which states that at some point increasing the opioid may actually worsen the pain [4]. Perhaps equally troubling has been the problem of drug

diversion, drug abuse and morbidity and mortality due to improper patient behavior, improper physician behavior or criminal activity [5]. This debacle has put us in a quandary. How do we treat those who suffer, while keeping them as safe as possible, doing our best job and protecting society from both the tremendous emotional and the financial toll of this conundrum? I would offer the thought process that we should convert when possible to digital drugs.

The digital drug

Neurostimulation is not a new concept, and in fact was first described and published more than 40 years ago by Shealy *et al.* [6]. The process involves targeting the central or peripheral nervous system with electrical current to change the process of neural transmission and thus the signal that is processed by the brain. This transformation, or neurostimulation, modulates the signal and replaces it with other sensations or paresthesias that supplant the previous noxious stimulus. The process involves implanting an electrode at the target that is controlled by a programmable generator that tells the system how to deliver current, at what rate and at what amplitude. Evidence suggests that this technique can reduce the need for opioids, reduce pain, improve quality of

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life and reduce healthcare utilization and costs [7,8,9]. All of these factors will continue to become more important in the current healthcare microcosm we find ourselves evolving into and meet the goals of the SAFE algorithm which suggest current and future care should be Safe, Appropriate, Fiscally neutral, Efficacious [10]. In this thought process, researchers are working to make implantable devices less invasive, more efficacious and with improved safety profiles [11].

The current technology is most commonly applied in the spinal cord dorsal columns with indications such as failed back surgery syndrome, nerve injury in the periphery, peripheral neuropathy and ischemic pain of the limbs [12]. Deep brain stimulation which is currently approved in the USA for Parkinson's disease, has shown promise for the treatment of pain, as has motor cortex stimulation which is a less invasive method of brain stimulation. Work in stimulation of the occipital nerve has been shown to be efficacious and has led to approval for migraine treatment in the European Union. This is particularly important considering the poor response of migraine to opioids where overprescribing is an issue. Other peripheral targets include the low back, intercostal nerves, median nerve, tibial nerve and ilioinguinal nerves [13]. Exciting new work will simplify the targets and the delivery. These new developments include peripheral nerve stimulation without the need for an internalized battery. This can be done by either using a transdermal programming and battery [14], or by using a microwave or wireless transmission [15]. Patients who may benefit from this therapy include those with trauma from surgery such as postmastectomy, postthoracotomy, carpal tunnel release or podiatric complications, and also include those with trauma or disease of the nerve such as in postherpetic neuralgia [16].

Even in this time of excitement of current treatment in the USA, the enthusiasm for the future treatment of complex patients can build even further when reviewing the experience of our colleagues in Europe and Australia. Two extremely exciting and therapy changing developments have been studied and obtained commercialization in those areas of the world. The dorsal root ganglion (DRG) is a part of the spinal cord that processes the peripheral nerve impulses and transmits the signals to the proper pathways. Stimulation of this target can lead

to more specific areas of neuromodulation, and can achieve pain improvement in areas of innervation that has been previously hard to stimulate. These areas include the axial low back, the hand, foot, groin and chest wall [17,18,19]. A major multi-centered US study is scheduled to start soon, in which the author is a primary investigator. The other areas of excitement involve current delivery. The electrical delivery of current at 10,000 Hz, known as HF10, is thought to be a unique way to deliver current to the spinal cord and create pain relief without the need for paresthesia. The experience in the European Union and Australia has been very encouraging and has led to an increased interest in stimulating the axial back. A prospective randomized comparative study in the USA is under way and should be completed by 2014 [20].

Burst stimulation is the second area of current delivery that excites the field with a potential to salvage patients who may fail conventional *spinal cord stimulation*. This area of neuromodulation involves delivering bursts of high frequency stimulation in machine gun type patterns surrounded by silent current periods. De Ridder *et al.* have shown this is a potential salvage for those who develop tolerance to conventional tonic stimulation. A multi-center US comparative trial has been proposed for 2014, and awaits the US FDA approval [21].

In some specific cases, there has been evidence that opioids can be reduced by the successful use of these therapies [22]. In large randomized studies, opioid reduction has also been demonstrated such as the PROCESS study which showed both improvement of pain and reduced opioids when compared with conventional medical management [7]. These reports and studies suggest that in cases of pain related to a nerve or in mixed pain syndromes such as seen with failed back surgery syndrome, neurostimulation should be a first line of therapy before concluding that a life time of high-dose opioids is the only option. The risks of neurostimulation is primarily at the time of implant and the long-term risks are minimal. The risks of high-dose opioids are unpredictable, and are complicated by abuse, addiction, diversion and criminal behavior. In some settings, opioids are appropriate, but in all cases of chronic non-cancer pain, neurostimulation should be given some consideration, and if appropriate trialed for possible long-term use.

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